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**FAX TRANSMISSION SHEET**

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Kathy

These are as approved by  
our Board of Health

Jake

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## PART 3

## LICENSING OF RADIOACTIVE MATERIAL

3.1.2

In addition to the requirements of this part, all licensees are subject to the requirements of Parts 1, 4, 10, 12 and 17 of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part 5 of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Part 7 of these regulations, licensees engaged in land disposal of radioactive material are subject to the requirements of EITHER Part 14 OR PART 18 of these regulations, licensees engaged in source material milling are subject to the requirements of Part 18 of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part 16 of these regulations.



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3.9.5 Financial assurance requirements, as described below, have been met:

3.9.5.1 Financial Requirements.

The Department will require financial assurance arrangements as follows:

3.9.5.1.1 A license applicant may be required to furnish financial assurance arrangements to ensure decontamination and decommissioning of the facility for the protection of the public health and safety and the environment in the event of abandonment, default or inability of the licensee to meet the requirements of the Act, these regulations, and the license.

3.9.5.1.2 The following specific licensees are required to furnish financial assurance arrangements:

3.9.5.1.2.1 Reserved.

3.9.5.1.2.2 Commercial waste handling licensees;

3.9.5.1.2.3 Reserved.

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1 3.9.5.1.2.4 Source material mills; and

2  
3 3.9.5.1.2.5 Each applicant for a specific license  
4 authorizing the possession and use of SOURCE  
5 MATERIAL, IN A READILY DISPERSIBLE FORM, GREATER  
6 THAN 10 mCi, OR OTHER licensed radioactive  
7 material with a half life greater than 120 days,  
8 in quantities:

9  
10 3.9.5.1.2.5.1 greater than  $10^5$  times the applicable  
11 quantity of Schedule B of Part 3 unsealed  
12 form. For a combination of isotopes if R  
13 divided by  $10^5$  is greater than 1 (unity  
14 rule), where R is defined here as the sum  
15 of the ratios of the quantity of each  
16 isotope in the applicable value in  
17 Schedule B.

18  
19 3.9.5.1.2.5.2 greater than  $10^{10}$  times the applicable  
20 quantity of Schedule B of Part 3 in sealed  
21 sources or plated foils. For a  
22 combination of isotopes if R divided by  
23  $10^{10}$  is greater than 1 (unity rule), where  
24 R is defined in RH 3.9.5.1.2.5.1.

25 3.9.5.1.3 Reserved.

26 ~~3.9.5.1.3.1 Reserved.~~

27 ~~3.9.5.1.3.2 Reserved.~~

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~~3.9.5.1.3.3~~ ~~Reserved~~~~3.9.5.1.3.4~~ ~~Reserved~~~~3.9.5.1.3.5~~ ~~Reserved~~

3.9.5.2

The financial assurance arrangements required by RH 3.9.5.1.1 shall be furnished to, and in a form approved by, the Department prior to the issuance of a license, or any amendment or renewal of an existing license, as required by the Department. The applicant shall furnish evidence of initial and continued financial responsibility sufficient to maintain the financial assurance arrangement in force, as required by and acceptable to the Department. The amount of funds to be provided by such financial assurance arrangements shall be based on Department-approved cost estimates.

~~Self insurance, or any arrangement which essentially constitutes self insurance (e.g. a contract with a State or Federal agency), will not satisfy the financial assurance requirement since this provides no additional assurance other than that which already exists through license requirements.~~

Acceptable financial assurance arrangements include:

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3.9.5.2.1

A bond issued by a fidelity or surety company with provisions and for a term and amount acceptable to the Department;

3.9.5.2.2

An irrevocable "letter of credit" or "line of credit" issued by a recognized financial institution whose financial condition and commitment are established to the satisfaction of the Department;

3.9.5.2.3

A cash deposit, certificate of deposit, or deposit of government securities posted by the licensee with provisions and for a term and amount acceptable to the Department; or

3.9.5.2.4

SELF ASSURANCE TEST

3.9.5.2.4.1

FOR ALL LICENSEES, EXCEPT URANIUM OR THORIUM MILL FACILITIES, ACCEPTABLE FINANCIAL ASSURANCE ARRANGEMENTS ALSO INCLUDE THE FOLLOWING: PARENT COMPANY GUARANTEE OF FUNDS FOR DECOMMISSIONING COSTS BASED ON A FINANCIAL TEST MAY BE USED IF THE GUARANTEE AND TEST ARE AS CONTAINED IN APPENDIX A OF THIS . A PARENT COMPANY GUARANTEE MAY NOT BE USED IN COMBINATION WITH OTHER FINANCIAL METHODS TO SATISFY THE REQUIREMENTS OF THIS SECTION.

3.9.5.2.4.2

A GUARANTEE OF FUNDS BY THE APPLICANT OR LICENSEE FOR DECOMMISSIONING COSTS BASED ON A FINANCIAL TEST MAY BE USED IF THE GUARANTEE AND TEST ARE AS CONTAINED IN APPENDIX B OF THIS PART. A GUARANTEE BY THE APPLICANT OR LICENSEE MAY NOT BE USED IN COMBINATION WITH ANY OTHER FINANCIAL METHODS TO SATISFY THE REQUIREMENTS OF THIS SECTION OR IN ANY SITUATION WHERE THE APPLICANT OR LICENSEE HAS A PARENT COMPANY HOLDING MAJORITY CONTROL OF THE VOTING STOCK OF THE COMPANY.

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3.9.5.2.4.3

SELF INSURANCE, OR ANY OTHER ARRANGEMENT WHICH ESSENTIALLY CONSTITUTES SELF INSURANCE (e.g. A CONTRACT WITH A STATE OR FEDERAL AGENCY).

3.9.5.2.4.5

EXCEPT FOR THE FINANCIAL ASSURANCE TESTS NOTED IN RH 3.9.5.2.4. ~~or~~ combinations of the above or such other evidence of initial and continued financial responsibility as may be required by the Department including financial assurance arrangements previously provided to any State, Federal and/or local governing bodies concerning activities subject to license under these regulations, where the amount, terms, and conditions of such financial assurance arrangements have been established to the satisfaction of the Department, provided such arrangements are considered by the Department to be adequate to satisfy the requirements of RH 3.9.5 and provided that the portion of the financial assurance arrangement which covers the decommissioning and reclamation of the facility and associated areas, and the long-term site surveillance and control funding charge, are clearly identified and committed for use in accomplishing these activities.

3.9.5.3

The amount of funds to be provided by such financial assurance arrangements shall be based on Department-approved cost estimates in an approved DECOMMISSIONING plan for (1) decontamination and decommissioning of buildings, facilities and the site to levels which would allow unrestricted use of these areas upon decommissioning, and (2) for the reclamation of tailings and/or waste disposal areas in accordance with technical criteria delineated in Part 14 and/or Part 18 as appropriate. The licensee shall submit this plan and complete proposed financial assurance arrangements in conjunction with the environmental report

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1 required by RM 3.8.8 that addresses the expected  
2 environmental impacts of the operation, decommissioning and  
3 reclamation, and evaluates alternatives for mitigating these  
4 impacts. In establishing specific financial assurance  
5 arrangements, the cost estimates shall take into account  
6 total costs that would be incurred if an independent  
7 contractor were hired to perform the decommissioning and  
8 reclamation work, and long-term care if included.

## 3.9.5.3.1

10 EACH DECOMMISSIONING FUNDING PLAN MUST CONTAIN A COST  
11 ESTIMATE FOR DECOMMISSIONING, REQUIRED IN THIS  
12 SECTION, INCLUDING MEANS FOR ADJUSTING COST ESTIMATES  
13 AND ASSOCIATED FUNDING LEVELS PERIODICALLY OVER THE  
14 LIFE OF THE FACILITY. THE DECOMMISSIONING FUNDING  
15 PLAN MUST ALSO INCLUDE A CERTIFICATION BY THE LICENSEE  
16 THAT FINANCIAL ASSURANCE DECOMMISSIONING HAS BEEN  
17 PROVIDED FOR IN THE AMOUNT OF THE COST ESTIMATE FOR  
18 DECOMMISSIONING OR A SIGNED ORIGINAL OF THE FINANCIAL  
19 INSTRUMENT OBTAINED TO SATISFY THE REQUIREMENTS OF  
20 THIS SECTION.

## 3.9.5.3.2

22 A SIGNED EXECUTED ORIGINAL COPY OF THE FINANCIAL  
23 INSTRUMENT OBTAINED TO SATISFY THE REQUIREMENTS OF  
24 THIS SECTION SHALL BE SUBMITTED TO THE DEPARTMENT  
25 PRIOR TO RECEIPT, USE, POSSESSION, STORAGE OR DISPOSAL  
26 OF LICENSED MATERIAL.



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3.9.5.4

The licensee shall provide in writing to the Department, no later than June 30th of each calendar year, any licensee proposed changes, including updated plans, costs or surety mechanisms, for consideration by the Department.

3.9.5.5

The licensee's financial assurance arrangements will be reviewed annually by the Department to assure that sufficient funds would be available for completion of the plans if the work had to be performed by an independent contractor and shall be adjusted to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether the work is phased through the life of the operation or takes place at the end of the operation, an appropriate portion of financial assurance liability shall be ~~re~~MAINTAINED by the licensee until final compliance with the ~~reclamation~~ DECOMMISSIONING plan is determined by the Department.

This will yield a financial assurance ARRANGEMENTS that are at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism shall be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g. 5 years) yet which must be automatically renewed unless the surety notifies the

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1 Department and the principal (the licensee) some reasonable  
2 time (e.g. 90 days) prior to the renewal date of their  
3 intention not to renew. In such a situation  
4 the surety requirement still exists and the licensee would  
5 be required to submit an acceptable replacement surety  
6 within a brief period of time to allow at least 60 days for  
7 the regulatory agency to collect.

8  
9 Proof of forfeiture shall not be necessary to collect the  
10 surety so that in the event that the licensee could not  
11 provide an acceptable replacement surety within the required  
12 time, the surety shall be automatically collected prior to  
13 its expiration. The conditions described above would have  
14 to be clearly stated on any surety instrument which is not  
15 open-ended and must be agreed to by all parties.

## 3.9.5.6

16  
17 The term of the financial assurance arrangement shall be for  
18 the period from issuance of the license until termination of  
19 the license by the Department, unless it can be demonstrated  
20 that another arrangement would provide an equivalent level  
21 of assurance. THE LICENSEE SHALL MAINTAIN IN EFFECT ALL  
22 DECOMMISSIONING FINANCIAL ASSURANCES ESTABLISHED BY THE  
23 LICENSEE, PURSUANT TO SECTION 3.9.5 OF THIS PART, IN  
24 CONJUNCTION WITH ANY LICENSE ISSUANCE, AMENDMENT OR RENEWAL.  
25 THE AMOUNT OF FINANCIAL ASSURANCE MUST BE INCREASED OR  
26 DECREASED, AS APPROPRIATE, TO COVER THE DETAILED COST  
27 ESTIMATE FOR DECOMMISSIONING ESTABLISHED PURSUANT TO SECTION  
28 3.9.5.3 OF THIS PART. ANY LICENSEE WHO  
29  
30

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1 HAS NOT PROVIDED FINANCIAL ASSURANCE TO COVER THE DETAILED  
2 COST ESTIMATE SUBMITTED WITH THE DECOMMISSIONING PLAN SHALL  
3 DO SO WHEN THIS RULE BECOMES EFFECTIVE JANUARY 1, 1997.  
4 FOLLOWING APPROVAL OF THE DECOMMISSIONING PLAN, A LICENSEE  
5 MAY REDUCE THE AMOUNT OF FINANCIAL ASSURANCE AS  
6 DECOMMISSIONING PROCEEDS AND WITH THE APPROVAL OF THE  
7 DEPARTMENT.  
8  
9  
10  
11  
12  
13





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3.12.11.2.1

the generator or reagent kit is to be manufactured, labeled and packaged in accordance with ~~the Federal Food, Drug and Cosmetic Act or the Public Health Service Act~~ PARTS A THROUGH G OF 21 CFR 312, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

3.12.11.2.2

the manufacture and distribution of the generator or reagent kit are not subject to PARTS A THROUGH G OF 21 CFR 312, ~~the Federal Food, Drug and Cosmetic Act and the Public Health Service Act,~~



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1      3.15.4      NOTICE AND DISPOSITION OF RECORDS PRIOR TO LICENSE TERMINATION.

2  
3      Each licensee shall notify the Department in writing when the  
4      licensee decides to permanently discontinue all activities  
5      involving materials authorized under the license.  
6

7      3.15.4.1      PRIOR TO LICENSE TERMINATION, EACH LICENSEE AUTHORIZED TO  
8      POSSESS RADIOACTIVE MATERIAL WITH A HALF-LIFE GREATER THAN  
9      120 DAYS, IN AN UNSEALED FORM, SHALL FORWARD THE FOLLOWING  
10      RECORDS TO THE DEPARTMENT.  
11

12      3.15.4.1.1      RECORDS OF DISPOSAL OF LICENSED MATERIAL MADE UNDER RH 4.34,  
13      4.35, 4.36, 4.37; AND  
14

15      3.15.4.1.2      RECORDS REQUIRED BY RH 4.42.  
16

17      3.15.4.2      IF LICENSED ACTIVITIES ARE TRANSFERRED OR ASSIGNED IN  
18      ACCORDANCE WITH RH 3.15.2, EACH LICENSEE AUTHORIZED TO  
19      POSSESS RADIOACTIVE MATERIAL, WITH A HALF-LIFE GREATER THAN  
20      120 DAYS, IN AN UNSEALED FORM, SHALL TRANSFER THE RECORDS  
21

22      REQUIRED IN RH 3.15.4.1 TO THE NEW LICENSEE AND THE NEW  
23      LICENSEE WILL BE RESPONSIBLE FOR MAINTAINING THESE RECORDS  
24      UNTIL THE LICENSE IS TERMINATED.  
25

26      3.15.4.3      PRIOR TO LICENSE TERMINATION, EACH LICENSEE SHALL FORWARD  
27      THE RECORDS REQUIRED BY RH 3.16.6.8 TO THE DEPARTMENT.  
28  
29  
30





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## 3.16.6.8

DECOMMISSIONING RECORDKEEPING

THE LICENSEE SHALL KEEP RECORDS OF INFORMATION IMPORTANT TO THE DECOMMISSIONING OF A FACILITY IN AN IDENTIFIED LOCATION UNTIL AUTHORIZED BY THE DEPARTMENT. BEFORE LICENSED ACTIVITIES ARE TRANSFERRED OR ASSIGNED IN ACCORDANCE WITH RH 3.15.2, LICENSEES SHALL TRANSFER ALL RECORDS DESCRIBED IN THIS PARAGRAPH TO THE NEW LICENSEE. IN THIS CASE, THE NEW LICENSEE WILL BE RESPONSIBLE FOR MAINTAINING THESE RECORDS UNTIL THE LICENSE IS TERMINATED. IF RECORDS IMPORTANT TO THE DECOMMISSIONING OF A FACILITY ARE KEPT FOR OTHER PURPOSES, REFERENCE TO THESE RECORDS AND THEIR LOCATIONS MAY BE USED. INFORMATION CONSIDERED IMPORTANT TO DECOMMISSIONING CONSISTS OF:

## 3.16.6.8.1

RECORDS OF SPILLS OR OTHER UNUSUAL OCCURRENCES INVOLVING THE SPREAD OF CONTAMINATION IN AND AROUND THE FACILITY, EQUIPMENT, OR SITE. THESE RECORDS MAY BE LIMITED TO INSTANCES WHEN CONTAMINATION REMAINS AFTER ANY CLEANUP PROCEDURES OR WHEN THERE IS REASONABLE LIKELIHOOD THAT CONTAMINANTS MAY HAVE SPREAD TO INACCESSIBLE AREAS AS IN THE CASE OF POSSIBLE SEEPAGE INTO POROUS MATERIALS SUCH AS CONCRETE. THESE RECORDS MUST INCLUDE ANY KNOWN INFORMATION ON IDENTIFICATION OF INVOLVED NUCLIDES, QUANTITIES, FORMS AND CONCENTRATIONS.

## 3.16.6.8.2

AS-BUILT DRAWINGS AND MODIFICATIONS OF STRUCTURES AND EQUIPMENT IN RESTRICTED AREAS WHERE RADIOACTIVE MATERIALS ARE USED AND/OR STORED, AND OF LOCATIONS OF POSSIBLE

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1 INACCESSIBLE CONTAMINATION SUCH AS BURIED PIPES WHICH MAY BE  
2 SUBJECT TO CONTAMINATION. IF REQUIRED DRAWINGS ARE  
3 REFERENCED, EACH RELEVANT DOCUMENT NEEDS TO BE INDEXED  
4 INDIVIDUALLY. IF DRAWINGS ARE NOT AVAILABLE, THE LICENSEE  
5 SHALL SUBSTITUTE APPROPRIATE RECORDS OF AVAILABLE  
6 INFORMATION CONCERNING THESE AREAS AND LOCATIONS.  
7

8 3.16.6.8.3 EXCEPT FOR AREAS CONTAINING ONLY SEALED SOURCES (PROVIDED  
9 THE SOURCES HAVE NOT LEAKED OR NO CONTAMINATION REMAINS  
10 AFTER ANY LEAK), BYPRODUCT MATERIALS HAVING ONLY HALF-LIVES  
11 OF LESS THAN 65 DAYS, OR AREAS CONTAINING DEPLETED URANIUM  
12 CASED ONLY FOR SHIELDING OR AS PENETRATORS IN UNUSED  
13 MUNITIONS, A LIST CONTAINED IN A SINGLE DOCUMENT AND UPDATED  
14 EVERY 2 YEARS, OF THE FOLLOWING:  
15

16 3.16.6.8.3.1 ALL AREAS DESIGNATED AND FORMERLY DESIGNATED  
17 RESTRICTED AREAS AS DEFINED IN RH 1.4;  
18

19 3.16.6.8.3.2 ALL AREAS OUTSIDE OF RESTRICTED AREAS THAT  
20 REQUIRE DOCUMENTATION UNDER RH 3.16.6.8.1;  
21

22 3.16.6.8.3.3 ALL AREAS OUTSIDE OF RESTRICTED AREAS WHERE CURRENT  
23 AND PREVIOUS WASTES HAVE BEEN BURIED AS DOCUMENTED  
24 UNDER RH 4.48; AND  
25

26 3.16.6.8.3.4 ALL AREAS OUTSIDE OF RESTRICTED AREAS WHICH CONTAIN  
27 MATERIAL SUCH THAT, IF THE LICENSE EXPIRED, THE  
28 LICENSEE WOULD BE REQUIRED TO EITHER DECONTAMINATE THE  
29 AREA TO UNRESTRICTED RELEASE LEVELS OR APPLY FOR  
30 APPROVAL FOR DISPOSAL UNDER RH 4.34.  
31

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3.16.6.8.3.5

A LIST CONTAINING THE LOCATION AND DESCRIPTION OF ALL  
EQUIPMENT TO REMAIN ONSITE AFTER LICENSE TERMINATION  
THAT WAS CONTAMINATED WHEN FINAL DECOMMISSIONING WAS  
INITIATED; AND

3.16.6.8.3.6

ANY OTHER INFORMATION NOT REQUIRED BY RH 3.16.6.8.3  
THAT IS CONSIDERED NECESSARY TO SUPPORT THE ADEQUACY  
OF THE DECOMMISSIONING PLAN FOR APPROVAL.

3.16.6.8.4 RECORDS OF THE COST ESTIMATE PERFORMED FOR THE DECOMMISSIONING  
FUNDING PLAN OR OF THE AMOUNT CERTIFIED FOR DECOMMISSIONING, AND  
RECORDS OF THE FUNDING METHOD USED FOR ASSURING FUNDS IF EITHER A  
FUNDING PLAN OR CERTIFICATION IS USED.



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## PART 3

## APPENDIX A

CRITERIA RELATING TO USE OF FINANCIAL  
TESTS AND PARENT COMPANY GUARANTEES FOR  
PROVIDING REASONABLE ASSURANCE  
OF FUNDS FOR DECOMMISSIONING

I. INTRODUCTION

AN APPLICANT OR LICENSEE MAY PROVIDE REASONABLE ASSURANCE OF THE  
AVAILABILITY OF FUNDS FOR DECOMMISSIONING BASED ON OBTAINING A PARENT  
COMPANY GUARANTEE THAT FUNDS WILL BE AVAILABLE FOR DECOMMISSIONING COSTS  
AND ON A DEMONSTRATION THAT THE PARENT COMPANY PASSES A FINANCIAL TEST.  
THIS APPENDIX ESTABLISHES CRITERIA FOR PASSING THE FINANCIAL TEST AND  
FOR OBTAINING THE PARENT COMPANY GUARANTEE.

II. FINANCIAL TEST

A. TO PASS THE FINANCIAL TEST, THE PARENT COMPANY MUST MEET THE  
CRITERIA OF EITHER PARAGRAPH A.1. OR A.2. OF THIS SECTION:

1. THE PARENT COMPANY MUST HAVE:

(1) TWO OF THE FOLLOWING THREE RATIOS: A RATIO OF TOTAL  
LIABILITIES TO NET WORTH LESS THAN 2.0; A RATIO OF THE  
SUM OF NET INCOME PLUS DEPRECIATION, DEPLETION, AND

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1 AMORTIZATION TO TOTAL LIABILITIES GREATER THAN 0.1;  
2 AND RATIO OF CURRENT ASSETS TO CURRENT LIABILITIES  
3 GREATER THAN 1.5; AND  
4

5 (II) NET WORKING CAPITAL AND TANGIBLE NET WORTH EACH AT  
6 LEAST TEN TIMES THE CURRENT DECOMMISSIONING COST  
7 ESTIMATES (OR PRESCRIBED AMOUNT IF A CERTIFICATION IS  
8 USED); AND  
9

10 (III) TANGIBLE NET WORTH OF AT LEAST \$10 MILLION; AND  
11

12 (IV) ASSETS LOCATED IN THE UNITED STATES AMOUNTING TO AT  
13 LEAST 90 PERCENT OF TOTAL ASSETS OR AT LEAST TEN TIMES  
14 THE CURRENT DECOMMISSIONING COST ESTIMATES (OR  
15 PRESCRIBED AMOUNT IF A CERTIFICATION IS USED).  
16

17 2. THE PARENT COMPANY MUST HAVE:  
18

19 (I) A CURRENT RATING FOR ITS MOST RECENT BOND ISSUANCE OF  
20 AAA, AA, A, OR BBB AS ISSUED BY STANDARD AND POOR'S OR  
21 AAA, AA, A, OR BAA AS ISSUED BY MOODY'S; AND  
22

23 (II) TANGIBLE NET WORTH AT LEAST TEN TIMES THE CURRENT  
24 DECOMMISSIONING COST ESTIMATE (OR PRESCRIBED AMOUNT IF  
25 A CERTIFICATION IS USED); AND  
26

27 (III) TANGIBLE NET WORTH OF AT LEAST \$10 MILLION; AND  
28

29 (IV) ASSETS LOCATED IN THE UNITED STATES AMOUNTING TO AT  
30 LEAST 90 PERCENT OF TOTAL ASSETS OR AT LEAST TEN TIMES

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1 THE CURRENT DECOMMISSIONING COST ESTIMATES (OR  
2 PRESCRIBED AMOUNT IF CERTIFICATION IS USED).

3  
4 B. THE PARENT COMPANY'S INDEPENDENT CERTIFIED PUBLIC ACCOUNTANT MUST  
5 HAVE COMPARED THE DATA USED BY THE PARENT COMPANY IN THE FINANCIAL  
6 TEST, WHICH IS DERIVED FROM INDEPENDENTLY AUDITED, YEAR END  
7 FINANCIAL STATEMENTS FOR THE LATEST FISCAL YEAR, WITH THE AMOUNTS  
8 IN SUCH FINANCIAL STATEMENT. IN CONNECTION WITH THAT PROCEDURE  
9 THE LICENSEE SHALL INFORM THE DEPARTMENT WITHIN 90 DAYS OF ANY  
10 MATTERS COMING TO THE AUDITOR'S ATTENTION WHICH CAUSE THE AUDITOR  
11 TO BELIEVE THAT THE DATA SPECIFIED IN THE FINANCIAL TEST SHOULD BE  
12 ADJUSTED AND THAT THE COMPANY NO LONGER PASSES THE TEST.

- 13  
14 C. 1. AFTER THE INITIAL FINANCIAL TEST, THE PARENT COMPANY MUST  
15 REPEAT THE PASSAGE OF THE TEST WITHIN 90 DAYS AFTER THE  
16 CLOSE OF EACH SUCCEEDING FISCAL YEAR.
- 17  
18 2. IF THE PARENT COMPANY NO LONGER MEETS THE REQUIREMENTS OF  
19 PARAGRAPH A OF THIS SECTION, THE LICENSEE MUST SEND NOTICE  
20 TO THE DEPARTMENT OF INTENT TO ESTABLISH ALTERNATE FINANCIAL  
21 ASSURANCE AS SPECIFIED IN THE DEPARTMENT'S REGULATIONS. THE  
22 NOTICE MUST BE SENT BY CERTIFIED MAIL WITHIN 90 DAYS AFTER  
23 THE END OF THE FISCAL YEAR FOR WHICH THE YEAR END FINANCIAL  
24 DATA SHOW THAT THE PARENT COMPANY NO LONGER MEETS THE  
25 FINANCIAL TEST REQUIREMENTS. THE LICENSEE MUST PROVIDE  
26 ALTERNATE FINANCIAL ASSURANCE WITHIN 120 DAYS AFTER THE END  
27 OF SUCH FISCAL YEAR.
- 28  
29

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1     III.   PARENT COMPANY GUARANTEE  
2

3           THE TERMS OF A PARENT COMPANY GUARANTEE WHICH AN APPLICANT OR LICENSEE  
4           OBTAINS MUST PROVIDE THAT:

5  
6           A.     THE PARENT COMPANY GUARANTEE WILL REMAIN IN FORCE UNLESS THE  
7           GUARANTOR SENDS NOTICE OF CANCELLATION BY CERTIFIED MAIL TO THE  
8           LICENSEE AND THE DEPARTMENT. CANCELLATION MAY NOT OCCUR, HOWEVER,  
9           DURING THE 120 DAYS BEGINNING ON THE DATE OF RECEIPT OF THE NOTICE  
10          OF CANCELLATION BY BOTH THE LICENSEE AND THE DEPARTMENT, AS  
11          EVIDENCED BY THE RETURN RECEIPTS.

12  
13          B.     IF THE LICENSEE FAILS TO PROVIDE ALTERNATE FINANCIAL ASSURANCE AS  
14          SPECIFIED IN THE DEPARTMENT'S REGULATIONS WITHIN 90 DAYS AFTER  
15          RECEIPT BY THE LICENSEE AND DEPARTMENT OF A NOTICE OF CANCELLATION  
16          OF THE PARENT COMPANY GUARANTEE FROM THE GUARANTOR, THE GUARANTOR  
17          WILL PROVIDE SUCH ALTERNATIVE FINANCIAL ASSURANCE IN THE NAME OF  
18          THE LICENSEE.

19  
20          C.     THE PARENT COMPANY GUARANTEE AND FINANCIAL TEST PROVISIONS MUST  
21          REMAIN IN EFFECT UNTIL THE DEPARTMENT HAS TERMINATED THE LICENSE  
22          OR UNTIL ANOTHER FINANCIAL ASSURANCE METHOD ACCEPTABLE TO THE  
23          DEPARTMENT HAS BEEN PUT IN EFFECT BY THE LICENSEE.

24  
25          D.     IF A TRUST IS ESTABLISHED FOR DECOMMISSIONING COSTS, THE TRUSTEE  
26          AND TRUST MUST BE ACCEPTABLE TO THE DEPARTMENT. AN ACCEPTABLE  
27          TRUSTEE INCLUDES THE FOLLOWING: AN APPROPRIATE STATE OR FEDERAL  
28          GOVERNMENT AGENCY OR AN ENTITY WHICH HAS THE AUTHORITY TO ACT AS A  
29          TRUSTEE AND WHOSE TRUST OPERATIONS ARE REGULATED AND EXAMINED BY A  
30          STATE OR FEDERAL AGENCY.



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## PART 3

## APPENDIX B

CRITERIA RELATING TO USE OF  
FINANCIAL TESTS AND SELF GUARANTEES FOR  
PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. INTRODUCTION

AN APPLICANT OR LICENSEE MAY PROVIDE REASONABLE ASSURANCE OF THE  
AVAILABILITY OF FUNDS FOR DECOMMISSIONING, BASED ON FURNISHING ITS OWN  
GUARANTEE THAT FUNDS WILL BE AVAILABLE FOR DECOMMISSIONING COSTS, AND ON  
A DEMONSTRATION THAT THE COMPANY PASSES THE FINANCIAL TEST SECTION II OF  
THIS APPENDIX. THE TERMS OF THIS SELF-GUARANTEE ARE IN SECTION III OF  
THIS APPENDIX. THIS APPENDIX ESTABLISHES CRITERIA FOR PASSING THE  
FINANCIAL TEST FOR THE SELF-GUARANTEE AND ESTABLISHES THE TERMS FOR A  
SELF-GUARANTEE.

II. FINANCIAL TEST

A. TO PASS THE FINANCIAL TEST, A COMPANY MUST MEET THE ALL OF THE  
FOLLOWING CRITERIA:

1. A TANGIBLE NET WORTH OF AT LEAST TEN TIMES THE TOTAL CURRENT  
DECOMMISSIONING COST ESTIMATE (OR THE CURRENT AMOUNT  
REQUIRED IF CERTIFICATION IS USED) FOR ALL DECOMMISSIONING  
ACTIVITIES FOR WHICH THE COMPANY IS RESPONSIBLE AS SELF-  
GUARANTEEING LICENSEE AND AS PARENT-GUARANTOR.

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1  
2 2. ASSETS LOCATED IN THE UNITED STATES AMOUNTING TO AT LEAST 90  
3 PERCENT OF TOTAL ASSETS OR AT LEAST TEN TIMES THE CURRENT  
4 DECOMMISSIONING COST ESTIMATES (OR THE CURRENT AMOUNT  
5 REQUIRED IF CERTIFICATION IS USED) FOR ALL DECOMMISSIONING  
6 ACTIVITIES FOR WHICH THE COMPANY IS RESPONSIBLE AS SELF-  
7 GUARANTEEING LICENSEE AND AS PARENT-GUARANTOR.

8  
9 3. A CURRENT RATING FOR ITS MOST RECENT BOND ISSUANCE OF AAA,  
10 AA, OR A AS ISSUED BY STANDARD AND POOR'S OR AAA, AA, OR A  
11 AS ISSUED BY MOODY'S; AND

12  
13 B. TO PASS THE FINANCIAL TEST, A COMPANY MUST MEET ALL OF  
14 THE FOLLOWING ADDITIONAL REQUIREMENTS:

15  
16 (1) THE COMPANY MUST HAVE AT LEAST ONE CLASS OF  
17 EQUITY SECURITIES REGISTERED UNDER THE  
18 SECURITIES EXCHANGE ACT OF 1934.

19  
20 (2) THE COMPANY'S INDEPENDENT CERTIFIED PUBLIC  
21 ACCOUNTANT MUST HAVE COMPARED THE DATA USED BY  
22 THE COMPANY IN THE FINANCIAL TEST WHICH IS  
23 DERIVED FROM THE INDEPENDENTLY AUDITED, YEAR END  
24 FINANCIAL STATEMENTS FOR THE LATEST FISCAL YEAR,  
25 WITH THE AMOUNTS IN SUCH FINANCIAL STATEMENT.  
26 IN CONNECTION WITH THAT PROCEDURE, THE LICENSEE  
27 SHALL INFORM THE DEPARTMENT WITHIN 90 DAYS OF  
28 ANY MATTERS COMING TO THE ATTENTION OF THE  
29 AUDITOR THAT CAUSE THE AUDITOR TO BELIEVE THAT  
30 THE DATA SPECIFIED IN THE FINANCIAL TEST SHOULD

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1 BE ADJUSTED AND THAT THE COMPANY NO LONGER  
2 PASSES THE TEST.

3  
4 (3) AFTER THE INITIAL FINANCIAL TEST, THE COMPANY  
5 MUST REPEAT PASSAGE OF THE TEST WITHIN 90 DAYS  
6 AFTER THE CLOSE OF EACH SUCCEEDING FISCAL YEAR.

7  
8 C. IF THE LICENSEE NO LONGER MEETS THE REQUIREMENTS OF SECTION  
9 II.A. OF THIS APPENDIX, THE LICENSEE MUST SEND IMMEDIATE  
10 NOTICE TO THE DEPARTMENT OF ITS INTENT TO ESTABLISH  
11 ALTERNATE FINANCIAL ASSURANCE AS SPECIFIED IN THE  
12 DEPARTMENT'S REGULATIONS WITHIN 120 DAYS OF SUCH NOTICE.

13  
14 III. COMPANY SELF-GUARANTEE

15  
16 THE TERMS OF A SELF-GUARANTEE WHICH AN APPLICANT OR LICENSEE FURNISHES  
17 MUST PROVIDE THAT:

18  
19 A. THE GUARANTEE WILL REMAIN IN FORCE UNLESS THE LICENSEE SENDS  
20 NOTICE OF CANCELLATION BY CERTIFIED MAIL TO THE DEPARTMENT.  
21 CANCELLATION MAY NOT OCCUR, HOWEVER, DURING THE 120 DAYS BEGINNING  
22 ON THE DATE OF RECEIPT OF THE NOTICE OF CANCELLATION BY THE  
23 DEPARTMENT, AS EVIDENCED BY THE RETURN RECEIPT.

24  
25 B. THE LICENSEE SHALL PROVIDE ALTERNATIVE FINANCIAL ASSURANCE AS  
26 SPECIFIED IN THE DEPARTMENT'S REGULATIONS WITHIN 90 DAYS FOLLOWING  
27 RECEIPT BY THE DEPARTMENT OF A NOTICE OF CANCELLATION OF THE  
28 GUARANTEE.  
29  
30

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- 1 C. THE GUARANTEE AND FINANCIAL TEST PROVISIONS MUST REMAIN IN EFFECT  
2 UNTIL THE DEPARTMENT HAS TERMINATED THE LICENSE OR UNTIL ANOTHER  
3 FINANCIAL ASSURANCE METHOD ACCEPTABLE TO THE DEPARTMENT HAS BEEN  
4 PUT IN EFFECT BY THE LICENSEE.  
5
- 6 D. THE LICENSEE WILL PROMPTLY FORWARD TO THE DEPARTMENT AND THE  
7 LICENSEE'S INDEPENDENT AUDITOR ALL REPORTS COVERING THE LATEST  
8 FISCAL YEAR FILED BY THE LICENSEE WITH THE SECURITIES AND EXCHANGE  
9 COMMISSION PURSUANT TO THE REQUIREMENTS OF SECTION 13 OF THE  
10 SECURITIES AND EXCHANGE ACT OF 1934.  
11
- 12 E. IF, AT ANY TIME, THE LICENSEE'S MOST RECENT BOND ISSUANCE CEASES  
13 TO BE RATED IN ANY CATEGORY OF "A" OR ABOVE BY EITHER STANDARD AND  
14 POORS AND MOODYS, THE LICENSEE WILL PROVIDE NOTICE IN WRITING OF  
15 SUCH FACT TO THE DEPARTMENT WITHIN 20 DAYS AFTER PUBLICATION OF  
16 THE CHANGE BY THE RATING SERVICE. IF THE LICENSEE'S MOST RECENT  
17 BOND ISSUANCE CEASES TO BE RATED IN ANY CATEGORY OF A OR ABOVE BY  
18 BOTH STANDARD AND POORS AND MOODYS, THE LICENSEE NO LONGER MEETS  
19 THE REQUIREMENTS OF SECTION II.A. OF THIS APPENDIX.  
20
- 21 F. THE APPLICANT OR LICENSEE MUST PROVIDE TO THE DEPARTMENT A WRITTEN  
22 GUARANTEE (A WRITTEN COMMITMENT BY A CORPORATE OFFICER) WHICH  
23 STATES THAT THE LICENSEE WILL FUND AND CARRY OUT THE REQUIRED  
24 DECOMMISSIONING ACTIVITIES OR, UPON ISSUANCE OF AN ORDER BY THE  
25 DEPARTMENT, THE LICENSEE WILL SET UP AND FUND A TRUST IN THE  
26 AMOUNT OF THE CURRENT COST ESTIMATES FOR DECOMMISSIONING.



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Colorado Department  
of Public Health  
and Environment

**RULES AND REGULATIONS**  
**Pertaining to**  
**RADIATION CONTROL**

**Radiation Control Division**

STATE OF COLORADO  
RULES AND REGULATIONS  
PERTAINING TO RADIATION CONTROL

	<u>Effective Date</u>
Part 1 - General Provisions	January 1, 1994
Part 2 - Registration of Radiation Machines, Facilities and Services	April 30, 1992
Part 3 - Licensing of Radioactive Material	December 30, 1990
Part 4 - Standards for Protection Against Radiation	January 1, 1994
Part 5 - Radiation Safety Requirements for Industrial Radiographic Operations	June 30, 1994
Part 6 - Use of X-Rays in the Healing Arts	September 1, 1992
Part 7 - Use of Radionuclides in the Healing Arts	December 30, 1990
Part 8 - Radiation Safety Requirements for Analytical X-Ray Equipment	December 30, 1990
Part 9 - Radiation Safety Requirements for Particle Accelerators	December 30, 1990
Part 10 - Notices, Instructions, and Reports to Workers: Inspections	November 30, 1990
Part 11 - Reserved	July 1, 1996
Part 12 - Fees for Materials Licenses and Other Radiation Control Services	July 1, 1993
Part 13 - Penalties for Violations	June 30, 1984
Part 14 - Licensing Requirements for Land Disposal of Low Level Radioactive Waste	December 30, 1985
Part 15 - Colorado Low Level Radioactive Waste Rate Regulations	December 30, 1985
Part 16 - Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies	December 30, 1990
Part 17 - Transportation of Radioactive Material	January 1, 1997
Part 18 - Milling of Uranium, Thorium and Related Radioactive Material	December 30, 1990
Part 19 - Licenses and Radiation Safety Requirements For Irradiators	July 1, 1997

STATE OF COLORADO  
RULES AND REGULATIONS  
PERTAINING TO RADIATION CONTROL

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\* May be used until March 1, 1998.

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## PART 1

### GENERAL PROVISIONS

- RH 1.1 Authority. Rules and regulations set forth herein are adopted pursuant to the provisions of Section 25-1-107(1)(s) and (1)(t), 25-1-108 and 25-11-104, CRS 1988. Rules and regulations pertaining to land disposal of low-level radioactive waste Parts 14 and 15 are adopted pursuant to the provisions of 24-60-2205.
- RH 1.2 Basis and Purposes. A statement of the basis and purpose of these regulations is incorporated as part of these regulations; a copy may be obtained from the Department.
- RH 1.3 Scope. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.<sup>1</sup>
- RH 1.4 Definitions. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form, low specific activity (LSA) and surface contaminated object (SCO) material, permitted in a Type A package. These values are either listed in Appendix A of Part 17 of these regulations, Table A-1, or may be derived in accordance with the procedure prescribed in Appendix A of Part 17 of these regulations.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

"Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

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<sup>1</sup> Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

"Act" means Title 25, Article 11, Colorado Revised Statutes 1989 Replacement Volume, as amended.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

"Adult" means an individual 18 or more years of age.

"Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations;

(1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Part 4 of these regulations, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

"As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material; and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Department.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration per second or transformation per second (dps or  $s^{-1}$ ).

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in-vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Byproduct material" means:

(1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations.

"Chelating agent" means amine polycarboxylic acids, hydroxy-carboxylic acids, gluconic acid, and polycarboxylic acids.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Committed dose equivalent" ( $H_{T,50}$ ) means the dose equivalent to organs or tissues of reference (t) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.



"Committed effective dose equivalent" ( $H_{e,50}$ ) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{e,50} = \sum W_T H_{T,50}$ ).

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7 \times 10^{10}$  transformations per second ( $s^{-1}$ ).

"Deep dose equivalent" ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).

"Department" means the Colorado Department of Health.

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

"Dose equivalent ( $H_T$ )" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

"Effective dose equivalent ( $H_e$ )" means the sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $W_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_e = \sum W_T H_T$ ).

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure" means the quotient of  $dQ$  by  $dm$  where " $dQ$ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " $dm$ " are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See RH 1.14 units of exposure and dose for the special unit.<sup>2</sup>

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 Centimeter (300 mg/cm<sup>2</sup>).

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Department regulations in 40 CFR Part 261.

"Healing arts" means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition.

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<sup>2</sup> When not underlined as above (or indicated as "exposure" (X), the term "exposure" has a more general meaning in these Regulations.

"High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

(1) Dose equivalent:

(A) by the use of individual monitoring devices; or

(B) by the use of survey data; or

(2) Committed effective dose equivalent:

(A) by bioassay; or

(B) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition of DAC-hours in Part 4).

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

"Inspection" means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, license conditions and other requirements of the Department.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"License" means a license issued by the Department in accordance with the regulations adopted by the Department.

"Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.



"Licensee" means any person who is licensed by the Department in accordance with these regulations and the Act.

"Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Limits" see "dose limits".

"Lost or missing licensed source of radiation" means licensed or registered source(s) of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Mammographer" means a person who operates a machine source of ionizing radiation, commonly known as an "x-ray machine", in the conduct of a mammography exam.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Part 17 of these regulations.

"Member of the public" means an individual, except an individual who is performing assigned duties for the licensee or registrant involving exposure to sources of radiation.

"Minor" means an individual less than 18 years of age.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

"NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.<sup>3</sup>

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

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<sup>3</sup> For the purpose of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight per cent thorium-232).

"Natural uranium" means uranium containing a mixture of the uranium isotopes 234, 235 and 238 (approximately 0.7 weight percent uranium-235 and the remainder by weight essentially uranium-238), that is neither enriched nor depleted in the isotope uranium 235.

"Normal form radioactive material" means radioactive material that has not been demonstrated to qualify as "special form radioactive material".

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the licensee or registrant involve exposure to sources of radiation. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator" (see "accelerator").

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

"Personnel monitoring equipment". [See "Individual monitoring devices"].

"Pharmacist" means an individual licensed by the State of Colorado to compound and dispense drugs, prescriptions, and poisons.

"Public dose" means the dose received by a member of the public from sources of radiation from licensed or registered operations. Public dose does not include occupational dose, or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

"Physician" means an individual licensed by the State of Colorado to dispense drugs in the practice of medicine.

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Qualified expert" means an individual, approved by the Department, having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. The individual shall:

(1) Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

(2) Hold a master's or doctor's degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed 1 year of documented, full time training in the appropriate field and also 1 year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or

(3) Receive approval from the Department for specific activities.

"Quality factor" (Q) means the modifying factor, listed in Tables I and II of RH 1.14, that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 jule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which Radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose" (see "dose").

"Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

"Radiation safety officer" means an individual who has the knowledge, responsibility and authority to apply appropriate radiation protection regulations.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (see "bioassay").

"Registrant" means any person who is registered with the Department and is legally obligated to register with the Department pursuant to these regulations and the Act.

"Registration" means registration with the Department in accordance with the regulations adopted by the Department.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sievert).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs/kilogram of air (see "Exposure").

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Shallow dose equivalent" ( $H_p$ ), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 Centimeter ( $7 \text{ mg/cm}^2$ ) averaged over an area of 1 square centimeter.

"SI" means the abbreviation for the international system of units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source material" means material, in any physical or chemical form, including ores, that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Special form radioactive material" means radioactive material that satisfies the following conditions:

- (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
- (2) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
- (3) It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

- (1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
- (2) any material artificially enriched by any of the foregoing but does not include source material.



"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 (\text{grams contained U-235})}{350} + \frac{50 (\text{grams U-233})}{200} + \frac{50 (\text{grams Pu})}{200} = 1$$

"Specific activity of a radionuclide" means the radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Test" means the process of verifying compliance with an applicable regulation.

"These regulations" mean all parts of the Colorado Rules and Regulations Pertaining to Radiation Control.

"Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" is an equivalent term.

"Uranium - depleted, enriched"

(1) "Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

(2) "Enriched uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

"Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission.

"Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

"Week" means 7 consecutive days starting on Sunday.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Worker" means an individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant.

"Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3E+5$  MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.



## Exemptions from the Regulatory Requirements

### RH 1.5 Exemptions.

- 1.5.1 General Provision. The Department may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.
- 1.5.2 U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:
- 1.5.2.1 prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
  - 1.5.2.2 prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;
  - 1.5.2.3 prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and
  - 1.5.2.4 any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:
    - 1.5.2.4.1 that the exemption of the prime contractor or subcontractor is authorized by law; and
    - 1.5.2.4.2 that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

## General Regulatory Requirements

- RH 1.6 Records. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these regulations.

RH 1.7      Inspections.

1.7.1      Each licensee and registrant shall afford the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

1.7.2      Each licensee and registrant shall make available to the Department for inspection, upon reasonable notice, records maintained pursuant to these regulations.

RH 1.8      Tests. Each licensee and registrant shall perform upon instructions from the Department, or shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

1.8.1      sources of radiation;

1.8.2      facilities wherein sources of radiation are used or stored;

1.8.3      radiation detection and monitoring instruments; and

1.8.4      other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

**Additional Regulatory Requirements**

RH 1.9      Additional Requirements. The Department may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

**Enforcement Requirements**

RH 1.10      Violations. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Additionally, any person who violates any provision of the Act or any regulation may be subject to a civil penalty as provided for in Part 13 or these regulations.

RH 1.11      Impounding. Sources of radiation shall be subject to impounding pursuant to the Act.

RH 1.12      Prohibited Uses.

- 1.12.1      A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the registry of sealed source and devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.
- 1.12.2      A shoe-fitting fluoroscopic device shall not be used.

Communications

- RH 1.13      Communications. All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Department.

Informational Provisions

RH 1.14      The International System of Units (SI).

- 1.14.1      Exposure. As used in these regulations, the unit of exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to  $2.58 \times 10^{-4}$  coulomb per kilogram.
- 1.14.2      As used in these regulations, the units of dose are:
- 1.14.2.1      Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).
- 1.14.2.2      Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 Joule per kilogram (0.01 Gy).
- 1.14.2.3      Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).
- 1.14.2.4      Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).
- 1.14.3      As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I  
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent <sup>a</sup>
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

<sup>a</sup>Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

1.14.4 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in RE 1.14.3, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II  
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE  
EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron energy (MeV)	Quality factor <sup>a</sup> (Q)	Fluence per unit dose equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> rem <sup>-1</sup> )	Fluence per unit dose equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )
(thermal)	2.5 E-8	2	980 E+6	980 E+8
	1 E-7	2	980 E+6	980 E+8
	1 E-6	2	810 E+6	810 E+8
	1 E-5	2	810 E+6	810 E+8
	1 E-4	2	840 E+6	840 E+8
	1 E-3	2	980 E+6	980 E+8
	1 E-2	2.5	1010 E+6	1010 E+8
	1 E-1	7.5	170 E+6	170 E+8
	5 E-1	11	39 E+6	39 E+8
	1	11	27 E+6	27 E+8
	2.5	9	29 E+6	29 E+8
	5	8	23 E+6	23 E+8
	7	7	24 E+6	24 E+8
	10	6.5	24 E+6	24 E+8
	14	7.5	17 E+6	17 E+8
	20	8	16 E+6	16 E+8
	40	7	14 E+6	14 E+8
	60	5.5	16 E+6	16 E+8
	1 E+2	4	20 E+6	20 E+8
	2 E+2	3.5	19 E+6	19 E+8
	3 E+2	3.5	16 E+6	16 E+8
	4 E+2	3.5	14 E+6	14 E+8

<sup>a</sup> Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

<sup>b</sup> Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

1.14.5 Units of activity. For purposes of these regulations, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

1.14.5.1 One becquerel (Bq) = 1 disintegration per second or transformation per second (dps or s<sup>-1</sup>).

1.14.5.2 One curie (Ci) = 3.7 E+10 disintegrations per second or transformations per second (dps or s<sup>-1</sup>) = 3.7 E+10 becquerel (Bq) = 2.22 E+12 disintegrations per minute (dpm).

RH 1.15     Severability. The provisions of this regulation are severable, and if any provisions or the application of the provisions to any circumstances is held invalid, the application of such provision to other circumstances, and the remainder of this regulation shall not be affected thereby.

RH 1.16     Referenced Materials.

1.16.1     These regulations incorporate by reference material originally published elsewhere. Certified copies of the complete text of incorporated materials referenced are available for public inspection during regular business hours at the Radiation Control Division. Copies of referenced material will be provided at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from:

Director, Radiation Control Division  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South (RCD-DO-B1)  
Denver, Colorado 80222-1530

1.16.2     Any material that has been incorporated by reference may be examined in any State Publications Depository Library. Copies of the incorporated materials have been sent to the State Publications Depository and Distribution Center, and are available for interlibrary loan.

1.16.3     Material referenced in these regulations does not include amendments to or revised editions of the material published later than the effective date of the relevant regulation.





PART 2

REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

RH 2.1 Purpose and Scope.

2.1.1 This part provides for the registration of facilities, for the certification of radiation machines, for the registration of persons providing radiation machine installation, servicing, and/or services, and for the registration of qualified inspectors.

2.1.2 In addition to the requirements of this part, all registrants are subject to the applicable provisions of other parts of these Regulations.

RH 2.2 Definitions. As used in this part:

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Calibrate" means to adjust or determine or both: (1) the response or reading of an instrument relative to a series of conventionally true values; or (2) the strength of a radiation source relative to a standard or conventionally true value.

"Certification Evaluation" means the evaluation of a radiation machine and/or facility by the Department, or by a qualified inspector, for the purpose of evaluating the performance of the radiation machine system and/or facility against these Regulations.

"Facility" means the location at which one or more radiation machines are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

"NIST" means National Institute of Standards and Technology.

"Qualified Expert" means:

(a) For radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in an appropriate field by the American Board of Radiology, or the American Board of Medical Physics, or by the American Board of Health Physics or the American Board of Nuclear Medicine Science, or persons who can demonstrate equivalent education, training, experience and knowledge).

(b) For radiation therapy calibrations, a person having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics, X-ray and Radium Physics, or Therapeutic Radiological Physics by the American Board of Radiology, or the American Board of Medical Physics, or persons who can demonstrate equivalent education, training, experience and knowledge).

"Qualified Inspector" means an individual who has demonstrated to the Department the ability to perform inspections and evaluate radiation machines and facilities, and who meet the criteria in Part 2, Appendix B.

"Servicing and Services" means each person who is engaged in the business of installing, or offering to install radiation machines and their related components, or is engaged in the business of furnishing, or offering to furnish radiation machine servicing or services.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

#### Exemptions from the Regulatory Requirements

##### RH 2.3

##### Exemptions.

- 2.3.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 micro Sv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.
- 2.3.2 Radiation machines while in transit or storage incident thereto are exempt from the requirements of this part.
- 2.3.3 Domestic television receivers are exempt from the requirement of this part.
- 2.3.4 Radiation machines which are in storage provided that the electrical circuitry is inactivated, dismantled, and made physically inoperable so that the radiation machine is not capable of producing radiation.

## Registration

- RH 2.4      Application for Registration.
- 2.4.1      Application for Registration of Radiation Machine Facilities.  
Each person possessing or in the process of coming into the possession of a radiation machine facility shall:
- 2.4.1.1      Be registered with the Department.
- 2.4.1.2      Apply for registration of such facility with the Department prior to the operation of a radiation machine facility.
- 2.4.1.3      Application for registration shall be completed on forms furnished by the Department and shall contain all the information required by the form and any accompanying instructions.
- 2.4.1.4      Designate on the application form an individual to be responsible for radiation protection.
- 2.4.2      Application for Registration of Servicing and Services.
- 2.4.2.1      Each person who is engaged in the business of installing or offering to install radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State, shall apply for registration of such services with the Department by July 1, 1992, or thereafter prior to furnishing or offering to furnish any such services.
- 2.4.2.2      Application for registration shall be completed on forms furnished by the Department and shall contain all information required by the Department as indicated on the forms and accompanying instructions. Each registration shall be for a period of 2 years.
- 2.4.2.2.1      Application fee(s) pursuant to Appendix A of this Part must accompany the application when it is filed. The Department shall not review or otherwise process applications for which no remittance is received. These applications may be returned to the applicant.
- 2.4.2.3      Each person applying for registration under this Part shall specify:

- 2.4.2.3.1 That they have read and understand the requirements of these Regulations; including the Federal Performance Standard (21 CFR Chapter I, Subchapter J);<sup>1</sup> and
- 2.4.2.3.2 The services for which they are applying for registration (see RE 2.4.2.4); and
- 2.4.2.3.3 The training and experience that qualify them to discharge the services for which they are applying for registration; and
- 2.4.2.3.4 The type of measurement instruments used to determine compliance with these Regulations, frequency of calibration, and source of calibration; and
- 2.4.2.3.5 The type of personnel monitoring supplied, frequency of reading, and replacement or exchange schedule (if appropriate). (See RE 4.17 and 4.18)
- 2.4.2.4 For purpose(s) of this Part, services may include but shall not be limited to:
  - 2.4.2.4.1 Installation of radiation machines and associated radiation machine components; and
  - 2.4.2.4.2 Servicing of radiation machines and associated radiation machine components; and
  - 2.4.2.4.3 Calibration of radiation machines or radiation measurement instruments or devices; and
  - 2.4.2.4.4 Radiation protection or health physics consultations or surveys (limited to be performed only by qualified experts).
- 2.4.2.5 No person shall perform services on radiation machine systems or facilities which are not specifically stated for that person on the Notice of Registration issued by the Department.
- 2.4.2.6 Assemblers and services and servicing personnel shall provide to the registrant instruction manuals, manufacturer specifications and other information, as required by the Federal Performance Standard,<sup>1</sup> and these Regulations, which are applicable to the newly installed x-ray machine systems or components.

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<sup>1</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-E1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.

- 2.4.2.7 If a service company has in its employment an individual that is authorized to provide certification evaluations, or if a qualified inspector is authorized to perform servicing and servicing, then the person providing servicing or the certification evaluation shall notify the registrant of their right and option to choose a different company to perform the service or evaluation as appropriate. Such notification shall be provided on Form RCD-65, and shall be furnished to the registrant prior to beginning the service or evaluation.

2.4.3 Application for Registration of Qualified Inspectors

Qualified inspectors shall meet the criteria established in Part 2 Appendix B.

- 2.4.3.1 Non-Department individuals requesting Department approval to perform certification evaluations of radiation machines and facilities shall submit to the Department an application for authorization to perform such evaluations. The application shall be submitted on Department Form RCD 53, together with the required fee prescribed in Appendix A of this Part 2.
- 2.4.3.2 Authorization to perform certification evaluations in accordance with the requirements of these Regulations shall be for a period of 2 years. The Department shall provide written notification of the authorization to the qualified inspector.
- 2.4.3.2.1 The Department may withdraw, limit or qualify its approval of individuals to perform certification evaluations upon determining that such action is necessary in order to prevent undue hazard to public health and safety.
- 2.4.3.2.2 In any case in which a qualified inspector, not less than 30 days prior to the expiration of his/her authorization to perform certification evaluations, has filed an application in proper form for renewal or for a new registration authorizing the same activities, such existing authorization shall not expire until final action by the Department.
- 2.4.3.2.3 Audits. The Department shall audit the evaluation findings and inspection procedures of qualified inspectors. Qualified inspectors who fail to adequately evaluate radiation machine systems and facilities, or who fail to provide complete and accurate certification reports, or fail to comply with the provisions of these Regulations shall be subject to the withdrawal of Departmental approval.

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<sup>1</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.



- 2.4.3.3            Instrumentation.    Measurements shall be made with instruments which are sufficiently sensitive to determine compliance with these Regulations. The instruments must be maintained and used in good working order. Such equipment shall be calibrated every 2 years, or in accordance with the manufacturer's recommendations, whichever is more frequent, or after any repair that could affect the calibration. Calibrations shall be traceable to the National Institute of Standards and Technology where such traceability exists. In lieu of calibration, instrument accuracy may, with Department approval, be determined by intercomparison with a suitable and appropriately calibrated instrument.
- 2.4.4            Application for Registration of Provisional Mammographers.
- 2.4.4.1            Mammographers who are not registered in mammography by the American Registry of Radiologic Technologists (ARRT) shall be registered with the Department for a provisional certificate. The provisional certificate shall be valid for a period up to:
- 2.4.4.1.1            One (1) year as part of a structured training program in mammography, while under the direct supervision of a radiologic technologist who is registered in mammography by the ARRT. The provisional certificate for training under this section, RH 2.4.4.1.1, may not be renewed.
- 2.4.4.1.2            Six (6) months subsequent to the training in RH 2.4.4.1.1 while waiting for the certification test to be given by the ARRT and for the test results to be released. The six (6) month provisional certificate may be renewed only once.
- 2.4.4.2            Application for registration for a provisional certificate shall be completed on forms furnished by the Department and shall contain all the information required by the form and any accompanying instructions. The application shall be submitted to the Department together with the applicable fee in Appendix A.
- 2.4.5            Registration by the Department.    This section applies to facility registrants, qualified inspectors, and servicing and services.
- 2.4.5.1            Upon a determination that an applicant meets the requirements of the Regulations, the Department shall issue a Notice of Registration.
- 2.4.5.2            The Department may incorporate in the Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's activities as it deems appropriate or necessary.

- 2.4.6 Report of Changes. The registrant shall notify the Department in writing within thirty (30) days of making any change which would render inaccurate the information contained in the application for registration and/or, as appropriate, the Notice of Registration.

#### Revocation of Registrations

- 2.4.7 Modification and Revocation of Registration. The terms and conditions of all registrations shall be subject to amendment, revision, or modification or the registration may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.

#### Certification Evaluations

- RH 2.5 Certification Evaluations.

- 2.5.1 Frequency of Certification Evaluations. Each radiation machine registrant shall have their radiation machine(s) and facility evaluated by a Department approved qualified inspector in accordance with the frequency established in RH 2.5.1.1 through 2.5.1.2. Such evaluations shall be capable of determining if the machine is safe for the intended uses and in compliance with the specifications of the State Board of Health and the equipment manufacturer. However, these evaluations are in addition to and not intended to replace the recommended equipment calibration procedures or facility quality assurance programs for purposes of manufacturer(s) equipment calibration or quality assurance.

- 2.5.1.1 Frequency by Type of Radiation Machine Facility:
- |   |                            |
|---|----------------------------|
| Hospitals, Osteopathic,<br>Medical and Chiropractic<br>Facilities . . . . .                       | Every year                 |
| Mobile Industrial Radiography<br>Excluding Cabinet X-ray<br>and Airport Baggage Systems . . . . . | Every year                 |
| Veterinary, Podiatrist,<br>and Dental facilities . . . . .  | Every 3 years <sup>2</sup> |

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<sup>2</sup>Podiatry and dental radiation machine facilities that operate radiographic x-ray machine(s) or tomographic systems that have variable kilovoltage peak (kVp), and variable milliamperage (Ma), and variable collimation shall have these systems evaluated on an annual (every year) frequency.



Out-of-State Radiation  
Machines . . . . . Within 1 year prior<sup>3</sup>  
to entering State

All others, e.g., fixed  
radiography, airport inspection,  
analytical systems . . . . . Every 2 years

- 2.5.1.1.1 Each certification evaluation subsequent to the initial certification evaluation shall be completed in the same month as the previous certification evaluation.
- 2.5.1.1.2 Notwithstanding the requirements of RH 2.5.1.1.1, the registrant may have a certification evaluation of a machine in a month prior to the month in which it is due, which shall become the new month in which the certification is due.
- 2.5.1.1.3 A certification evaluation conducted after the month in which it was due shall not alter or change the month in which subsequent certification evaluations are due.
- 2.5.1.2 New Installations. All new installations of radiation machine systems or replacement components which affect or could potentially affect a change in the radiation output shall be evaluated within 3 months of installation.
- 2.5.1.3 State Inspections. Any radiation machine facility not inspected in accordance with RH 2.5.1.1 through 2.5.1.2, or otherwise determined to be out of compliance with these Regulations, shall be subject to a Department enforcement inspection and subject to the fees in Appendix A of this Part 2.
- 2.5.2 Procedures for Certification Evaluations.
- 2.5.2.1 Inspection Procedures.
- 2.5.2.1.1 Evaluation of radiation machines and facilities shall be in accordance with procedures which are capable of determining compliance with the Regulations.
- 2.5.2.1.2 Each qualified inspector shall perform radiation machine system and facility evaluations within the category(s) authorized by the Department.

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<sup>3</sup>Persons proposing to bring radiation machines into the state should note the specific requirements of RH 2.8.

2.5.2.2

Reporting and Labeling Procedures.

2.5.2.2.1

Each qualified inspector shall certify and be responsible to provide accurate and complete Certification Evaluation Reports to the registrant/facility and to the Department on Department form RCD 59-1, in accordance with the instructions contained in that form. A clear and legible report may be substituted for the Department form RCD 59-1, provided that it is in the same format and provides all of the information required by form RCD 59-1.

2.5.2.2.2

Qualified inspectors shall provide to the registrant and Department a copy of the Certification Evaluation Report. The Report shall indicate compliance or specific violations with these Regulations. Recommendations for corrective actions should be provided to the registrant (if applicable) to assist in achieving full compliance and/or improving the quality of the imaging process, and improving radiation Safety.

2.5.2.2.3

When it is determined that the requirements of these Regulations or manufacturer's required specifications are met, the qualified inspector shall affix a certification label issued by the Department in a location clearly visible to the machine operator and/or patient.

2.5.2.2.4

If the radiation machine fails to meet these Regulations or manufacturer's required specifications, the qualified inspector shall:

2.5.2.2.4.1

Reserved.

2.5.2.2.4.2

Notify the registrant/owner immediately and shall notify the Department within 3 business days after identifying that the facility is in noncompliance.

2.5.2.2.5

If the radiation machine fails to meet these Regulations or required manufacturer specifications and is determined to be UNSAFE FOR HUMAN USE, the qualified inspector shall:

2.5.2.2.5.1

Affix to such radiation machine system an Unsafe For Human Use label issued by the Department indicating such machine is not authorized for human use. The label shall be affixed in a location clearly visible to the patient.

2.5.2.2.5.2

Notify the registrant/owner immediately and shall notify the Department within 3 business days after identifying that the facility is in noncompliance.

2.5.2.2.6 Concealing, defacing or altering of Department issued labels is prohibited.

2.5.2.2.7 Labels shall only be affixed by:

2.5.2.2.7.1 A qualified inspector on the basis of the certification evaluation.

2.5.2.2.7.2 Reserved.

2.5.2.2.7.3 Reserved.

2.5.2.3 Department Actions.

2.5.2.3.1 The Department shall notify the registrant regarding inaction on any item of violation. The Department shall specify a date by which compliance must be achieved.

2.5.2.3.2 The Department shall confirm and, if appropriate, verify by inspection, registrants corrective actions to assure compliance of these Regulations.

2.5.2.3.3 The Department shall charge an inspection fee for the inspection of a radiation machine system or facility if the registrant fails the requirements stated in RH 2.5.1, or if any item of violation has not been corrected in accordance with the compliance schedule established in RH 2.5.2.3. The Department inspection and fee schedule payment shall be in accordance with Appendix A of this Part 2.

RH 2.6 Facility Registrant Responsibilities.

2.6.1 The registrant shall be responsible to ensure that the requirements of these Regulations are being complied with for the operation of the radiation machine facility.

2.6.2 If a radiation machine or facility fails to meet these Regulations or required manufacturer specifications the facility registrant shall:

2.6.2.1 If a radiation machine has been determined to be unsafe for human use;

2.6.2.1.1 Not use the radiation machine thereafter for human use until subsequent certification by a Department approved qualified inspector; and

2.6.2.1.2 Notify the Department of the appropriate corrective action plan within 15 calendar days of the inspection.

2.6.2.2 Correct any items of violation within the time specified by the Department.

- 2.6.2.3 Provide documentation to the Qualified Inspector upon correction of any radiation machine items of violation to confirm that indicated violations and repairs have been completed to bring the radiation machine system and/or facility into compliance<sup>4</sup>.
- 2.6.2.4 Provide documentation to the Department upon correction of any facility items of violation to confirm that indicated violations have been addressed to bring the facility into compliance.
- 2.6.2.5 The facility registrant shall pay the required fee for certification labels issued to the registrant by the Qualified Inspector.
- 2.6.3 Record Retention.
- 2.6.3.1 The registrant shall maintain for a period of three years copies of written communications concerning radiation safety including certification evaluations, notice of violations, complaints, investigations, instructions or explanations affecting the use, repair, adjustment, maintenance or testing of the radiation machine and/or facility for review by the Department.
- 2.6.3.2 The registrant shall maintain for the duration of the registration, records of shielding evaluations performed for the facility; and until a machine is retired from service, the operator's and service manual provided by the manufacturer, if available.
- 2.6.3.2.1 If the operator's manual is not obtainable from the manufacturer, one must be developed and maintained by the registrant. This shall contain written operating procedures to be followed, including:
- 2.6.3.2.1.1 A description of each control panel knob, button, and meter, its purpose and function;
- 2.6.3.2.1.2 Techniques for collimation and centering of the beam to the image receptor;
- 2.6.3.2.1.3 The function of all locks and detentes; and
- 2.6.3.2.1.4 Emergency shut-down instructions.
- 2.6.3.3 Personnel monitoring records shall be maintained in accordance with the requirements of RH 4.10.4.
- 2.6.4 The registrant shall permit radiation machine servicing or services as described in RH 2.4.2.4 only by a person that provides evidence that he is currently registered with the Department as a provider of services in accordance with these Regulations.
- 2.6.5 Reserved.
- 2.6.6 The registrant shall meet the requirements of Part 10 of these Regulations.
- 2.6.7 The registrant shall report changes in facility or equipment pursuant to RH 2.4.5.

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<sup>4</sup>Copies of service reports may be acceptable evidence of completed corrective actions.

RH 2.7      Assembler and/or Transfer Obligation.

- 2.7.1      Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines, or components which affect radiation output in this State shall notify the Department in writing within 15 days of installation with the following information:
- 2.7.1.1      The full name and address of persons who have received these radiation machines or components and the specific location within the facility; and
- 2.7.1.2      Specific information of the x-ray system or sub-system to include the manufacturer, model, and serial number of each radiation machine or component transferred; and
- 2.7.1.3      The date of transfer, assembly, or installation of each radiation machine or component; and
- 2.7.1.4      An affirmation that all instruction manuals and other information as required by the Federal Performance Standard<sup>1</sup> and these Regulations applicable to the newly installed x-ray machine system or components have been delivered to the registrant.
- 2.7.1.5      A report of assembly of a diagnostic x-ray system submitted in compliance with requirements of the Federal Performance Standard (21 CFR 1020.30(d))<sup>1</sup> shall be submitted to the Department within 15 days following completion of the assembly. Such report shall suffice in lieu of any reports required in RH 2.7.1.
- 2.7.1.6      The assembly is considered completed and operational when the unit is ready for its intended use.
- 2.7.2      No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines, components or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the manufacturer's specifications and the requirements of these Regulations.

Reciprocity

RH 2.8      Out-of-State Radiation Machines.

- 2.8.1      Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Department at least 3 working days before such machine is to be used in the State. The notice shall include:
- 2.8.1.1      The name, address, and telephone number of the following:
- 2.8.1.1.1      The owner of the radiation machine(s); and

<sup>1</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.



- 2.8.1.1.2 The individual responsible for the use and operation of the radiation machine(s) while in the state.
- 2.8.1.2 The type of radiation machine, the manufacturer, the model number, the serial number of the control, and the serial number of the tube housing; and
- 2.8.1.3 The nature, duration, and scope of use; and
- 2.8.1.4 The exact location(s) where the radiation machine(s) is to be used. If the facility is mobile, the geographic areas and locations within Colorado to be covered; and
- 2.8.1.5 State(s) in which this machine(s) is registered, date of application and signature of the person responsible for the use of the x-ray system or facility; and
- 2.8.1.6 Copies of documentation that the radiation machine(s) have been evaluated in accordance with these Regulations, or other State Regulations which are equivalent, or recommended manufacturer's specifications. Evaluations shall be performed within one year prior to entry into the state as required in RH 2.5.1.1.
- 2.8.2 If, for a specific case, the three working-day period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted.
- 2.8.3 The person referred to in RH 2.8.1 shall:
- 2.8.3.1 Comply with all applicable regulations of the Department<sup>5</sup>;
- 2.8.3.2 Supply the Department with such other information as the Department may reasonably request; and
- 2.8.3.3 Not operate within the State on a temporary basis in excess of 180 calendar days per year.

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<sup>5</sup>Persons proposing to bring radiation machines into the state should note the specific requirements of RH 2.5.1.1 and RH 6.3.1.1.11.

PART 2  
APPENDIX A  
SCHEDULE OF FEES FOR RADIATION MACHINE SERVICES

<u>Category of Radiation Machine Services</u>	<u>Type of Fee<sup>1</sup></u>	<u>Maximum Fee<sup>2</sup></u>	<u>Maximum Frequency</u>
Hourly Rate <sup>3</sup>		\$ 129	Per Hour <sup>3</sup>
1. Hospitals, Osteopathic, Medical and Chiropractic Radiation Machines and Facilities	Certification	\$ 30 <sup>4</sup>	every year
2. Industrial Radiography,	Certification	\$ 30 <sup>4</sup>	every year
3. Veterinarian, Dental, and Podiatrist Radiation Machines and Facilities	Certification	\$ 30 <sup>4</sup>	every 3 years
4. Out-of-State Radiation Machine(s)	Certification	\$ 30 <sup>4</sup>	within one year, prior to entering the State
5. All Radiation Machines and Facilities Not Listed in Category 1, 2, 3, or 4.	Certification	\$ 30 <sup>4</sup>	every 2 years
6. Certification of Qualified Inspectors	Certification	\$ 100 <sup>5</sup>	every 2 years
7. Servicing and Services	Registration	\$ 100 <sup>5</sup>	every 2 years
8. Enforcement action <sup>6</sup>	Inspection	\$1,157 <sup>7</sup>	each enforce- ment action
9. Provisional Mammography Certificate	Registration	\$ 50	

(SEE FOOTNOTES AT END OF TABLE)



Footnotes:

1. Types of Fees. Any hours expended by Department personnel for the determination of a facility's compliance status or for enforcement actions against a registrant on or after the effective date of this rule shall be assessed at the current applicable hourly rate or maximum fee.
2. Fees listed in Part 2 Appendix A "Schedule of Fees for Radiation Machine Services" are maximum amounts which may be billed for these categories. In no event will the fee exceed that shown in this schedule. For each service rendered by the Department, records will be maintained of time spent, by at least 15-minute intervals, using reasonable accounting procedures. A statement will be sent to the registrant indicating the actual costs incurred.
3. Hourly Rate. All services rendered by the Department will be based on actual cost and the hourly fee for services will be adjusted every six months from the effective date of these Regulations, and an updated version of the fee schedule shall be available upon request. The adjustment will be based on the Denver Consumer Price Index for All Urban Consumers. Every two years from the effective date of these Regulations, the Department will review the fees and the Department's costs. If the adjusted fees and costs for any categories differ by more than ten percent (10%), the Department will propose a revised fee to the Board of Health for those categories.
4. Fee is the actual costs for each radiation machine tube certification label issued by the Department. For any system which received a Notice of Noncompliance or Unsafe for Human Use label, the department shall issue a certification label to replace the Notice of Noncompliance or Unsafe for Human Use label upon determination of compliance.
5. The annual fee is \$50.00 and is payable every 2 years in the amount of \$100.00.
6. Any registrant that fails the requirements of RE 2.5.1 or any violation that has not been corrected in accordance with the compliance schedule established in RE 2.5.2.3, shall be subject to a Department Enforcement Action at the current hourly rate and/or maximum fee. The Department shall charge enforcement fees for the inspection of radiation machines and facilities which have been determined, by either a qualified inspector or by the Department, to be in noncompliance with these Regulations and with the certification frequency.
7. Represents the maximum fee which may be incurred for the Department Enforcement Actions of each radiation machine and/or facility determined to be in violation with these Regulations by either a qualified inspector or by the Department.

PART 2

APPENDIX B

MINIMUM QUALIFICATIONS FOR  
QUALIFIED INSPECTOR

Tier I<sup>1</sup>

The established minimum criteria for individuals to meet the education and experience are listed for inspector status. The following are representative but not all inclusive lists of the qualifications of individuals who may have sufficient experience and or training to be given the status of qualified inspector.

1. Education and Experience

a. General Requirements

<u>Education/Certification Preparation</u>	<u>Experience</u>
--	-------------------

Board certified in Diagnostic Radiological Physics or Radiological Physics by the American Board of Radiology; or Board certified in Diagnostic Imaging Physics by the American Board of Medical Physics . . . . .	N/A
--	-----

Other Board certifications by the American Board of Radiology or comprehensive certification by the American Board of Health Physics . . . . .	6 months
--	----------

Doctorate or Masters . . . . .	1 year
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BA/BS . . . . .	2 years
-----------------	---------

Associate Degree . . . . .	3 years
----------------------------	---------

Registered Radiologic Technologist (Radiography) . . . . .	4 years
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b. The formal education shall be in a related discipline, such as medical physics, health physics, physics, biophysics, biomedical engineering, or equivalent.

- c. For each category of radiation producing machine for which approval is requested, the experience shall include but not be limited to measuring ionizing radiation; evaluating radiation machines and components; film processing; and familiarity with the appropriate requirements stated in these regulations.
- d. Specific Qualifications for Qualified Inspectors to Inspect Mammography Facilities. Applicants seeking authorization as a qualified inspector for mammography facilities shall additionally meet the following criteria:
  - 1) Board certified in diagnostic radiological physics or radiological physics by the American Board of Radiology; or board certified in diagnostic imaging physics by the American Board of Medical Physics; or board certified in an equivalent specialty area by another certifying body recognized by the American College of Radiology; or
  - 2) Hold a master of science, master of arts, or higher degree in the field of physics, applied physics, radiological physics, biophysics or health physics; have at least two (2) years of training in medical physics in the area of clinical diagnostic radiological physics; and have had at least three (3) years of experience in conducting mammography equipment performance evaluations; or
  - 3) Possess documented equivalent education and experience and training from nationally recognized education institutions and certification bodies; and
  - 4) All individuals shall have received at least 8 hours of documented continuing education specifically related to mammography within two years prior to application to the Department.

2. Proficiency testing for all applicants

The Department shall audit proficiency of all qualified inspectors.

In addition, all applicants must demonstrate to the Department a satisfactory knowledge of the applicable provisions of the Colorado Rules and Regulations Pertaining to Radiation Control.

- 3. Applicable measuring instruments and devices shall be sufficiently sensitive and calibrated in accordance to RH 2.4.3.3 to determine compliance with the applicable provisions of the Colorado Rules and Regulations Pertaining to Radiation Control. Current calibration records shall be submitted upon initial application and each subsequent renewal application. These records shall be readily available for the Departments review upon reasonable request.

## Tier II

Tier II is a preparatory program for individuals who do not meet the minimum requirements for education and experience for qualified inspector status.

Individuals who meet the educational but not the experience qualifications listed for Tier I inspectors can apply for Department approval to perform evaluations under the tutelage and supervision of a Tier I inspector. Before an individual can apply for Tier II status they must have worked directly with a Tier I inspector for 3 months. The Tier I sponsor shall provide the Department adequate documentation that these requirements are met.

All individuals in this category must submit applications to the Department prior to performing any certification evaluations. The application shall include the name(s) and signature of the Tier I individual(s) with whom they will be working.

All submitted Certification Evaluation Reports shall be signed by the Tier II inspector and the Tier I sponsor. The final responsibility for the content of the report belongs to the Tier I inspector who sponsors the Tier II inspector.

### Footnotes:

1. Tier I inspectors are required to meet more stringent qualifications and assume the primary responsibility for all inspections. Tier II inspectors are defined as less qualified individuals who are required to work under the direction of Tier I inspector(s). This system provides for a mechanism whereby individuals could gain the experience to qualify as Tier I inspectors.

Receiving approval in one category does not automatically permit inspectors to perform inspections in other categories.

## PART 3

### LICENSING OF RADIOACTIVE MATERIAL

#### RH 3.1 Purpose and Scope.

3.1.1 This part, and Parts 5, 7, 14, 16, 17, and 18 of these regulations, provide for the licensing of radioactive material. No person shall receive, possess, use, own, transfer, or acquire radioactive material except as authorized pursuant to this part or Parts 7, 14, 17, or 18 of these regulations, or as otherwise provided in these parts.

3.1.2 In addition to the requirements of this part, all licensees are subject to the requirements of Parts 1, 4, 10, 12 and 17 of these regulations. Furthermore, licensees engaged in industrial radiographic operations are subject to the requirements of Part 5 of these regulations, licensees using radionuclides in the healing arts are subject to the requirements of Part 7 of these regulations, licensees engaged in land disposal of radioactive material are subject to the requirements of Part 14 of these regulations, licensees engaged in source material milling are subject to the requirements of Part 18 of these regulations, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of Part 16 of these regulations.

3.1.3 The department may engage the services of qualified persons in order to assist the department in meeting the requirements of these regulations, including, but not limited to, evaluating information that may be required under RH 3.8.8. Fees for these services may be charged by the department as a part of fees charged for radiation control services under Part 12 of these regulations

#### Exemptions From The Regulatory Requirements

#### RH 3.2 Source Material.

3.2.1 Any person is exempt from this part to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

3.2.2 Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

3.2.3 Any person is exempt from this part to the extent that such person receives, possesses, uses, or transfers:



- 3.2.3.1 any quantities of thorium contained in
  - 3.2.3.1.1 incandescent gas mantles,
  - 3.2.3.1.2 vacuum tubes,
  - 3.2.3.1.3 welding rods,
  - 3.2.3.1.4 electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,
  - 3.2.3.1.5 germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,
  - 3.2.3.1.6 rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or
  - 3.2.3.1.7 personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
- 3.2.3.2 source material contained in the following products:
  - 3.2.3.2.1 glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,
  - 3.2.3.2.2 glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction,
  - 3.2.3.2.3 glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or
  - 3.2.3.2.4 piezoelectric ceramic containing not more than 2 percent by weight source material;
- 3.2.3.3 photographic film, negatives, and prints containing uranium or thorium;
- 3.2.3.4 any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;



3.2.3.5 uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that

3.2.3.5.1 the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40,

3.2.3.5.2 each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",<sup>1/</sup>

3.2.3.5.3 each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",<sup>1/</sup> and

3.2.3.5.4 this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

3.2.3.6 natural or depleted uranium used as shielding constituting part of any shipping container, provided that:

3.2.3.6.1 the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and

3.2.3.6.2 the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

3.2.3.7 thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either

3.2.3.7.1 the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

3.2.3.7.2 the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

<sup>1/</sup> The requirements specified in RH 3.2.3.5.2 and RH 3.2.3.5.3 need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the regulations.

3.2.3.8 uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie (185 Bq) of uranium; or

3.2.3.9 thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that

3.2.3.9.1 the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thorium (thorium dioxide), and

3.2.3.9.2 the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

3.2.4 The exemptions in RH 3.2.3 do not authorize the manufacture of any of the products described.

RH 3.3 Radioactive Material Other Than Source Material.

3.3.1 Exempt Concentrations.

3.3.1.1 Except as provided in RH 3.3.1.2, any person is exempt from this part to the extent that such person receives, possesses, uses, transfers, or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A of this part.

3.3.1.2 No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH 3.3.1.1 or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued pursuant to RH 3.12.1 or the general license provided in RH 3.24.

3.3.2 Exempt Quantities.

3.3.2.1 Except as provided in RH 3.3.2.3 and RH 3.3.2.4, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B of this part.

3.3.2.2 Any person who possesses radioactive material received or acquired under the general license formerly provided in RH 3.6.2 is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium-226.

- 3.3.2.3 This paragraph (RH 3.3.2) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
- 3.3.2.4 No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this part, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under RH 3.3.2 or equivalent regulations of the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the Department pursuant to RH 3.12.2 which license states that the radioactive material may be transferred by the licensee to persons exempt under RH 3.3.2 or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State. 2/
- 3.3.3 Exempt Items.
- 3.3.3.1 Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from these regulations to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:2/
- 3.3.3.1.1 Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:
- 3.3.3.1.1.1 25 millicuries (925 MBq) of tritium per timepiece.
- 3.3.3.1.1.2 5 millicuries (185 MBq) of tritium per hand.
- 3.3.3.1.1.3 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).
- 3.3.3.1.1.4 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

2/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

- 3.3.3.1.1.5 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand.
- 3.3.3.1.1.6 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).
- 3.3.3.1.1.7 The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
- 3.3.3.1.1.7.1 For wrist watches, 0.1 millirad (1 uGy) per hour at 10 centimeters from any surface.
- 3.3.3.1.1.7.2 For pocket watches, 0.1 millirad (1 uGy) per hour at 1 centimeter from any surface.
- 3.3.3.1.1.7.3 For any other timepiece, 0.2 millirad (2 uGy) per hour at 10 centimeters from any surface.
- 3.3.3.1.1.8 One microcurie (37 kBq) of radium-226 per timepiece in timepieces acquired prior to the effective date of this regulation.
- 3.3.3.1.2 Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad (10 uGy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.
- 3.3.3.1.3 Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.
- 3.3.3.1.4 Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.
- 3.3.3.1.5 Marine compasses containing not more than .750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.
- 3.3.3.1.6 Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.

- 3.3.3.1.7 Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:
- 3.3.3.1.7.1 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube.
- 3.3.3.1.7.2 1 microcurie (37 kBq) of cobalt-60.
- 3.3.3.1.7.3 5 microcuries (185 kBq) of nickel-63.
- 3.3.3.1.7.4 30 microcuries (1.11 MBq) of krypton-85.
- 3.3.3.1.7.5 5 microcuries (185 kBq) of cesium-137.
- 3.3.3.1.7.6 30 microcuries (1.11 MBq) of promethium-147.

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad (10 uGy) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.<sup>3/</sup>

- 3.3.3.1.8 Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:
- 3.3.3.1.8.1 Each source contains no more than one exempt quantity set forth in Schedule B of this part, and
- 3.3.3.1.8.2 Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this part, provided that the sum of such fractions shall not exceed unity.
- 3.3.3.1.8.3 For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under RH 3.3.3.1.8.
- 3.3.3.1.9 Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 l) per hour.

<sup>3/</sup> For purposes of RH 3.3.3.1.7, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.



3.3.3.2

Self-Luminous Products Containing Radioactive Material.

3.3.3.2.1

Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in RH 3.3.3.2 does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

3.3.3.2.2

Radium-226. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of this regulation.

3.3.3.3

Gas and Aerosol Detectors Containing Radioactive Material.

3.3.3.3.1

Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission <sup>2/</sup> pursuant to Section 32.26 of 10 CFR Part 32; or a Licensing State pursuant to RH 3.12.3, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

<sup>2/</sup> Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.



3.3.3.3.2

Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under RH 3.3.3.3.1, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of RH 3.12.3.

3.3.3.3.3

Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under RH 3.3.3.3.1, provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of RH 3.12.3.

3.3.3.4

Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from these regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sect. 32.16 and 32.17 of 10 CFR Part 32 of the regulation of the U. S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

Licenses

RH 3.4

Types of Licenses. Licenses for radioactive materials are of two types: general and specific.

3.4.1

General licenses provided in this part are effective without the filing of applications with the Department or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Department may be required by the particular general license. The general licensee is subject to all other applicable portions of these regulations and any limitations of the general license.

3.4.2

Specific licenses require the submission of an application to the Department and the issuance of a licensing document by the Department. The licensee is subject to all applicable portions of these regulations as well as any limitations specified in the licensing document.

## General Licenses

### RH 3.5 General Licenses - Source Material.

3.5.1 A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and State and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

3.5.1.1 Persons who receive, possess, use or transfer source material pursuant to the general license in RH 3.5.1 are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized in a specific license.

3.5.2 Persons who receive, possess, use, or transfer source material pursuant to the general license issued in RH 3.5.1 are exempt from the provisions of Parts 4 and 10 of these regulations to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

3.5.3 A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

3.5.4 A general license is hereby issued authorizing the possession of source material involved in mining operations provided such operations meet the regulatory requirements of the Division of Mines, Colorado Department of Natural Resources, or any successor thereto, and except as authorized in a specific license, such mining operations shall not refine or process such ore.

### 3.5.5 Depleted Uranium in Industrial Products and Devices.

3.5.5.1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of RH 3.5.5.2, RH 3.5.5.3, RH 3.5.5.4, and RH 3.5.5.5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

3.5.5.2 The general license in RH 3.5.5.1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to RH 3.12.13 or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3.5.5.3.1 Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by RH 3.5.5.1 shall file Department Form OR-RH-52 "Registration Certificate - Use of Depleted Uranium Under General License", with the Department. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on Department Form OR-RH-52 the following information and such other information as may be required by that form:

3.5.5.3.1.1 name and address of the general licensee;

3.5.5.3.1.2 a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in RH 3.5.5.1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

3.5.5.3.1.3 name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in RH 3.5.5.3.1.2.

3.5.5.3.2 The general licensee possessing or using depleted uranium under the general license established by RH 3.5.5.1 shall report in writing to the Department any changes in information furnished by him in Department Form OR-RH-52 "Registration Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

3.5.5.4 A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by RH 3.5.5.1:

- 3.5.5.4.1 shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
- 3.5.5.4.2 shall not abandon such depleted uranium;
- 3.5.5.4.3 shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of RH 3.22. In the case where the transferee receives the depleted uranium pursuant to the general license established by RH 3.5.5.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form OR-RH-52. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to RH 3.5.5.1, the transferor shall furnish the transferee a copy of this regulation and a copy of Department Form OR-RH-52 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation;
- 3.5.5.4.4 within 30 days of any transfer, shall report in writing to the Department the name and address of the person receiving the depleted uranium pursuant to such transfer; and
- 3.5.5.4.5 shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.
- 3.5.5.5 Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by RH 3.5.5.1 is exempt from the requirements of Parts 4 and 10 of these regulations with respect to the depleted uranium covered by that general license.

RH 3.6 General Licenses\* - Radioactive Material Other Than Source Material.

3.6.1 Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of RH 1.4 through 1.9, RH 3.3.1.2, 3.15, 3.22, 3.23 and 3.25, Part 4, 4/ Part 10 and Part 17 of these regulations.

3.6.1.1 Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

3.6.1.2 Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

3.6.2 Reserved.

3.6.3 Reserved.

3.6.4 Certain Measuring, Gauging or Controlling Devices.

3.6.4.1 A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to receive, acquire, possess, use or transfer in accordance with the provisions of RH 3.6.4.2, RH 3.6.4.3, and RH 3.6.4.4, radioactive material,

excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

\* Note: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

4/ Attention is directed particularly to the provisions of Part 4 of these regulations which relate to the labeling of containers.



- 3.6.4.2 The general license in RH 3.6.4.1 applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Department pursuant to RH 3.12.4 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.<sup>5/</sup>
- 3.6.4.3 Any person who owns, receives, acquires, possesses, uses, owns, or transfers radioactive material in a device pursuant to the general license in RH 3.6.4.1:
- 3.6.4.3.1 shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;
- 3.6.4.3.2 shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, however,
- 3.6.4.3.2.1 devices containing only krypton need not be tested for leakage of radioactive material, and
- 3.6.4.3.2.2 devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta- and/or gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
- 3.6.4.3.3 shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:
- 3.6.4.3.3.1 in accordance with the instructions provided by the labels, or

<sup>5/</sup> Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.



3.6.4.3.3.2

by a person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to perform such activities;

3.6.4.3.4

shall maintain records showing compliance with the requirements of RH 3.6.4.3.2 and RH 3.6.4.3.3. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by RH 3.6.4.3.2 shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by RH 3.6.4.3.2 shall be maintained for 1 year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by RH 3.6.4.3.3 shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

3.6.4.3.5

upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Department a report containing a brief description of the event and the remedial action taken;

3.6.4.3.6

shall not abandon the device containing radioactive material;

3.6.4.3.7

except as provided in RH 3.6.4.3.8, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

3.6.4.3.8

shall transfer the device to another general licensee only:

3.6.4.3.8.1

where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and within 30 days of the transfer, report to the Department the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Department and the transferee; or

3.6.4.3.8.2

where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

3.6.4.3.9

shall comply with the provisions of RH 4.51 and 4.52 of these regulations for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Parts 4 and 10 of these regulations.

3.6.4.4

The general license in RH 3.6.4.1 does not authorize the manufacture of devices containing radioactive material.

3.6.4.5

The general license provided in RH 3.6.4.1 is subject to the provisions of RH 1.4 through 1.9, 3.15, 3.22, 3.23 and Part 17 of these regulations.

3.6.5

Luminous Safety Devices for Aircraft.

3.6.5.1

A general license is hereby issued to receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

- 3.6.5.1.1 each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and
- 3.6.5.1.2 each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.
- 3.6.5.2 Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in RH 3.6.5.1 are exempt from the requirements of Parts 4 and 10 of these regulations except that they shall comply with the provisions of RH 4.51 and 4.52.
- 3.6.5.3 This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.
- 3.6.5.4 This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.
- 3.6.5.5 This general license is subject to the provisions of RH 1.4 through 1.9, 3.15, 3.22, 3.23, and Part 17 of these regulations.
- 3.6.6 Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.
- 3.6.7 Calibration and Reference Sources.
- 3.6.7.1 A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of RH 3.6.7.4 and RH 3.6.7.5, americium-241 in the form of calibration or reference sources:
- 3.6.7.1.1 any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material; and
- 3.6.7.1.2 any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

- 3.6.7.2 A general license is hereby issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of RH 3.6.7.4 and RH 3.6.7.5 to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.
- 3.6.7.3 A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of RH 3.6.7.4 and RH 3.6.7.5 to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use, and transfer radioactive material.
- 3.6.7.4 The general licenses in RH 3.6.7.1, RH 3.6.7.2, and RH 3.6.7.3 apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Department, any Agreement State or Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.
- 3.6.7.5 The general licenses provided in RH 3.6.7.1, RH 3.6.7.2, and RH 3.6.7.3 are subject to the provisions of RH 1.4 through 1.9, 3.15, 3.22, 3.23 and 3.25, and Parts 4 and 10 of these regulations. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:
- 3.6.7.5.1 shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium-241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium-226 in such sources;
- 3.6.7.5.2 shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

3.6.7.5.2.1

The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM-241).  
(PLUTONIUM) 6/ DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

\_\_\_\_\_  
Name of manufacturer or importer

3.6.7.5.2.2

The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No: \_\_\_\_\_, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS RADIUM-226.  
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. ---

\_\_\_\_\_  
Name of manufacturer or importer

-- 3.6.7.5.3

shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;

3.6.7.5.4

shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

3.6.7.5.5

shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

3.6.7.6

These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium or radium-226.

6/ Showing only the name of the appropriate material.



3.6.8 Reserved.

3.6.9 General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.<sup>7/</sup>

3.6.9.1 A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of RH 3.6.9.2, RH 3.6.9.3, RH 3.6.9.4, RH 3.6.9.5, and RH 3.6.9.6, the following radioactive materials in prepackaged units for use in in Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

3.6.9.1.1 Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.

3.6.9.1.2 Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.

3.6.9.1.3 Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

3.6.9.1.4 Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.

3.6.9.1.5 Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of americium-241 each.

3.6.9.1.6 Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.

3.6.9.1.7 Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

3.6.9.1.8 Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

<sup>7/</sup> The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.



- 3.6.9.2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by RH 3.6.9.1 until the person has filed Department Form OR-RH-27, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Department and received from the Department a validated copy of Department Form OR-RH-27 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Department Form OR-RH-27 the following information and such other information as may be required by that form:
- 3.6.9.2.1 Name and address of the physician, veterinarian, clinical laboratory or hospital;
- 3.6.9.2.2 the location of use; and
- 3.6.9.2.3 a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in Vitro clinical or laboratory tests with radioactive material as authorized under the general license in RH 3.6.9.1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.
- 3.6.9.3 A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by RH 3.6.9.1 shall comply with the following:
- 3.6.9.3.1 The general licensee shall not possess at any one time, pursuant to the general license in RH 3.6.9.1, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 200 microcuries (7.4 MBq).
- 3.6.9.3.2 The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
- 3.6.9.3.3 The general licensee shall use the radioactive material only for the uses authorized by RH 3.6.9.1.
- 3.6.9.3.4 The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

3.6.9.3.5

The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in RH 3.6.9.1.5 as required by RH 4.33 of these regulations.

3.6.9.4

The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to RH 3.6.9.1:

3.6.9.4.1

Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to RH 3.12.8 or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under RH 3.6.9 or its equivalent, and

3.6.9.4.2

unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

3.6.9.4.2.1

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in Vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

3.6.9.4.2.2

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in Vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

---

Name of manufacturer

3.6.9.5

The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of RH 3.6.9.1 shall report in writing to the Department, any changes in the information furnished by him in the "Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form OR-RH-27. The report shall be furnished within 30 days after the effective date of such change.

3.6.9.6

Any person using radioactive material pursuant to the general license of RH 3.6.9.1 is exempt from the requirements of Parts 4 and 10 of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in RH 3.6.9.1.5 shall comply with the provisions of RH 4.33, 4.51 and 4.52 of these regulations.

3.6.10

Ice Detection Devices.

3.6.10.1

A general license is hereby issued to receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Department or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

3.6.10.2

Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in RH 3.6.10.1,

- 3.6.10.2.1 shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of RH 4.33 of these regulations;
- 3.6.10.2.2 shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and
- 3.6.10.2.3 are exempt from the requirements of Parts 4 and 10 of these regulations except that such persons shall comply with the provisions of RH 4.33, 4.51, and 4.52.
- 3.6.10.3 This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.
- 3.6.10.4 This general license is subject to the provisions of RH 1.4 through 1.9, 3.15, 3.22, 3.23 and Part 17 of these regulations.

RH 3.7 Reserved.

#### Specific Licenses

RH 3.8 Filing Application for Specific Licenses.

- 3.8.1 Applications for specific licenses shall be filed in duplicate on a form prescribed by the Department.
- 3.8.2 The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- 3.8.3 Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.
- 3.8.4 An application for a license may include a request for a license authorizing one or more activities.
- 3.8.5 In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.

3.8.6 Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection pursuant to 24-72-204 C.R.S., 1988.

3.8.7 Pre-licensing Construction

3.8.7.1 An application for a license, or to amend or renew an existing license, for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of wastes from treatment or incineration, (4) commercial waste disposal by land burial or by underground injection, or the (5) conduct of any other activity within the licensing authority of the Department which the Department determines will significantly affect the radiological quality of the human environment, shall be filed with the Department at least nine (9) months prior to the anticipated commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by the environmental report required by RH 3.8.8 of these regulations, unless an exemption from the requirement of furnishing such a report has been obtained from the Department. No construction shall be commenced until the license has been issued. For the purpose of RH 3.8.7 the term "commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site; this term does not include changes desirable for the temporary use of the land for public recreational uses, limited borings to determine site characteristics as necessary for environmental assessment of other pre-construction monitoring to establish background information related to the suitability of a site, or to the protection of environmental values.



3.8.8

Environmental Impact Assessment.

3.8.8.1

In the case of an application for a license, or to amend or renew an existing license, for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of any other activity which will affect the quality of the human environment by reason of exposure to radiation, before "commencement of construction", as defined in RH 3.8.7.1, of the plant or facility in or at which the activity will be conducted, or in case of a renewal of such a license, the applicant shall submit all information required under these regulations and such other material as the Department may deem necessary. Such information shall include the environmental report and other information required by RH 3.8.8.2 to be submitted to assist the Department in the evaluation of the short-term and long-range environmental impact of the project and activity so that the Department may weigh environmental, economic, technical, and other benefits against environmental costs, while considering available alternatives.

3.8.8.1.1

In the event that an environmental report acceptable to the Department is on file with the Department in regard to the specific licensed activity authorized under an existing license, and upon request of the applicant to amend or renew an existing license or at the initiation of the Department, the Department may grant an exemption of the requirement to submit an additional environmental report or require such amendment of the existing environmental report as will demonstrate the environmental impact to result from the proposed activity. The request for exemption shall provide the Department with such information as the Department requires of the applicant to demonstrate that no significant environmental impact will result from the licensed activity.

3.8.8.2

An environmental report shall be required of the applicant and shall contain all information deemed necessary by the Department as authorized by the Act. Upon receipt of the environmental report or any amendment thereto, and of any other documents required, the Department shall determine the necessity to transmit and, if appropriate, shall transmit the same for review and comment to Federal, State, and local agencies having expertise in and jurisdiction over the proposed project and activity. Written comments and reports of reviewing agencies shall be considered by the Department in its decision-making review process on the license application request.



- 3.8.8.2.1 If an environmental impact statement (EIS) is required of a Federal agency pursuant to the National Environment Policy Act of 1969 (NEPA) and is provided by such Federal agency, it shall be used by the Department in its decision-making review process on the license application request.
- 3.8.8.2.2 The Department shall consider applicable regulations of Federal, State, and local regulatory agencies and permit requirements thereof.
- RH 3.9 General Requirements for the Issuance of Specific Licenses. A license application will be approved if the Department determines that:
- 3.9.1 The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these regulations in such a manner as to minimize danger to public health and safety or property;
- 3.9.2 The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
- 3.9.3 The issuance of the license will not be inimical to the health and safety of the public; and
- 3.9.4 The applicant satisfies any applicable special requirements in RH 3.10, 3.11, 3.12, or 3.13.
- 3.9.5 Financial assurance requirements, as described below, have been met:
- 3.9.5.1 Financial Requirements.
- The Department will require financial assurance arrangements as follows:
- 3.9.5.1.1 A license applicant may be required to furnish financial assurance arrangements to ensure decontamination and decommissioning of the facility for the protection of the public health and safety and the environment in the event of abandonment, default or inability of the licensee to meet the requirements of the Act, these regulations, and the license.
- 3.9.5.1.2 The following specific licensees are required to furnish financial assurance arrangements:
- 3.9.5.1.2.1 Reserved.
- 3.9.5.1.2.2 Commercial waste handling licensees;

- 3.9.5.1.2.3 Reserved.
- 3.9.5.1.2.4 Source material mills; and
- 3.9.5.1.2.5 Each applicant for a specific license authorizing the possession and use of licensed radioactive material with a half life greater than 120 days in quantities:
- 3.9.5.1.2.5.1 greater than  $10^3$  times the applicable quantity of Schedule B of Part 3 unsealed form. For a combination of isotopes if R divided by  $10^3$  is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope in the applicable value in Schedule B.
- 3.9.5.1.2.5.2 greater than  $10^{10}$  times the applicable quantity of Schedule B of Part 3 in sealed sources or plated foils. For a combination of isotopes if R divided by  $10^{10}$  is greater than 1 (unity rule), where R is defined in RH 3.9.5.1.2.5.1.
- 3.9.5.1.3 Reserved.
- 3.9.5.1.3.1 Reserved.
- 3.9.5.1.3.2 Reserved.
- 3.9.5.1.3.3 Reserved.
- 3.9.5.1.3.4 Reserved.
- 3.9.5.1.3.5 Reserved.
- 3.9.5.2 The financial assurance arrangements required by RH 3.9.5.1.1 shall be furnished to, and in a form approved by, the Department prior to the issuance of a license, or any amendment or renewal of an existing license, as required by the Department. The applicant shall furnish evidence of initial and continued financial responsibility sufficient to maintain the financial assurance arrangement in force, as required by and acceptable to the Department. The amount of funds to be provided by such financial assurance arrangements shall be based on Department-approved cost estimates.
- Self insurance, or any arrangement which essentially constitutes self insurance (e.g. a contract with a State or Federal agency), will not satisfy the financial assurance requirement since this provides no additional assurance other than that which already exists through license requirements.

Acceptable financial assurance arrangements include:

- 3.9.5.2.1 A bond issued by a fidelity or surety company with provisions and for a term and amount acceptable to the Department;
- 3.9.5.2.2 An irrevocable "letter of credit" or "line of credit" issued by a recognized financial institution whose financial condition and commitment are established to the satisfaction of the Department;
- 3.9.5.2.3 A cash deposit, certificate of deposit, or deposit of government securities posted by the licensee with provisions and for a term and amount acceptable to the Department; or
- 3.9.5.2.4 Combinations of the above or such other evidence of initial and continued financial responsibility as may be required by the Department, including financial assurance arrangements previously provided to any State, Federal and/or local governing bodies concerning activities subject to license under these regulations, where the amount, terms, and conditions of such financial assurance arrangements have been established to the satisfaction of the Department, provided such arrangements are considered by the Department to be adequate to satisfy the requirements of RE 3.9.5 and provided that the portion of the financial assurance arrangement which covers the decommissioning and reclamation of the facility and associated areas, and the long-term site surveillance and control funding charge, are clearly identified and committed for use in accomplishing these activities.

3.9.5.3

The amount of funds to be provided by such financial assurance arrangements shall be based on Department-approved cost estimates in an approved plan for (1) decontamination and decommissioning of buildings, facilities and the site to levels which would allow unrestricted use of these areas upon decommissioning, and (2) for the reclamation of tailings and/or waste disposal areas in accordance with technical criteria delineated in Part 14 and/or Part 18 as appropriate. The licensee shall submit this plan and complete proposed financial assurance arrangements in conjunction with the environmental report required by RH 3.8.8 that addresses the expected environmental impacts of the operation, decommissioning and reclamation, and evaluates alternatives for mitigating these impacts. In establishing specific financial assurance arrangements, the cost estimates shall take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work, and long-term care if included.

3.9.5.4

The licensee shall provide in writing to the Department, no later than June 30th of each calendar year, any licensee proposed changes, including updated plans, costs or surety mechanisms, for consideration by the Department.

3.9.5.5

The licensee's financial assurance arrangements will be reviewed annually by the Department to assure that sufficient funds would be available for completion of the plans if the work had to be performed by an independent contractor and shall be adjusted to recognize any increases or decreases resulting from inflation or deflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether the work is phased through the life of the operation or takes place at the end of the operation, an appropriate portion of financial assurance liability shall be retained by the licensee until final compliance with the reclamation plan is determined by the Department.

This will yield a financial assurance that are at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism shall be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g. 5 years) yet which must be automatically renewed unless the surety notifies the Department and the principal (the licensee) some reasonable time (e.g. 90 days) prior to the renewal date of their intention not to renew. In such a situation

the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

Proof of forfeiture shall not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended and must be agreed to by all parties.

3.9.5.6 The term of the financial assurance arrangement shall be for the period from issuance of the license until termination of the license by the Department, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance.

3.9.6 Long-term care is provided for as follows: —

3.9.6.1 A long-term monitoring and maintenance fund may be required for any licensee or applicant as the Department may deem appropriate.

3.9.6.2 Except as provided in RH 3.9.6.3, the following specific licensees are required to provide long-term care funding:

3.9.6.2.1 Waste handling licensees;

3.9.6.2.2 Formerly U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;

3.9.6.2.3 Source material mills; and

3.9.6.2.4 All other activities or situations which will affect the quality of the human environment by reason of exposure to radiation.

3.9.6.3 In the event that the disposal of any radioactive materials by the licensees identified in RH 3.9.6.2 is made in such a manner as the Department determines does not require long-term monitoring and maintenance of the site, a long-term monitoring and maintenance fund will not be required.



### 3.9.6.4

#### Long-Term Care Requirements

##### 3.9.6.4.1

The final disposition of wastes should be such that ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where wastes are stored to confirm the integrity of the stabilized waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the agency within 60 days following each inspection. The agency may require more frequent site inspection if, on the basis of a site-specific evaluation, such inspection appears necessary at a particular site.

##### 3.9.6.4.2

The fund shall be provided by the licensee to the State. The fund shall be based on Department-approved cost estimates, after consultation with the licensee or applicant. For source material milling sites, a minimum charge of \$250,000 (1978 dollars) to cover the costs of long-term surveillance must be paid by each mill operator prior to the termination of a uranium or thorium mill license. In any case, the total charge to cover the costs of long term surveillance must be such that, with an assumed one (1) percent annual real interest rate, the collected funds will yield interest in an amount sufficient to cover the annual costs of site surveillance. The total charge will be adjusted annually prior to actual payment to recognize inflation. The inflation rate to be used is that indicated by the change in the Consumer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics. The Department may modify the assumption of one (1) percent annual real interest rate and use other indicators of the inflation rate if reasonable; provided, however, that the license shall not terminate unless the amount of the fund, the assumed percent annual real interest rate, and the inflation rate to be used are acceptable to the U.S. Nuclear Regulatory Commission.

##### 3.9.6.4.3

Upon termination of a waste disposal license, provision shall be made for transfer of appropriate funds, collected by the State pursuant to RH 3.9.6.4, to the Federal government, and transfer of the site to Federal government custody. If such funds are transferred to the Federal government and are in excess of the amount required by the Federal government, such excess shall revert to the licensee.



3.9.7 In the case of an application for a license for (1) source material milling, (2) commercial waste storage, treatment or disposal by incineration, (3) transfer for disposal of waste from incineration, (4) commercial waste disposal by land burial or by underground injection, or for (5) the conduct of any other activity which the Department determines will significantly affect the quality of the human environment, the Department has concluded that the action called for is the issuance of the proposed license with any appropriate conditions to protect environmental values.

Such determination shall be made before commencement of construction of the plant or facility in which the activity will be conducted and based on information filed and evaluation made pursuant to RH 3.8.8.

3.9.8 Commencement of construction prior to the issuance of a license, or of an amendment or renewal thereof, or of an exemption under the requirements of RH 3.8.7, may be grounds for denial of such license, amendment or renewal; and

3.9.9 The applicant shall satisfy any applicable special requirements of RH 3.10, 3.11, and 3.12.

3.9.10 License Hearings.

3.9.10.1 There shall be an opportunity for public hearings to be held in the following circumstances in accordance with the procedures in 24-4-104 and -105, C.R.S. and this paragraph:

3.9.10.1.1 prior to the licensing or leasing of state-owned property for the concentration, storage or permanent disposal of radioactive materials.

3.9.11 Emergency Plans

3.9.11.1 Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Schedule E of Part 3 - "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release", must contain either:

3.9.11.1.1 An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.01 Sievert (1 rem) effective dose equivalent or 0.05 Sievert (5 rems) to the thyroid; or

3.9.11.1.2 An emergency plan for responding to a release of radioactive material.

3.9.11.2 One or more of the following factors may be used to support an evaluation submitted under RH 3.9.11.1.1 of this section:

- 3.9.11.2.1 The radioactive material is physically separated so that only a portion could be involved in an accident;
- 3.9.11.2.2 All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
- 3.9.11.2.3 The release fraction in the respirable size range would be lower than the release fraction shown in Schedule E of Part 3 due to the chemical or physical form of the material;
- 3.9.11.2.4 The solubility of the radioactive material would reduce the dose received;
- 3.9.11.2.5 Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule E of Part 3.
- 3.9.11.2.6 Operating restrictions or procedures would prevent a release fraction as large as that shown in Schedule E of Part 3; or
- 3.9.11.2.7 Other factors appropriate for the specific facility.
- 3.9.11.3 An emergency plan for responding to a release of radioactive material submitted under RH 3.9.11.1.2 of this section must include the following information:
- 3.9.11.3.1 Facility description. A brief description of the licensee's facility and area near the site.
- 3.9.11.3.2 Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.
- 3.9.11.3.3 Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.
- 3.9.11.3.4 Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
- 3.9.11.3.5 Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

- 3.9.11.3.6 Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.
- 3.9.11.3.7 Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the department; also responsibilities for developing, maintaining, and updating the plan.
- 3.9.11.3.8 Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.
- 3.9.11.3.9 Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the Department.
- 3.9.11.3.10 Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
- 3.9.11.3.11 Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

3.9.11.3.12

Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. --- Deficiencies found by the critiques must be corrected.

3.9.11.3.13

Hazardous chemicals. A certification that the applicant has met its responsibilities under the emergency planning and community Right-To-Know Act of 1988, Title III, Pub. L. 99-499,<sup>1</sup> if applicable to the applicant's activities at the proposed place of use of the radioactive material.

3.9.11.4

The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Department. The licensee shall provide any comments received within 60 days to the Department with the emergency plan.

RH 3.10      Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material.

3.10.1      Reserved.

3.10.2      Reserved.

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<sup>1</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.

3.10.3 Reserved.

3.10.4 Reserved.

3.10.5 Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in RE 3.9, a specific license for use of sealed sources in industrial radiography will be issued if:

3.10.5.1 the applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the Department a schedule or description of such program which specifies the:

3.10.5.1.1 initial training,

3.10.5.1.2 periodic training,

3.10.5.1.3 on-the-job training;

3.10.5.1.4 means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Department regulations and licensing requirements, and the operating and emergency procedures of the applicant, and

3.10.5.1.5 means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

3.10.5.2 the applicant has established and submits to the Department satisfactory written operating and emergency procedures described in RE 5.13 of these regulations;

3.10.5.3 the applicant will have an internal inspection system adequate to assure that these regulations, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed 3 months and the retention of records of such inspections for 2 years;

3.10.5.4 the applicant submits to the Department a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

3.10.5.5 the applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Department a description of such procedures including:



- 3.10.5.5.1 instrumentation to be used,
- 3.10.5.5.2 method of performing tests, and
- 3.10.5.5.3 pertinent experience of the individual who will perform the test; and
- 3.10.5.6 the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

3.10.6 Reserved.

RH 3.11 Special Requirements for Specific Licenses of Broad Scope. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.<sup>8/</sup>

3.11.1 The different types of broad scope licenses are set forth below:

3.11.1.1 A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

3.11.1.2 A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D of this part, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

<sup>8/</sup> Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.



3.11.1.3 A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Schedule D of this part, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3.11.2 An application for a Type A specific license of broad scope will be approved if:

3.11.2.1 the applicant satisfies the general requirements specified in RE 3.9;

3.11.2.2 the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

3.11.2.3 the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

3.11.2.3.1 the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

3.11.2.3.2 the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

3.11.2.3.3 the establishment of appropriate administrative procedures to assure:

3.11.2.3.3.1 control of procurement and use of radioactive material;

3.11.2.3.3.2 completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

- 3.11.2.3.3.3 review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with RH 3.11.2.3.3.2 prior to use of the radioactive material.
- 3.11.3 An application for a Type B specific license of broad scope will be approved if:
- 3.11.3.1 the applicant satisfies the general requirements specified in RH 3.9; and
- 3.11.3.2 the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:
- 3.11.3.2.1 the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and
- 3.11.3.2.2 the establishment of appropriate administrative procedures to assure,
- 3.11.3.2.2.1 control of procurement and use of radioactive material,
- 3.11.3.2.2.2 completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and
- 3.11.3.2.2.3 review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with RH 3.11.3.2.2.2 prior to use of the radioactive material.
- 3.11.4 An application for a Type C specific license of broad scope will be approved if:
- 3.11.4.1 the applicant satisfies the general requirements specified in RH 3.9;
- 3.11.4.2 the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
- 3.11.4.2.1 a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

- 3.11.4.2.2 at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and
- 3.11.4.3 the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.
- 3.11.5 Specific licenses of broad scope are subject to the following conditions:
- 3.11.5.1 Unless specifically authorized, persons licensed pursuant to RH 3.11 shall not:
- 3.11.5.1.1 conduct tracer studies in the environment involving direct release of radioactive material;
- 3.11.5.1.2 receive, acquire, own, possess, use; or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;
- 3.11.5.1.3 conduct activities for which a specific license issued by the Department under RH 3.10, RH 3.12, or Parts 7, 14, and 18 of these regulations is required; or
- 3.11.5.1.4 add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.
- 3.11.5.2 Each Type A specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
- 3.11.5.3 Each Type B specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

- 3.11.5.4 Each Type C specific license of broad scope issued under this part shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of RH 3.11.4.
- RH 3.12 Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices which Contain Radioactive Material.
- 3.12.1 Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.
- 3.12.1.1 In addition to the requirements set forth in RH 3.9, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under RH 3.3.1.1 will be issued if:
- 3.12.1.1.1 the applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and
- 3.12.1.1.2 the applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A of this part, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

3.12.1.2

Each person licensed under RH 3.12.1 shall file an annual report with the Department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to RH 3.12.1 during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

3.12.2

Licensing the Distribution of Radioactive Material in Exempt Quantities.8/

3.12.2.1

An application for a specific license to distribute NARM to persons exempted from these regulations pursuant to RH 3.3.2 will be approved if:

3.12.2.1.1

the radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

3.12.2.1.2

the radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

3.12.2.1.3

the applicant submits copies of prototype labels and brochures and the Department approves such labels and brochures.

3.12.2.2

The license issued under RH 3.12.2.1 is subject to the following conditions:

8/ Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.



3.12.2.2.1 No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

3.12.2.2.2 Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to RH 3.3.2. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 uSv) per hour.

3.12.2.2.3 The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

3.12.2.2.3.1 identifies the radionuclide and the quantity of radioactivity, and

3.12.2.2.3.2 bears the words "Radioactive Material".

3.12.2.2.4 In addition to the labeling information required by RH 3.12.2.2.3, the label affixed to the immediate container, or an accompanying brochure, shall:

3.12.2.2.4.1 state that the contents are exempt from Licensing State requirements,

3.12.2.2.4.2 bear the words "Radioactive Material-Not for Human Use-Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined", and

3.12.2.2.4.3 set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3.12.2.3 Each person licensed under RH 3.12.2 shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under RH 3.3.2 or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Department. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to RH 3.12.2 during the reporting period, the report shall so indicate.



3.12.3      Licensing the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under RH 3.3.3.3 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

3.12.4      Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under RH 3.6.4.

3.12.4.1      An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under RH 3.6.4 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

3.12.4.1.1      the applicant satisfies the general requirements of RH 3.9;

3.12.4.1.2      the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

3.12.4.1.2.1      the device can be safely operated by persons not having training in radiological protection,

3.12.4.1.2.2      under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in RH 4.6.1, and

3.12.4.1.2.3      under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk;  
active blood-forming  
organs; gonads; or lens  
of eye . . . . . 15 rems (150 mSv)

Hands and forearms;  
feet and ankles; localized  
areas of skin averaged  
over areas no larger  
than 1 square centimeter . . . . . 200 rems (2 Sv)

Other organs . . . . . 50 rems (500 mSv); and

3.12.4.1.3 each device bears a durable, legible, clearly  
visible label or labels approved by the Department,  
which contain in a clearly identified and separate  
statement:

3.12.4.1.3.1 instructions and precautions necessary to  
assure safe installation, operation, and  
servicing of the device; documents such as  
operating and service manuals may be  
identified in the label and used to provide  
this information,

3.12.4.1.3.2 the requirement, or lack of requirement, for  
leak testing, or for testing any "on-off"  
mechanism and indicator, including the  
maximum time interval for such testing, and  
the identification of radioactive material  
by isotope, quantity of radioactivity, and  
date of determination of the quantity, and

3.12.4.1.3.3 the information called for in one of the  
following statements, as appropriate, in the  
same or substantially similar form:

3.12.4.1.3.3.1 The receipt, possession, use, and  
transfer of this device, Model \_\_\_\_\_  
, Serial No. \_\_\_\_\_ 9/, are subject  
to a general license or the  
equivalent and the regulations of  
the U.S. Nuclear Regulatory  
Commission or a State with which the  
U.S. Nuclear Regulatory Commission  
has entered into an agreement for  
the exercise of regulatory  
authority. This label shall be  
maintained on the device in a  
legible condition. Removal of this  
label is prohibited.

9/ The model, serial number, and name of the manufacturer or distributor may  
be omitted from this label provided the information is elsewhere specified in  
labeling affixed to the device.

CAUTION - RADIOACTIVE MATERIAL

\_\_\_\_\_  
Name of manufacturer or distributor

3.12.4.1.3.3.2

The receipt, possession, use, and transfer of this device, Model\_\_\_\_\_, Serial No. \_\_\_\_\_  
9/, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

\_\_\_\_\_  
Name of manufacturer or distributor

3.12.4.2

In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

- 3.12.4.2.1 primary containment or source capsule;
- 3.12.4.2.2 protection of primary containment;
- 3.12.4.2.3 method of sealing containment;
- 3.12.4.2.4 containment construction materials;
- 3.12.4.2.5 form of contained radioactive material;

9/ The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

- 3.12.4.2.6 maximum temperature withstood during prototype tests;
- 3.12.4.2.7 maximum pressure withstood during prototype tests;
- 3.12.4.2.8 maximum quantity of contained radioactive material;
- 3.12.4.2.9 radiotoxicity of contained radioactive material; and
- 3.12.4.2.10 operating experience with identical devices or similarly designed and constructed devices.
- 3.12.4.3 In the event the applicant desires that the general licensee under RH 3.6.4, or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in RH 4.6.1 of these regulations.
- 3.12.4.4 Each person licensed under RH 3.12.4 to distribute devices to generally licensed persons shall:
- 3.12.4.4.1 furnish a copy of the general license contained in RH 3.6.4 to each person to whom the licensee directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in RH 3.6.4;

3.12.4.4.2

furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulation equivalent to RH 3.6.4, or alternatively, furnish a copy of the general license contained in RH 3.6.4 to each person to whom the licensee directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the Agreement State, or the Licensing State. If a copy of the general license in RH 3.6.4 is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State under requirements substantially the same as those in RH 3.6.4;

3.12.4.4.3

report to the Department all transfers of such devices to persons for use under the general license in RH 3.6.4. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under RH 3.6.4 during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

3.12.4.4.4

furnish reports to other agencies.

3.12.4.4.4.1

Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

3.12.4.4.4.2

Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to RH 3.12.4 for use under a general license in that State's regulations equivalent to RH 3.6.4.



3.12.4.4.4.3

Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

3.12.4.4.4.4

If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

3.12.4.4.4.5

If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency; and

3.12.4.4.5

Keep records showing the name, address, and the point of contact for each general licensee to whom the transferor directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in RH 3.6.4, or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of RH 3.12.4.4.

3.12.5

Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under RH 3.6.5 will be approved if:

3.12.5.1

the applicant satisfies the general requirements specified in RH 3.9; and



- 3.12.5.2 the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.
- 3.12.6 Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under RH 3.6.7. An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under RH 3.6.7 will be approved if:
- 3.12.6.1 the applicant satisfies the general requirement of RH 3.9; and
- 3.12.6.2 the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.
- 3.12.7 Reserved.
- 3.12.8 Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of RH 3.6.9 will be approved if:
- 3.12.8.1 the applicant satisfies the general requirements specified in RH 3.9.
- 3.12.8.2 the radioactive material is to be prepared for distribution in prepackaged units of:
- 3.12.8.2.1 carbon-14 in units not exceeding 10 microcuries (370 kBq) each.
- 3.12.8.2.2 cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.
- 3.12.8.2.3 hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.
- 3.12.8.2.4 iodine-125 in units not exceeding 10 microcuries (370 kBq) each.
- 3.12.8.2.5 Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.
- 3.12.8.2.6 iodine-131 in units not exceeding 10 microcuries (370 kBq) each.
- 3.12.8.2.7 iron-59 in units not exceeding 20 microcuries (740 kBq) each.

- 3.12.8.2.8 selenium-75 in units not exceeding 10 microcuries (370 kBq) each.
- 3.12.8.3 each prepackaged unit bears a durable, clearly visible label:
- 3.12.8.3.1 identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and
- 3.12.8.3.2 displaying the radiation caution symbol described in RE 4.27.1 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".
- 3.12.8.4 one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
- 3.12.8.4.1 This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

3.12.8.4.2

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.

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Name of manufacturer

3.12.8.5

the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in RH 4.33 of these regulations.

3.12.9

Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under RH 3.6.10 will be approved if:

3.12.9.1

the applicant satisfies the general requirements of RH 3.9; and

3.12.9.2

the criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

3.12.10

Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to this part for the uses listed in RH 7.30, RH 7.32, and RH 7.36 of these regulations will be approved if:

3.12.10.1

the applicant satisfies the general requirements specified in RH 3.9 of this part;

3.12.10.2

the applicant submits evidence that:

3.12.10.2.1

the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

- 3.12.10.2.2 the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;
- 3.12.10.3 the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
- 3.12.10.4.1 the label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Department for distribution to persons licensed pursuant to this part for the uses listed in RH 7.30, RH 7.32, and RH 7.36 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.
- 3.12.10.4.2 the labels, leaflets, or brochures required by RH 3.12.10.4.1 are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.
- 3.12.11 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.<sup>10/</sup> An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this part for the uses listed in RH 7.32 will be approved if:
- 3.12.11.1 the applicant satisfies the general requirements specified in RH 3.9;
- 3.12.11.2 the applicant submits evidence that:

<sup>10/</sup> Although the Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have the reagent kits approved by the Department for use by persons licensed pursuant to RH 7.32 of this part may submit the pertinent information specified in RH 3.12.11.

- 3.12.11.2.1 the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or
- 3.12.11.2.2 the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;
- 3.12.11.3 the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;
- 3.12.11.4 the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and
- 3.12.11.5 the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:
  - 3.12.11.5.1 adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and
  - 3.12.11.5.2 a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Department pursuant to RH 7.32 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by RH 3.12.11 are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

- 3.12.12 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to Part 7 for use as a calibration or reference source or for the uses listed in RH 7.40 and RH 7.42 of these regulations will be approved if:
  - 3.12.12.1 the applicant satisfies the general requirements in RH 3.9 of this part;
  - 3.12.12.2 the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
    - 3.12.12.2.1 the radioactive material contained, its chemical and physical form, and amount,
    - 3.12.12.2.2 details of design and construction of the source or device,
    - 3.12.12.2.3 procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,



- 3.12.12.2.4 for devices containing radioactive material, the radiation profile of a prototype device,
- 3.12.12.2.5 details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
- 3.12.12.2.6 procedures and standards for calibrating sources and devices,
- 3.12.12.2.7 legend and methods for labeling sources and devices as to their radioactive content, and
- 3.12.12.2.8 instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;
- 3.12.12.3 the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the Department for distribution to persons licensed pursuant to RH 7.40 and RH 7.42 of these regulations or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;
- 3.12.12.4 in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
- 3.12.12.5 in determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:
- 3.12.12.5.1 primary containment or source capsule,
- 3.12.12.5.2 protection of primary containment,
- 3.12.12.5.3 method of sealing containment,
- 3.12.12.5.4 containment construction materials,
- 3.12.12.5.5 form of contained radioactive material,
- 3.12.12.5.6 maximum temperature withstood during prototype tests,
- 3.12.12.5.7 maximum pressure withstood during prototype tests,
- 3.12.12.5.8 maximum quantity of contained radioactive material,
- 3.12.12.5.9 radiotoxicity of contained radioactive material, and



- 3.12.12.5.10 operating experience with identical sources or devices or similarly designed and constructed sources or devices.
- 3.12.13 Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.
- 3.12.13.1 An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to RH 3.5.5 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:
- 3.12.13.1.1 the applicant satisfies the general requirements specified in RH 3.9;
- 3.12.13.1.2 the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of 1 calendar quarter a radiation dose in excess of 10 percent of the limits specified in RH 4.6.1 of these regulations; and
- 3.12.13.1.3 the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
- 3.12.13.2 In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under RH 3.12.13 only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
- 3.12.13.3 The Department may deny any application for a specific license under RH 3.12.13 if the end use(s) of the industrial product or device cannot be reasonably foreseen.
- 3.12.13.4 Each person licensed pursuant to RH 3.12.13.1 shall:
- 3.12.13.4.1 maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;
- 3.12.13.4.2 label or mark each unit to:
- 3.12.13.4.2.1 identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

- 3.12.13.4.2.2 state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;
- 3.12.13.4.3 assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";
- 3.12.13.4.4.1 furnish a copy of the general license contained in RH 3.5.5 and a copy of Department Form OR-RH-52 to each person to whom the specific licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in RH 3.5.5, or
- 3.12.13.4.4.2 furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to RH 3.5.5 and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in RH 3.5.5 and a copy of Department Form OR-RH-52 to each person to whom the specific licensee transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in RH 3.5.5;
- 3.12.13.4.5 report to the Department all transfers of industrial products or devices to persons for use under the general license in RH 3.5.5. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under RH 3.5.5 during the reporting period, the report shall so indicate;
- 3.12.13.4.6.1 report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40,
- 3.12.13.4.6.2 report to the responsible State agency all transfers of devices manufactured and distributed pursuant to RH 3.12.13 for use under a general license in that State's regulations equivalent to RH 3.5.5,

3.12.13.4.6.3

such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person,

3.12.13.4.6.4

if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission, and

3.12.13.4.6.5

if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

3.12.13.4.7

keep records showing the name, address, and point of contact for each general licensee to whom the specific licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in RH 3.5.5 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

RH 3.13

Third Party Method. If the applicant consents, the Department may enter into third party agreements for the applicant to engage and pay for the services of a third party contractor to prepare the environmental impact analysis required under RH 18.4 and/or to furnish an opinion of independent experts, satisfactory to the Department, in respect to the completeness and adequacy of any information or data furnished by the applicant and on any aspect of the applicant's project or effects thereof.

3.13.1

When the license applicant pays for a third party agreement, the monies paid for the consultant shall not be charged as part of the fees required under Part 12 of these regulations.

3.13.2

In proceeding under the third party agreement, the Department shall carry out the following practices:

3.13.2.1

Such contractor shall be chosen solely by the Department.

3.13.2.2

The Department shall manage the contract.

3.13.2.3

The consultant shall be selected based on the consultant's ability relevant and applicable work experience and an absence of conflict of interest. Third party contractors will be required to execute a disclosure statement signifying they have no financial or other conflicting interest in the outcome of the project.

3.13.2.4 The Department shall specify the information to be developed and supervise the gathering, analysis and presentation of the information. The Department shall have sole authority for approval and modification of the statement, analysis, and conclusions included in third party's report.

RH 3.14 Issuance of Specific Licenses.

3.14.1 Upon a determination that an application meets the requirements of the Act and the regulations of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

3.14.2 The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

3.14.2.1 minimize danger to public health and safety or property;

3.14.2.2 require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3.14.2.3 prevent loss or theft of material subject to this part.

3.14.3 Whenever the Department denies an application for a new license or a license renewal, the Department will notify the applicant in writing stating the grounds for denial. Upon denial, the applicant may request a hearing pursuant to sections 24-4-104 and 24-4-105, C.R.S.

RH 3.15 Specific Terms and Conditions of License.

3.15.1 Each license issued pursuant to this part shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Department.

3.15.2 No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations, and orders of the Department, and shall give its consent in writing.

3.15.3 Each person licensed by the Department pursuant to this part shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

3.15.4 Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

3.15.5 Each licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

3.15.5.1 the licensee;



- 3.15.5.2 an entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or
- 3.15.5.3 an affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.
- 3.15.6 The notification specified in RH 3.15.5 shall include the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.
- RH 3.16 Expiration, Termination, and Timely Decommissioning of Licenses.
- 3.16.1 Definition:  
As used in this regulation "principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.
- 3.16.2 Expiration.
- 3.16.2.1 Except as provided in RH 3.17.2, each specific license shall expire at the end of the specified day in the month and year stated therein.
- 3.16.2.2 Each specific license revoked by the Department expires at the end of the day on the date of final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by order.
- 3.16.2.3 Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive materials until the Department notifies the licensee in writing that the license is terminated.
- 3.16.3 Each licensee shall notify the Department immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license must include the reports and information specified in RH 3.16.9.1 and RH 3.16.9.2.
- 3.16.3.1 No less than 30 days before the expiration date specified in the license, the licensee shall either:
  - 3.16.3.1.1 submit an application for license renewal under RH 3.17; or
  - 3.16.3.1.2 notify the Department, in writing, if the licensee decides not to renew the license.
- 3.16.4 If a licensee does not submit an application for license renewal under RH 3.17, the licensee shall, on or before the expiration date specified in the license:
  - 3.16.4.1 terminate use of radioactive material; and
  - 3.16.4.2 meet the requirements of RH 3.16.6.

- 3.16.5 If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the Department notifies the licensee in writing that the license is terminated.
- 3.16.5.1 Each licensee who possesses residual radioactive material under RH 3.16.5, following the expiration date specified in the license shall:
- 3.16.5.1.1 limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and
- 3.16.5.1.2 continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Department notifies the licensee in writing that the license is terminated.
- 3.16.6 Timely Decommissioning.
- 3.16.6.1 Within 60 days of the occurrence of any of the following, the licensee shall notify the Division in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with requirements, or submit within 12 months of notification a decommissioning plan, if required by RH 3.16.6.3, and begin decommissioning upon approval of that plan if:
- 3.16.6.1.1 The license has expired pursuant to RH 3.16.2.1 or 3.16.2.2 of this section; or
- 3.16.6.1.2 The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or
- 3.16.6.1.3 No principal activities under the license have been conducted for a period of 24 months; or
- 3.16.6.1.4 No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.
- 3.16.6.2 The Department may grant a request to extend the time periods established in RH 3.16.6.1 if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to RH 3.16.6.1 of this section. The schedule for decommissioning set forth in RH 3.16.6.1 may not commence until the Department has made a determination on the request.



- 3.16.6.3 A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:
- 3.16.6.3.1 Procedures would involve techniques not applied routinely during cleanup or maintenance operations;
- 3.16.6.3.2 Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
- 3.16.6.3.3 Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or
- 3.16.6.3.4 Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.
- 3.16.6.4 The Department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to RH 3.16.6.1 of this section if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and present no undue risk from radiation to the public health and safety and is otherwise in the public interest.
- 3.16.6.5 Procedures such as those listed in RH 3.16.6.3 of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.
- 3.16.6.6 The proposed decommissioning plan for the site or separate building or outdoor area must include:
- 3.16.6.6.1 A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
- 3.16.6.6.2 A description of planned decommissioning activities;
- 3.16.6.6.3 A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
- 3.16.6.6.4 A description of the planned final radiation survey and;
- 3.16.6.6.5 An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
- 3.16.6.6.6 For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in RH 3.16.8 of this section.

- 3.16.6.7 The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.
- 3.16.7 Except as provided in RH 3.16.8 of this section:
- 3.16.7.1 Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.
- 3.16.7.2 When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.
- 3.16.8 The Department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:
- 3.16.8.1 Whether it is technically feasible to complete decommissioning within the allotted 24-month period;
- 3.16.8.2 Whether sufficient waste disposal capacity is available to allow completion of decommissioning with the allotted 24-month period;
- 3.16.8.3 Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;
- 3.16.8.4 Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and
- 3.16.8.5 Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.
- 3.16.9 As the final step in decommissioning, the licensee shall:
- 3.16.9.1 Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Department Form AOR-RH-23 or equivalent information; and
- 3.16.9.2 Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

- 3.16.9.2.1 Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute of microcuries) per 100 square centimeters-removable and fixed-for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and
- 3.16.9.2.2 Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.
- 3.16.10 Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the department determines that:
- 3.16.10.1 Radioactive materials has been properly disposed;
- 3.16.10.2 Reasonable effort has been made to eliminate residual radioactive contamination if present; and
- 3.16.10.3 A radiation survey has been performed which demonstrates;
- 3.16.10.3.1 That the premises are suitable for release in accordance with Department requirements; or
- 3.16.10.3.2 Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Department requirements.

RH 3.17 Renewal of Licenses.

- 3.17.1 Applications for renewal of specific licenses shall be filed in accordance with RH 3.8.
- 3.17.2 In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Department.

RH 3.18 Amendment of Licenses at Request of Licensee. Applications for amendment of a license shall be filed in accordance with RH 3.8 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

RH 3.19 Agency Action on Applications to Renew and Amend. In considering an application by a licensee to renew or amend the license, the Department will apply the criteria set forth in RH 3.9 and RH 3.10, RH 3.11, RH 3.12, and in Parts 5, 7, 14, 16 and 18 of these regulations, as applicable.

Licenses Held at the Time of the Effective Date of These Regulations

RH 3.20 Reserved.

RH 3.21 Reserved.

Transfer of Materials

RH 3.22 Transfer of Material.

- 3.22.1 No licensee shall transfer radioactive material except as authorized pursuant to RH 3.22.
- 3.22.2 Except as otherwise provided in his license and subject to the provisions of RH 3.22.3 and RH 3.22.4, any licensee may transfer radioactive material:
- 3.22.2.1 to the Department;<sup>11/</sup>
  - 3.22.2.2 to the U.S. Department of Energy;
  - 3.22.2.3 to any person exempt from the regulations in this part to the extent permitted under such exemption;
  - 3.22.2.4 to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department, an Agreement State, or a Licensing State; or
  - 3.22.2.5 as otherwise authorized by the Department in writing.
- 3.22.3 Before transferring radioactive material to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Department, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.
- 3.22.4 Any of the following methods for the verification required by RH 3.22.3 is acceptable:
- 3.22.4.1 The transferor may possess and read a current copy of the transferee's specific license or registration certificate.
  - 3.22.4.2 The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.
  - 3.22.4.3 For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

<sup>11/</sup> A licensee may transfer material to the Department only after receiving prior approval from the Department.

- 3.22.4.4 The transferor may obtain other information compiled by a reporting service from official records of the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State regarding the identity of licensees and the scope and expiration dates of licenses and registration
- 3.22.4.5 When none of the methods of verification described in RH 3.22.4.1 through RH 3.22.4.4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State, or a Licensing State that the transferee is licensed to receive the radioactive material.
- 3.22.5 Shipment and transport of radioactive material shall be in accordance with the provisions of Part 17 of these regulations.

#### Modification and Revocation of Licenses

#### RH 3.23 Modification and Revocation of Licenses.

- 3.23.1 The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Department.
- 3.23.2 Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule, regulation, or order of the Department.
- 3.23.3 Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

#### Reciprocity

#### RH 3.24 Reciprocal Recognition of Licenses.

#### 3.24.1 Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

- 3.24.1.1 Subject to these regulations, any person who holds a specific license from the U. S. Nuclear Regulatory Commission or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:
- 3.24.1.1.1 the licensing document does not limit the activity authorized by such document to specified installations or locations;



- 3.24.1.1.2 the out-of-state licensee notifies the Department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in RH 3.24.1.1;
- 3.24.1.1.3 the out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department;
- 3.24.1.1.4 the out-of-state licensee supplies such other information as the Department may request; and
- 3.24.1.1.5 the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH 3.24.1.1 except by transfer to a person:
- 3.24.1.1.5.1 specifically licensed by the Department or by the U. S. Nuclear Regulatory Commission to receive such material, or
- 3.24.1.1.5.2 exempt from the requirements for a license for such material under RH 3.3.1.
- 3.24.1.2 Notwithstanding the provisions of RH 3.24.1.1, any person who holds a specific license issued by the U. S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in RH 3.6.4.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:
- 3.24.1.2.1 such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
- 3.24.1.2.2 the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U. S. Nuclear Regulatory Commission or an Agreement State;



- 3.24.1.2.3 such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
- 3.24.1.2.4 the holder of the specific license shall furnish to each general licensee to whom the specific licensee transfers such device or on whose premises the specific licensee installs such device a copy of the general license contained in RH 3.6.4 or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- 3.24.1.3 The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U. S. Nuclear Regulatory Commission or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.
- 3.24.2 Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material.
- 3.24.2.1 Subject to these regulations, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:
- 3.24.2.1.1 the licensing document does not limit the activity authorized by such document to specified installations or locations;
- 3.24.2.1.2 the out-of-state licensee notifies the Department in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in RH 3.24.2.1;
- 3.24.2.1.3 the out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department;
- 3.24.2.1.4 the out-of-state licensee supplies such other information as the Department may request; and

- 3.24.2.1.5 the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH 3.24.2.1 except by transfer to a person:
- 3.24.2.1.5.1 specifically licensed by the Department or by another Licensing State to receive such material, or
- 3.24.2.1.5.2 exempt from the requirements for a license for such material under RH 3.3.
- 3.24.2.2 Notwithstanding the provisions of RH 3.24.2.1, any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in RH 3.6.4.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:
- 3.24.2.2.1 Such person shall file a report with the Department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
- 3.24.2.2.2 The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;
- 3.24.2.2.3 Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
- 3.24.2.2.4 The holder of the specific license shall furnish to each general licensee to whom the specific licensee transfers such device or on whose premises the specific licensee installs such device a copy of the general license contained in RH 3.6.4 or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.
- 3.24.2.3 The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

#### Transportation

- RH 3.25 Reserved.
- RH 3.26 Reserved.
- RH 3.27 Reserved.
- RH 3.28 Reserved.
- RH 3.29 Reserved.

## PART 3

## SCHEDULE A

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration uCi/ml 1/	Column II Liquid and solid concentration uCi/ml 2/
Antimony (51)	Sb-122		$3 \times 10^{-4}$
	Sb-124		$2 \times 10^{-4}$
	Sb-125		$1 \times 10^{-3}$
Argon (18)	Ar-37	$1 \times 10^{-3}$	
	Ar-41	$4 \times 10^{-7}$	
Arsenic (33)	As-73		$5 \times 10^{-3}$
	As-74		$5 \times 10^{-4}$
	As-76		$2 \times 10^{-4}$
	As-77		$8 \times 10^{-4}$
Barium (56)	Ba-131		$2 \times 10^{-3}$
	Ba-140		$3 \times 10^{-4}$
Beryllium (4)	Be-7		$2 \times 10^{-2}$
Bismuth (83)	Bi-206		$4 \times 10^{-4}$
Bromine (35)	Br-82	$4 \times 10^{-7}$	$3 \times 10^{-3}$
Cadmium (48)	Cd-109		$2 \times 10^{-3}$
	Cd-115m		$3 \times 10^{-4}$
	Cd-115		$3 \times 10^{-4}$
Calcium (20)	Ca-45		$9 \times 10^{-5}$
	Ca-47		$5 \times 10^{-4}$
Carbon (6)	C-14	$1 \times 10^{-6}$	$8 \times 10^{-3}$
Cerium (58)	Ce-141		$9 \times 10^{-4}$
	Ce-143		$4 \times 10^{-4}$
	Ce-144		$1 \times 10^{-4}$
Cesium (55)	Cs-131		$2 \times 10^{-2}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ uCi/g for solids.

Element (atomic number)	Isotope	Column I	Column II
		Gas con- centration uCi/ml <u>1</u> /	Liquid and solid concent- ration uCi/ml <u>2</u> /
	Cs-134m		$6 \times 10^{-2}$
	Cs-134		$9 \times 10^{-5}$
Chlorine (17)	Cl-38	$9 \times 10^{-7}$	$4 \times 10^{-3}$
Chromium (24)	Cr-51		$2 \times 10^{-2}$
Cobalt (27)	Co-57		$5 \times 10^{-3}$
	Co-58		$1 \times 10^{-3}$
	Co-60		$5 \times 10^{-4}$
Copper (29)	Cu-64		$3 \times 10^{-3}$
Dysprosium (66)	Dy-165		$4 \times 10^{-3}$
	Dy-166		$4 \times 10^{-4}$
Erbium (68)	Er-169		$9 \times 10^{-4}$
	Er-171		$1 \times 10^{-3}$
Europium (63)	Eu-152 (9.2 h)		$6 \times 10^{-4}$
	Eu-155		$2 \times 10^{-3}$
Fluorine (9)	F-18	$2 \times 10^{-6}$	$8 \times 10^{-3}$
Gadolinium (64)	Gd-153		$2 \times 10^{-3}$
	Gd-159		$8 \times 10^{-4}$
Gallium (31)	Ga-72		$4 \times 10^{-4}$
Germanium (32)	Ge-71		$2 \times 10^{-2}$
Gold (79)	Au-196		$2 \times 10^{-3}$
	Au-198		$5 \times 10^{-4}$
	Au-199		$2 \times 10^{-3}$
Hafnium (72)	Hf-181		$7 \times 10^{-4}$
Hydrogen (1)	H-3	$5 \times 10^{-6}$	$3 \times 10^{-2}$
Indium (49)	In-113m		$1 \times 10^{-2}$
	In-114m		$2 \times 10^{-4}$
Iodine (53)	I-126	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-131	$3 \times 10^{-9}$	$2 \times 10^{-5}$
	I-132	$8 \times 10^{-8}$	$6 \times 10^{-4}$
	I-133	$1 \times 10^{-8}$	$7 \times 10^{-5}$
	I-134	$2 \times 10^{-7}$	$1 \times 10^{-3}$
Iridium (77)	Ir-190		$2 \times 10^{-3}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ uCi/g for solids.

Element (atomic number)	Isotope	Column I Gas con- centration uCi/ml 1/	Column II Liquid and solid concen- tration uCi/ml 2/
	Ir-192		4X10 <sup>-4</sup>
	Ir-194		3X10 <sup>-4</sup>
Iron (26)	Fe-55		8X10 <sup>-3</sup>
	Fe-59		6X10 <sup>-4</sup>
Krypton (36)	Kr-85m	1X10 <sup>-6</sup>	
	Kr-85	3X10 <sup>-6</sup>	
Lanthanum (57)	La-140		2X10 <sup>-4</sup>
Lead (82)	Pb-203		4X10 <sup>-3</sup>
Lutetium (71)	Lu-177		1X10 <sup>-3</sup>
Manganese (25)	Mn-52		3X10 <sup>-4</sup>
	Mn-54		1X10 <sup>-3</sup>
	Mn-56		1X10 <sup>-3</sup>
Mercury (80)	Hg-197m		2X10 <sup>-3</sup>
	Hg-197		3X10 <sup>-3</sup>
	Hg-203		2X10 <sup>-4</sup>
Molybdenum (42)	Mo-99		2X10 <sup>-3</sup>
Neodymium (60)	Nd-147		6X10 <sup>-4</sup>
	Nd-149		3X10 <sup>-3</sup>
Nickel (28)	Ni-65		1X10 <sup>-3</sup>
Niobium (Columbium) (41)	Nb-95		1X10 <sup>-3</sup>
	Nb-97		9X10 <sup>-3</sup>
Osmium (76)	Os-185		7X10 <sup>-4</sup>
	Os-191m		3X10 <sup>-2</sup>
	Os-191		2X10 <sup>-3</sup>
	Os-193		6X10 <sup>-4</sup>
Palladium (46)	Pd-103		3X10 <sup>-3</sup>
Phosphorus (15)	P-32		2X10 <sup>-4</sup>
Platinum (78)	Pt-191		1X10 <sup>-3</sup>
	Pt-193m		1X10 <sup>-2</sup>
	Pt-197m		1X10 <sup>-2</sup>
	Pt-197		1X10 <sup>-3</sup>

1/ Values are given in Column I only for those materials normally used as gases.

2/ uCi/g for solids.



Element (atomic number)	Isotope	Column I	Column II
		Gas concentration uCi/ml <u>1</u> /	Liquid and solid concentration uCi/ml <u>2</u> /
Potassium (19)	K-42		$3 \times 10^{-3}$
Praseodymium (59)	Pr-142		$3 \times 10^{-4}$
	Pr-143		$5 \times 10^{-4}$
Promethium (61)	Pm-147		$2 \times 10^{-3}$
	Pm-149		$4 \times 10^{-4}$
Rhenium (75)	Re-183		$6 \times 10^{-3}$
	Re-186		$9 \times 10^{-4}$
	Re-188		$6 \times 10^{-4}$
Rhodium (45)	Rh-103m		$1 \times 10^{-1}$
	Rh-105		$1 \times 10^{-3}$
Rubidium (37)	Rb-86		$7 \times 10^{-4}$
Ruthenium (44)	Ru-97		$4 \times 10^{-3}$
	Ru-103		$8 \times 10^{-4}$
	Ru-105		$1 \times 10^{-3}$
	Ru-106		$1 \times 10^{-4}$
Samarium (62)	Sm-153		$8 \times 10^{-4}$
Scandium (21)	Sc-46		$4 \times 10^{-4}$
	Sc-47		$9 \times 10^{-4}$
	Sc-48		$3 \times 10^{-4}$
Selenium (34)	Se-75		$3 \times 10^{-3}$
Silicon (14)	Si-31		$9 \times 10^{-3}$
Silver (47)	Ag-105		$1 \times 10^{-3}$
	Ag-110m		$3 \times 10^{-4}$
	Ag-111		$4 \times 10^{-4}$
Sodium (11)	Na-24		$2 \times 10^{-3}$
Strontium (38)	Sr-85		$1 \times 10^{-3}$
	Sr-89		$1 \times 10^{-4}$
	Sr-91		$7 \times 10^{-4}$
	Sr-92		$7 \times 10^{-4}$
Sulfur (16)	S-35	$9 \times 10^{-2}$	$6 \times 10^{-4}$
Tantalum (73)	Ta-182		$4 \times 10^{-4}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ uCi/g for solids.

Element (atomic number)	Isotope	Column I	Column II
		Gas concentration uCi/ml <u>1</u> /	Liquid and solid concentration uCi/ml <u>2</u> /
Technetium (43)	Tc-96m		$1 \times 10^{-1}$
	Tc-96		$1 \times 10^{-3}$
Tellurium (52)	Te-125m		$2 \times 10^{-3}$
	Te-127m		$6 \times 10^{-4}$
	Te-127		$3 \times 10^{-3}$
	Te-129m		$3 \times 10^{-4}$
	Tc-131m		$6 \times 10^{-4}$
	Te-132		$3 \times 10^{-4}$
Terbium (65)	Tb-160		$4 \times 10^{-4}$
Thallium (81)	Tl-200		$4 \times 10^{-3}$
	Tl-201		$3 \times 10^{-3}$
	Tl-202		$1 \times 10^{-3}$
	Tl-204		$1 \times 10^{-3}$
Thulium (69)	Tm-170		$5 \times 10^{-4}$
	Tm-171		$5 \times 10^{-3}$
Tin (50)	Sn-113		$9 \times 10^{-4}$
	Sn-125		$2 \times 10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4 \times 10^{-3}$
	W-187		$7 \times 10^{-4}$
	V-48		$3 \times 10^{-4}$
Vanadium (23)			
Xenon (54)	Xe-131m	$4 \times 10^{-6}$	
	Xe-133	$3 \times 10^{-6}$	
	Xe-135	$1 \times 10^{-6}$	
Ytterbium (70)	Yb-175		$1 \times 10^{-3}$
Yttrium (39)	Y-90		$2 \times 10^{-4}$
	Y-91m		$3 \times 10^{-2}$
	Y-91		$3 \times 10^{-4}$
	Y-92		$6 \times 10^{-4}$
	Y-93		$3 \times 10^{-6}$

1/ Values are given in Column I only for those materials normally used as gases.

2/ uCi/g for solids.

Element (atomic number)	Isotope	Column I	Column II
		Gas con- centration uCi/ml 1/	Liquid and solid concen- tration uCi/ml 2/
Zinc (30)	Zn-65		$1 \times 10^{-3}$
	Zn-69m		$7 \times 10^{-4}$
	Zn-69		$2 \times 10^{-2}$
Zirconium (40)	Zr-95		$6 \times 10^{-4}$
	Zr-97		$2 \times 10^{-4}$
Beta- and/or gamma- emitting radioactive material not listed above with half-life of less than 3 years.		$1 \times 10^{-10}$	$1 \times 10^{-6}$

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Schedule A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: For purposes of Section RH 3.3 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1".

Example: 
$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}}$$

$$\frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$$

Note 3: To convert uCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 ( $2 \times 10^{-4}$  uCi/ml multiplied by 37 is equivalent to  $74 \times 10^{-4}$  MBq/l).

## PART 3

## SCHEDULE B

EXEMPT QUANTITIES

Radioactive Material	Micro- curies
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10

Radioactive Material	Micro- curies
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10

Radioactive Material	Micro- curies
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10



<u>Radioactive Material</u>	<u>Micro- curies</u>
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	30
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100

Radioactive Material	Micro- curies
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10

Any radioactive material  
not listed above other than  
alpha-emitting radioactive  
material

0.1

Note 1: For purposes of RH 3.9.5.1.2.5.1 and 3.9.5.1.2.5.2 where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Schedule B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

Amt. of Radionuclide A possessed + Amt. of Radionuclide B possessed < 1

1000 x Schedule B quantity  
for Radionuclide A

1000 x Schedule B quantity  
for Radionuclide B

Note 2: To convert microcuries (uCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 uCi multiplied by 37 is equivalent to 370 kBq).

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PART 3  
SCHEDULE C  
RESERVED

## PART 3

## SCHEDULE D

LIMITS FOR BROAD LICENSES (RH 3.11)

Radioactive Material	Col. I curies	Col. II curies
Antimony-122	.	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.

Radioactive Material	Col. I curies	Col. II curies
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.



Radioactive Material	Col. I curies	Col. II curies
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1

Radioactive Material	Col. I curies	Col. II curies
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01

Radioactive Material	Col. I curies	Col. II curies
Any radioactive material other than source material, special nuclear material, or alpha emitting radio- active material not listed above.	0.1	0.001

Note 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

PART 3  
SCHEDULE E

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION  
OF THE NEPO FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE.

Radioactive material <sup>1</sup>	Release fraction	Quantity	
		teraBecquerels	(curies)
Actinium-228	0.001	148	(4,000)
Americium-241	.001	0.074	(2)
Americium-242	.001	0.074	(2)
Americium-243	.001	0.074	(2)
Antimony-124	.01	148	— (4,000)
Antimony-126	.01	222	— (6,000)
Barium-133	.01	370	(10,000)
Barium-140	.01	1,100	(30,000)
Bismuth-207	.01	185	(5,000)
Bismuth-210	.01	22.2	(600)
Cadmium-109	.01	37	(1,000)
Cadmium-113	.01	2.96	(80)
Calcium-45	.01	740	(20,000)
Californium-252	.001	0.333	(9) (20 mg)
Carbon-14	.01	1,850	(50,000)
	Non CO		
Cerium-141	.01	370	(10,000)
Cerium-144	.01	11.1	(300)
Cesium-134	.01	74	(2,000)
Cesium-137	.01	111	(3,000)
Chlorine-36	.5	3.7	(100)
Chromium-51	.01	11,100	(300,000)
Cobalt-60	.001	185	(5,000)
Copper-64	.01	7,400	(200,000)
Curium-242	.001	2.22	(60)
Curium-243	.001	0.111	(3)
Curium-244	.001	0.148	(4)
Curium-245	.001	0.074	(2)
Europium-152	.01	18.5	(500)
Europium-154	.01	14.8	(400)
Europium-155	.01	111	(3,000)
Germanium-68	.01	74	(2,000)
Gadolinium-153	.01	185	(5,000)
Gold-198	.01	1,110	(30,000)
Hafnium-172	.01	14.8	(400)
Hafnium-181	.01	259	(7,000)
Holmium-166m	.01	3.7	(100)
Hydrogen-3	.5	740	(20,000)
Iodine-125	.5	0.37	(10)

## PART 3

SCHEDULE E  
(continued)

Radioactive material <sup>1</sup>	Release fraction	Quantity	
		teraBecquerels	(curies)
Iodine-131	.5	0.37	(10)
Indium-114m	.01	37	(1,000)
Iridium-192	.001	1,480	(40,000)
Iron-55	.01	1,480	(40,000)
Iron-59	.01	259	(7,000)
Krypton-85	1.0	222,000	(6,000,000)
Lead-210	.01	0.296	(8)
Manganese-56	.01	2,200	(60,000)
Mercury-203	.01	370	(10,000)
Molybdenum-99	.01	1,100	(30,000)
Neptunium-237	.001	0.074	(2)
Nickel-63	.01	740	(20,000)
Niobium-94	.01	11.1	(300)
Phosphorus-32	.5	3.7	(100)
Phosphorus-33	.5	37	(1,000)
Polonium-210	.01	0.37	(10)
Potassium-42	.01	333	(9,000)
Promethium-145	.01	148	(4,000)
Promethium-147	.01	148	(4,000)
Ruthenium-106	.01	7.4	(200)
Samarium-151	.01	148	(4,000)
Scandium-46	.01	111	(3,000)
Selenium-75	.01	370	(10,000)
Silver-110m	.01	37	(1,000)
Sodium-22	.01	333	(9,000)
Sodium-24	.01	370	(10,000)
Strontium-89	.01	111	(3,000)
Strontium-90	.01	3.33	(90)
Sulfur-35	.5	33.3	(900)
Technetium-99	.01	370	(10,000)
Technetium-99m	.01	14,800	(400,000)
Tellurium-127m	.01	185	(5,000)
Tellurium-129m	.01	185	(5,000)
Terbium-160	.01	148	(4,000)
Thulium-170	.01	148	(4,000)
Tin-113	.01	370	(10,000)
Tin-123	.01	111	(3,000)
Tin-126	.01	37	(1,000)
Titanium-44	.01	3.7	(100)

PART 3  
SCHEDULE E  
(continued)

Radioactive material <sup>1</sup>	Release fraction	Quantity	
		teraBecquerels	(curies)
Vanadium-48	.01	259	(7,000)
Xenon-133	1.0	33,300	(900,000)
Yttrium-91	.01	74	(2,000)
Zinc-65	.01	185	(5,000)
Zirconium-93	.01	14.8	(400)
Zirconium-95	.01	185	(5,000)
Any other beta-gamma emitter	.01	370	(10,000)
Mixed fission products	.01	37	(1,000)
Mixed corrosion products	.01	370	(10,000)
Contaminated equipment	.001	370	(10,000)
beta-gamma			
Irradiated material, any form other than solid noncombustible	.01	37	(1,000)
Irradiated material, solid noncombustible	.001	370	(10,000)
Mixed radioactive waste, beta-gamma	.01	37	(1,000)
Packaged mixed waste, beta-gamma <sup>2</sup>	.001	370	(10,000)
Any other alpha emitter	.001	0.074	(2)
Contaminated equipment, alpha	.0001	0.74	(20)
Packaged waste, alpha <sup>2</sup>	.0001	0.74	(20)
Combinations of radioactive materials listed above <sup>1</sup>			

<sup>1</sup> For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive materials authorized to the quantity listed for that material in Schedule E exceeds one.

<sup>2</sup> Waste packaged in Type B containers does not requires an emergency plan.



## PART 4

### STANDARDS FOR PROTECTION AGAINST RADIATION

#### GENERAL PROVISIONS

##### RH 4.1 Purpose.

4.1.1 Part 4 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department. These regulations are issued pursuant to the 25-11-101 CRS, 1988.

4.1.2 The requirements of Part 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in Part 4. However, nothing in Part 4 shall be construed as limiting actions that may be necessary to protect health and safety.

RH 4.2 Scope. Except as specifically provided in other parts of these regulations, Part 4 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in Part 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

RH 4.3 Definitions. As used in Part 4:

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these regulations, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Inhalation class" (see "Class").

"Lung class" (see "Class").

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these regulations, "Deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the Reference Man is contained in the International Commission on Radiological Protection Report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these regulations, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.<sup>1</sup>

"Weighting factor"  $w_T$  for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of  $w_T$  are:

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ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	$w_T$
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 <sup>a</sup>
<hr/>	
Whole Body	1.00 <sup>b</sup>

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<sup>a</sup> 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

<sup>b</sup> For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor,  $w_T = 1.0$ , has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

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#### RH 4.4

#### Implementation.

##### 4.4.1

Any existing license or registration condition that is more restrictive than Part 4 remains in force until there is an amendment or renewal of the license or registration.

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<sup>1</sup>At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

- 4.4.2 If a license or registration condition exempts a licensee or registrant from a provision of Part 4 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of revised Part 4.
- 4.4.3 If a license or registration condition cites provisions of Part 4 in effect prior to January 1, 1994, which do not correspond to any provisions of Part 4, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

#### RADIATION PROTECTION PROGRAMS

- RH 4.5 Radiation Protection Programs.
- 4.5.1 Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of Part 4. See RH 4.41 for recordkeeping requirements relating to these programs.
- 4.5.2 The licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).
- 4.5.3 The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

#### OCCUPATIONAL DOSE LIMITS

- RH 4.6 Occupational Dose Limits for Adults.
- 4.6.1 The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to RH 4.11, to the following dose limits:
- 4.6.1.1 An annual limit, which is the more limiting of:
- 4.6.1.1.1 The total effective dose equivalent being equal to 0.05 Sv (5 rem); or
- 4.6.1.1.2 The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).
- 4.6.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:
- 4.6.1.2.1 An eye dose equivalent of 0.15 Sv (15 rem), and
- 4.6.1.2.2 A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

- 4.6.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See RH 4.11.5.1 and 4.11.5.2.
- 4.6.3 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:
- 4.6.3.1 The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or
- 4.6.3.2 Re ved.
- 4.6.4 Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See RH 4.46.
- 4.6.5 Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.
- 4.6.6 The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See RH 4.10.3.1 and 4.10.5.
- RH 4.7 Compliance with Requirements for Summation of External and Internal Doses.
- 4.7.1 If the licensee or registrant is required to monitor pursuant to both RH 4.18.1 and 4.18.2, the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to RH 4.18.1 or only pursuant to RH 4.18.2, then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to RH 4.7.2, 4.7.3 and 4.7.4. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.



- 4.7.2 Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:
- 4.7.2.1 The sum of the fractions of the inhalation ALI for each radionuclide, or
  - 4.7.2.2 The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
  - 4.7.2.3 The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors,  $w_T$ , and the committed dose equivalent,  $H_{T,50}$ , per unit intake is greater than 10 percent of the maximum weighted value of  $H_{50}$ , that is,  $w_T H_{T,50}$ , per unit intake for any organ or tissue.
- 4.7.3 Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.
- 4.7.4 Intake through Wounds or Absorption through Skin. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to RH 4.7.4.
- RH 4.8 Determination of External Dose from Airborne Radioactive Material.
- 4.8.1 Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.
  - 4.8.2 Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.



RH 4.9      Determination of Internal Exposure.

- 4.9.1      For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, when required pursuant to RH 4.18, take suitable and timely measurements of:
- 4.9.1.1      Concentrations of radioactive materials in air in work areas; or
  - 4.9.1.2      Quantities of radionuclides in the body; or
  - 4.9.1.3      Quantities of radionuclides excreted from the body; or
  - 4.9.1.4      Combinations of these measurements.
- 4.9.2      Unless respiratory protective equipment is used, as provided in RH 4.24, or the assessment of intake is based on bioassays, the licensee or registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.
- 4.9.3      When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee or registrant may:
- 4.9.3.1      Use that information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document that information in the individual's record; and
  - 4.9.3.2      Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
  - 4.9.3.3      Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.
- 4.9.4      If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in RH 4.9.1.2 or 4.9.1.3, the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by RH 4.52 or 4.53. This delay permits the licensee or registrant to make additional measurements basic to the assessments.
- 4.9.5      If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:
- 4.9.5.1      The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

- 4.9.5.2 The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.
- 4.9.6 If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
- 4.9.7 When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:
- 4.9.7.1 The licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in RH 4.6 and in complying with the monitoring requirements in RH 4.18.2, and
- 4.9.7.2 The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and
- 4.9.7.3 The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- 4.9.8 When determining the committed effective dose equivalent, the following information may be considered:
- 4.9.8.1 In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
- 4.9.8.2 For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in RH 4.6.1.1.2 is met.
- RH 4.10 Determination of Prior Occupational Dose.
- 4.10.1 For each individual who may enter the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RH 4.18, the licensee or registrant shall:
- 4.10.1.1 Determine the occupational radiation dose received during the current year; and

- 4.10.1.2 Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- 4.10.2 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
- 4.10.2.1 The internal and external doses from all previous planned special exposures; and
- 4.10.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
- 4.10.2.3 All lifetime cumulative occupational radiation dose.
- 4.10.3 In complying with the requirements of RH 4.10.1, a licensee or registrant may:
- 4.10.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
- 4.10.3.2 Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form OR-RH-16, Cumulative Occupational Exposure History, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and
- 4.10.3.3 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- 4.10.4 Record of Exposure History.
- 4.10.4.1 The licensee or registrant shall record the exposure history, as required by RH 4.10.1, on Department Form OR-RH-16, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form OR-RH-16 or equivalent. For any period in which the

licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form OR-RH-16 or equivalent indicating the periods of time for which data are not available.

- 4.10.4.2 Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the Regulations in Part 4 in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Department Form OR-RH-16 or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.
- 4.10.5 If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
- 4.10.5.1 In establishing administrative controls pursuant to RH 4.6.6 for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
- 4.10.5.2 That the individual is not available for planned special exposures.
- 4.10.6 The licensee or registrant shall retain the records on Department Form OR-RH-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form OR-RH-16 or equivalent for 3 years after the record is made.
- RH 4.11 Planned Special Exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in RH 4.6 provided that each of the following conditions in RH 4.11.1 through 4.11.7 is satisfied:
- 4.11.1 The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.
- 4.11.2 The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- 4.11.3 Before a planned special exposure, the licensee or registrant ensures that each individual involved is:
- 4.11.3.1 Informed of the purpose of the planned operation; and

- 4.11.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
- 4.11.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- 4.11.4 Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by RH 4.10.2 during the lifetime of the individual for each individual involved.
- 4.11.5 Subject to RH 4.6.2, the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
- 4.11.5.1 The numerical values of any of the dose limits in RH 4.6.1 in any year; and
- 4.11.5.2 Five times the annual dose limits in RH 4.6.1 during the individual's lifetime.
- 4.11.6 The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with RH 4.45 and submits a written report in accordance with RH 4.54.
- 4.11.7 The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to RH 4.6.1 but shall be included in evaluations required by RH 4.11.4 and 4.11.5.
- RH 4.12 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in RH 4.6
- RH 4.13 Dose to an Embryo/Fetus.
- 4.13.1 The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See RH 4.46 for recordkeeping requirements.
- 4.13.2 The licensee or registrant shall make efforts to avoid substantial variation<sup>2</sup> above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in RH 4.13.1.

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<sup>2</sup> The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.



- 4.13.3 The dose to an embryo/fetus shall be taken as the sum of:
- 4.13.3.1 The deep dose equivalent to the declared pregnant woman; and
- 4.13.3.2 The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- 4.13.4 If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with RH 4.13.1 if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

#### RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

##### RH 4.14 Dose Limits for Individual Members of the Public.

- 4.14.1 Each licensee or registrant shall conduct operations so that:
  - 4.14.1.1 The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with RH 4.35,<sup>3</sup> and
  - 4.14.1.2 The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour.
- 4.14.2 Reserved.
- 4.14.3 A licensee, registrant, or an applicant for a license or registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:
  - 4.14.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in RH 4.14.1; and
  - 4.14.3.2 The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and
  - 4.14.3.3 The procedures to be followed to maintain the dose ALARA.

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<sup>3</sup>Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.



- 4.14.4 In addition to the requirements of Part 4, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.
- 4.14.5 The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.
- RH 4.15 Compliance with Dose Limits for Individual Members of the Public.
- 4.15.1 The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in RH 4.14.
- 4.15.2 A licensee or registrant shall show compliance with the annual dose limit in RH 4.14 by:
- 4.15.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
- 4.15.2.2 Demonstrating that:
- 4.15.2.2.1 The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and
- 4.15.2.2.2 If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.
- 4.15.3 Upon approval from the Department, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.
- 4.15.4 Rooms or areas in which diagnostic x-ray systems are the only source of radiation shall demonstrate compliance with RH 4.15.2.1 after construction of a new x-ray facility, after modification or renovation of an existing x-ray facility, or installation of a new x-ray machine in an existing x-ray facility when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or where there is a projected increase in the x-ray workload from that which was used for a prior x-ray shielding design.

- 4.15.5 Facilities using only dental intraoral or panoramic machines in single occupancy rooms are exempt from the requirements of RH 4.15.2.1.

#### TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

RH 4.16 Testing for Leakage or Contamination of Sealed Sources.

- 4.16.1 The licensee or registrant in possession of any sealed source shall assure that:
- 4.16.1.1 Each sealed source, except as specified in RH 4.16.2, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee or registrant has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant. Sources that indicate contamination in excess of 185 Bq (0.005 microcuries) shall not be put into use.
- 4.16.1.2 Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Department, after evaluation of information specified by RH 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.
- 4.16.1.3 Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Department, after evaluation of information specified by RH 3.12.12.4 and 3.12.12.5 of these regulations, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.
- 4.16.1.4 For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.
- 4.16.1.5 Tests, and evaluations of tests, for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005  $\mu$ Ci) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

- 4.16.1.6 The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001  $\mu$ Ci) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.
- 4.16.1.7 Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005  $\mu$ Ci) of a radium daughter which has a half-life greater than 4 days.
- 4.16.2 A licensee or registrant need not perform test for leakage or contamination on the following sealed sources:
- 4.16.2.1 Sealed sources containing only radioactive material with a half-life of less than 30 days;
- 4.16.2.2 Sealed sources containing only radioactive material as a gas;
- 4.16.2.3 Sealed sources containing 3.7 MBq (100  $\mu$ Ci) or less of beta or photon-emitting material or 370 kBq (10  $\mu$ Ci) or less of alpha-emitting material;
- 4.16.2.4 Sealed sources containing only hydrogen-3;
- 4.16.2.5 Seeds of iridium-192 encased in nylon ribbon; and
- 4.16.2.6 Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee or registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.
- 4.16.3 Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.
- 4.16.4 Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Department.
- 4.16.5 The following shall be considered evidence that a sealed source is leaking:
- 4.16.5.1 The presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination on any test sample.
- 4.16.5.2 Leakage of 37 Bq (0.001  $\mu$ Ci) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.
- 4.16.5.3 The presence of removable contamination resulting from the decay of 185 Bq (0.005  $\mu$ Ci) or more of radium.

- 4.16.6 The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Part.
- 4.16.7 Reports of test results for leaking or contaminated sealed sources shall be made pursuant to RH 4.58.

#### SURVEYS AND MONITORING

RH 4.17 General.

- 4.17.1 Each licensee or registrant shall make, or cause to be made, surveys that:
- 4.17.1.1 Are necessary for the licensee or registrant to comply with Part 4; and
  - 4.17.1.2 Are necessary under the circumstances to evaluate:
    - 4.17.1.2.1 Radiation levels; and
    - 4.17.1.2.2 Concentrations or quantities of radioactive material; and
    - 4.17.1.2.3 The potential radiological hazards that could be present.
  - 4.17.2 The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured unless otherwise noted in these regulations.
  - 4.17.3 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with RH 4.6, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
    - 4.17.3.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
    - 4.17.3.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
  - 4.17.4 The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

RH 4.18      Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part 4. As a minimum:

- 4.18.1      Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
  - 4.18.1.1      Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in RH 4.6.1; and
  - 4.18.1.2      Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in RH 4.12 or 4.13; and
  - 4.18.1.3      Individuals entering a high or very high radiation area.
  - 4.18.1.4      Reserved.
- 4.18.2      Each licensee or registrant shall monitor, to determine compliance with RH 4.9, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
  - 4.18.2.1      Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
  - 4.18.2.2      Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES  
IN RESTRICTED AREAS

RH 4.19      Control of Access to High Radiation Areas.

- 4.19.1      The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
  - 4.19.1.1      A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or
  - 4.19.1.2      A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or



- 4.19.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.
- 4.19.2 In place of the controls required by RH 4.19.1 for a high radiatici area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.
- 4.19.3 The licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.
- 4.19.4 The licensee or registrant shall establish the controls required by RH 4.19.1 and 4.19.3 in a way that does not prevent individuals from leaving a high radiation area.
- 4.19.5 The licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:
- 4.19.5.1 The packages do not remain in the area longer than 3 days; and
- 4.19.5.2 The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.
- 4.19.6 The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Part 4 and to operate within the ALARA provisions of the licensee's or registrant's radiation protection program.
- 4.19.7 The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in RH 4.19 if the licensee or registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.
- RH 4.20 Control of Access to Very High Radiation Areas.



4.20.1 In addition to the requirements in RH 4.19, the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

4.20.2 The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in RH 4.20.1 if the registrant has met all the specific requirements for access and control specified in other applicable parts of these regulations, such as, Part 5 for industrial radiography, Part 6 for x-rays in the healing arts, and Part 9 for particle accelerators.

RH 4.21 Control of Access to Very High Radiation Areas -- Irradiators.

4.21.1 Section RH 4.21 applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Section RH 4.21 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

4.21.2 Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

4.21.2.1 Each entrance or access point shall be equipped with entry control devices which:

4.21.2.1.1 Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

4.21.2.1.2 Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

4.21.2.1.3 Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

- 4.21.2.2 Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by RH 4.21.2.1:
- 4.21.2.2.1 The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
- 4.21.2.2.2 Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
- 4.21.2.3 The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:
- 4.21.2.3.1 The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and
- 4.21.2.3.2 Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.
- 4.21.2.4 When the shield for stored sealed sources is a liquid, the licensee or registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- 4.21.2.5 Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of RH 4.21.2.3 and 4.21.2.4.
- 4.21.2.6 Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.
- 4.21.2.7 Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

- 4.21.2.8 Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.
- 4.21.2.9 The entry control devices required in RH 4.21.2.1 shall be tested for proper functioning. See RH 4.49 for recordkeeping requirements.
- 4.21.2.9.1 Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and
- 4.21.2.9.2 Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and
- 4.21.2.9.3 The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
- 4.21.2.10 The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.
- 4.21.2.11 Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.
- 4.21.3 Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of RH 4.21.2 which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of RH 4.21.2, such as those for the automatic control of radiation levels, may apply to the Department for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in RH 4.21.2. At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

- 4.21.4 The entry control devices required by RH 4.21.2 and 4.21.3 shall be established in such a way that no individual will be prevented from leaving the area.

**RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT  
INTERNAL EXPOSURE IN RESTRICTED AREAS**

- RH 4.22 Use of Process or Other Engineering Controls. The licensee shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.
- RH 4.23 Use of Other Controls. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:
- 4.23.1 Control of access; or
- 4.23.2 Limitation of exposure times; or
- 4.23.3 Use of respiratory protection equipment; or
- 4.23.4 Other controls.
- RH 4.24 Use of Individual Respiratory Protection Equipment.
- 4.24.1 If the licensee uses respiratory protection equipment to limit intakes pursuant to RH 4.23:
- 4.24.1.1 Except as provided in RH 4.24.1.2, the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
- 4.24.1.2 If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
- 4.24.1.3 The licensee shall implement and maintain a respiratory protection program that includes:

- 4.24.1.3.1 Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and
- 4.24.1.3.2 Surveys and bioassays, as appropriate, to evaluate actual intakes; and
- 4.24.1.3.3 Testing of respirators for operability immediately prior to each use; and
- 4.24.1.3.4 Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
- 4.24.1.3.5 Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.
- 4.24.1.4 The licensee shall issue a written policy statement on respirator usage covering:
  - 4.24.1.4.1 The use of process or other engineering controls, instead of respirators; and
  - 4.24.1.4.2 The routine, nonroutine, and emergency use of respirators; and
  - 4.24.1.4.3 The length of periods of respirator use and relief from respirator use.
- 4.24.1.5 The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
- 4.24.1.6 The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
- 4.24.2 When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to RH 4.23, provided that the following conditions, in addition to those in RH 4.24.1, are satisfied:



- 4.24.2.1 The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in RH 4.23 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.
- 4.24.2.2 The licensee shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix A. The Department may authorize a licensee to use higher protection factors on receipt of an application that:
- 4.24.2.2.1 Describes the situation for which a need exists for higher protection factors, and
- 4.24.2.2.2 Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.
- 4.24.3 In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
- 4.24.4 The licensee shall notify the Department in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either RH 4.24.1 or 4.24.2.

#### STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

- RH 4.25 Security of Stored Sources of Radiation. The licensee shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.



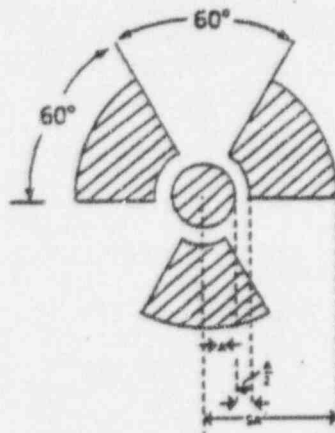
- RH 4.26      Control of Sources of Radiation not in Storage.
- 4.26.1      The licensee shall control and maintain constant surveillance of licensed or registered radioactive material that is in an unrestricted area and that is not in storage or in a patient.
- 4.26.2      The registrant shall maintain control of radiation machines that are in an unrestricted area and that are not in storage.

#### PRECAUTIONARY PROCEDURES

- RH 4.27      Caution Signs.
- 4.27.1      Standard Radiation Symbol. Unless otherwise authorized by the Department, the symbol prescribed by RH 4.27 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

#### RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



- 4.27.2      Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of RH 4.27.1, licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.
- 4.27.3      Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part 4, the licensee shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RH 4.28 Posting Requirements.

4.28.1 Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

4.28.2 Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

4.28.3 Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

4.28.4 Posting of Airborne Radioactivity Areas. The licensee or registrant shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

4.28.5 Posting of Areas or Rooms in which Licensed or Registered Material is Used or Stored. The licensee or registrant shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

RH 4.29 Exceptions to Posting Requirements.

4.29.1 A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

4.29.1.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in Part 4; and

4.29.1.2 The area or room is subject to the licensee's or registrant's control.

4.29.2 Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to RH 4.28 provided that the patient could be released from confinement pursuant to RH 7.26 of these regulations.

4.29.3 A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

- 4.29.4 A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.
- RH 4.30 Labeling Containers and Radiation Machines.
- 4.30.1 The licensee or registrant shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.
- 4.30.2 Each licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- 4.30.3 Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.
- RH 4.31 Exemptions to Labeling Requirements. A licensee or registrant is not required to label:
- 4.31.1 Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or
- 4.31.2 Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or
- 4.31.3 Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by Part 4; or
- 4.31.4 Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;<sup>4</sup> or

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<sup>4</sup>Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

4.31.5 Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

4.31.6 Installed manufacturing or process equipment, such as piping and tanks.

RH 4.32 Procedures for Receiving and Opening Packages.

4.32.1 Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in RH 17.2 and Appendix A of Part 17 of these regulations, shall make arrangements to receive:

4.32.1.1 The package when the carrier offers it for delivery; or

4.32.1.2 The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

4.32.2 Each licensee or registrant shall:

4.32.2.1 Monitor the external surfaces of a labeled<sup>5</sup> package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in RH 1.4 of these regulations; and

4.32.2.2 Monitor the external surfaces of a labeled<sup>5</sup> package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in RH 17.2 and Appendix A to Part 17 of these regulations; and

4.32.2.3 Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

4.32.3 The licensee or registrant shall perform the monitoring required by RH 4.32.2 as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's or registrant's facility if it is received during the licensee's or registrant's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

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<sup>5</sup>Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

- 4.32.4 The licensee or registrant shall immediately notify the final delivery carrier and the Department by telephone, and by telegram, mailgram, or facsimile if:
- 4.32.4.1 Removable radioactive surface contamination exceeds the limits of RH 17.15.8 of these regulations; or
- 4.32.4.2 External radiation levels exceed the limits of RH 17.15.9 and 17.15.10 of these regulations.
- 4.32.5 Each licensee or registrant shall:
- 4.32.5.1 Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
- 4.32.5.2 Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.
- 4.32.6 Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of RH 4.32.2, but are not exempt from the monitoring requirement in RH 4.32.2 for measuring radiation levels that ensures that the source is still properly lodged in its shield.

#### WASTE DISPOSAL

##### RH 4.33 General Requirements.

- 4.33.1 A licensee or registrant shall dispose of licensed or registered material only:
- 4.33.1.1 By transfer to an authorized recipient as provided in RH 4.38 or in Parts 3, 14, or 18 of these regulations, or to the U.S. Department of Energy; or
- 4.33.1.2 By decay in storage; or
- 4.33.1.3 By release in effluents within the limits in RH 4.14; or
- 4.33.1.4 As authorized pursuant to RH 4.34, 4.35, 4.36 or 4.37.
- 4.33.2 A person shall be specifically licensed or registered to receive waste containing licensed or registered material from other persons for:
- 4.33.2.1 Treatment prior to disposal; or
- 4.33.2.2 Treatment or disposal by incineration; or
- 4.33.2.3 Decay in storage; or



- 4.33.2.4 Disposal at a land disposal facility licensed pursuant to Part 14 of these regulations; or
- 4.33.2.5 Storage until transferred to a storage or disposal facility authorized to receive the waste.
- RH 4.34 Method for Obtaining Approval of Proposed Disposal Procedures. A licensee or registrant or applicant for a license or registration may apply to the Department for approval of proposed procedures, not otherwise authorized in these regulations, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:
- 4.34.1 A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and
- 4.34.2 An analysis and evaluation of pertinent information on the nature of the environment; and
- 4.34.3 The nature and location of other potentially affected facilities; and
- 4.34.4 Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in Part 4.
- RH 4.35 Disposal by Release into Sanitary Sewerage.
- 4.35.1 A licensee or registrant may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:
- 4.35.1.1 The material is readily soluble, or is readily dispersible biological material, in water; and
- 4.35.1.2 The quantity of licensed or registered radioactive material that the licensee or registrant releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Table III of Appendix B; and
- 4.35.1.3 If more than one radionuclide is released, the following conditions must also be satisfied:
- 4.35.1.3.1 The licensee or registrant shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and
- 4.35.1.3.2 The sum of the fractions for each radionuclide required by RH 4.35.1.3.1 does not exceed unity; and



- 4.35.1.4 The total quantity of licensed or registered radioactive material that the licensee or registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.
- 4.35.2 Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in RH 4.35.1.
- RH 4.36 Treatment or Disposal by Incineration. A licensee or registrant may treat or dispose of licensed or registered material by incineration only in the amounts and forms specified in RH 4.37 or as specifically approved by the Department pursuant to RH 4.34.
- RH 4.37 Disposal of Specific Wastes.
- 4.37.1 A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:
- 4.37.1.1 1.85 kBq (0.05  $\mu$ Ci), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and
- 4.37.1.2 1.85 kBq (0.05  $\mu$ Ci), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.
- 4.37.2 A licensee or registrant shall not dispose of tissue pursuant to RH 4.37.1.2. in a manner that would permit its use either as food for humans or as animal feed.
- 4.37.3 The licensee or registrant shall maintain records in accordance with RH 4.48.
- RH 4.38 Transfer for Disposal and Manifests.
- 4.38.1 The requirements of RH 4.38 and Appendix G, or Appendix D if prior to March 1, 1998, are designed to control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes. Beginning March 1, 1998, all affected licensees must use Appendix G. Prior to March 1, 1998, a disposal facility operator or its regulatory authority may require the shipper to use Appendix D or Appendix G.
- 4.38.2 Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility shall document the information required on the uniform low-level radioactive waste manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G, or each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility prior to March 1, 1998, shall be accompanied by a shipment manifest as specified in Section I of Appendix D.
- 4.38.3 Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix G or Appendix D as appropriate in accordance with RH 4.38.1.
- 4.38.4 Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G or Appendix D as appropriate in accordance with RH 4.38.1.

RH 4.39

Compliance with Environmental and Health Protection Regulations.  
Nothing in RH 4.33, 4.34, 4.35, 4.37 or 4.38 relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to RH 4.33, 4.34, 4.35, 4.37 or 4.38.

## RECORDS

RH 4.40

### General Provisions.

4.40.1

Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part 4.

4.40.2

The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part 4, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

4.40.3

The licensee or registrant shall be consistent in their use of SI or special units. The licensee or registrant shall not change the units used on records required by Part 4 except at the beginning of the calendar year or with Department approval.

RH 4.41

### Records of Radiation Protection Programs.

4.41.1

Each licensee or registrant shall maintain records of the radiation protection program, including:

4.41.1.1

The provisions of the program; and

4.41.1.2

Audits and other reviews of program content and implementation.

4.41.2

The licensee or registrant shall retain the records required by RH 4.41.1.1 until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by RH 4.41.1.2 for 3 years after the record is made.

RH 4.42

### Records of Surveys.

4.42.1

Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH 4.17 and 4.32.2. The licensee or registrant shall retain these records for 3 years after the record is made.

- 4.42.2 The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:
- 4.42.2.1 Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and
- 4.42.2.2 Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
- 4.42.2.3 Records showing the results of air sampling, surveys, and bioassays required pursuant to RH 4.24.1.3.1 and 4.24.1.3.2; and
- 4.42.2.4 Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.
- 4.42.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.
- RH 4.43 Records of Tests for Leakage or Contamination of Sealed Sources.  
Records of tests for leakage or contamination of sealed sources required by RH 4.16 shall be kept in units of becquerel or microcurie and maintained for inspection by the Department for 5 years after the records are made.
- RH 4.44 Records of Prior Occupational Dose.
- 4.44.1 The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in RH 4.10 on Department Form OR-RH-16 or equivalent until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Department Form OR-RH-16 or equivalent for 3 years after the record is made.
- 4.44.2 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.
- RH 4.45 Records of Planned Special Exposures.
- 4.45.1 For each use of the provisions of RH 4.11 for planned special exposures, the licensee or registrant shall maintain records that describe:
- 4.45.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

- 4.45.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- 4.45.1.3 What actions were necessary; and
- 4.45.1.4 Why the actions were necessary; and
- 4.45.1.5 What precautions were taken to assure that doses were maintained ALARA; and
- 4.45.1.6 What individual and collective doses were expected to result; and
- 4.45.1.7 The doses actually received in the planned special exposure.
- 4.45.2 The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.
- 4.45.3 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.
- RH 4.46 Records of Individual Monitoring Results.
- 4.46.1 Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH 4.18, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:
- 4.46.1.1 The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- 4.46.1.2 The estimated intake of radionuclides, when required by RH 4.7; and
- 4.46.1.3 The committed effective dose equivalent assigned to the intake of radionuclides; and
- 4.46.1.4 The specific information used to calculate the committed effective dose equivalent pursuant to RH 4.9.3; and
- 4.46.1.5 The total effective dose equivalent when required by RH 4.7; and
- 4.46.1.6 The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
- 4.46.2 Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in RH 4.46.1 at intervals not to exceed 1 year.

- 4.46.3 Recordkeeping Format. The licensee or registrant shall maintain the records specified in RH 4.46.1 on Department Form OR-RH-17, Occupational Exposure Record for a Monitoring Period, in accordance with the instructions for Department Form OR-RH-17, or in clear and legible records containing all the information required by Department Form OR-RH-17.
- 4.46.4 The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.
- 4.46.5 The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.
- 4.46.6 Upon termination of the license or registration, the licensee or registrant shall permanently store records on Department Form OR-RH-16 or equivalent, or shall make provision with the Department for transfer to the Department.
- RH 4.47 Records of Dose to Individual Members of the Public.
- 4.47.1 Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See RH 4.14.
- 4.47.2 The licensee or registrant shall retain the records required by RH 4.47.1 until the Department terminates each pertinent license or registration requiring the record.
- RH 4.48 Records of Waste Disposal.
- 4.48.1 Each licensee or registrant shall maintain records of the disposal of licensed or registered materials made pursuant to RH 4.34, 4.35, 4.36, 4.37, Part 14 of these regulations, and disposal by burial in soil, including burials authorized before December 30, 1985.
- 4.48.2 The licensee or registrant shall retain the records required by RH 4.48.1 in accordance with RH 3.15.4 until the Department terminates each pertinent license or registration requiring the record.
- RH 4.49 Records of Testing Entry Control Devices for Very High Radiation Areas.
- 4.49.1 Each licensee or registrant shall maintain records of tests made pursuant to RH 4.21.2.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.



4.49.2 The licensee or registrant shall retain the records required by RH 4.49.1 for 3 years after the record is made.

RH 4.50 Form of Records. Each record required by Part 4 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in Department-approved electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

#### REPORTS

RH 4.51 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

4.51.1 Telephone Reports. Each licensee or registrant shall report to the Department by telephone as follows:

4.51.1.1 Immediately after its occurrence becomes known to the licensee or registrant, stolen, lost, or missing licensed or registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee or registrant that an exposure could result to individuals in unrestricted areas; or

4.51.1.2 Within 30 days after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.

4.51.1.3 Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

4.51.2 Written Reports. Each licensee or registrant required to make a report pursuant to RH 4.51.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

4.51.2.1 A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

4.51.2.2 A description of the circumstances under which the loss or theft occurred; and



- 4.51.2.3 A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and
- 4.51.2.4 Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
- 4.51.2.5 Actions that have been taken, or will be taken, to recover the source of radiation; and
- 4.51.2.6 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.
- 4.51.3 Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.
- 4.51.4 The licensee or registrant shall prepare any report filed with the Department pursuant to RH 4.51 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.
- RH 4.52 Notification of Incidents.
- 4.52.1 Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event:
  - 4.52.1.1 Involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:
    - 4.52.1.1.1 An individual to receive:
      - 4.52.1.1.1.1 A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
      - 4.52.1.1.1.2 An eye dose equivalent of 0.75 Sv (75 rem) or more; or
      - 4.52.1.1.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or
    - 4.52.1.1.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
  - 4.52.1.2 That prevents immediate protective actions necessary to avoid exposures to radiation and/or radioactive materials that could exceed regulatory limits, or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).
- 4.52.2 Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department:
  - 4.52.2.1 Each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

- 4.52.2.1.1 An individual to receive, in a period of 24 hours:
- 4.52.2.1.1.1 A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
- 4.52.2.1.1.2 An eye dose equivalent exceeding 0.15 Sv (15 rem); or
- 4.52.2.1.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
- 4.52.2.1.2 The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- 4.52.2.2 An unplanned contamination event that:
  - 4.52.2.2.1 Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
  - 4.52.2.2.2 Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Part 4 for the material; and
  - 4.52.2.2.3 Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
- 4.52.2.3 An event in which equipment is disabled or fails to function as designed when:
  - 4.52.2.3.1 The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and/or radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; and
  - 4.52.2.3.2 The equipment is required to be available and operable when it is disabled or fails to function during the event; and
  - 4.52.2.3.3 No redundant equipment is available and operable to perform the required safety function.
- 4.52.2.4 An event that requires unplanned medical treatment at a medical facility of an individual who's body or clothing is contaminated with spreadable radioactive material.
- 4.52.2.5 An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
  - 4.52.2.5.1 The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part 4 for the material; and
  - 4.52.2.5.2 The damage affects the integrity of the licensed material or its container.
- RH 4.53 Preparation and Submission of Reports.
- 4.53.1 Reports made by licensees or registrants in response to the requirements of RH 4.52, must be made as follows:

- 4.53.1.1 Licensees or registrants shall make the reports required by RH 4.52.1 and 4.52.2 to the Department by telephone, and by telegram, mailgram, or facsimile. To the extent that the information is available at the time of notification, the information provided in these reports must included:
- 4.53.1.1.1 The caller's name and call back telephone number;
  - 4.53.1.1.2 A description of the event including date and time;
  - 4.53.1.1.3 The exact location of the event;
  - 4.53.1.1.4 The isotopes, quantities, and chemical and physical form of the licensed material involved; and
  - 4.53.1.1.5 Any personnel radiation exposure data available.
- 4.53.1.2 Each licensee or registrant who makes a report required by RH 4.52.1 or 4.52.2 shall submit a written follow-up report to the Department pursuant to RH 4.53.3 within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made.
- 4.53.1.3 The provisions of RH 4.52 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to RH 4.54.
- 4.53.2 Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits. In addition to the notification required by RH 4.52, each licensee or registrant shall submit a written report to the Department within 30 days after learning of any of the following occurrences:
- 4.53.2.1 Incidents for which notification is required by RH 4.52; or
  - 4.53.2.2 Doses in excess of any of the following:
    - 4.53.2.2.1 The occupational dose limits for adults in RH 4.6; or
    - 4.53.2.2.2 The occupational dose limits for a minor in RH 4.12; or
    - 4.53.2.2.3 The limits for an embryo/fetus of a declared pregnant woman in RH 4.13; or
    - 4.53.2.2.4 The limits for an individual member of the public in RH 4.14; or
    - 4.53.2.2.5 Any applicable limit in the license or registration; or
  - 4.53.2.3 Levels of radiation or concentrations of radioactive material in:
    - 4.53.2.3.1 A restricted area in excess of applicable limits in the license or registration; or
    - 4.53.2.3.2 An unrestricted area in excess of 10 times the applicable limit set forth in Part 4 or in the license or registration, whether or not involving exposure of any individual in excess of the limits in RH 4.14; or

- 4.53.2.4 For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190<sup>6</sup>, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.
- 4.53.3 Contents of Written Reports.
- 4.53.3.1 Each report required by RH 4.53.1.2 or 4.53.2 shall include the following, as appropriate:
- 4.53.3.1.1 A description of the event, including the possible cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- 4.53.3.1.2 The exact location of the event;
- 4.53.3.1.3 The isotopes, quantities, and chemical and physical form of the licensed material involved;
- 4.53.3.1.4 Date and time of the event;
- 4.53.3.1.5 The results of any evaluations or assessments, including:
- 4.53.3.1.5.1 Estimates of each individual's dose;
- 4.53.3.1.5.2 The levels of radiation and concentrations of radioactive material involved;
- 4.53.3.1.5.3 The cause of the elevated exposures, dose rates, or concentrations; and
- 4.53.3.1.5.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license or registration conditions.
- 4.53.3.2 Each report filed pursuant to RH 4.53 shall include for each individual exposed: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in RH 4.13, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.
- RH 4.54 Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with RH 4.11, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RH 4.45.

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<sup>6</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, B-1, Denver, Colorado. These rules do not include later amendments of the referenced material. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80220-1530.

RH 4.55 Reserved.

RH 4.56 Reports of Individual Monitoring.

4.56.1 This section applies to each person licensed or registered by the Department to:

4.56.1.1 Possess or use sources of radiation for purposes of industrial radiography pursuant to Parts 3 and 5 of these regulations; or

4.56.1.2 Receive radioactive waste from other persons for disposal pursuant to Part 14 of these regulations; or

4.56.1.3 Possess or use at any time, for processing or manufacturing or distribution pursuant to Part 3 or 7 of these regulations, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	Activity <sup>a</sup>	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

<sup>a</sup> The Department may require as a license condition, or by rule, regulation, or order pursuant to RH 1.9, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

4.56.2 Each licensee or registrant in a category listed in RH 4.56.1 shall submit an annual report to the Department of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by RH 4.18 during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Department Form OR-RH-17 or equivalent or Department-approved electronic media containing all the information required by Department Form OR-RH-17.

4.56.3 The licensee or registrant shall file the report required by RH 4.56.2, covering the preceding year, on or before April 30 of each year.

RH 4.57 Notifications and Reports to Individuals.

4.57.1 Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in RH 10.4 of these regulations.

4.57.2 When a licensee or registrant is required pursuant to RH 4.53 to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of RH 10.4.1 of these regulations.

RH 4.58 Reports of Leaking or Contaminated Sealed Sources. The licensee or registrant shall file a report within 5 days with the Department if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.



## ADDITIONAL REQUIREMENTS

- RH 4.59      Vacating Premises. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's or registrant's activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.
- RH 4.60      Permissible Levels of Radioactive Material in Uncontrolled Areas.
- 4.60.1      Plutonium. Contamination of the soil in excess of 2.0 disintegrations per minute (0.03 Bq) of plutonium per gram of dry soil or square centimeter of surface area (0.01 microcurie [370 Bq] per square meter) presents a sufficient hazard to the public health to require the utilization of special techniques of construction upon property so contaminated. Evaluation of proposed control techniques shall be available from the Department of Health upon request.



Part 4

APPENDIX A

PROTECTION FACTORS FOR RESPIRATORS<sup>1</sup>

Protection Factors <sup>(4)</sup>					
Tested & Certified Equipment					
Description <sup>(2)</sup>	Modes <sup>(3)</sup>	Particu- lates only	Particu- lates, gases, vapors <sup>(5)</sup>	National Institute for Occupational Safety and Health & Mine Safety and Health Administration tests for permissibility	
I. AIR-PURIFYING RESPIRATORS <sup>(6)</sup>					
Facepiece, half-mask <sup>(7)</sup>	NP	10		30 CFR 11, Subpart K.	
Facepiece, full	NP	50			
Facepiece, half-mask full, or hood	PP	1000			
II. ATMOSPHERE-SUPPLYING RESPIRATORS					
1. Air-line respirator					
Facepiece, half-mask	CF		1000		
Facepiece, half-mask	D		<sup>(5)</sup>		
Facepiece, full	CF		2000		
Facepiece, full	D		<sup>(5)</sup>	30 CFR 11, Subpart J.	
Facepiece, full	PD		2000		
Hood	CF		<sup>(8)</sup>		
Suit	CF		<sup>(9)</sup>	<sup>(10)</sup>	
2. Self-contained breathing apparatus (SCBA)					
Facepiece, full	D		50		
Facepiece, full	PD		10,000 <sup>(11)</sup>	30 CFR 11, Subpart H.	
Facepiece, full	RD		50		
Facepiece, full	RP		5,000 <sup>(12)</sup>		

See next page for footnotes.

### III. COMBINATION RESPIRATORS

Any combination of  
air-purifying and  
atmosphere-supplying  
respirators

Protection factor  
for type and mode  
of operation as  
listed above

30 CFR 11,  
Sec. 11.63(b).

#### FOOTNOTES

1. For use in the selection of respiratory protective equipment to be used only where the contaminants have been identified and the concentrations, or possible concentrations, are known.
2. Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. Hoods and suits are excepted.
3. The mode symbols are defined as follows:  
CF = continuous flow  
D = demand  
NP = negative pressure, that is, negative phase during inhalation  
PD = pressure demand, that is, always positive pressure  
PP = positive pressure  
RD = demand, recirculating or closed circuit  
RP = pressure demand, recirculating or closed circuit
4. a. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment, usually inside the facepiece, under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:  
$$\text{Concentration inhaled} = \frac{\text{Ambient airborne concentration}}{\text{Protection factor}}$$
  
b. The protection factors apply:
  - (i) Only for individuals trained in using respirators and wearing properly fitted respirators that are used and maintained under supervision in a well-planned respiratory protective program.
  - (ii) For air-purifying respirators only when high efficiency particulate filters, above 99.97% removal efficiency by thermally generated 0.3  $\mu\text{m}$  dioctyl phthalate (DOP) test or equivalent, are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.
  - (iii) No adjustment is to be made for the use of sorbents against radioactive material in the form of gases or vapors.
  - (iv) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration certification described in 30 CFR 11. Oxygen and air shall not be used in the same apparatus.

5. Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere--supplying respirators are used to protect against tritium oxide. If the protection factor for respiratory protective equipment is 5, the effective protection factor for tritium is about 1.4; with protection factors of 10, the effective factor for tritium oxide is about 1.7; and with protection factors of 100 or more, the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote 9 concerning supplied-air suits.
6. Canisters and cartridges shall not be used beyond service-life limitations.
7. Under-chin type only. This type of respirator is not satisfactory for use where it might be possible, such as, if an accident or emergency were to occur, for the ambient airborne concentrations to reach instantaneous values greater than 10 times the pertinent values in Table I, Column 3 of Appendix B of Part 4. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.
8. a. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000 may be utilized for tested-and-certified supplied-air hoods when a minimum air flow of 6 cubic feet per minute ( $0.17 \text{ m}^3/\text{min}$ ) is maintained and calibrated air line pressure gauges or flow measuring devices are used. A protection factor of up to 2000 may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than 6 cubic feet per minute ( $0.17 \text{ m}^3/\text{min}$ ) and calibrated air line pressure gauges or flow measuring devices are used.  
b. The design of the supplied-air hood or helmet, with a minimum flow of 6 cubic feet per minute ( $0.17 \text{ m}^3/\text{min}$ ) of air, may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres. See footnote 9.
9. Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used.
10. No approval schedules are currently available for this equipment. Equipment is to be evaluated by testing or on the basis of reliable test information.

11. This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption, must be taken into account in such circumstances.
12. Quantitative fit testing shall be performed on each individual, and no more than 0.02% leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer.

Note 1: Protection factors for respirators approved by the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health, according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radioactive hazards. The selection and use of respirators for such circumstances should take into account applicable approvals of the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health.

Note 2: Radioactive contaminants, for which the concentration values in Table I, Column 3 of Appendix B of Part 4 are based on internal dose due to inhalation, may present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

## Part 4

### APPENDIX B

#### ANNUAL LIMITS ON INTAKE (ALI) AND DERIVED AIR CONCENTRATIONS (DAC) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SANITARY SEWERAGE

##### Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1  $\mu$ m, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

##### Note:

The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of  $6 \times 10^{-2}$  or 0.06, 6E+2 represents  $6 \times 10^2$  or 600, and 6E+0 represents  $6 \times 10^0$  or 6.

##### Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor,  $w_T$ . This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of  $w_T$  are listed under the definition of weighting factor in RH 4.3. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of  $w_T = 0.06$  is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.



Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;  
St. wall = stomach wall;  
Blad wall = bladder wall; and  
Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs ( $ALI_{ns}$ ) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is,  $\sum (intake \text{ (in } \mu\text{Ci) of each radionuclide} / ALI_{ns}) \leq 1.0$ . If there is an external deep dose equivalent contribution of  $H_d$ , then this sum must be less than  $1 - (H_d/50)$ , instead of  $\leq 1.0$ .

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

$$DAC = ALI(\text{in } \mu\text{Ci}) / (2000 \text{ hours per working year} \times 60 \text{ minutes/hour} \times 2 \times 10^4 \text{ ml per minute}) = (ALI/2.4 \times 10^5) \mu\text{Ci/ml},$$

where  $2 \times 10^4$  ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See RH 4.7. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of RH 4.15. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as they were in Appendix A of Part D of the Eighth Edition of Volume I of the *Suggested State Regulations for Control of Radiation*.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by  $2.4 \times 10^5$ , relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by  $7.3 \times 10^7$ . The factor of  $7.3 \times 10^7$  (ml) includes the following components: the factors of 50 and 2 described above and a factor of  $7.3 \times 10^5$  (ml) which is the annual water intake of Reference Man.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

#### Table III "Releases to Sewerage"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in RH 4.35. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by  $7.3 \times 10^6$  (ml). The factor of  $7.3 \times 10^6$  (ml) is composed of a factor of  $7.3 \times 10^5$  (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 0.5 rem.

# LIST OF ELEMENTS

Atomic			Atomic		
Name	Symbol	Number	Name	Symbol	Number
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybdenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Antimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Osmium	Os	76
Barium	Ba	56	Palladium	Pd	46
Berkelium	Bk	97	Phosphorus	P	15
Beryllium	Be	4	Platinum	Pt	78
Bismuth	Bi	83	Plutonium	Pu	94
Bromine	Br	35	Polonium	Po	84
Cadmium	Cd	48	Potassium	K	19
Calcium	Ca	20	Praseodymium	Pr	59
Californium	Cf	98	Promethium	Pm	61
Carbon	C	6	Protactinium	Pa	91
Cerium	Ce	58	Radium	Ra	88
Cesium	Cs	55	Radon	Rn	86
Chlorine	Cl	17	Rhenium	Re	75
Chromium	Cr	24	Rhodium	Rh	45
Cobalt	Co	27	Rubidium	Rb	37
Copper	Cu	29	Ruthenium	Ru	44
Curium	Cm	96	Samarium	Sm	62
Dysprosium	Dy	66	Scandium	Sc	21
Einsteinium	Es	99	Selenium	Se	34
Erbium	Er	68	Silicon	Si	14
Europium	Eu	63	Silver	Ag	47
Fermium	Fm	100	Sodium	Na	11
Fluorine	F	9	Strontium	Sr	38
Francium	Fr	87	Sulfur	S	16
Gadolinium	Gd	64	Tantalum	Ta	73
Gallium	Ga	31	Technetium	Tc	43
Germanium	Ge	32	Tellurium	Te	52
Gold	Au	79	Terbium	Tb	65
Hafnium	Hf	72	Thallium	Tl	81
Holmium	Ho	67	Thorium	Th	90
Hydrogen	H	1	Thulium	Tm	69
Indium	In	49	Tin	Sn	50
Iodine	I	53	Titanium	Ti	22
Iridium	Ir	77	Tungsten	W	74
Iron	Fe	26	Uranium	U	92
Krypton	Kr	36	Vanadium	V	23
Lanthanum	La	57	Xenon	Xe	54
Lead	Pb	82	Ytterbium	Yb	70
Lutetium	Lu	71	Yttrium	Y	39
Magnesium	Mg	12	Zinc	Zn	30
Manganese	Mn	25	Zirconium	Zr	40
Mendelevium	Md	101			

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 <u>Inhalation</u> ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
89 Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	-	-	-
		LLI wall (2E+3)	Bone surf (4E+1)	-	5E+11	3E-5	3E-4
		-	5E+1	2E-8	7E-11	-	-
89 Actinium-225	D, see $^{224}\text{Ac}$	-	5E+1	2E-8	6E-11	-	-
		5E+1	3E-1	1E-10	-	-	-
		LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
89 Actinium-226	D, see $^{224}\text{Ac}$	-	6E-1	3E-10	9E-13	-	-
		-	6E-1	3E-10	9E-13	-	-
		1E+2	3E+0	1E-9	-	-	-
89 Actinium-227	D, see $^{224}\text{Ac}$	LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		-	5E+0	2E-9	7E-12	-	-
		-	5E+0	2E-9	6E-12	-	-
89 Actinium-228	D, see $^{224}\text{Ac}$	2E-1	4E-4	2E-13	-	-	-
		Bone surf (4E-1)	Bone surf (8E-4)	-	1E-15	5E-9	5E-8
		-	2E-3	7E-13	-	-	-
89 Actinium-229	D, see $^{224}\text{Ac}$	-	Bone surf (3E-3)	-	4E-15	-	-
		-	4E-3	2E-12	6E-15	-	-
		2E+3	9E+0	4E-9	-	3E-5	3E-4
89 Actinium-230	D, see $^{224}\text{Ac}$	-	Bone surf (2E+1)	-	2E-11	-	-
		-	4E+1	2E-8	-	-	-
		-	Bone surf (6E+1)	-	8E-11	-	-
13 Aluminum-26	D, all compounds except those given for W	-	4E+1	2E-8	6E-11	-	-
		4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		-	9E+1	4E-8	1E-10	-	-
95 Americium-237 <sup>2</sup>	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95 Americium-238 <sup>2</sup>	W, all compounds	4E+4	3E+3	1E-6	-	5E-4	5E-3
		-	Bone surf (6E+3)	-	9E-9	-	-
95 Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			Inhalation				
			ALI (μCi)	DAC (μCi/ml)			
95 Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95 Americium-241	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95 Americium-242	W, all compounds	4E+3 -	8E+1 Bone surf (9E+1)	4E-8 -	- 1E-10	5E-5 -	5E-4 -
95 Americium-242m	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95 Americium-243	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95 Americium-244	W, all compounds	3E+3 -	2E+2 Bone surf (3E+2)	8E-8 -	- 4E-10	4E-5 -	4E-4 -
95 Americium-244m <sup>2</sup>	W, all compounds	6E+4 St wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 -	- 1E-8	- 1E-3	- 1E-2
95 Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95 Americium-246 <sup>2</sup>	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
95 Americium-246m <sup>2</sup>	W, all compounds	5E+4 St wall (6E+4)	2E+5 -	8E-5 -	3E-7 -	- 8E-4	- 8E-3
51 Antimony-115 <sup>2</sup>	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
	W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51 Antimony-116 <sup>2</sup>	D, see <sup>115</sup> Sb	7E+4 St wall (9E+4)	3E+5 -	1E-4 -	4E-7 -	- 1E-3	- 1E-2
	W, see <sup>115</sup> Sb	-	3E+5	1E-4	5E-7	-	-
51 Antimony-116m <sup>2</sup>	D, see <sup>115</sup> Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
	W, see <sup>115</sup> Sb	-	1E+5	6E-5	2E-7	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu$ Ci)	Col. 2		Col. 1 Air ( $\mu$ Ci/ml)	Col. 2 Water ( $\mu$ Ci/ml)	Monthly Average Concentration ( $\mu$ Ci/ml)
			Inhalation	Col. 3			
51 Antimony-117	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	7E+4 -	2E+5 3E+5	9E-5 1E-4	3E-7 4E-7	9E-4 -	9E-3 -
51 Antimony-118m	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	6E+3 5E+3	2E+4 3E+4	8E-6 9E-6	3E-8 3E-8	7E-5 -	7E-4 -
51 Antimony-119	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	2E+4 2E+4	5E+4 3E+4	2E-5 1E-5	6E-8 4E-8	2E-4 -	2E-3 -
51 Antimony-120 (5.76 d)	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	1E+3 9E+2	2E+3 1E+3	9E-7 5E-7	3E-9 2E-9	1E-5 -	1E-4 -
51 Antimony-120 <sup>2</sup> (16 min)	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	1E+5 St wall (2E+5) -	4E+5 - 5E+5	2E-4 - 2E-4	6E-7 - 7E-7	- 2E-3 -	- 2E-2 -
51 Antimony-122	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	8E+2 LLI wall (8E+2) 7E+2	2E+3 - 1E+3	1E-6 - 4E-7	3E-9 - 2E-9	- 1E-5 -	- 1E-4 -
51 Antimony-124	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	6E+2 5E+2	9E+2 2E+2	4E-7 1E-7	1E-9 3E-10	7E-6 -	7E-5 -
51 Antimony-124m <sup>2</sup>	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	3E+5 2E+5	8E+5 6E+5	4E-4 2E-4	1E-6 8E-7	3E-3 -	3E-2 -
51 Antimony-125	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	2E+3 -	2E+3 5E+2	1E-6 2E-7	3E-9 7E-10	3E-5 -	3E-4 -
51 Antimony-126	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	6E+2 5E+2	1E+3 5E+2	5E-7 2E-7	2E-9 7E-10	7E-6 -	7E-5 -
51 Antimony-126m <sup>2</sup>	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	5E+4 St wall (7E+4) -	2E+5 - 2E+5	8E-5 - 8E-5	3E-7 - 3E-7	- 9E-4 -	- 9E-3 -
51 Antimony-127	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	8E+2 LLI wall (8E+2) 7E+2	2E+3 - 9E+2	9E-7 - 4E-7	3E-9 - 1E-9	- 1E-5 -	- 1E-4 -
51 Antimony-128 (9.01 h)	D, see <sup>115</sup> Sb W, see <sup>115</sup> Sb	1E+3 -	4E+3 3E+3	2E-6 1E-6	6E-9 5E-9	2E-5 -	2E-4 -

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
51 Antimony-128 <sup>2</sup> (10.4 min)	D, see <sup>115</sup> Sb	8E+4 St wall (1E+5)	4E+5	2E-4	5E-7	-	-
	W, see <sup>115</sup> Sb	-	4E+5	2E-4	6E-7	1E-3	1E-2
51 Antimony-129	D, see <sup>115</sup> Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	W, see <sup>115</sup> Sb	-	9E+3	4E-6	1E-8	-	-
51 Antimony-130 <sup>2</sup>	D, see <sup>115</sup> Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
	W, see <sup>115</sup> Sb	-	8E+4	3E-5	1E-7	-	-
51 Antimony-131 <sup>2</sup>	D, see <sup>115</sup> Sb	1E+4 Thyroid (2E+4)	2E+4 Thyroid (4E+4)	1E-5	-	-	-
	W, see <sup>115</sup> Sb	-	2E+4 Thyroid (4E+4)	1E-5	6E-8	2E-4	2E-3
		-	-	-	6E-8	-	-
18 Argon-37	Submersion <sup>1</sup>	-	-	1E+0	6E-3	-	-
18 Argon-39	Submersion <sup>1</sup>	-	-	2E-4	8E-7	-	-
18 Argon-41	Submersion <sup>1</sup>	-	-	3E-6	1E-8	-	-
33 Arsenic-69 <sup>2</sup>	W, all compounds	3E+4 St wall (4E+4)	1E+5	5E-5	2E-7	-	-
		-	-	-	-	6E-4	6E-3
33 Arsenic-70 <sup>2</sup>	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33 Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33 Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33 Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33 Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33 Arsenic-77	W, all compounds	4E+3 LLI wall (5E+3)	5E+3	2E-6	7E-9	-	-
		-	-	-	-	6E-5	6E-4
33 Arsenic-78 <sup>2</sup>	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
85 Astatine-207 <sup>2</sup>	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
	W	-	2E+3	9E-7	3E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			Inhalation				
			ALI (μCi)	DAL (μCi/ml)			
85 Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
	W	-	5E+1	2E-8	8E-11	-	-
56 Barium-126 <sup>2</sup>	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56 Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56 Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56 Barium-131m <sup>2</sup>	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
		St wall (5E+5)	-	-	-	7E-3	7E-2
56 Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56 Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
		LLI wall (3E+3)	-	-	-	4E-5	4E-4
56 Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56 Barium-139 <sup>2</sup>	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56 Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
56 Barium-141 <sup>2</sup>	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56 Barium-142 <sup>2</sup>	D, all compounds	3E+4	1E+5	6E-5	2E-7	7E-4	7E-3
97 Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97 Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97 Berkelium-247	W, all compounds	5E-1	4E-3	2E-12	-	-	-
		Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97 Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
		Bone surf (5E+2)	Bone surf (4E+0)	-	5E-12	6E-6	6E-5
97 Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
		-	Bone surf (7E+2)	-	1E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
4 Beryllium-10	W, see $^7\text{Be}$	1E+3 LLI wall (1E+3)	2E+2	6E-8	2E-10	-	-
	Y, see $^7\text{Be}$	-	1E+1	6E-9	2E-11	2E-5	2E-4
4 Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
	Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
83 Bismuth-200 <sup>2</sup>	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
	W, all other compounds	-	1E+5	4E-5	1E-7	-	-
83 Bismuth-201 <sup>2</sup>	D, see $^{200}\text{Bi}$	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see $^{200}\text{Bi}$	-	4E+4	2E-5	5E-8	-	-
83 Bismuth-202 <sup>2</sup>	D, see $^{200}\text{Bi}$	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see $^{200}\text{Bi}$	-	8E+4	3E-5	1E-7	-	-
83 Bismuth-203	D, see $^{200}\text{Bi}$	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
	W, see $^{200}\text{Bi}$	-	6E+3	3E-6	9E-9	-	-
83 Bismuth-205	D, see $^{200}\text{Bi}$	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
	W, see $^{200}\text{Bi}$	-	1E+3	5E-7	2E-9	-	-
83 Bismuth-206	D, see $^{200}\text{Bi}$	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
	W, see $^{200}\text{Bi}$	-	9E+2	4E-7	1E-9	-	-
83 Bismuth-207	D, see $^{200}\text{Bi}$	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
	W, see $^{200}\text{Bi}$	-	4E+2	1E-7	5E-10	-	-
83 Bismuth-210	D, see $^{200}\text{Bi}$	8E+2	2E+2	1E-7	-	1E-5	1E-4
		-	Kidneys	-	-	-	-
		-	(4E+2)	-	5E-10	-	-
	W, see $^{200}\text{Bi}$	-	3E+1	1E-8	4E-11	-	-
83 Bismuth-210m	D, see $^{200}\text{Bi}$	4E+1	5E+0	2E-9	-	-	-
		Kidneys	Kidneys	-	-	-	-
		(6E+1)	(6E+0)	-	9E-12	8E-7	8E-6
	W, see $^{200}\text{Bi}$	-	7E-1	3E-10	9E-13	-	-
83 Bismuth-212 <sup>2</sup>	D, see $^{200}\text{Bi}$	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
	W, see $^{200}\text{Bi}$	-	3E+2	1E-7	4E-10	-	-
83 Bismuth-213 <sup>2</sup>	D, see $^{200}\text{Bi}$	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
	W, see $^{200}\text{Bi}$	-	4E+2	1E-7	5E-10	-	-



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	DAC (μCi/ml)			
83 Bismuth-214 <sup>2</sup>	D, see <sup>200</sup> Bi	2E+4 St wall (2E+4)	8E+2	3E-7	1E-9	-	-
	W, see <sup>200</sup> Bi	-	9E-2	4E-7	1E-9	3E-4	3E-3
35 Bromine-74 <sup>2</sup>	D, see <sup>74m</sup> Br	2E+4 St wall (4E+4)	7E+4	3E-5	1E-7	-	-
	W, see <sup>74m</sup> Br	-	8E+4	4E-5	1E-7	5E-4	5E-3
35 Bromine-74m <sup>2</sup>	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4 St wall (2E+4)	4E+4	2E-5	5E-8	-	-
	W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Cu, Pt, Au, Ag, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	3E-4	3E-3
35 Bromine-75 <sup>2</sup>	D, see <sup>74m</sup> Br	3E+4 St wall (4E+4)	5E+4	2E-5	7E-8	-	-
	W, see <sup>74m</sup> Br	-	5E+4	2E-5	7E-8	5E-4	5E-3
35 Bromine-76	D, see <sup>74m</sup> Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
	W, see <sup>74m</sup> Br	-	4E+3	2E-6	6E-9	-	-
35 Bromine-77	D, see <sup>74m</sup> Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
	W, see <sup>74m</sup> Br	-	2E+4	8E-6	3E-8	-	-
35 Bromine-80 <sup>2</sup>	D, see <sup>74m</sup> Br	5E+4 St wall (9E+4)	2E+5	8E-5	3E-7	-	-
	W, see <sup>74m</sup> Br	-	2E+5	9E-5	3E-7	1E-3	1E-2
35 Bromine-80m	D, see <sup>74m</sup> Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
	W, see <sup>74m</sup> Br	-	1E+4	6E-6	2E-8	-	-
35 Bromine-82	D, see <sup>74m</sup> Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
	W, see <sup>74m</sup> Br	-	4E+3	2E-6	5E-9	-	-
35 Bromine-83	D, see <sup>74m</sup> Br	5E+4 St wall (7E+4)	6E+4	3E-5	9E-8	-	-
	W, see <sup>74m</sup> Br	-	6E+4	3E-5	9E-8	9E-4	9E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	DAC (μCi/ml)				
35	Bromine-84 <sup>2</sup>	D, see <sup>76m</sup> Br	2E+4 St wall (3E+4)	6E+4	2E-5	8E-8	-	-
	W, see <sup>76m</sup> Br		-	6E+4	3E-5	9E-8	4E-4	4E-3
48	Cadmium-104 <sup>2</sup>	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
	W, sulfides, halides, and nitrates		-	1E+5	5E-5	2E-7	-	-
	Y, oxides and hydroxides		-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see <sup>104</sup> Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
	W, see <sup>104</sup> Cd		-	6E+4	2E-5	8E-8	-	-
	Y, see <sup>104</sup> Cd		-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see <sup>104</sup> Cd	3E+2 Kidneys (4E+2)	4E+1 Kidneys (5E+1)	1E-8	-	-	-
	W, see <sup>104</sup> Cd		-	1E+2 Kidneys (1E+2)	5E-8	7E-11	6E-6	6E-5
	Y, see <sup>104</sup> Cd		-	1E+2	5E-8	2E-10	-	-
48	Cadmium-113	D, see <sup>104</sup> Cd	2E+1 Kidneys (3E+1)	2E+0 Kidneys (3E+0)	9E-10	-	-	-
	W, see <sup>104</sup> Cd		-	8E+0 Kidneys (1E+1)	3E-9	5E-12	4E-7	4E-6
	Y, see <sup>104</sup> Cd		-	1E+1	6E-9	2E-11	-	-
48	Cadmium-113m	D, see <sup>104</sup> Cd	2E+1 Kidneys (4E+1)	2E+0 Kidneys (4E+0)	1E-9	-	-	-
	W, see <sup>104</sup> Cd		-	8E+0 Kidneys (1E+1)	4E-9	5E-12	5E-7	5E-6
	Y, see <sup>104</sup> Cd		-	1E+1	5E-9	2E-11	-	-
48	Cadmium-115	D, see <sup>104</sup> Cd	9E+2 LLI wall (1E+3)	1E+3	6E-7	2E-9	-	-
	W, see <sup>104</sup> Cd		-	1E+3	5E-7	-	1E-5	1E-4
	Y, see <sup>104</sup> Cd		-	1E+3	6E-7	2E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion: ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			Inhalation				
			ALI (μCi)	DAC (μCi/ml)			
48 Cadmium-115m	D, see <sup>104</sup> Cd	3E+2	5E+1 Kidneys (8E+1)	2E-8	-	4E-6	4E-5
	W, see <sup>104</sup> Cd	-	1E+2	5E-8	1E-10	-	-
	Y, see <sup>104</sup> Cd	-	1E+2	6E-8	2E-10	-	-
48 Cadmium-117	D, see <sup>104</sup> Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	W, see <sup>104</sup> Cd	-	2E+4	7E-6	2E-8	-	-
	Y, see <sup>104</sup> Cd	-	1E+4	6E-6	2E-8	-	-
48 Cadmium-117m	D, see <sup>104</sup> Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
	W, see <sup>104</sup> Cd	-	2E+4	7E-6	2E-8	-	-
	Y, see <sup>104</sup> Cd	-	1E+4	6E-6	2E-8	-	-
20 Calcium-41	W, all compounds	3E+3 Bone surf (4E+3)	4E+3 Bone surf (4E+3)	2E-6	-	-	-
					5E-9	6E-5	6E-4
20 Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20 Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
98 Californium-244 <sup>2</sup>	W, all compounds except those given for Y	3E+4 St wall (3E+4)	6E+2	2E-7	8E-10	-	-
	Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	4E-4	4E-3
98 Californium-246	W, see <sup>244</sup> Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
	Y, see <sup>244</sup> Cf	-	9E+0	4E-9	1E-11	-	-
98 Californium-248	W, see <sup>244</sup> Cf	8E+0 Bone surf (2E+1)	6E-2 Bone surf (1E-1)	3E-11	-	-	-
	Y, see <sup>244</sup> Cf	-	1E-1	4E-11	2E-13 1E-13	2E-7	2E-6
98 Californium-249	W, see <sup>244</sup> Cf	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12	-	-	-
	Y, see <sup>244</sup> Cf	-	1E-2	4E-12	1E-14	2E-8	2E-7
		-	Bone surf (1E-2)	-	2E-14	-	-
98 Californium-250	W, see <sup>244</sup> Cf	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12	-	-	-
	Y, see <sup>244</sup> Cf	-	3E-2	1E-11	3E-14 4E-14	3E-8	3E-7

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
98 Californium-251	W, see $^{241}\text{Cf}$	5E-1	4E-3	2E-12	-	-	-
		Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
	Y, see $^{241}\text{Cf}$	-	1E-2	4E-12	-	-	-
		-	Bone surf (1E-2)	-	2E-14	-	-
98 Californium-252	W, see $^{244}\text{Cf}$	2E+0	2E-2	8E-12	-	-	-
		Bone surf (5E+0)	Bone surf (4E-2)	-	5E-14	7E-8	7E-7
	Y, see $^{244}\text{Cf}$	-	3E-2	1E-11	5E-14	-	-
98 Californium-253	W, see $^{244}\text{Cf}$	2E+2	2E+0	8E-10	3E-12	-	-
		Bone surf (4E+2)	-	-	-	5E-6	5E-5
	Y, see $^{244}\text{Cf}$	-	2E+0	7E-10	2E-12	-	-
98 Californium-254	W, see $^{244}\text{Cf}$	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
	Y, see $^{244}\text{Cf}$	-	2E-2	7E-12	2E-14	-	-
6 Carbon-11 <sup>2</sup>	Monoxide	-	1E+6	5E-4	2E-6	-	-
	Dioxide	-	6E+5	3E-4	9E-7	-	-
	Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6 Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
	Dioxide	-	2E+5	9E-5	3E-7	-	-
	Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
58 Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58 Cerium-135	W, see $^{134}\text{Ce}$	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	Y, see $^{134}\text{Ce}$	-	4E+3	1E-6	5E-9	-	-
58 Cerium-137	W, see $^{134}\text{Ce}$	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
	Y, see $^{134}\text{Ce}$	-	1E+5	5E-5	2E-7	-	-
58 Cerium-137m	W, see $^{134}\text{Ce}$	2E+3	4E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	3E-5	3E-4
	Y, see $^{134}\text{Ce}$	-	4E+3	2E-6	5E-9	-	-
58 Cerium-139	W, see $^{134}\text{Ce}$	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
	Y, see $^{134}\text{Ce}$	-	7E+2	3E-7	9E-10	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
			Inhalation				
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
58 Cerium-141	W, see $^{134}\text{Ce}$	2E+3 LLI wall (2E+3)	7E+2	3E-7	1E-9	-	-
	Y, see $^{134}\text{Ce}$	-	6E+2	2E-7	8E-10	3E-5	3E-4
58 Cerium-143 LLI wall	W, see $^{134}\text{Ce}$	1E+3 (1E+3)	2E+3	8E-7	3E-9	-	-
	Y, see $^{134}\text{Ce}$	-	2E+3	7E-7	2E-9	2E-5	2E-4
58 Cerium-144	W, see $^{134}\text{Ce}$	2E+2 LLI wall (3E+2)	3E+1	1E-8	4E-11	-	-
	Y, see $^{134}\text{Ce}$	-	1E+1	6E-9	2E-11	3E-6	3E-5
55 Cesium-125 <sup>2</sup>	D, all compounds	5E+4 St wall (9E+4)	1E+5	6E-5	2E-7	-	-
		-	-	-	-	1E-3	1E-2
55 Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55 Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55 Cesium-130 <sup>2</sup>	D, all compounds	6E+4 St wall (1E+5)	2E+5	8E-5	3E-7	-	-
		-	-	-	-	1E-3	1E-2
55 Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55 Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55 Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55 Cesium-134m	D, all compounds	1E+5 St wall (1E+5)	1E+5	6E-5	2E-7	-	-
		-	-	-	-	2E-3	2E-2
55 Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55 Cesium-135m <sup>2</sup>	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55 Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55 Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55 Cesium-138 <sup>2</sup>	D, all compounds	2E+4 St wall (3E+4)	6E+4	2E-5	8E-8	-	-
		-	-	-	-	4E-4	4E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
			Inhalation				
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
17 Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
17 Chlorine-38 <sup>2</sup>	D, see <sup>36</sup> Cl	2E+4 St wall (3E+4)	4E+4	2E-5	6E-8	-	-
	W, see <sup>36</sup> Cl	-	5E+4	2E-5	6E-8	3E-4	3E-3
17 Chlorine-39 <sup>2</sup>	D, see <sup>36</sup> Cl	2E+4 St wall (4E+4)	5E+4	2E-5	7E-8	-	-
	W, see <sup>36</sup> Cl	-	6E+4	2E-5	8E-8	5E-4	5E-3
24 Chromium-48	D, all compounds except those given for W and Y W, halides and nitrates Y, oxides and hydroxides	6E+3	1E+4 7E+3 7E+3	5E-6 3E-6 3E-6	2E-8 1E-8 1E-8	8E-5	8E-4
24 Chromium-49 <sup>2</sup>	D, see <sup>48</sup> Cr W, see <sup>48</sup> Cr Y, see <sup>48</sup> Cr	3E+4	8E+4 1E+5 9E+4	4E-5 4E-5 4E-5	1E-7 1E-7 1E-7	4E-4	4E-3
24 Chromium-51	D, see <sup>48</sup> Cr W, see <sup>48</sup> Cr Y, see <sup>48</sup> Cr	4E+4	5E+4 2E+4 2E+4	2E-5 1E-5 8E-6	6E-8 3E-8 3E-8	5E-4	5E-3
27 Cobalt-55	W, all compounds except those given for Y Y, oxides, hydroxides, halides, and nitrates	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
27 Cobalt-56	W, see <sup>56</sup> Co Y, see <sup>56</sup> Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
27 Cobalt-57	W, see <sup>56</sup> Co Y, see <sup>56</sup> Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
27 Cobalt-58	W, see <sup>56</sup> Co Y, see <sup>56</sup> Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
			Inhalation				
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
27 Cobalt-58m	W, see $^{55}\text{Co}$ Y, see $^{55}\text{Co}$	6E+4 -	9E+4 6E+4	4E-5 3E-5	1E-7 9E-8	8E-4 -	8E-3 -
27 Cobalt-60	W, see $^{55}\text{Co}$ Y, see $^{55}\text{Co}$	5E+2 2E+2	2E+2 3E+1	7E-8 1E-8	2E-10 5E-11	3E-6 -	3E-5 -
27 Cobalt-60m <sup>2</sup>	W, see $^{55}\text{Co}$  Y, see $^{55}\text{Co}$	1E+6 St wall (1E+6) -	4E+6 - 3E+6	2E-3 - 1E-3	6E-6 - 4E-6	- 2E-2 -	- 2E-1 -
27 Cobalt-61 <sup>2</sup>	W, see $^{55}\text{Co}$ Y, see $^{55}\text{Co}$	2E+4 2E+4	6E+4 6E+4	3E-5 2E-5	9E-8 8E-8	3E-4 -	3E-3 -
27 Cobalt-62m <sup>2</sup>	W, see $^{55}\text{Co}$  Y, see $^{55}\text{Co}$	4E+4 St wall (5E+4) -	2E+5 - 2E+5	7E-5 - 6E-5	2E-7 - 2E-7	- 7E-4 -	- 7E-3 -
29 Copper-60 <sup>2</sup>	D, all compounds except those given for W and Y  W, sulfides, halides, and nitrates Y, oxides and hydroxides	3E+4 St wall (3E+4) - - -	9E+4 - - 1E+5 1E+5	4E-5 - - 5E-5 4E-5	1E-7 - - 2E-7 1E-7	- 4E-4 - - -	- 4E-3 - - -
29 Copper-61	D, see $^{60}\text{Cu}$ W, see $^{60}\text{Cu}$ Y, see $^{60}\text{Cu}$	1E+4 - -	3E+4 4E+4 4E+4	1E-5 2E-5 1E-5	4E-8 6E-8 5E-8	2E-4 - -	2E-3 - -
29 Copper-64	D, see $^{60}\text{Cu}$ W, see $^{60}\text{Cu}$ Y, see $^{60}\text{Cu}$	1E+4 - -	3E+4 2E+4 2E+4	1E-5 1E-5 9E-6	4E-8 3E-8 3E-8	2E-4 - -	2E-3 - -
29 Copper-67	D, see $^{60}\text{Cu}$ W, see $^{60}\text{Cu}$ Y, see $^{60}\text{Cu}$	5E+3 - -	8E+3 5E+3 5E+3	3E-6 2E-6 2E-6	1E-8 7E-9 6E-9	6E-5 - -	6E-4 - -
96 Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96 Curium-240	W, all compounds	6E+1 Bone surf (8E+1)	6E-1 Bone surf (6E-1)	2E-10 - -	- 9E-13	- 1E-6	- 1E-5
96 Curium-241	W, all compounds	1E+3 -	3E+1 Bone surf (4E+1)	1E-8 - -	- 5E-11	2E-5 -	2E-4 -

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	DAC (μCi/ml)			
96 Curium-242	W, all compounds	3E+1 Bone surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 -	- 4E-13	- 7E-7	- 7E-6
96 Curium-243	W, all compounds	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 -	- 2E-14	- 3E-8	- 3E-7
96 Curium-244	W, all compounds	1E+0 Bone surf (3E+0)	1E-2 Bone surf (2E-2)	5E-12 -	- 3E-14	- 3E-8	- 3E-7
96 Curium-245	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96 Curium-246	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96 Curium-247	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
96 Curium-248	W, all compounds	2E-1 Bone surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 -	- 4E-15	- 5E-9	- 5E-8
96 Curium-249 <sup>2</sup>	W, all compounds	5E+4 -	2E+4 Bone surf (3E+4)	7E-6 -	- 4E-8	7E-4 -	7E-3 -
96 Curium-250	W, all compounds	4E-2 Bone surf (6E-2)	3E-4 Bone surf (5E-4)	1E-13 -	- 8E-16	- 9E-10	- 9E-9
66 Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66 Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66 Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66 Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66 Dysprosium-166	W, all compounds	6E+2 LLI wall (8E+2)	7E+2 -	3E-7 -	1E-9 -	- 1E-5	- 1E-4

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases to Sewers
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			Inhalation				
			ALI (μCi)	DAC (μCi/ml)			
99 Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	-	6E-4	6E-3
		-	Bone surf (1E+3)	-	2E-9	-	-
99 Einsteinium-251	W, all compounds	7E+3	9E+2	4E-7	-	1E-4	1E-3
		-	Bone surf (1E+3)	-	2E-9	-	-
99 Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99 Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
		Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
99 Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
		LLI wall (3E+2)	-	-	-	4E-6	4E-5
68 Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68 Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68 Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
		LLI wall (4E+3)	-	-	-	5E-5	5E-4
68 Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68 Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
		LLI wall (E+3)	-	-	-	2E-5	2E-4
63 Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63 Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63 Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63 Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63 Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63 Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63 Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	DAC (μCi/ml)				
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158 <sup>2</sup>	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
		Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7		5E-6
9	Fluorine-18 <sup>2</sup>	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
		St wall (5E+4)	-	-	-	7E-4		7E-3
	W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-		-
	Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-		-
87	Francium-222 <sup>2</sup>	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223 <sup>2</sup>	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
64	Gadolinium-145 <sup>2</sup>	D, all compounds except those given for W	5E+4 St wall (5E+4)	2E+5	6E-5	2E-7	-	-
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	6E-4	6E-3
64	Gadolinium-146	D, see <sup>145</sup> Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see <sup>145</sup> Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see <sup>145</sup> Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see <sup>145</sup> Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see <sup>145</sup> Gd	1E+1 Bone surf (2E+1)	8E+3 Bone surf (2E+2)	3E-12	-	-	-
		W, see <sup>145</sup> Gd	-	3E-2	1E-11	2E-14	3E-7	3E-6
			-	Bone surf (6E-2)	-	8E-14	-	-
64	Gadolinium-149	D, see <sup>145</sup> Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see <sup>145</sup> Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see <sup>145</sup> Gd	6E+3	4E+2	2E-7	-	9E-5	9E-4
			-	Bone surf (6E+2)	-	9E-10	-	-
		W, see <sup>145</sup> Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see <sup>145</sup> Gd	2E+1 Bone surf (3E+1)	1E-2 Bone surf (2E-2)	4E-12	-	-	-
		W, see <sup>145</sup> Gd	-	4E-2	2E-11	3E-14	4E-7	4E-6
			-	Bone surf (8E-2)	-	1E-13	-	-
64	Gadolinium-153	D, see <sup>145</sup> Gd	5E+3	1E+2	6E-8	-	6E-5	6E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
		W, see <sup>145</sup> Gd	-	6E+2	2E-7	8E-10	-	-
64	Gadolinium-159	D, see <sup>145</sup> Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see <sup>145</sup> Gd	-	6E+3	2E-6	8E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2   Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3   DAC ( $\mu\text{Ci/ml}$ )	Col. 1   Air ( $\mu\text{Ci/ml}$ )	Col. 2   Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
31	Gallium-65 <sup>1</sup>	D, all compounds except those given for W	5E+4 St wall (6E+4)	2E+5	7E-5	2E-7	-	-
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	9E-4	9E-3
31	Gallium-66	D, see <sup>66</sup> Ga W, see <sup>66</sup> Ga	1E+3 -	4E+3 3E+3	1E-6 1E-6	5E-9 4E-9	1E-5 -	1E-4 -
31	Gallium-67	D, see <sup>66</sup> Ga W, see <sup>66</sup> Ga	7E+3 -	1E+4 1E+4	6E-6 4E-6	2E-8 1E-8	1E-4 -	1E-3 -
31	Gallium-68 <sup>2</sup>	D, see <sup>66</sup> Ga W, see <sup>66</sup> Ga	2E+4 -	4E+4 5E+4	2E-5 2E-5	6E-8 7E-8	2E-4 -	2E-3 -
31	Gallium-70 <sup>2</sup>	D, see <sup>66</sup> Ga  W, see <sup>66</sup> Ga	5E+4 St wall (7E+4) -	2E+5 - 2E+5	7E-5 - 8E-5	2E-7 - 3E-7	- 1E-3 -	- 1E-2 -
31	Gallium-72	D, see <sup>66</sup> Ga W, see <sup>66</sup> Ga	1E+3 -	4E+3 3E+3	1E-6 1E-6	5E-9 4E-9	2E-5 -	2E-4 -
31	Gallium-73	D, see <sup>66</sup> Ga W, see <sup>66</sup> Ga	5E+3 -	2E+4 2E+4	6E-6 6E-6	2E-8 2E-8	7E-5 -	7E-4 -
32	Germanium-66	D, all compounds except those given for W W, oxides, sulfides, and halides	2E+4 -	3E+4 2E+4	1E-5 8E-6	4E-8 3E-8	3E-4 -	3E-3 -
32	Germanium-67 <sup>2</sup>	D, see <sup>66</sup> Ge  W, see <sup>66</sup> Ge	3E+4 St wall (4E+4) -	9E+4 - 1E+5	4E-5 - 4E-5	1E-7 - 1E-7	- 6E-4 -	- 6E-3 -
32	Germanium-68	D, see <sup>66</sup> Ge W, see <sup>66</sup> Ge	5E+3 -	4E+3 1E+2	2E-6 4E-8	5E-9 1E-10	6E-5 -	6E-4 -
32	Germanium-69	D, see <sup>66</sup> Ge W, see <sup>66</sup> Ge	1E+4 -	2E+4 8E+3	6E-6 3E-6	2E-8 1E-8	2E-4 -	2E-3 -
32	Germanium-71	D, see <sup>66</sup> Ge W, see <sup>66</sup> Ge	5E+5 -	4E+5 4E+4	2E-4 2E-5	6E-7 6E-8	7E-3 -	7E-2 -



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table I Releases Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
32 Germanium-75 <sup>2</sup>	D, see <sup>66</sup> Ge	4E+4 St wall (7E+4)	8E+4	3E-5	1E-7	-	-
	W, see <sup>66</sup> Ge	-	8E+4	4E-5	1E-7	9E-4	9E-3
32 Germanium-77	D, see <sup>66</sup> Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
	W, see <sup>66</sup> Ge	-	6E+3	2E-6	8E-9	-	-
32 Germanium-78 <sup>2</sup>	D, see <sup>66</sup> Ge	2E+4 St wall (2E+4)	2E+4	9E-6	3E-8	-	-
	W, see <sup>66</sup> Ge	-	2E+4	9E-6	3E-8	3E-4	3E-3
79 Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
	Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79 Gold-194	D, see <sup>193</sup> Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
	W, see <sup>193</sup> Au	-	5E+3	2E-6	8E-9	-	-
	Y, see <sup>193</sup> Au	-	5E+3	2E-6	7E-9	-	-
79 Gold-195	D, see <sup>193</sup> Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see <sup>193</sup> Au	-	1E+3	6E-7	2E-9	-	-
	Y, see <sup>193</sup> Au	-	4E+2	2E-7	6E-10	-	-
79 Gold-198	D, see <sup>193</sup> Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see <sup>193</sup> Au	-	2E+3	8E-7	3E-9	-	-
	Y, see <sup>193</sup> Au	-	2E+3	7E-7	2E-9	-	-
79 Gold-198m	D, see <sup>193</sup> Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	W, see <sup>193</sup> Au	-	1E+3	5E-7	2E-9	-	-
	Y, see <sup>193</sup> Au	-	1E+3	5E-7	2E-9	-	-
79 Gold-199	D, see <sup>193</sup> Au	3E+3 LLI wall (3E+3)	9E+3	4E-6	1E-8	-	-
	W, see <sup>193</sup> Au	-	4E+3	2E-6	6E-9	4E-5	4E-4
	Y, see <sup>193</sup> Au	-	4E+3	2E-6	5E-9	-	-
79 Gold-200 <sup>2</sup>	D, see <sup>193</sup> Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
	W, see <sup>193</sup> Au	-	8E+4	3E-5	1E-7	-	-
	Y, see <sup>193</sup> Au	-	7E+4	3E-5	1E-7	-	-
79 Gold-200m	D, see <sup>193</sup> Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see <sup>193</sup> Au	-	3E+3	1E-6	4E-9	-	-
	Y, see <sup>193</sup> Au	-	2E+4	1E-6	3E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
79 Gold-201 <sup>2</sup>	D, see <sup>193</sup> Au	7E+4 St wall (9E+4)	2E+5	9E-5	3E-7	-	-
	W, see <sup>193</sup> Au	-	2E+5	1E-4	3E-7	1E-3	1E-2
	Y, see <sup>193</sup> Au	-	2E+5	9E-5	3E-7	-	-
72 Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
	W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72 Hafnium-172	D, see <sup>176</sup> Hf	1E+3	9E+0 Bone surf (2E+1)	4E-9	-	2E-5	2E-4
	W, see <sup>176</sup> Hf	-	4E+1 Bone surf (6E+1)	2E-8	3E-11	-	-
		-	-	-	8E-11	-	-
72 Hafnium-173	D, see <sup>176</sup> Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see <sup>176</sup> Hf	-	1E+4	5E-6	2E-8	-	-
72 Hafnium-175	D, see <sup>176</sup> Hf	3E+3	9E+2 Bone surf (1E+3)	4E-7	-	4E-5	4E-4
	W, see <sup>176</sup> Hf	-	1E+3	5E-7	1E-9	-	-
		-	-	-	2E-9	-	-
72 Hafnium-177m <sup>2</sup>	D, see <sup>176</sup> Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
	W, see <sup>176</sup> Hf	-	9E+4	4E-5	1E-7	-	-
72 Hafnium-178m	D, see <sup>176</sup> Hf	3E+2	1E+0 Bone surf (2E+0)	5E-10	-	3E-6	3E-5
	W, see <sup>176</sup> Hf	-	5E+0 Bone surf (9E+0)	2E-9	3E-12	-	-
		-	-	-	1E-11	-	-
72 Hafnium-179m	D, see <sup>176</sup> Hf	1E+3	3E+2 Bone surf (6E+2)	1E-7	-	1E-5	1E-4
	W, see <sup>176</sup> Hf	-	6E+2	3E-7	8E-10	-	-
		-	-	-	8E-10	-	-
72 Hafnium-180m	D, see <sup>176</sup> Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
	W, see <sup>176</sup> Hf	-	3E+4	1E-5	4E-8	-	-
72 Hafnium-181	D, see <sup>176</sup> Hf	1E+3	2E+2 Bone surf (4E+2)	7E-8	-	2E-5	2E-4
	W, see <sup>176</sup> Hf	-	4E+2	2E-7	6E-10	-	-
		-	-	-	6E-10	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )	Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
72 Hafnium-182	D, see $^{176}\text{Hf}$	2E+2 Bone surf (4E+2)	8E-1 Bone surf (2E+0)	3E-10	-	-	-
	W, see $^{176}\text{Hf}$	-	3E+0 Bone surf (7E+0)	1E-9	2E-12	5E-6	5E-5
		-	-	-	1E-11	-	-
72 Hafnium-182 <sup>m2</sup>	D, see $^{176}\text{Hf}$	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
	W, see $^{176}\text{Hf}$	-	1E+5	6E-5	2E-7	-	-
72 Hafnium-183 <sup>2</sup>	D, see $^{176}\text{Hf}$	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
	W, see $^{176}\text{Hf}$	-	6E+4	2E-5	8E-8	-	-
72 Hafnium-184	D, see $^{176}\text{Hf}$	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	W, see $^{176}\text{Hf}$	-	6E+3	3E-6	9E-9	-	-
67 Holmium-155 <sup>2</sup>	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67 Holmium-157 <sup>2</sup>	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67 Holmium-159 <sup>2</sup>	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67 Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67 Holmium-162 <sup>2</sup>	W, all compounds	5E+5 St wall (8E+5)	2E+6	1E-3	3E-6	-	-
		-	-	-	-	1E-2	1E-1
67 Holmium-162 <sup>m2</sup>	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67 Holmium-164 <sup>2</sup>	W, all compounds	2E+5 St wall (2E+5)	6E+5	3E-4	9E-7	-	-
		-	-	-	-	3E-3	3E-2
67 Holmium-164 <sup>m2</sup>	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67 Holmium-166	W, all compounds	9E+2 LLI wall (9E+2)	2E+3	7E-7	2E-9	-	-
		-	-	-	-	1E-5	1E-4
67 Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
67 Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
1 Hydrogen-3	Water, DAC includes skin absorption Gas (HT or T <sub>2</sub> ) Submersion <sup>1</sup> : Use above values as HT and T <sub>2</sub> oxidize in air and in the body to HTO.	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
49 Indium-109	D, all compounds except those given for W, oxides, hydroxides, halides, and nitrates	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		-	6E+4	3E-5	9E-8	-	-
49 Indium-110 (4.9 h)	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	5E+3 -	2E+4 2E+4	7E-6 8E-6	2E-8 3E-8	7E-5 -	7E-4 -
49 Indium-110 <sup>2</sup> (69.1 min)	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	2E+4 -	4E+4 6E+4	2E-5 2E-5	6E-8 8E-8	2E-4 -	2E-3 -
49 Indium-111	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	4E+3 -	6E+3 6E+3	3E-6 3E-6	9E-9 9E-9	6E-5 -	6E-4 -
49 Indium-112 <sup>2</sup>	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	2E+5 -	6E+5 7E+5	3E-4 3E-4	9E-7 1E-6	2E-3 -	2E-2 -
49 Indium-113m <sup>2</sup>	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	5E+4 -	1E+5 2E+5	6E-5 8E-5	2E-7 3E-7	7E-4 -	7E-3 -
49 Indium-114m	D, see $^{109}\text{In}$	3E+2	6E+1	3E-8	9E-11	-	-
		LLI wall (4E+2)	-	-	-	5E-6	5E-5
	W, see $^{109}\text{In}$	-	1E+2	4E-8	1E-10	-	-
49 Indium-115	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	4E+1 -	1E+0 5E+0	6E-10 2E-9	2E-12 8E-12	5E-7 -	5E-6 -
49 Indium-115m	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	1E+4 -	4E+4 5E+4	2E-5 2E-5	6E-8 7E-8	2E-4 -	2E-3 -
49 Indium-116m <sup>2</sup>	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	2E+4 -	8E+4 1E+5	3E-5 5E-5	1E-7 2E-7	3E-4 -	3E-3 -
49 Indium-117 <sup>2</sup>	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	6E+4 -	2E+5 2E+5	7E-5 9E-5	2E-7 3E-7	8E-4 -	8E-3 -
49 Indium-117m <sup>2</sup>	D, see $^{109}\text{In}$ W, see $^{109}\text{In}$	1E+4 -	3E+4 4E+4	1E-5 2E-5	5E-8 6E-8	2E-4 -	2E-3 -
49 Indium-119m <sup>2</sup>	D, see $^{109}\text{In}$	4E+4	1E+5	5E-5	2E-7	-	-
		St wall (5E+4)	-	-	-	7E-4	7E-3
	W, see $^{109}\text{In}$	-	1E+5	6E-5	2E-7	-	-
53 Iodine-120 <sup>2</sup>	D, all compounds	4E+3	9E+3	4E-6	-	-	-
		Thyroid (8E+3)	Thyroid (1E+4)	-	2E-8	1E-4	1E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases to Sewers	
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
53	Iodine-120m <sup>2</sup>	D, all compounds	1E+4 Thyroid (1E+4)	2E+4	9E-6	3E-8	-	-
53	Iodine-121	D, all compounds	1E+4 Thyroid (3E+4)	2E+4 Thyroid (5E+4)	8E-6	-	2E-4	2E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6	-	-	-
53	Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8	-	-	-
53	Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8	-	-	-
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8	-	-	-
53	Iodine-128 <sup>2</sup>	D, all compounds	4E+4 St wall (6E+4)	1E+5	5E-5	2E-7	-	-
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9	-	-	-
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7	-	-	-
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8	-	-	-
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6	-	-	-
53	Iodine-132m <sup>2</sup>	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6	-	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
53 Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 - -	- 1E-9	- 7E-6	- 7E-5
53 Iodine-134 <sup>2</sup>	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 - -	2E-5 - -	6E-8 - -	- 4E-4	- 4E-3
53 Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 - -	- 6E-9	- 3E-5	- 3E-4
77 Iridium-182 <sup>2</sup>	D, all compounds except those given for W and Y	4E+4 St wall (4E+4)	1E+5 - -	6E-5 - -	2E-7 - -	- 6E-4	- 6E-3
	W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
	Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77 Iridium-184	D, see <sup>182</sup> Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
	W, see <sup>182</sup> Ir	-	3E+4	1E-5	5E-8	-	-
	Y, see <sup>182</sup> Ir	-	3E+4	1E-5	4E-8	-	-
77 Iridium-185	D, see <sup>182</sup> Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
	W, see <sup>182</sup> Ir	-	1E+4	5E-6	2E-8	-	-
	Y, see <sup>182</sup> Ir	-	1E+4	4E-6	1E-8	-	-
77 Iridium-186	D, see <sup>182</sup> Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	W, see <sup>182</sup> Ir	-	6E+3	3E-6	9E-9	-	-
	Y, see <sup>182</sup> Ir	-	6E+3	2E-6	8E-9	-	-
77 Iridium-187	D, see <sup>182</sup> Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
	W, see <sup>182</sup> Ir	-	3E+4	1E-5	4E-8	-	-
	Y, see <sup>182</sup> Ir	-	3E+4	1E-5	4E-8	-	-
77 Iridium-188	D, see <sup>182</sup> Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
	W, see <sup>182</sup> Ir	-	4E+3	1E-6	5E-9	-	-
	Y, see <sup>182</sup> Ir	-	3E+3	1E-6	5E-9	-	-
77 Iridium-189	D, see <sup>182</sup> Ir	5E+3 LLI wall (5E+3)	5E+3 - -	2E-6 - -	7E-9 - -	- 7E-5	- 7E-4
	W, see <sup>182</sup> Ir	-	4E+3	2E-6	5E-9	-	-
	Y, see <sup>182</sup> Ir	-	4E+3	1E-6	5E-9	-	-
77 Iridium-190	D, see <sup>182</sup> Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
	W, see <sup>182</sup> Ir	-	1E+3	4E-7	1E-9	-	-
	Y, see <sup>182</sup> Ir	-	9E+2	4E-7	1E-9	-	-



		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci}/\text{ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci}/\text{ml}$ )	Water ( $\mu\text{Ci}/\text{ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci}/\text{ml}$ )				
77	Iridium-190m <sup>2</sup>	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	2E+5 - -	2E+5 2E+5 2E+5	8E-5 9E-5 8E-5	3E-7 3E-7 3E-7	2E-3 - -	2E-2 - -
77	Iridium-192	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	9E+2 - -	3E+2 4E+2 2E+2	1E-7 2E-7 9E-8	4E-10 6E-10 3E-10	1E-5 - -	1E-4 - -
77	Iridium-192m	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	3E+3 - -	9E+1 2E+2 2E+1	4E-8 9E-8 6E-9	1E-10 3E-10 2E-11	4E-5 - -	4E-4 - -
77	Iridium-194	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	1E+3 - -	3E+3 2E+3 2E+3	1E-6 9E-7 8E-7	4E-9 3E-9 3E-9	1E-5 - -	1E-4 - -
77	Iridium-194m	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	6E+2 - -	9E+1 2E+2 1E+2	4E-8 7E-8 4E-8	1E-10 2E-10 1E-10	9E-6 - -	9E-5 - -
77	Iridium-195	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	1E+4 - -	4E+4 5E+4 4E+4	2E-5 2E-5 2E-5	6E-8 7E-8 6E-8	2E-4 - -	2E-3 - -
77	Iridium-195m	D, see <sup>182</sup> Ir W, see <sup>182</sup> Ir Y, see <sup>182</sup> Ir	8E+3 - -	2E+4 3E+4 2E+4	1E-5 1E-5 9E-6	3E-8 4E-8 3E-8	1E-4 - -	1E-3 - -
26	Iron-52	D, all compounds except those given for W W, oxides, hydroxides, and halides	9E+2 -	3E+3 4E+3	1E-6 1E-6	4E-9 3E-9	1E-5 -	1E-4 -
26	Iron-55	D, see <sup>52</sup> Fe W, see <sup>52</sup> Fe	9E+3 -	2E+3 4E+3	8E-7 2E-6	3E-9 6E-9	1E-4 -	1E-3 -
26	Iron-59	D, see <sup>52</sup> Fe W, see <sup>52</sup> Fe	8E+2 -	3E+2 5E+2	1E-7 2E-7	5E-10 7E-10	1E-5 -	1E-4 -
26	Iron-60	D, see <sup>52</sup> Fe W, see <sup>52</sup> Fe	3E+1 -	6E+0 2E+1	3E-9 8E-9	9E-12 3E-11	4E-7 -	4E-6 -
36	Krypton-74 <sup>2</sup>	Submersion <sup>1</sup>	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion <sup>1</sup>	-	-	9E-6	4E-8	-	-
36	Krypton-77 <sup>2</sup>	Submersion <sup>1</sup>	-	-	4E-6	2E-8	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)	
			Inhalation	DAC (μCi/ml)				
								ALI (μCi)
36	Krypton-79	Submersion <sup>1</sup>	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion <sup>1</sup>	-	-	7E-4	3E-6	-	-
36	Krypton-83m <sup>2</sup>	Submersion <sup>1</sup>	-	-	1E-2	5E-5	-	-
36	Krypton-85	Submersion <sup>1</sup>	-	-	1E-4	7E-7	-	-
36	Krypton-85m	Submersion <sup>1</sup>	-	-	2E-5	1E-7	-	-
36	Krypton-87 <sup>2</sup>	Submersion <sup>1</sup>	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion <sup>1</sup>	-	-	2E-6	9E-9	-	-
57	Lanthanum-131 <sup>2</sup>	D, all compounds except those given for W W, oxides and hydroxides	5E+4 -	1E+5 2E+5	5E-5 7E-5	2E-7 7E-7	6E-4 -	6E-3 -
57	Lanthanum-132	D, see <sup>131</sup> La W, see <sup>131</sup> La	3E+3 -	1E+4 1E+4	4E-6 5E-6	1E-8 2E-8	4E-5 -	4E-4 -
57	Lanthanum-135	D, see <sup>131</sup> La W, see <sup>131</sup> La	4E+4 -	1E+5 9E+4	4E-5 4E-5	1E-7 1E-7	5E-4 -	5E-3 -
57	Lanthanum-137	D, see <sup>131</sup> La  W, see <sup>131</sup> La	1E+4  -	6E+1 Liver (7E+1) 3E+2 Liver (3E+2)	3E-8 - 1E-7 -	- 1E-10 - 4E-10	2E-4 - - -	2E-3 - - -
57	Lanthanum-138	D, see <sup>131</sup> La W, see <sup>131</sup> La	9E+2 -	4E+0 1E+1	1E-9 6E-9	5E-12 2E-11	1E-5 -	1E-4 -
57	Lanthanum-140	D, see <sup>131</sup> La W, see <sup>131</sup> La	6E+2 -	1E+3 1E+3	6E-7 5E-7	2E-9 2E-9	9E-6 -	9E-5 -
57	Lanthanum-141	D, see <sup>131</sup> La W, see <sup>131</sup> La	4E+3 -	9E+3 1E+4	4E-6 5E-6	1E-8 2E-8	5E-5 -	5E-4 -
57	Lanthanum-142 <sup>2</sup>	D, see <sup>131</sup> La W, see <sup>131</sup> La	8E+3 -	2E+4 3E+4	9E-6 1E-5	3E-8 5E-8	1E-4 -	1E-3 -
57	Lanthanum-143 <sup>2</sup>	D, see <sup>131</sup> La  St wall (4E+4) W, see <sup>131</sup> La	4E+4  -	1E+5  9E+4	4E-5  4E-5	1E-7  1E-7	-  5E-4 -	-  5E-3 -
82	Lead-195m <sup>2</sup>	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)	
			ALI (μCi)	DAC (μCi/ml)			
82 Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82 Lead-199 <sup>2</sup>	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82 Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82 Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82 Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82 Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82 Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82 Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82 Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82 Lead-210	D, all compounds	6E1 Bone surf (1E+0)	2E1 Bone surf (4E-1)	1E-10	-	-	-
82 Lead-211 <sup>2</sup>	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82 Lead-212	D, all compounds	8E+1 Bone surf (1E+2)	3E+1	1E-8	5E-11	-	-
			-	-	-	2E-6	2E-5
82 Lead-214 <sup>2</sup>	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
71 Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
	Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71 Lutetium-170	W, see <sup>169</sup> Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
	Y, see <sup>169</sup> Lu	-	2E+3	8E-7	3E-9	-	-
71 Lutetium-171	W, see <sup>169</sup> Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
	Y, see <sup>169</sup> Lu	-	2E+3	8E-7	3E-9	-	-
71 Lutetium-172	W, see <sup>169</sup> Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
	Y, see <sup>169</sup> Lu	-	1E+3	5E-7	2E-9	-	-
71 Lutetium-173	W, see <sup>169</sup> Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			Bone surf (5E+2)	-	6E-10	-	-
	Y, see <sup>169</sup> Lu	-	3E+2	1E-7	4E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table II' Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu$ Ci)	Col. 2	Col. 3	Col. 1 Air ( $\mu$ Ci/ml)	Col. 2 Water ( $\mu$ Ci/ml)	Monthly Average Concentration ( $\mu$ Ci/ml)	
			Inhalation ALI ( $\mu$ Ci)	DAC ( $\mu$ Ci/ml)				
71	Lutetium-174	W, see $^{169}\text{Lu}$	5E+3	1E+2	5E-8	-	7E-5	7E-4
			-	Bone surf (2E+2)	-	3E-10	-	-
	Y, see $^{169}\text{Lu}$		-	2E+2	6E-8	2E-10	-	-
71	Lutetium-174m	W, see $^{169}\text{Lu}$	2E+3	2E+2	1E-7	-	-	-
			LLI wall (3E+3)	Bone surf (3E+2)	-	5E-10	4E-5	4E-4
	Y, see $^{169}\text{Lu}$		-	2E+2	9E-8	3E-10	-	-
71	Lutetium-176	W, see $^{169}\text{Lu}$	7E+2	5E+0	2E-9	-	1E-5	1E-4
			-	Bone surf (1E+1)	-	2E-11	-	-
	Y, see $^{169}\text{Lu}$		-	8E+0	3E-9	1E-11	-	-
71	Lutetium-176m	W, see $^{169}\text{Lu}$	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	Y, see $^{169}\text{Lu}$		-	2E+4	9E-6	3E-8	-	-
71	Lutetium-177	W, see $^{169}\text{Lu}$	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
	Y, see $^{169}\text{Lu}$		-	2E+3	9E-7	3E-9	-	-
71	Lutetium-177m	W, see $^{169}\text{Lu}$	7E+2	1E+2	5E-8	-	1E-5	1E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
	Y, see $^{169}\text{Lu}$		-	8E+1	3E-8	1E-10	-	-
71	Lutetium-178 <sup>2</sup>	W, see $^{169}\text{Lu}$	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
	Y, see $^{169}\text{Lu}$		-	1E+5	5E-5	2E-7	-	-
71	Lutetium-178m <sup>2</sup>	W, see $^{169}\text{Lu}$	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall (6E+4)	-	-	-	8E-4	8E-3
	Y, see $^{169}\text{Lu}$		-	2E+5	7E-5	2E-7	-	-
71	Lutetium-179	W, see $^{169}\text{Lu}$	5E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	Y, see $^{169}\text{Lu}$		-	2E+4	6E-6	3E-8	-	-
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
25	Manganese-51 <sup>2</sup>	D, all compounds except those given for W, oxides, hydroxides, halides, and nitrates	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
			-	6E+4	3E-5	8E-8	-	-
25	Manganese-52	D, see <sup>51</sup> Mn W, see <sup>51</sup> Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
			-	9E+2	4E-7	1E-9	-	-
25	Manganese-52m <sup>2</sup>	D, see <sup>51</sup> Mn	3E+4	9E+4	4E-5	1E-7	-	-
		St wall (4E+4)	-	-	-	5E-4	5E-3	-
		W, see <sup>51</sup> Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-53	D, see <sup>51</sup> Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
			-	Bone surf (2E+4)	-	3E-8	-	-
		W, see <sup>51</sup> Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see <sup>51</sup> Mn W, see <sup>51</sup> Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
			-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see <sup>51</sup> Mn W, see <sup>51</sup> Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
			-	2E+4	9E-6	3E-8	-	-
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
		Bone surf (5E+1)	-	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3	-
	D, see <sup>193m</sup> Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3	-
	W, see <sup>193m</sup> Hg	-	4E+4	2E-5	6E-8	-	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4	-
	D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4	-
	W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-	-
80	Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
	Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6	-
	D, see <sup>193m</sup> Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4	-
	W, see <sup>193m</sup> Hg	-	1E+2	5E-8	2E-10	-	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	DAC (μCi/ml)				
80	Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
	Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3	2E-3
	D, see <sup>195</sup> Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3	2E-3
	W, see <sup>195</sup> Hg	-	3E+4	1E-5	5E-8	-	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
	Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4	4E-4
	D, see <sup>195m</sup> Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4	3E-4
	W, see <sup>195m</sup> Hg	-	4E+3	2E-6	5E-9	-	-	-
80	Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
	Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4	9E-4
	D, see <sup>197</sup> Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4	8E-4
	W, see <sup>197</sup> Hg	-	9E+3	4E-6	1E-8	-	-	-
80	Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
	Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4	5E-4
	D, see <sup>197m</sup> Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4	4E-4
	W, see <sup>197m</sup> Hg	-	5E+3	2E-6	7E-9	-	-	-
80	Mercury-199m <sup>2</sup>	Vapor	-	8E+4	3E-5	1E-7	-	-
	Organic D	6E+4	2E+5	7E-5	2E-7	-	-	-
	St wall (1E+5)	-	-	-	-	1E-3	1E-2	1E-2
	D, see <sup>199m</sup> Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3	8E-3
	W, see <sup>199m</sup> Hg	-	2E+5	7E-5	2E-7	-	-	-
80	Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
	Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5	7E-5
	D, see <sup>203</sup> Hg	2E+3	1E+3	5E-7	2E-9	5E-5	3E-4	3E-4
	W, see <sup>203</sup> Hg	-	1E+3	5E-7	2E-9	-	-	-
42	Molybdenum-101 <sup>2</sup>	D, see <sup>96</sup> Mo	4E+4	1E+5	6E-5	2E-7	-	-
	St wall (5E+4)	-	-	-	-	7E-4	7E-3	7E-3
	Y, see <sup>96</sup> Mo	-	1E+5	6E-5	2E-7	-	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
	Y, oxides, hydroxides, and MoS	2E+3	5E+3	2E-6	6E-9	-	-	-
42	Molybdenum-93	D, see <sup>96</sup> Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
	Y, see <sup>96</sup> Mo	2E+4	2E+2	8E-8	2E-10	-	-	-
42	Molybdenum-93m	D, see <sup>96</sup> Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
	Y, see <sup>96</sup> Mo	4E+3	1E+4	6E-6	2E-8	-	-	-



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )	Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )			
42	Molybdenum-99	D, see $^{90}\text{Mo}$	2E+3 LLI wall (1E+3)	3E+3	1E-6	4E-9	-	-
		Y, see $^{90}\text{Mo}$	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
60	Neodymium-136 <sup>2</sup>	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see $^{136}\text{Nd}$	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see $^{136}\text{Nd}$	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-137 <sup>2</sup>	W, see $^{136}\text{Nd}$	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see $^{136}\text{Nd}$	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-139m	W, see $^{136}\text{Nd}$	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see $^{136}\text{Nd}$	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-141	W, see $^{136}\text{Nd}$	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see $^{136}\text{Nd}$	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see $^{136}\text{Nd}$	1E+3 LLI wall (1E+3)	9E+2	4E-7	1E-9	-	-
		Y, see $^{136}\text{Nd}$	-	8E+2	4E-7	1E-9	2E-5	2E-4
60	Neodymium-149 <sup>2</sup>	W, see $^{136}\text{Nd}$	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see $^{136}\text{Nd}$	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151 <sup>2</sup>	W, see $^{136}\text{Nd}$	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see $^{136}\text{Nd}$	-	2E+5	8E-5	3E-7	-	-
93	Neptunium-232 <sup>2</sup>	W, all compounds	1E+5	2E+3 Bone surf (5E+2)	7E-7	-	2E-3	2E-2
			-	-	6E-9	-	-	-
93	Neptunium-233 <sup>2</sup>	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7	-	-	-
			-	-	2E-9	3E-4	3E-4	3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12	-	-	-
			-	-	8E-14	9E-8	9E-8	9E-7

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
93 Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 -	- 1E-10	- 5E-5	- 5E-4
93 Neptunium-237	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
93 Neptunium-238	W, all compounds	1E+3 -	6E+1 Bone surf (2E+2)	3E-8 -	- 2E-10	2E-5 -	2E-4 -
93 Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	9E-7 -	3E-9 -	- 2E-5	- 2E-4
93 Neptunium-240 <sup>2</sup>	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
28 Nickel-56	D, all compounds except those given for W W, oxides, hydroxides, and carbides Vapor	1E+3 - -	2E+3 1E+3 1E+3	8E-7 5E-7 5E-7	3E-9 2E-9 2E-9	2E-5 - -	2E-4 - -
28 Nickel-57	D, see <sup>56</sup> Ni W, see <sup>56</sup> Ni Vapor	2E+3 - -	5E+3 3E+3 6E+3	2E-6 1E-6 3E-6	7E-9 4E-9 9E-9	2E-5 - -	2E-4 - -
28 Nickel-59	D, see <sup>56</sup> Ni W, see <sup>56</sup> Ni Vapor	2E+4 - -	4E+3 7E+3 2E+3	2E-6 3E-6 8E-7	5E-9 1E-8 3E-9	3E-4 - -	3E-3 - -
28 Nickel-63	D, see <sup>56</sup> Ni W, see <sup>56</sup> Ni Vapor	9E+3 - -	2E+3 3E+3 8E+2	7E-7 1E-6 3E-7	2E-9 4E-9 1E-9	1E-4 - -	1E-3 - -
28 Nickel-65	D, see <sup>56</sup> Ni W, see <sup>56</sup> Ni Vapor	8E+3 - -	2E+4 3E+4 2E+4	1E-5 1E-5 7E-6	3E-8 4E-8 2E-8	1E-4 - -	1E-3 - -
28 Nickel-66	D, see <sup>56</sup> Ni  W, see <sup>56</sup> Ni Vapor	4E+2 LLI wall (5E+2) - -	2E+3 - 6E+2 3E+3	7E-7 - 3E-7 1E-6	2E-9 - 9E-10 4E-9	- 6E-6 - -	- 6E-5 - -

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
41	Niobium-88 <sup>2</sup>	W, all compounds except those given for Y	5E+4 St wall (7E+4)	2E+5	9E-5	3E-7	-	-
	Y, oxides and hydroxides		-	2E+5	9E-5	3E-7	1E-3	1E-2
41	Niobium-89 (122 min)	W, see <sup>80</sup> Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
	Y, see <sup>80</sup> Nb		-	2E+4	6E-6	2E-8	-	-
41	Niobium-89 <sup>2</sup> (66 min)	W, see <sup>80</sup> Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
	Y, see <sup>80</sup> Nb		-	4E+4	2E-5	5E-8	-	-
41	Niobium-90	W, see <sup>80</sup> Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
	Y, see <sup>80</sup> Nb		-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see <sup>80</sup> Nb	9E+3 LLI wall (1E+4)	2E+3	8E-7	3E-9	-	-
	Y, see <sup>80</sup> Nb		-	2E+2	7E-8	2E-10	2E-4	2E-3
41	Niobium-94	W, see <sup>80</sup> Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
	Y, see <sup>80</sup> Nb		-	2E+1	6E-9	2E-11	-	-
41	Niobium-95	W, see <sup>80</sup> Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
	Y, see <sup>80</sup> Nb		-	1E+3	5E-7	2E-9	-	-
41	Niobium-95m	W, see <sup>80</sup> Nb	2E+3 LLI wall (2E+3)	3E+3	1E-6	4E-9	-	-
	Y, see <sup>80</sup> Nb		-	2E+3	9E-7	3E-9	3E-5	3E-4
41	Niobium-96	W, see <sup>80</sup> Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
	Y, see <sup>80</sup> Nb		-	2E+3	1E-6	3E-9	-	-
41	Niobium-97 <sup>2</sup>	W, see <sup>80</sup> Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
	Y, see <sup>80</sup> Nb		-	7E+4	3E-5	1E-7	-	-
41	Niobium-98 <sup>2</sup>	W, see <sup>80</sup> Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
	Y, see <sup>80</sup> Nb		-	5E+4	2E-5	7E-8	-	-
76	Osmium-180 <sup>2</sup>	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
	W, halides and nitrates		-	5E+5	2E-4	7E-7	-	-
	Y, oxides and hydroxides		-	5E+5	2E-4	6E-7	-	-
76	Osmium-181 <sup>2</sup>	D, see <sup>180</sup> Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, see <sup>180</sup> Os		-	5E+4	2E-5	6E-8	-	-
	Y, see <sup>180</sup> Os		-	4E+4	2E-5	6E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
76 Osmium-182	D, see $^{180}\text{Os}$	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
	W, see $^{180}\text{Os}$	-	4E+3	2E-6	6E-9	-	-
	Y, see $^{180}\text{Os}$	-	4E+3	2E-6	6E-9	-	-
76 Osmium-185	D, see $^{180}\text{Os}$	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
	W, see $^{180}\text{Os}$	-	8E+2	3E-7	1E-9	-	-
	Y, see $^{180}\text{Os}$	-	8E+2	3E-7	1E-9	-	-
76 Osmium-189m	D, see $^{180}\text{Os}$	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
	W, see $^{180}\text{Os}$	-	2E+5	9E-5	3E-7	-	-
	Y, see $^{180}\text{Os}$	-	2E+5	7E-5	2E-7	-	-
76 Osmium-191	D, see $^{180}\text{Os}$	2E+3	2E+3	9E-7	3E-9	-	-
		LLI wall (3E+3)	-	-	-	3E-5	3E-4
	W, see $^{180}\text{Os}$	-	2E+3	7E-7	2E-9	-	-
	Y, see $^{180}\text{Os}$	-	1E+3	6E-7	2E-9	-	-
76 Osmium-191m	D, see $^{180}\text{Os}$	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
	W, see $^{180}\text{Os}$	-	2E+4	8E-6	3E-8	-	-
	Y, see $^{180}\text{Os}$	-	2E+4	7E-6	2E-8	-	-
76 Osmium-193	D, see $^{180}\text{Os}$	2E+3	5E+3	2E-6	6E-9	-	-
		LLI wall (2E+3)	-	-	-	2E-5	2E-4
	W, see $^{180}\text{Os}$	-	3E+3	1E-6	4E-9	-	-
	Y, see $^{180}\text{Os}$	-	3E+3	1E-6	4E-9	-	-
76 Osmium-194	D, see $^{180}\text{Os}$	4E+2	4E+1	2E-8	6E-11	-	-
		LLI wall (6E+2)	-	-	-	8E-6	8E-5
	W, see $^{180}\text{Os}$	-	6E+1	2E-8	8E-11	-	-
	Y, see $^{180}\text{Os}$	-	8E+0	3E-9	1E-11	-	-
46 Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
	W, nitrates	-	1E+3	5E-7	2E-9	-	-
	Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46 Palladium-101	D, see $^{100}\text{Pd}$	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
	W, see $^{100}\text{Pd}$	-	3E+4	1E-5	5E-8	-	-
	Y, see $^{100}\text{Pd}$	-	3E+4	1E-5	4E-8	-	-
46 Palladium-103	D, see $^{100}\text{Pd}$	6E+3	6E+3	3E-6	9E-9	-	-
		LLI wall (7E+3)	-	-	-	1E-4	1E-3
	W, see $^{100}\text{Pd}$	-	4E+3	2E-6	6E-9	-	-
	Y, see $^{100}\text{Pd}$	-	4E+3	1E-6	5E-9	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )	Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
46	Palladium-107	D, see $^{100}\text{Pd}$	3E+4 LLI wall (4E+4)	2E+4 Kidneys (2E+4)	9E-6	-	-
	W, see $^{100}\text{Pd}$	-	7E+3	3E-6	3E-8 1E-8	5E-4	5E-3
	Y, see $^{100}\text{Pd}$	-	4E+2	2E-7	6E-10	-	-
46	Palladium-109	D, see $^{100}\text{Pd}$	2E+3	6E+3	3E-6	9E-9	3E-4
	W, see $^{100}\text{Pd}$	-	5E+3	2E-6	8E-9	-	-
	Y, see $^{100}\text{Pd}$	-	5E+3	2E-6	6E-9	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-5
	W, phosphates of $\text{Zn}^{2+}$ , $\text{S}^{2-}$ , $\text{Mg}^{2+}$ , $\text{Fe}^{3+}$ , $\text{Bi}^{3+}$ , and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see $^{32}\text{P}$	6E+3	8E+3	4E-6	1E-8	8E-4
	W, see $^{32}\text{P}$	-	3E+3	1E-6	4E-9	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-4
78	Platinum-193	D, all compounds	4E+4 LLI wall (5E+4)	2E+4	1E-5	3E-8	-
			-	-	-	6E-4	6E-3
78	Platinum-193m	D, all compounds	3E+3 LLI wall (3E+4)	6E+3	3E-6	8E-9	-
			-	-	-	4E-5	4E-4
78	Platinum-195m	D, all compounds	2E+3 LLI wall (2E+3)	4E+3	2E-6	6E-9	-
			-	-	-	3E-5	3E-4
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-4
78	Platinum-197m <sup>2</sup>	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-3
78	Platinum-199 <sup>2</sup>	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-8	2E-4
94	Plutonium-234	W, all compounds except $\text{PuO}$	8E+3	2E+2	9E-8	3E-10	1E-3
	Y, $\text{PuO}$	-	2E+2	8E-8	3E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )		
		Oral Ingestion	Inhalation					Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )
		ALI ( $\mu\text{Ci}$ )	ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )					
94	Plutonium-235 <sup>2</sup>	W, see <sup>234</sup> Pu Y, see <sup>234</sup> Pu	9E+5 -	3E+6 3E+6	1E-3 1E-3	4E-6 3E-6	1E-2 -	1E-1 -	
94	Plutonium-236	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	2E+0 Bone surf (4E+0) -	2E-2 Bone surf (4E-2) 4E-2	8E-12 - 2E-11	- 5E-14 6E-14	- 6E-8 -	- 6E-7 -	
94	Plutonium-237	W, see <sup>234</sup> Pu Y, see <sup>234</sup> Pu	1E+4 -	3E+3 3E+3	1E-6 1E-6	5E-9 4E-9	2E-4 -	2E-3 -	
94	Plutonium-238	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	9E-1 Bone surf (2E+0) -	7E-3 Bone surf (1E-2) 2E-2	3E-12 - 8E-12	- 2E-14 2E-14	- 2E-8 -	- 2E-7 -	
94	Plutonium-239	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	8E-1 Bone surf (1E+0) -	6E-3 Bone surf (1E-2) 2E-2 Bone surf (2E-2)	3E-12 - 7E-12 -	- 2E-14 - 2E-14	- 2E-8 -	- 2E-7 -	
94	Plutonium-240	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	8E-1 Bone surf (1E+0) -	6E-3 Bone surf (1E-2) 2E-2 Bone surf (2E-2)	3E-12 - 7E-12 -	- 2E-14 - 2E-14	- 2E-8 -	- 2E-7 -	
94	Plutonium-241	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	4E+1 Bone surf (7E+1) -	3E-1 Bone surf (6E-1) 8E-1 Bone surf (1E+0)	1E-10 - 3E-10 -	- 8E-13 - 1E-12	- 1E-6 -	- 1E-5 -	
94	Plutonium-242	W, see <sup>234</sup> Pu  Y, see <sup>234</sup> Pu	8E-1 Bone surf (1E+0) -	7E-3 Bone surf (1E-2) 2E-2 Bone surf (2E-2)	3E-12 - 7E-12 -	- 2E-14 - 2E-14	- 2E-8 -	- 2E-7 -	
94	Plutonium-243	W, see <sup>234</sup> Pu Y, see <sup>234</sup> Pu	2E+4 -	4E+4 4E+4	2E-5 2E-5	5E-8 5E-8	2E-4 -	2E-3 -	



		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
		ALI ( $\mu\text{Ci}$ )	ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
94	Plutonium-244	W, see $^{234}\text{Pu}$	8E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-7
		Y, see $^{234}\text{Pu}$	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -
94	Plutonium-245	W, see $^{234}\text{Pu}$	2E+3	5E+3	2E-6	6E-9	3E-4
		Y, see $^{234}\text{Pu}$	-	4E+3	2E-6	6E-9	-
94	Plutonium-246	W, see $^{234}\text{Pu}$	4E+2 LLI wall (4E+2)	3E+2	1E-7	4E-10	-
		Y, see $^{234}\text{Pu}$	-	3E+2	1E-7	4E-10	6E-5
84	Polonium-203 <sup>2</sup>	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-
84	Polonium-205 <sup>2</sup>	D, see $^{203}\text{Po}$	2E+4	4E+4	2E-5	5E-8	3E-3
		W, see $^{203}\text{Po}$	-	7E+4	3E-5	1E-7	-
84	Polonium-207	D, see $^{203}\text{Po}$	8E+3	3E+4	1E-5	3E-8	1E-3
		W, see $^{203}\text{Po}$	-	3E+4	1E-5	4E-8	-
84	Polonium-210	D, see $^{203}\text{Po}$	3E+0	6E-1	3E-10	9E-13	4E-7
		W, see $^{203}\text{Po}$	-	6E-1	3E-10	9E-13	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-4
19	Potassium-44 <sup>2</sup>	D, all compounds	2E+4 St wall (4E+4)	7E+4 -	3E-5 -	9E-8 -	- 5E-4
19	Potassium-45 <sup>2</sup>	D, all compounds	3E+6 St wall (5E+4)	1E+5 -	5E-5 -	2E-7 -	- 7E-4
59	Praseodymium-136 <sup>2</sup>	W, all compounds except those given for Y	5E+4 St wall (7E+4)	2E+5 -	1E-4 -	3E-7 -	- 1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
			Inhalation ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
59	Praseodymium-137 <sup>2</sup> W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	4E+4 -	2E+5 1E+5	6E-5 6E-5	2E-7 2E-7	5E-4 -	5E-3 -
59	Praseodymium-138m W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	1E+4 -	5E+4 4E+4	2E-5 2E-5	8E-8 6E-8	1E-4 -	1E-3 -
59	Praseodymium-139 W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	4E+4 -	1E+5 1E+5	5E-5 5E-5	2E-7 2E-7	6E-4 -	6E-3 -
59	Praseodymium-142 W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	1E+3 -	2E+3 2E+3	9E-7 8E-7	3E-9 3E-9	1E-5 -	1E-4 -
59	Praseodymium-142m W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	8E+4 -	2E+5 1E+5	7E-5 6E-5	2E-7 2E-7	1E-3 -	1E-2 -
59	Praseodymium-143 W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	9E+2 LLI wall (1E+3) -	8E+2 - 7E+2	3E-7 - 3E-7	1E-9 - 9E-10	- 2E-5 -	- 2E-4 -
59	Praseodymium-144 <sup>2</sup> W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	3E+4 St wall (4E+4) -	1E+5 - 1E+5	5E-5 - 5E-5	2E-7 - 2E-7	- 6E-4 -	- 6E-3 -
59	Praseodymium-145 W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	3E+3 -	9E+3 8E+3	4E-6 3E-6	1E-8 1E-8	4E-5 -	4E-4 -
59	Praseodymium-147 <sup>2</sup> W, see <sup>136</sup> Pr Y, see <sup>136</sup> Pr	5E+4 St wall (8E+4) -	2E+5 - 2E+5	8E-5 - 7E-5	3E-7 - 3E-7	- 1E-3 -	- 1E-2 -
61	Promethium-141 <sup>2</sup> W, all compounds except those given for Y Y, oxides, hydroxides, carbides, and fluorides	5E+4 St wall (6E+4) -	2E+5 - 2E+5	8E-5 - 7E-5	3E-7 - 2E-7	- 8E-4 -	- 8E-3 -
61	Promethium-143 W, see <sup>141</sup> Pm Y, see <sup>141</sup> Pm	5E+3 -	6E+2 7E+2	2E-7 3E-7	8E-10 1E-9	7E-5 -	7E-4 -
61	Promethium-144 W, see <sup>141</sup> Pm Y, see <sup>141</sup> Pm	1E+3 -	1E+2 1E+2	5E-8 5E-8	2E-10 2E-10	2E-5 -	2E-4 -

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
			Inhalation ALI ( $\mu\text{Ci}$ ) DAC ( $\mu\text{Ci/ml}$ )		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
61	Promethium-145	W, see $^{141}\text{Pm}$	1E+4	2E+2 Bone surf (2E+2)	7E-8	-	1E-4	1E-3
		Y, see $^{141}\text{Pm}$	-	2E+2	8E-8	3E-10 3E-10	-	-
61	Promethium-146	W, see $^{141}\text{Pm}$	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see $^{141}\text{Pm}$	-	4E+1	2E-8	6E-11	-	-
61	Promethium-147	W, see $^{141}\text{Pm}$	4E+3 LLI wall (5E+3)	1E+2 Bone surf (2E+2)	5E-8	-	-	-
		Y, see $^{141}\text{Pm}$	-	1E+2	6E-8	3E-10 2E-10	7E-5	7E-4
61	Promethium-148	W, see $^{141}\text{Pm}$	4E+2 LLI wall (5E+2)	5E+2	2E-7	8E-10	-	-
		Y, see $^{141}\text{Pm}$	-	5E+2	2E-7	- 7E-10	7E-6	7E-5
61	Promethium-148m	W, see $^{141}\text{Pm}$	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see $^{141}\text{Pm}$	-	3E+2	1E-7	5E-10	-	-
61	Promethium-149	W, see $^{141}\text{Pm}$	1E+3 LLI wall (1E+3)	2E+3	8E-7	3E-9	-	-
		Y, see $^{141}\text{Pm}$	-	2E+3	8E-7	- 2E-9	2E-5	2E-4
61	Promethium-150	W, see $^{141}\text{Pm}$	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see $^{141}\text{Pm}$	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see $^{141}\text{Pm}$	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see $^{141}\text{Pm}$	-	3E+3	1E-6	4E-9	-	-
91	Protactinium-227 <sup>2</sup>	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see $^{227}\text{Pa}$	1E+3	1E+1 Bone surf (2E+1)	5E-9	-	2E-5	2E-4
		Y, see $^{227}\text{Pa}$	-	1E+1	5E-9	3E-11 2E-11	-	-
91	Protactinium-230	W, see $^{227}\text{Pa}$	6E+2 Bone surf (9E+2)	5E+0	2E-9	7E-12	-	-
		Y, see $^{227}\text{Pa}$	-	4E+0	1E-9	- 5E-12	1E-5	1E-4

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
91 Protactinium-231 W, see $^{227}\text{Pa}$		2E-1 Bone surf (5E-1)	2E-3 Bone surf (4E-3)	6E-13	-	-	-
	Y, see $^{227}\text{Pa}$	-	4E-3 Bone surf (6E-3)	2E-12	6E-15	6E-9	6E-8
		-	-	-	8E-15	-	-
91 Protactinium-232 W, see $^{227}\text{Pa}$		1E+3	2E+1 Bone surf (6E+1)	9E-9	-	2E-5	2E-4
	Y, see $^{227}\text{Pa}$	-	6E+1 Bone surf (7E+1)	2E-8	8E-11	-	-
		-	-	-	1E-10	-	-
91 Protactinium-233 W, see $^{227}\text{Pa}$		1E+3 LLI wall (2E+3)	7E+2	3E-7	1E-9	-	-
	Y, see $^{227}\text{Pa}$	-	6E+2	2E-7	8E-10	2E-5	2E-4
91 Protactinium-234 W, see $^{227}\text{Pa}$		2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
	Y, see $^{227}\text{Pa}$	-	7E+3	3E-6	9E-9	-	-
88 Radium-223	W, all compounds	5E+0 Bone surf (9E+0)	7E-1	3E-10	9E-13	-	-
		-	-	-	-	1E-7	1E-6
88 Radium-224	W, all compounds	8E+0 Bone surf (2E+1)	2E+0	7E-10	2E-12	-	-
		-	-	-	-	2E-7	2E-6
88 Radium-225	W, all compounds	8E+0 Bone surf (2E+1)	7E-1	3E-10	9E-13	-	-
		-	-	-	-	2E-7	2E-6
88 Radium-226	W, all compounds	2E+0 Bone surf (5E+0)	6E-1	3E-10	9E-13	-	-
		-	-	-	-	6E-8	6E-7
88 Radium-227 <sup>2</sup>	W, all compounds	2E+4 Bone surf (2E+4)	1E+4 Bone surf (2E+4)	6E-6	-	-	-
		-	-	-	3E-8	3E-4	3E-3
88 Radium-228	W, all compounds	2E+0 Bone surf (4E+0)	1E+0	5E-10	2E-12	-	-
		-	-	-	-	6E-8	6E-7

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
86 Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
	With daughters present	-	2E+1 (or 12 working level months)	9E-9 (or 1.0 working level)	3E-11	-	-
86 Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
	With daughters present	-	1E+2 (or 4 working level months)	3E-8 (or 0.33 working level)	1E-10	-	-
75 Rhenium-177 <sup>2</sup>	D, all compounds except those given for W	9E+4 St wall (1E+5)	3E+5	1E-4	4E-7	-	-
	W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	2E-3	2E-2
75 Rhenium-178 <sup>2</sup>	D, see <sup>177</sup> Re	7E+4 St wall (1E+5)	3E+5	1E-4	4E-7	-	-
	W, see <sup>177</sup> Re	-	3E+5	1E-4	4E-7	1E-3	1E-2
75 Rhenium-181	D, see <sup>177</sup> Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
	W, see <sup>177</sup> Re	-	9E+3	4E-6	1E-8	-	-
75 Rhenium-182 (12.7 h)	D, see <sup>177</sup> Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
	W, see <sup>177</sup> Re	-	2E+4	6E-6	2E-8	-	-
75 Rhenium-182 (64.0 h)	D, see <sup>177</sup> Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
	W, see <sup>177</sup> Re	-	2E+3	9E-7	3E-9	-	-
75 Rhenium-184	D, see <sup>177</sup> Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
	W, see <sup>177</sup> Re	-	1E+3	6E-7	2E-9	-	-
75 Rhenium-184m	D, see <sup>177</sup> Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see <sup>177</sup> Re	-	4E+2	2E-7	6E-10	-	-
75 Phenium-186	D, see <sup>177</sup> Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see <sup>177</sup> Re	-	2E+3	7E-7	2E-9	-	-
75 Rhenium-186m	D, see <sup>177</sup> Re	1E+3 St wall (2E+3)	2E+3 St wall (2E+3)	7E-7	-	-	-
	W, see <sup>177</sup> Re	-	2E+2	6E-8	3E-9 2E-10	2E-5	2E-4

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)		
		Oral Ingestion	Inhalation					Air (μCi/ml)	Water (μCi/ml)
		ALI (μCi)	ALI (μCi)	DAC (μCi/ml)					
75	Rhenium-187	D, see <sup>177</sup> Re	6E+5	8E+5	4E-4	-	8E-3	8E-2	
		St wall	-	(9E+5)	-	1E-6	-	-	
		W, see <sup>177</sup> Re	-	1E+5	4E-5	1E-7	-	-	
75	Rhenium-188	D, see <sup>177</sup> Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4	
		W, see <sup>177</sup> Re	-	3E+3	1E-6	4E-9	-	-	
75	Rhenium-188m <sup>2</sup>	D, see <sup>177</sup> Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2	
		W, see <sup>177</sup> Re	-	1E+5	6E-5	2E-7	-	-	
75	Rhenium-189	D, see <sup>177</sup> Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4	
		W, see <sup>177</sup> Re	-	4E+3	2E-6	6E-9	-	-	
45	Rhodium-100	D, see <sup>99a</sup> Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4	
		W, see <sup>99a</sup> Rh	-	4E+3	2E-6	6E-9	-	-	
		Y, see <sup>99a</sup> Rh	-	4E+3	2E-6	5E-9	-	-	
45	Rhodium-101	D, see <sup>99a</sup> Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4	
		W, see <sup>99a</sup> Rh	-	8E+2	3E-7	1E-9	-	-	
		Y, see <sup>99a</sup> Rh	-	2E+2	6E-8	2E-10	-	-	
45	Rhodium-101m	D, see <sup>99a</sup> Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4	
		W, see <sup>99a</sup> Rh	-	8E+3	4E-6	1E-8	-	-	
		Y, see <sup>99a</sup> Rh	-	8E+3	3E-6	1E-8	-	-	
45	Rhodium-102	D, see <sup>99a</sup> Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5	
		W, see <sup>99a</sup> Rh	-	2E+2	7E-8	2E-10	-	-	
		Y, see <sup>99a</sup> Rh	-	6E+1	2E-8	8E-11	-	-	
45	Rhodium-102m	D, see <sup>99a</sup> Rh	1E+3	5E+2	2E-7	7E-10	-	-	
		LLI wall	(1E+3)	-	-	-	2E-5	2E-4	
		W, see <sup>99a</sup> Rh	-	4E+2	2E-7	5E-10	-	-	
		Y, see <sup>99a</sup> Rh	-	1E+2	5E-8	2E-10	-	-	
45	Rhodium-103m <sup>2</sup>	D, see <sup>99a</sup> Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2	
		W, see <sup>99a</sup> Rh	-	1E+6	5E-4	2E-6	-	-	
		Y, see <sup>99a</sup> Rh	-	1E+6	5E-4	2E-6	-	-	
45	Rhodium-105	D, see <sup>99a</sup> Rh	4E+3	1E+4	5E-6	2E-8	-	-	
		LLI wall	(4E+3)	-	-	-	5E-5	5E-4	
		W, see <sup>99a</sup> Rh	-	6E+3	3E-6	9E-9	-	-	
		Y, see <sup>99a</sup> Rh	-	6E+3	2E-6	8E-9	-	-	
45	Rhodium-106m	D, see <sup>99a</sup> Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3	
		W, see <sup>99a</sup> Rh	-	4E+4	2E-5	5E-8	-	-	
		Y, see <sup>99a</sup> Rh	-	4E+4	1E-5	5E-8	-	-	



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
45 Rhodium-107 <sup>2</sup>	D, see <sup>99m</sup> Rh	7E+4 St wall (9E+4)	2E+5	1E-4	3E-7	-	-
	W, see <sup>99m</sup> Rh	-	3E+5	1E-4	4E-7	1E-3	1E-2
	Y, see <sup>99m</sup> Rh	-	3E+5	1E-4	3E-7	-	-
45 Rhodium-99	D, see <sup>99m</sup> Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
	W, see <sup>99m</sup> Rh	-	2E+3	9E-7	3E-9	-	-
	Y, see <sup>99m</sup> Rh	-	2E+3	8E-7	3E-9	-	-
45 Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
	W, halides	-	8E+4	3E-5	1E-7	-	-
	Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
37 Rubidium-79 <sup>2</sup>	D, all compounds	4E+4 St wall (6E+4)	1E+5	5E-5	2E-7	-	-
		-	-	-	-	8E-4	8E-3
37 Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37 Rubidium-81m <sup>2</sup>	D, all compounds	2E+5 St wall (3E+5)	3E+5	1E-4	5E-7	-	-
		-	-	-	-	4E-3	4E-2
37 Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37 Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37 Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37 Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37 Rubidium-88 <sup>2</sup>	D, all compounds	2E+4 St wall (3E+4)	6E+4	3E-5	9E-8	-	-
		-	-	-	-	4E-4	4E-3
37 Rubidium-89 <sup>2</sup>	D, all compounds	4E+4 St wall (6E+4)	1E+5	6E-5	2E-7	-	-
		-	-	-	-	9E-4	9E-3
44 Ruthenium-103	D, see <sup>94</sup> Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
	W, see <sup>94</sup> Ru	-	1E+3	4E-7	1E-9	-	-
	Y, see <sup>94</sup> Ru	-	6E+2	3E-7	9E-10	-	-
44 Ruthenium-105	D, see <sup>94</sup> Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
	W, see <sup>94</sup> Ru	-	1E+4	6E-6	2E-8	-	-
	Y, see <sup>94</sup> Ru	-	1E+4	5E-6	2E-8	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
44	Ruthenium-106	D, see $^{94}\text{Ru}$	2E+2	9E+1	4E-8	1E-10	-	-
		LLI wall (2E+2)	-	-	-	-	3E-6	3E-5
	W, see $^{94}\text{Ru}$	-	5E+1	2E-8	8E-11	-	-	-
	Y, see $^{94}\text{Ru}$	-	1E+1	5E-9	2E-11	-	-	-
44	Ruthenium-96 <sup>2</sup>	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	W, halides	-	6E+4	3E-5	9E-8	-	-	-
	Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-	-
44	Ruthenium-97	D, see $^{94}\text{Ru}$	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
	W, see $^{94}\text{Ru}$	-	1E+4	5E-6	2E-8	-	-	-
	Y, see $^{94}\text{Ru}$	-	1E+4	5E-6	2E-8	-	-	-
62	Samarium-141 <sup>2</sup>	W, all compounds	5E+4 St wall (6E+4)	2E+5	8E-5	2E-7	-	-
			-	-	-	8E-4	8E-3	8E-3
62	Samarium-141m <sup>2</sup>	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-142 <sup>2</sup>	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1 Bone surf (3E+1)	4E2 Bone surf (6E-2)	1E-11	-	-	-
			-	-	9E-14	3E-7	3E-6	3E-6
62	Samarium-147	W, all compounds	2E+1 Bone surf (3E+1)	4E2 Bone surf (7E-2)	2E-11	-	-	-
			-	-	1E-13	4E-7	4E-6	4E-6
62	Samarium-151	W, all compounds	1E+4 LLI wall (1E+4)	1E+2 Bone surf (2E+2)	4E-8	-	-	-
			-	-	2E-10	2E-4	2E-3	2E-3
62	Samarium-153	W, all compounds	2E+3 LLI wall (2E+3)	3E+3	1E-6	4E-9	-	-
			-	-	-	3E-5	3E-4	3E-4
62	Samarium-155 <sup>2</sup>	W, all compounds	6E+4 St wall (8E+4)	2E+5	9E-5	3E-7	-	-
			-	-	-	1E-3	1E-2	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases Sewers	
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2	Col. 3	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
			Inhalation					
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3 LLI wall (3E+3)	3E+3	1E-6	4E-9	-	-
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49 <sup>2</sup>	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
34	Selenium-70 <sup>2</sup>	D, all compounds except those given for W W, oxides, hydroxides, carbides, and elemental Se	2E+4 1E+4	4E+4	2E-5	5E-8	1E-4	1E-3
34	Selenium-73	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	3E+3 -	1E+4 2E+4	5E-6 7E-6	2E-8 2E-8	4E-5 -	4E-4 -
34	Selenium-73m <sup>2</sup>	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	6E+4 3E+4	2E+5 1E+5	6E-5 6E-5	2E-7 2E-7	4E-4 -	4E-3 -
34	Selenium-75	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	5E+2 -	7E+2 6E+2	3E-7 3E-7	1E-9 8E-10	7E-6 -	7E-5 -
34	Selenium-79	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	6E+2 -	8E+2 6E+2	3E-7 2E-7	1E-9 8E-10	8E-6 -	8E-5 -
34	Selenium-81 <sup>2</sup>	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	6E+4 St wall (8E+4) -	2E+5	9E-5	3E-7	- 1E-3	- 1E-2
34	Selenium-81m <sup>2</sup>	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	4E+4 2E+4	7E+4 7E+4	3E-5 3E-5	9E-8 1E-7	3E-4 -	3E-3 -
34	Selenium-83 <sup>2</sup>	D, see <sup>70</sup> Se W, see <sup>70</sup> Se	4E+4 3E+4	1E+5 1E+5	5E-5 5E-5	2E-7 2E-7	4E-4 -	4E-3 -
14	Silicon-31	D, all compounds except those given for W and Y W, oxides, hydroxides, carbides, and nitrates Y, aluminosilicate glass	9E+3 - -	3E+4 3E+4 3E+4	1E-5 1E-5 1E-5	4E-8 5E-8 4E-8	1E-4 - -	1E-3 - -

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation					Air ( $\mu\text{Ci/ml}$ )
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
14	Silicon-32	D, see $^{31}\text{Si}$	2E+3 LLI wall (3E+3)	2E+2	1E-7	3E-10	-	-
		W, see $^{31}\text{Si}$	-	1E+2	5E-8	2E-10	4E-5	4E-4
		Y, see $^{31}\text{Si}$	-	5E+0	2E-9	7E-12	-	-
47	Silver-102 <sup>2</sup>	D, all compounds except those given for W and Y	5E+4 St wall (6E+4)	2E+5	8E-5	2E-7	-	-
		W, nitrates and sulfides	-	2E+5	9E-5	3E-7	9E-4	9E-3
		Y, oxides and hydroxides	-	2E+5	8E-5	3E-7	-	-
47	Silver-103 <sup>2</sup>	D, see $^{102}\text{Ag}$	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see $^{102}\text{Ag}$	-	1E+5	5E-5	2E-7	-	-
		Y, see $^{102}\text{Ag}$	-	1E+5	5E-5	2E-7	-	-
47	Silver-104 <sup>2</sup>	D, see $^{102}\text{Ag}$	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see $^{102}\text{Ag}$	-	1E+5	6E-5	2E-7	-	-
		Y, see $^{102}\text{Ag}$	-	1E+5	6E-5	2E-7	-	-
47	Silver-104m <sup>2</sup>	D, see $^{102}\text{Ag}$	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see $^{102}\text{Ag}$	-	1E+5	5E-5	2E-7	-	-
		Y, see $^{102}\text{Ag}$	-	1E+5	5E-5	2E-7	-	-
47	Silver-105	D, see $^{102}\text{Ag}$	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see $^{102}\text{Ag}$	-	2E+3	7E-7	2E-9	-	-
		Y, see $^{102}\text{Ag}$	-	2E+3	7E-7	2E-9	-	-
47	Silver-106 <sup>2</sup>	D, see $^{102}\text{Ag}$	6E+4 St. wall (6E+4)	2E+5	8E-5	3E-7	-	-
		W, see $^{102}\text{Ag}$	-	2E+5	9E-5	3E-7	9E-4	9E-3
		Y, see $^{102}\text{Ag}$	-	2E+5	8E-5	3E-7	-	-
47	Silver-106m	D, see $^{102}\text{Ag}$	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see $^{102}\text{Ag}$	-	9E+2	4E-7	1E-9	-	-
		Y, see $^{102}\text{Ag}$	-	9E+2	4E-7	1E-9	-	-
47	Silver-108m	D, see $^{102}\text{Ag}$	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see $^{102}\text{Ag}$	-	3E+2	1E-7	4E-10	-	-
		Y, see $^{102}\text{Ag}$	-	2E+1	1E-8	3E-11	-	-
47	Silver-110m	D, see $^{102}\text{Ag}$	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see $^{102}\text{Ag}$	-	2E+2	8E-8	3E-10	-	-
		Y, see $^{102}\text{Ag}$	-	9E+1	4E-8	1E-10	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2   Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3   DAC ( $\mu\text{Ci/ml}$ )	Col. 1   Air ( $\mu\text{Ci/ml}$ )	Col. 2   Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
47	Silver-111	D, see $^{102}\text{Ag}$	9E+2 LLI wall (1E+3)	2E+3 Liver (2E+3)	6E-7	-	-
	W, see $^{102}\text{Ag}$	-	9E+2	4E-7	2E-9	2E-5	2E-4
	Y, see $^{102}\text{Ag}$	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see $^{102}\text{Ag}$	3E+3	8E+3	3E-6	1E-8	4E-4
	W, see $^{102}\text{Ag}$	-	1E+4	4E-6	1E-8	-	-
	Y, see $^{102}\text{Ag}$	-	9E+3	4E-6	1E-8	-	-
47	Silver-115 <sup>2</sup>	D, see $^{102}\text{Ag}$	3E+4 St wall (3E+4)	9E+4	4E-5	1E-7	-
	W, see $^{102}\text{Ag}$	-	9E+4	4E-5	-	4E-4	4E-3
	Y, see $^{102}\text{Ag}$	-	8E+4	3E-5	1E-7	-	-
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-4
38	Strontium-80 <sup>2</sup>	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-4
	Y, all insoluble com- pounds and SrTiO	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81 <sup>2</sup>	D, see $^{80}\text{Sr}$	3E+4	8E+4	3E-5	1E-7	3E-3
	Y, see $^{80}\text{Sr}$	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see $^{80}\text{Sr}$	3E+2 LLI wall (2E+2)	4E+2	2E-7	6E-10	-
	Y, see $^{80}\text{Sr}$	2E+2	9E+1	4E-8	1E-10	3E-6	3E-5
38	Strontium-83	D, see $^{80}\text{Sr}$	3E+3	7E+3	3E-6	1E-8	3E-4
	Y, see $^{80}\text{Sr}$	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85	D, see $^{80}\text{Sr}$	3E+3	3E+3	1E-6	4E-9	4E-4
	Y, see $^{80}\text{Sr}$	-	2E+3	6E-7	2E-9	-	-
38	Strontium-85m <sup>2</sup>	D, see $^{80}\text{Sr}$	2E+5	6E+5	3E-4	9E-7	3E-2
	Y, see $^{80}\text{Sr}$	-	8E+5	4E-4	1E-6	-	-
38	Strontium-87m	D, see $^{80}\text{Sr}$	5E+4	1E+5	5E-5	2E-7	6E-3
	Y, see $^{80}\text{Sr}$	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see $^{80}\text{Sr}$	6E+2 LLI wall (6E+2)	8E+2	4E-7	1E-9	-
	Y, see $^{80}\text{Sr}$	5E+2	1E+2	6E-8	2E-10	8E-6	8E-5

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
38 Strontium-90	D, see $^{86}\text{Sr}$	3E+1 Bone surf (4E+1)	2E+1 Bone surf (2E+1)	8E-9	-	-	-
	Y, see $^{86}\text{Sr}$	-	4E+0	2E-9	3E-11 6E-12	5E-7	5E-6
38 Strontium-91	D, see $^{86}\text{Sr}$	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
	Y, see $^{86}\text{Sr}$	-	4E+3	1E-6	5E-9	-	-
38 Strontium-92	D, see $^{86}\text{Sr}$	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
	Y, see $^{86}\text{Sr}$	-	7E+3	3E-6	9E-9	-	-
16 Sulfur-35	Vapor	1E+4	6E-6	2E-8	-	-	-
	D, sulfides and sulfates except those given for W	1E+4 LLI wall (8E+3)	2E+4	7E-6	2E-8	-	-
	W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3	-	-	-	1E-4	1E-3
73 Tantalum-172 <sup>2</sup>	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
	Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73 Tantalum-173	W, see $^{172}\text{Ta}$	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	Y, see $^{172}\text{Ta}$	-	2E+4	7E-6	2E-8	-	-
73 Tantalum-174 <sup>2</sup>	W, see $^{172}\text{Ta}$	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
	Y, see $^{172}\text{Ta}$	-	9E+4	4E-5	1E-7	-	-
73 Tantalum-175	W, see $^{172}\text{Ta}$	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
	Y, see $^{172}\text{Ta}$	-	1E+4	6E-6	2E-8	-	-
73 Tantalum-176	W, see $^{172}\text{Ta}$	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
	Y, see $^{172}\text{Ta}$	-	1E+4	5E-6	2E-8	-	-
73 Tantalum-177	W, see $^{172}\text{Ta}$	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
	Y, see $^{172}\text{Ta}$	-	2E+4	7E-6	2E-8	-	-
73 Tantalum-178	W, see $^{172}\text{Ta}$	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
	Y, see $^{172}\text{Ta}$	-	7E+4	3E-5	1E-7	-	-
73 Tantalum-179	W, see $^{172}\text{Ta}$	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
	Y, see $^{172}\text{Ta}$	-	9E+2	4E-7	1E-9	-	-



		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu$ Ci)	Col. 2   <u>Inhalation</u> ALI ( $\mu$ Ci)	Col. 3   DAC ( $\mu$ Ci/ml)	Col. 1   Air ( $\mu$ Ci/ml)	Col. 2   Water ( $\mu$ Ci/ml)	Monthly Average Concentration ( $\mu$ Ci/ml)	
73	Tantalum-180	W, see $^{172}\text{Ta}$ Y, see $^{172}\text{Ta}$	1E+3 -	4E+2 2E+1	2E-7 1E-8	6E-10 3E-11	2E-5 -	2E-4 -
73	Tantalum-180m	W, see $^{172}\text{Ta}$ Y, see $^{172}\text{Ta}$	2E+4 -	7E+4 6E+4	3E-5 2E-5	9E-8 8E-8	3E-4 -	3E-3 -
73	Tantalum-182	W, see $^{172}\text{Ta}$ Y, see $^{172}\text{Ta}$	8E+2 -	3E+2 1E+2	1E-7 6E-8	5E-10 2E-10	1E-5 -	1E-4 -
73	Tantalum-182m <sup>2</sup>	W, see $^{172}\text{Ta}$  Y, see $^{172}\text{Ta}$	2E+5 St wall (2E+5) -	5E+5 - 4E+5	2E-4 - 2E-4	8E-7 - 6E-7	- 3E-3 -	- 3E-2 -
73	Tantalum-183	W, see $^{172}\text{Ta}$  Y, see $^{172}\text{Ta}$	9E+2 LLI wall (1E+3) -	1E+3 - 1E+3	5E-7 - 4E-7	2E-9 - 1E-9	- 2E-5 -	- 2E-4 -
73	Tantalum-184	W, see $^{172}\text{Ta}$ Y, see $^{172}\text{Ta}$	2E+3 -	5E+3 5E+3	2E-6 2E-6	8E-9 7E-9	3E-5 -	3E-4 -
73	Tantalum-185 <sup>2</sup>	W, see $^{172}\text{Ta}$ Y, see $^{172}\text{Ta}$	3E+4 -	7E+4 6E+4	3E-5 3E-5	1E-7 9E-8	4E-4 -	4E-3 -
73	Tantalum-186 <sup>2</sup>	W, see $^{172}\text{Ta}$  Y, see $^{172}\text{Ta}$	5E+4 St wall (7E+4) -	2E+5 - 2E+5	1E-4 - 9E-5	3E-7 - 3E-7	- 1E-3 -	- 1E-2 -
43	Technetium-101 <sup>2</sup>	D, see $^{99\text{m}}\text{Tc}$  W, see $^{99\text{m}}\text{Tc}$	9E+4 St wall (1E+5) -	3E+5 - 4E+5	1E-4 - 2E-4	5E-7 - 5E-7	- 2E-3 -	- 2E-2 -
43	Technetium-104 <sup>2</sup>	D, see $^{99\text{m}}\text{Tc}$  W, see $^{99\text{m}}\text{Tc}$	2E+4 St wall (3E+4) -	7E+4 - 9E+4	3E-5 - 4E-5	1E-7 - 1E-7	- 4E-4 -	- 4E-3 -
43	Technetium-93	D, see $^{99\text{m}}\text{Tc}$ W, see $^{99\text{m}}\text{Tc}$	3E+4 -	7E+4 1E+5	3E-5 4E-5	1E-7 1E-7	4E-4 -	4E-3 -
43	Technetium-93m <sup>2</sup>	D, all compounds except those given for W W, oxides, hydroxides, halides, and nitrates	7E+4 - -	2E+5 3E+5 -	6E-5 1E-4 -	2E-7 4E-7 -	1E-3 - -	1E-2 - -
43	Technetium-94	D, see $^{99\text{m}}\text{Tc}$ W, see $^{99\text{m}}\text{Tc}$	9E+3 -	2E+4 2E+4	8E-6 1E-5	3E-8 3E-8	1E-4 -	1E-3 -

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 <div>Inhalation</div> <div>ALI (<math>\mu\text{Ci}</math>)</div>	Col. 3 <div>DAC (<math>\mu\text{Ci/ml}</math>)</div>	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
43	Technetium-94m <sup>2</sup>	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	2E+4 -	4E+4 6E+4	2E-5 2E-5	6E-8 8E-8	3E-4 -	3E-3 -
43	Technetium-95	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	1E+4 -	2E+4 2E+4	9E-6 8E-6	3E-8 3E-8	1E-4 -	1E-3 -
43	Technetium-95m	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	4E+3 -	5E+3 2E+3	2E-6 8E-7	8E-9 3E-9	5E-5 -	5E-4 -
43	Technetium-96	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	2E+3 -	3E+3 2E+3	1E-6 9E-7	5E-9 3E-9	3E-5 -	3E-4 -
43	Technetium-96m <sup>2</sup>	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	2E+5 -	3E+5 2E+5	1E-4 1E-4	4E-7 3E-7	2E-3 -	2E-2 -
43	Technetium-97	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	4E+4 -	5E+4 6E+3	2E-5 2E-6	7E-8 8E-9	5E-4 -	5E-3 -
43	Technetium-97m	D, see <sup>93m</sup> Tc	5E+3 St wall	7E+3	3E-6	-	6E-5	6E-4
		W, see <sup>93m</sup> Tc	- (7E+3) 1E+3	- 5E-7	1E-8 2E-9	-	-	-
43	Technetium-98	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	1E+3 -	2E+3 3E+2	7E-7 1E-7	2E-9 4E-10	1E-5 -	1E-4 -
43	Technetium-99	D, see <sup>93m</sup> Tc	4E+3	5E+3 St wall	2E-6	-	6E-5	6E-4
		W, see <sup>93m</sup> Tc	- (6E+3) 7E+2	- 3E-7	8E-9 9E-10	-	-	-
43	Technetium-99m	D, see <sup>93m</sup> Tc W, see <sup>93m</sup> Tc	8E+4 -	2E+5 2E+5	6E-5 1E-4	2E-7 3E-7	1E-3 -	1E-2 -
52	Tellurium-116	D, all compounds except those given for W W, oxides, hydroxides, and nitrates	8E+3 -	2E+4 3E+4	9E-6 1E-5	3E-8 4E-8	1E-4 -	1E-3 -
52	Tellurium-121	D, see <sup>116</sup> Te W, see <sup>116</sup> Te	3E+3 -	4E+3 3E+3	2E-6 1E-6	6E-9 4E-9	4E-5 -	4E-4 -
52	Tellurium-121m	D, see <sup>116</sup> Te	5E+2 Bone surf (7E+2)	2E+2 Bone surf (4E+2)	8E-8 -	-	-	-
		W, see <sup>116</sup> Te	- 4E+2	- 2E-7	5E-10 6E-10	1E-5 -	1E-4 -	-

		Table I Occupational Values			Table II Effluent Concentrations		Table II. Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 <div>Inhalation</div> ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
52	Tellurium-123	D, see $^{116}\text{Te}$	5E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	8E-8 -	- 7E-10	- 2E-5	- 2E-4
		W, see $^{116}\text{Te}$	- -	4E+2 Bone surf (1E+3)	- 2E-7	- 2E-9	- -	- -
52	Tellurium-123m	D, see $^{116}\text{Te}$	6E+2 Bone surf (1E+3)	2E+2 Bone surf (5E+2)	9E-8 -	- 8E-10	- 1E-5	- 1E-4
		W, see $^{116}\text{Te}$	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-125m	D, see $^{116}\text{Te}$	1E+3 Bone surf (1E+3)	4E+2 Bone surf (1E+3)	2E-7 -	- 1E-9	- 2E-5	- 2E-4
		W, see $^{116}\text{Te}$	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127	D, see $^{116}\text{Te}$	7E+2	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see $^{116}\text{Te}$	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-127m	D, see $^{116}\text{Te}$	6E+2	3E+2 Bone surf (4E+2)	1E-7 -	- 6E-10	9E-6 -	9E-5 -
		W, see $^{116}\text{Te}$	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-129 <sup>2</sup>	D, see $^{116}\text{Te}$	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see $^{116}\text{Te}$	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-129m	D, see $^{116}\text{Te}$	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see $^{116}\text{Te}$	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-131 <sup>2</sup>	D, see $^{116}\text{Te}$	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- 8E-5	- 8E-4
		W, see $^{116}\text{Te}$	-	5E+3 Thyroid (1E+4)	2E-6 -	- 2E-8	- -	- -
52	Tellurium-131m	D, see $^{116}\text{Te}$	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 -	- 2E-9	- 8E-6	- 8E-5
		W, see $^{116}\text{Te}$	-	4E+2 Thyroid (9E+2)	2E-7 -	- 1E-9	- -	- -

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )	Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
52 Tellurium-132	D, see $^{116}\text{Te}$	2E+2 Thyroid (7E+2)	2E+2 Thyroid (8E+2)	9E-8	-	-	-
	W, see $^{116}\text{Te}$	-	2E+2 Thyroid (6E+2)	9E-8	1E-9	9E-6	9E-5
		-	-	-	9E-10	-	-
52 Tellurium-133 <sup>2</sup>	D, see $^{116}\text{Te}$	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6	-	-	-
	W, see $^{116}\text{Te}$	-	2E+4 Thyroid (6E+4)	9E-6	8E-8	4E-4	4E-3
		-	-	-	8E-8	-	-
52 Tellurium-133m <sup>2</sup>	D, see $^{116}\text{Te}$	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6	-	-	-
	W, see $^{116}\text{Te}$	-	5E+3 Thyroid (1E+4)	2E-6	2E-8	9E-5	9E-4
		-	-	-	2E-8	-	-
52 Tellurium-134 <sup>2</sup>	D, see $^{116}\text{Te}$	2E+4 Thyroid (2E+4)	2E+4 Thyroid (5E+4)	1E-5	-	-	-
	W, see $^{116}\text{Te}$	-	2E+4 Thyroid (5E+4)	1E-5	7E-8	3E-4	3E-3
		-	-	-	7E-8	-	-
65 Terbium-147 <sup>2</sup>	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65 Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65 Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65 Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65 Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65 Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65 Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65 Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65 Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65 Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	DAC (μCi/ml)				
65	Terbium-157	W, all compounds	5E+4 LLI wall (5E+4)	3E+2 Bone surf (6E+2)	1E-7	-	-	-
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3 LLI wall (2E+3)	2E+3	7E-7	2E-9	-	-
							3E-5	3E-4
81	Thallium-194 <sup>2</sup>	D, all compounds	3E+5 St wall (3E+5)	6E+5	2E-4	8E-7	-	-
							4E-3	4E-2
81	Thallium-194m <sup>2</sup>	D, all compounds	5E+4 St wall (7E+4)	2E+5	6E-5	2E-7	-	-
							1E-3	1E-2
81	Thallium-195 <sup>2</sup>	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-198m <sup>2</sup>	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
90	Thorium-226 <sup>2</sup>	W, all compounds except those given for Y	5E+3 St wall (5E+3)	2E+2	6E-8	2E-10	-	-
	Y, oxides and hydroxides		-	1E+2	6E-8	2E-10	7E-5	7E-4
90	Thorium-227	W, see <sup>226</sup> Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
	Y, see <sup>226</sup> Th		-	3E-1	1E-10	5E-13	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			
90 Thorium-228	W, see $^{226}\text{Th}$	6E+0 Bone surf (1E+1)	1E-2 Bone surf (2E-2)	4E-12 -	- 3E-14	- 2E-7	- 2E-6
	Y, see $^{226}\text{Th}$	-	2E-2	7E-12	2E-14	-	-
90 Thorium-229	W, see $^{226}\text{Th}$	6E-1 Bone surf (1E+0)	9E-4 Bone surf (2E-3)	4E-13 -	- 3E-15	- 2E-8	- 2E-7
	Y, see $^{226}\text{Th}$	-	2E-3 Bone surf (3E-3)	1E-12 -	- 4E-15	-	-
90 Thorium-230	W, see $^{226}\text{Th}$	4E+0 Bone surf (9E+0)	6E-3 Bone surf (2E-2)	3E-12 -	- 2E-14	- 1E-7	- 1E-6
	Y, see $^{226}\text{Th}$	-	2E-2 Bone surf (2E-2)	6E-12 -	- 3E-14	-	-
90 Thorium-231	W, see $^{226}\text{Th}$	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
	Y, see $^{226}\text{Th}$	-	6E+3	3E-6	9E-9	-	-
90 Thorium-232	W, see $^{226}\text{Th}$	7E-1 Bone surf (2E+0)	1E-3 Bone surf (3E-3)	5E-13 -	- 4E-15	- 3E-8	- 3E-7
	Y, see $^{226}\text{Th}$	-	3E-3 Bone surf (4E-3)	1E-12 -	- 6E-15	-	-
90 Thorium-234	W, see $^{226}\text{Th}$	3E+2 LLI wall (4E+2)	2E+2	8E-8	3E-10	-	-
	Y, see $^{226}\text{Th}$	-	2E+2	6E-8	2E-10	5E-6	5E-5
69 Thulium-162 <sup>2</sup>	W, all compounds	7E+4 St wall (7E+4)	3E+5	1E-4	4E-7	- 1E-3	- 1E-2
69 Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69 Thulium-167	W, all compounds	2E+3 LLI wall (2E+3)	2E+3	8E-7	3E-9	- 3E-5	- 3E-4
69 Thulium-170	W, all compounds	8E+2 LLI wall (1E+3)	2E+2	9E-8	3E-10	- 1E-5	- 1E-4



Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration (μCi/ml)	
		Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)		
			ALI (μCi)	DAC (μCi/ml)				
69	Thulium-171	W, all compounds	1E+4 LLI wall (1E+4)	3E+2 Bone surf (6E+2)	1E-7	- 8E-10	- 2E-4	- 2E-3
69	Thulium-172	W, all compounds	7E+2 LLI wall (8E+2)	1E+3	5E-7	2E-9	- 1E-5	- 1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175 <sup>2</sup>	W, all compounds	7E+4 St wall (9E+4)	3E+5	1E-4	4E-7	- 1E-3	- 1E-2
50	Tin-110	D, all compounds except those given for W W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
			-	1E+4	5E-6	2E-8	-	-
50	Tin-111 <sup>2</sup>	D, see <sup>110</sup> Sn W, see <sup>110</sup> Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
			-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see <sup>110</sup> Sn	2E+3 LLI wall (2E+3)	1E+3	5E-7	2E-9	-	-
		W, see <sup>110</sup> Sn	-	5E+2	2E-7	8E-10	3E-5	3E-4
50	Tin-117m	D, see <sup>110</sup> Sn	2E+3 LLI wall (2E+3)	1E+3 Bone surf (2E+3)	5E-7	-	-	-
		W, see <sup>110</sup> Sn	-	1E+3	6E-7	3E-9 2E-9	3E-5	3E-4
50	Tin-119m	D, see <sup>110</sup> Sn	3E+3 LLI wall (4E+3)	2E+3	1E-6	3E-9	-	-
		W, see <sup>110</sup> Sn	-	1E+3	4E-7	1E-9	6E-5	6E-4
50	Tin-121	D, see <sup>110</sup> Sn	6E+3 LLI wall (6E+3)	2E+4	6E-6	2E-8	-	-
		W, see <sup>110</sup> Sn	-	1E+4	5E-6	2E-8	8E-5	8E-4
50	Tin-121m	D, see <sup>110</sup> Sn	3E+3 LLI wall (4E+3)	9E+2	4E-7	1E-9	-	-
		W, see <sup>110</sup> Sn	-	5E+2	2E-7	8E-10	5E-5	5E-4

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
50 Tin-123	D, see $^{110}\text{Sn}$	5E+2 LLI wall (6E+2)	6E+2	3E-7	9E-10	-	-
	W, see $^{110}\text{Sn}$	-	2E+2	7E-8	2E-10	9E-6	9E-5
50 Tin-123m <sup>2</sup>	D, see $^{110}\text{Sn}$	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
	W, see $^{110}\text{Sn}$	-	1E+5	6E-5	2E-7	-	-
50 Tin-125	D, see $^{110}\text{Sn}$	4E+2 LLI wall (5E+2)	9E+2	4E-7	1E-9	-	-
	W, see $^{110}\text{Sn}$	-	4E+2	1E-7	5E-10	6E-6	6E-5
50 Tin-126	D, see $^{110}\text{Sn}$	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
	W, see $^{110}\text{Sn}$	-	7E+1	3E-8	9E-11	-	-
50 Tin-127	D, see $^{110}\text{Sn}$	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
	W, see $^{110}\text{Sn}$	-	2E+4	8E-6	3E-8	-	-
50 Tin-128 <sup>2</sup>	D, see $^{110}\text{Sn}$	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
	W, see $^{110}\text{Sn}$	-	4E+4	1E-5	5E-8	-	-
22 Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
	W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
	Y, SrTiO <sub>3</sub>	-	6E+0	2E-9	8E-12	-	-
22 Titanium-45	D, see $^{44}\text{Ti}$	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
	W, see $^{44}\text{Ti}$	-	4E+4	1E-5	5E-8	-	-
	Y, see $^{44}\text{Ti}$	-	3E+4	1E-5	4E-8	-	-
74 Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74 Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74 Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74 Tungsten-179 <sup>2</sup>	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74 Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74 Tungsten-185	D, all compounds	2E+3 LLI wall (3E+3)	7E+3	3E-6	9E-9	-	-
		-	-	-	-	4E-5	4E-4
74 Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers		
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )		
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation					Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )					
74	Tungsten-188	D, all compounds	4E+2 LLI wall (5E+2)	1E+3	5E-7	2E-9	-	-	
92	Uranium-230	D, UF, UOF, UO(NO <sub>3</sub> )	4E+0 Bone surf (6E+0)	4E-1 Bone surf (6E-1)	2E-10	-	-	-	
	W, UO, UF, UCl	-	4E-1	1E-10	8E-13	8E-8	8E-7		
	Y, UO, UO	-	3E-1	1E-10	4E-13	-	-		
92	Uranium-231	D, see <sup>230</sup> U	5E+3 LLI wall (4E+3)	8E+3	3E-6	1E-8	-	-	
	W, see <sup>230</sup> U	-	6E+3	2E-6	8E-9	6E-5	6E-4		
	Y, see <sup>230</sup> U	-	5E+3	2E-6	6E-9	-	-		
92	Uranium-232	D, see <sup>230</sup> U	2E+0 Bone surf (4E+0)	2E-1 Bone surf (4E-1)	9E-11	-	-	-	
	W, see <sup>230</sup> U	-	4E-1	2E-10	6E-13	6E-8	6E-7		
	Y, see <sup>230</sup> U	-	8E-3	3E-12	5E-13	-	-		
92	Uranium-233	D, see <sup>230</sup> U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10	-	-	-	
	W, see <sup>230</sup> U	-	7E-1	3E-10	3E-12	3E-7	3E-6		
	Y, see <sup>230</sup> U	-	4E-2	2E-11	1E-12	-	-		
92	Uranium-234 <sup>3</sup>	D, see <sup>230</sup> U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10	-	-	-	
	W, see <sup>230</sup> U	-	7E-1	3E-10	3E-12	3E-7	3E-6		
	Y, see <sup>230</sup> U	-	4E-2	2E-11	1E-12	-	-		
92	Uranium-235 <sup>3</sup>	D, see <sup>230</sup> U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10	-	-	-	
	W, see <sup>230</sup> U	-	8E-1	3E-10	3E-12	3E-7	3E-6		
	Y, see <sup>230</sup> U	-	4E-2	2E-11	1E-12	-	-		
92	Uranium-236	D, see <sup>230</sup> U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10	-	-	-	
	W, see <sup>230</sup> U	-	8E-1	3E-10	3E-12	3E-7	3E-6		
	Y, see <sup>230</sup> U	-	4E-2	2E-11	1E-12	-	-		

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation ALI ( $\mu\text{Ci}$ )      DAC ( $\mu\text{Ci/ml}$ )		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	
92 Uranium-237	D, see $^{238}\text{U}$	2E+3 LLI wall (2E+3)	3E+3	1E-6	4E-9	-	-
	W, see $^{238}\text{U}$	-	2E+3	7E-7	2E-9	3E-5	3E-4
	Y, see $^{238}\text{U}$	-	2E+3	6E-7	2E-9	-	-
92 Uranium-238 <sup>1</sup>	D, see $^{238}\text{U}$	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10	-	-	-
	W, see $^{238}\text{U}$	-	8E-1	3E-10	3E-12	3E-7	3E-6
	Y, see $^{238}\text{U}$	-	4E-2	2E-11	1E-12 6E-14	-	-
92 Uranium-239 <sup>2</sup>	D, see $^{239}\text{U}$	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
	W, see $^{239}\text{U}$	-	2E+5	7E-5	2E-7	-	-
	Y, see $^{239}\text{U}$	-	2E+5	6E-5	2E-7	-	-
92 Uranium-240	D, see $^{239}\text{U}$	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
	W, see $^{239}\text{U}$	-	3E+3	1E-6	4E-9	-	-
	Y, see $^{239}\text{U}$	-	2E+3	1E-6	3E-9	-	-
92 Uranium-natural <sup>3</sup>	D, see $^{238}\text{U}$	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10	-	-	-
	W, see $^{238}\text{U}$	-	8E-1	3E-10	3E-12 9E-13	3E-7	3E-6
	Y, see $^{238}\text{U}$	-	5E-2	2E-11	7E-14	-	-
23 Vanadium-47 <sup>2</sup>	D, all compounds except those given for W	3E+4 St wall (3E+4)	8E+4	3E-5	1E-7	-	-
	W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	-	4E-4	4E-3
23 Vanadium-48	D, see $^{47}\text{V}$	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
	W, see $^{47}\text{V}$	-	6E+2	3E-7	9E-10	-	-
23 Vanadium-49	D, see $^{47}\text{V}$	7E+4 LLI wall (9E+4)	3E+4 Bone surf (3E+4)	1E-5	-	-	-
	W, see $^{47}\text{V}$	-	2E+4	8E-6	5E-8 2E-8	1E-3	1E-2
54 Xenon-120 <sup>2</sup>	Submersion <sup>1</sup>	-	-	1E-5	4E-8	-	-
54 Xenon-121 <sup>2</sup>	Submersion <sup>1</sup>	-	-	2E-6	1E-8	-	-
54 Xenon-122	Submersion <sup>1</sup>	-	-	7E-5	3E-7	-	-
54 Xenon-123	Submersion <sup>1</sup>	-	-	6E-6	3E-8	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI (μCi)	Col. 2	Col. 3	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
			Inhalation				
			ALI (μCi)	DAC (μCi/ml)			
54 Xenon-125	Submersion <sup>1</sup>	-	-	2E-5	7E-8	-	-
54 Xenon-127	Submersion <sup>1</sup>	-	-	1E-5	6E-8	-	-
54 Xenon-129m	Submersion <sup>1</sup>	-	-	2E-4	9E-7	-	-
54 Xenon-131m	Submersion <sup>1</sup>	-	-	4E-4	2E-6	-	-
54 Xenon-133	Submersion <sup>1</sup>	-	-	1E-4	5E-7	-	-
54 Xenon-133m	Submersion <sup>1</sup>	-	-	1E-4	6E-7	-	-
54 Xenon-135	Submersion <sup>1</sup>	-	-	1E-5	7E-8	-	-
54 Xenon-135m <sup>2</sup>	Submersion <sup>1</sup>	-	-	9E-6	4E-8	-	-
54 Xenon-138 <sup>2</sup>	Submersion <sup>1</sup>	-	-	4E-6	2E-8	-	-
70 Ytterbium-162 <sup>2</sup>	W, all compounds except those given for Y, oxides, hydroxides, and fluorides	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		-	3E+5	1E-4	4E-7	-	-
70 Ytterbium-166	W, see <sup>162</sup> Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
	Y, see <sup>162</sup> Yb	-	2E+3	8E-7	3E-9	-	-
70 Ytterbium-167 <sup>2</sup>	W, see <sup>162</sup> Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
	Y, see <sup>162</sup> Yb	-	7E+5	3E-4	1E-6	-	-
70 Ytterbium-169	W, see <sup>162</sup> Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
	Y, see <sup>162</sup> Yb	-	7E+2	3E-7	1E-9	-	-
70 Ytterbium-175	W, see <sup>167</sup> Yb	3E+3	4E+3	1E-6	5E-9	-	-
	LLI wall (3E+3)	-	-	-	-	4E-5	4E-4
	Y, see <sup>162</sup> Yb	-	3E+3	1E-6	5E-9	-	-
70 Ytterbium-177 <sup>2</sup>	W, see <sup>162</sup> Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
	Y, see <sup>162</sup> Yb	-	5E+4	2E-5	6E-8	-	-
70 Ytterbium-178 <sup>2</sup>	W, see <sup>162</sup> Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
	Y, see <sup>162</sup> Yb	-	4E+4	2E-5	5E-8	-	-
39 Yttrium-86	W, see <sup>86m</sup> Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
	Y, see <sup>86m</sup> Y	-	3E+3	1E-6	5E-9	-	-
39 Yttrium-86m <sup>2</sup>	W, all compounds except those given for Y, oxides and hydroxides	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		-	5E+4	2E-5	8E-8	-	-

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1 Oral Ingestion ALI ( $\mu\text{Ci}$ )	Col. 2 Inhalation ALI ( $\mu\text{Ci}$ )	Col. 3 DAC ( $\mu\text{Ci/ml}$ )	Col. 1 Air ( $\mu\text{Ci/ml}$ )	Col. 2 Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
39 Yttrium-87	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	2E+3 -	3E+3 3E+3	1E-6 1E-6	5E-9 5E-9	3E-5 -	3E-4 -
39 Yttrium-88	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	1E+3 -	3E+2 2E+2	1E-7 1E-7	3E-10 3E-10	1E-5 -	1E-4 -
39 Yttrium-90	W, see $^{86}\text{SrY}$  Y, see $^{86}\text{SrY}$	4E+2 LLI wall (5E+2) -	7E+2 - 6E+2	3E-7 - 3E-7	9E-10 - 9E-10	- 7E-6 -	- 7E-5 -
39 Yttrium-90m	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	8E+3 -	1E+4 1E+4	5E-6 5E-6	2E-8 2E-8	1E-4 -	1E-3 -
39 Yttrium-91	W, see $^{86}\text{SrY}$  Y, see $^{86}\text{SrY}$	5E+2 LLI wall (6E+2) -	2E+2 - 1E+2	7E-8 - 5E-8	2E-10 - 2E-10	- 8E-6 -	- 8E-5 -
39 Yttrium-91m <sup>2</sup>	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	1E+5 -	2E+5 2E+5	1E-4 7E-5	3E-7 2E-7	2E-3 -	2E-2 -
39 Yttrium-92	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	3E+3 -	9E+3 8E+3	4E-6 3E-6	1E-8 1E-8	4E-5 -	4E-4 -
39 Yttrium-93	W, see $^{86}\text{SrY}$ Y, see $^{86}\text{SrY}$	1E+3 -	3E+3 2E+3	1E-6 1E-6	4E-9 3E-9	2E-5 -	2E-4 -
39 Yttrium-94 <sup>2</sup>	W, see $^{86}\text{SrY}$  Y, see $^{86}\text{SrY}$	2E+4 St wall (3E+4) -	8E+4 - 8E+4	3E-5 - 3E-5	1E-7 - 1E-7	- 4E-4 -	- 4E-3 -
39 Yttrium-95 <sup>2</sup>	W, see $^{86}\text{SrY}$  Y, see $^{86}\text{SrY}$	4E+4 St wall (5E+4) -	2E+5 - 1E+5	6E-5 - 6E-5	2E-7 - 2E-7	- 7E-4 -	- 7E-3 -
30 Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30 Zinc-63 <sup>2</sup>	Y, all compounds	2E+4 St wall (3E+4)	7E+4 - -	3E-5 - -	9E-8 - -	- 3E-4	- 3E-3
30 Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30 Zinc-69 <sup>2</sup>	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3



		Table I Occupational values			Table II Effluent Concentrations		Table III Releases to Sewers	
Atomic Radionuclide No.	Class	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
	W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-	-
	Y, carbide	-	2E+3	1E-6	3E-9	-	-	-
40	Zirconium-88	D, see $^{86}\text{Zr}$	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
	W, see $^{86}\text{Zr}$	-	5E+2	2E-7	7E-10	-	-	-
	Y, see $^{86}\text{Zr}$	-	3E+2	1E-7	4E-10	-	-	-
40	Zirconium-89	D, see $^{86}\text{Zr}$	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
	W, see $^{86}\text{Zr}$	-	2E+3	1E-6	3E-9	-	-	-
	Y, see $^{86}\text{Zr}$	-	2E+3	1E-6	3E-9	-	-	-
40	Zirconium-93	D, see $^{86}\text{Zr}$	1E+3	6E+0	3E-9	-	-	-
	Bone surf	(3E+3)	Bone surf	(2E+1)	-	2E-11	4E-5	4E-4
	W, see $^{86}\text{Zr}$	-	2E+1	1E-8	-	-	-	-
	-	-	Bone surf	(6E+1)	-	9E-11	-	-
	see $^{86}\text{Zr}$	-	6E+1	2E-8	-	-	-	-
	-	-	Bone surf	(7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see $^{86}\text{Zr}$	1E+3	1E+2	5E-8	-	2E-5	2E-4
	-	-	Bone surf	(3E+2)	-	4E-10	-	-
	W, see $^{86}\text{Zr}$	-	4E+2	2E-7	5E-10	-	-	-
	Y, see $^{86}\text{Zr}$	-	3E+2	1E-7	4E-10	-	-	-
40	Zirconium-97	D, see $^{86}\text{Zr}$	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
	W, see $^{86}\text{Zr}$	-	1E+3	6E-7	2E-9	-	-	-
	Y, see $^{86}\text{Zr}$	-	1E+3	5E-7	2E-9	-	-	-

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	Inhalation				Monthly Average Concentration
Atomic Radionuclide No.	Class	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Concentration (μCi/ml)
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours	Submersion <sup>1</sup>	2E+2	1E-7	1E-9	-	-
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours	. . . .	2E-1	1E-10	1E-12	1E-8	1E-7
-	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known	. . . .	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

<sup>1</sup>"Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

<sup>2</sup>These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See § 20.1203.)

<sup>3</sup>For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see § 20.1201(e)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

$$SA = 3.6E-7 \text{ curies/gram U} \quad \text{U-depleted}$$

$$SA = [0.4 + 0.38 (\text{enrichment}) + 0.0034 (\text{enrichment})^2] E-6, \quad \text{enrichment} \geq 0.72$$

where enrichment is the percentage by weight of U-235, expressed as percent.

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table II Releases to Sewers	
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )	
		Oral Ingestion ALI ( $\mu\text{Ci}$ )	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )		
			ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )				

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.
2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

If it is known that Ac-227-D and Cm-250-W are not present

7E-4      3E-13      -      -      -

If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present

7E-3      3E-12      -      -      -

If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present

7E-2      3E-11      -      -      -

If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present

7E-1      3E-10      -      -      -

If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present

7E+0      3E-9      -      -      -

		Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	Inhalation				Monthly Average Concentration
Atomic Radionuclide No.	Class	ALI ( $\mu\text{Ci}$ )	ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )	Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	Concentration ( $\mu\text{Ci/ml}$ )

If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-246-W, and Cm-250-W are not present

- - - 1E-14 - -

If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present

- - - 1E-13 - -

If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present

- - - 1E-12 -

If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present

- - - 1E-6 1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10  $\mu\text{m}$  AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11  $\mu\text{Ci}$  of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11  $\mu\text{Ci}$  of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B to §§ 20.1901 - 20.2401 for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Atomic Radionuclide No.	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
		Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
		Oral Ingestion	Inhalation		Air ( $\mu\text{Ci/ml}$ )	Water ( $\mu\text{Ci/ml}$ )	Monthly Average Concentration ( $\mu\text{Ci/ml}$ )
		ALI ( $\mu\text{Ci}$ )	ALI ( $\mu\text{Ci}$ )	DAC ( $\mu\text{Ci/ml}$ )			

Example: If radionuclides "A," "B," and "C" are present in concentrations  $C_A$ ,  $C_B$ , and  $C_C$ , and if the applicable DACs are  $\text{DAC}_A$ ,  $\text{DAC}_B$ , and  $\text{DAC}_C$ , respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{\text{DAC}_A} + \frac{C_B}{\text{DAC}_B} + \frac{C_C}{\text{DAC}_C} \leq 1$$

## Part 4

## APPENDIX C

QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity ( $\mu$ Ci)*	Radionuclide	Quantity ( $\mu$ Ci)*
Actinium-224	1	Barium-126	1,000
Actinium-225	0.01	Barium-128	100
Actinium-226	0.1	Barium-131	100
Actinium-227	0.001	Barium-131m	1,000
Actinium-228	1	Barium-133	100
Aluminum-26	10	Barium-133m	100
Americium-237	1,000	Barium-135m	100
Americium-238	100	Barium-139	1,000
Americium-239	1,000	Barium-140	100
Americium-240	100	Barium-141	1,000
Americium-241	0.001	Barium-142	1,000
Americium-242	10	Berkelium-245	100
Americium-242m	0.001	Berkelium-246	100
Americium-243	0.001	Berkelium-247	0.001
Americium-244	10	Berkelium-249	0.1
Americium-244m	100	Berkelium-250	10
Americium-245	1,000	Beryllium-10	1
Americium-246	1,000	Beryllium-7	1,000
Americium-246m	1,000	Bismuth-200	1,000
Antimony-115	1,000	Bismuth-201	1,000
Antimony-116	1,000	Bismuth-202	1,000
Antimony-116m	1,000	Bismuth-203	100
Antimony-117	1,000	Bismuth-205	100
Antimony-118m	1,000	Bismuth-206	100
Antimony-119	1,000	Bismuth-207	10
Antimony-120 (16m)	1,000	Bismuth-210	1
Antimony-120 (5.76d)	100	Bismuth-210m	0.1
Antimony-122	100	Bismuth-212	10
Antimony-124	10	Bismuth-213	10
Antimony-124m	1,000	Bismuth-214	100
Antimony-125	100	Bromine-74	1,000
Antimony-126	100	Bromine-74m	1,000
Antimony-126m	1,000	Bromine-75	1,000
Antimony-127	100	Bromine-76	100
Antimony-128 (10.4m)	1,000	Bromine-77	1,000
Antimony-128 (9.01h)	100	Bromine-80	1,000
Antimony-129	100	Bromine-80m	1,000
Antimony-130	1,000	Bromine-82	100
Antimony-131	1,000	Bromine-83	1,000
Argon-39	1,000	Bromine-84	1,000
Argon-41	1,000	Cadmium-104	1,000
Arsenic-69	1,000	Cadmium-107	1,000
Arsenic-70	1,000	Cadmium-109	1
Arsenic-71	100	Cadmium-113	100
Arsenic-72	100	Cadmium-113m	0.1
Arsenic-73	100	Cadmium-115	100
Arsenic-74	100	Cadmium-115m	10
Arsenic-76	100	Cadmium-117	1,000
Arsenic-77	100	Cadmium-117m	1,000
Arsenic-78	1,000	Calcium-41	100
Astatine-207	100	Calcium-45	100
Astatine-211	10	Calcium-47	100

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.



# APPENDIX C

## QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity ( $\mu$ Ci)*	Radionuclide Quantity	Quantity ( $\mu$ Ci)*
Californium-244	100	Curium-245	0.001
Californium-246	1	Curium-246	0.001
Californium-248	0.01	Curium-247	0.001
Californium-249	0.001	Curium-248	0.001
Californium-250	0.001	Curium-249	1,000
Californium-251	0.001	Dysprosium-155	1,000
Californium-252	0.001	Dysprosium-157	1,000
Californium-253	0.1	Dysprosium-159	100
Californium-254	0.001	Dysprosium-165	1,000
Carbon-11	1,000	Dysprosium-166	100
Carbon-14	1,000	Einsteinium-250	100
Cerium-134	100	Einsteinium-251	100
Cerium-135	100	Einsteinium-253	0.1
Cerium-137	1,000	Einsteinium-254	0.01
Cerium-137m	100	Einsteinium-254m	1
Cerium-139	100	Erbium-161	1,000
Cerium-141	100	Erbium-165	1,000
Cerium-143	100	Erbium-169	100
Cerium-144	1	Erbium-171	100
Cesium-125	1,000	Erbium-172	100
Cesium-127	1,000	Europium-145	100
Cesium-129	1,000	Europium-146	100
Cesium-130	1,000	Europium-147	100
Cesium-131	1,000	Europium-148	10
Cesium-132	100	Europium-149	100
Cesium-134	10	Europium-150 (12.62h)	100
Cesium-134m	1,000	Europium-150 (34.2y)	1
Cesium-135	100	Europium-152	1
Cesium-135m	1,000	Europium-152m	100
Cesium-136	10	Europium-154	1
Cesium-137	10	Europium-155	10
Cesium-138	1,000	Europium-156	100
Chlorine-36	10	Europium-157	100
Chlorine-38	1,000	Europium-158	1,000
Chlorine-39	1,000	Fermium-252	1
Chromium-48	1,000	Fermium-253	1
Chromium-49	1,000	Fermium-254	10
Chromium-51	1,000	Fermium-255	1
Cobalt-55	100	Fermium-257	0.01
Cobalt-56	10	Fluorine-18	1,000
Cobalt-57	100	Francium-22	100
Cobalt-58	100	Francium-223	100
Cobalt-58m	1,000	Gadolinium-145	1,000
Cobalt-60	1	Gadolinium-146	10
Cobalt-60m	1,000	Gadolinium-147	100
Cobalt-61	1,000	Gadolinium-148	0.001
Cobalt-62m	1,000	Gadolinium-149	100
Copper-60	1,000	Gadolinium-151	10
Copper-61	1,000	Gadolinium-152	100
Copper-64	1,000	Gadolinium-153	10
Copper-67	1,000	Gadolinium-159	100
Curium-238	100	Gallium-65	1,000
Curium-240	0.1	Gallium-66	100
Curium-241	1	Gallium-67	1,000
Curium-242	0.01	Gallium-68	1,000
Curium-243	0.001	Gallium-70	1,000
Curium-244	0.001	Gallium-72	100

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

# APPENDIX C

## QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity ( $\mu$ Ci) *	Radionuclide Quantity	Quantity ( $\mu$ Ci) *
Gallium-73	1,000	Indium-119m	1,000
Germanium-66	1,000	Iodine-120	100
Germanium-67	1,000	Iodine-120m	1,000
Germanium-68	10	Iodine-121	1,000
Germanium-69	1,000	Iodine-123	100
Germanium-71	1,000	Iodine-124	10
Germanium-75	1,000	Iodine-125	1
Germanium-77	1,000	Iodine-126	1
Germanium-78	1,000	Iodine-128	1,000
Gold-193	1,000	Iodine-129	1
Gold-194	100	Iodine-130	10
Gold-195	10	Iodine-131	1
Gold-198	100	Iodine-132	100
Gold-198m	100	Iodine-132m	100
Gold-199	100	Iodine-133	10
Gold-200	1,000	Iodine-134	1,000
Gold-200m	100	Iodine-135	100
Gold-201	1,000	Iridium-182	1,000
Hafnium-170	100	Iridium-184	1,000
Hafnium-172	1	Iridium-185	1,000
Hafnium-173	1,000	Iridium-186	100
Hafnium-175	100	Iridium-187	1,000
Hafnium-177m	1,000	Iridium-188	100
Hafnium-178m	0.1	Iridium-189	100
Hafnium-179m	10	Iridium-190	100
Hafnium-180m	1,000	Iridium-190m	1,000
Hafnium-181	10	Iridium-192 (73.8d)	1
Hafnium-182	0.1	Iridium-192m (1.4m)	10
Hafnium-182m	1,000	Iridium-194	100
Hafnium-183	1,000	Iridium-194m	10
Hafnium-184	100	Iridium-195	1,000
Holmium-155	1,000	Iridium-195m	1,000
Holmium-157	1,000	Iron-52	100
Holmium-159	1,000	Iron-55	100
Holmium-161	1,000	Iron-59	10
Holmium-162	1,000	Iron-60	1
Holmium-162m	1,000	Krypton-74	1,000
Holmium-164	1,000	Krypton-76	1,000
Holmium-164m	1,000	Krypton-77	1,000
Holmium-166	100	Krypton-79	1,000
Holmium-166m	1	Krypton-81	1,000
Holmium-167	1,000	Krypton-83m	1,000
Hydrogen-3	1,000	Krypton-85	1,000
Indium-109	1,000	Krypton-85m	1,000
Indium-110 (69.1m)	1,000	Krypton-87	1,000
Indium-110m (4.9h)	1,000	Krypton-88	1,000
Indium-111	100	Lanthanum-131	1,000
Indium-112	1,000	Lanthanum-132	100
Indium-113m	1,000	Lanthanum-135	1,000
Indium-114m	10	Lanthanum-137	10
Indium-115	100	Lanthanum-138	100
Indium-115m	1,000	Lanthanum-14	1,000
Indium-116m	1,000	Lanthanum-140	100
Indium-117	1,000	Lanthanum-141	100
Indium-117m	1,000	Lanthanum-143	1,000

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

APPENDIX C

QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	( $\mu$ Ci)*	Quantity	Radionuclide ( $\mu$ Ci)*
Lead-195m	1,000	Neodymium-147	100
Lead-198	1,000	Neodymium-149	1,000
Lead-199	1,000	Neodymium-151	1,000
Lead-200	100	Neptunium-232	100
Lead-201	1,000	Neptunium-233	1,000
Lead-202	10	Neptunium-235	100
Lead-202m	1,000	Neptunium-236 (1.15E+5y)	0.001
Lead-203	1,000	Neptunium-236 (22.5h)	1
Lead-205	100	Neptunium-237	0.001
Lead-209	1,000	Neptunium-238	10
Lead-210	0.01	Neptunium-239	100
Lead-211	100	Neptunium-240	1,000
Lead-212	1	Neptunium-234	100
Lead-214	100	Nickel-56	100
Lutetium-169	100	Nickel-57	100
Lutetium-170	100	Nickel-59	100
Lutetium-171	100	Nickel-63	100
Lutetium-172	100	Nickel-65	1,000
Lutetium-173	10	Nickel-66	10
Lutetium-174	10	Niobium-88	1,000
Lutetium-174m	10	Niobium-89 (122 min)	1,000
Lutetium-176	100	Niobium-89m (66 min)	1,000
Lutetium-176m	1,000	Niobium-90	100
Lutetium-177	100	Niobium-93m	10
Lutetium-177m	10	Niobium-94	1
Lutetium-178	1,000	Niobium-95	100
Lutetium-178m	1,000	Niobium-95m	100
Lutetium-179	1,000	Niobium-96	100
Magnesium-28	100	Niobium-97	1,000
Manganese-51	1,000	Niobium-98	1,000
Manganese-52	100	Osmium-180	1,000
Manganese-52m	1,000	Osmium-181	1,000
Manganese-53	1,000	Osmium-182	100
Manganese-54	100	Osmium-185	100
Manganese-56	1,000	Osmium-189m	1,000
Mendelevium-257	10	Osmium-191	100
Mendelevium-258	0.01	Osmium-191m	1,000
Mercury-193	1,000	Osmium-193	100
Mercury-193m	100	Osmium-194	1
Mercury-194	1	Palladium-100	100
Mercury-195	1,000	Palladium-101	1,000
Mercury-195m	100	Palladium-103	100
Mercury-197	1,000	Palladium-107	10
Mercury-197m	100	Palladium-109	100
Mercury-199m	1,000	Phosphorus-32	10
Mercury-203	100	Phosphorus-33	100
Molybdenum-101	1,000	Platinum-186	1,000
Molybdenum-90	100	Platinum-188	100
Molybdenum-93	10	Platinum-189	1,000
Molybdenum-93m	100	Platinum-191	100
Molybdenum-99	100	Platinum-193	1,000
Neodymium-136	1,000	Platinum-193m	100
Neodymium-138	100	Platinum-195m	100
Neodymium-139	1,000	Platinum-197	100
Neodymium-139m	1,000	Platinum-197m	1,000
Neodymium-141	1,000		

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

# APPENDIX C

## QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity ( $\mu$ Ci)*	Radionuclide Quantity	Quantity ( $\mu$ Ci)*
Platinum-199	1,000	Radium-225	0.1
Platinum-200	100	Radium-226	0.1
Plutonium-234	10	Radium-227	1,000
Plutonium-235	1,000	Radium-228	0.1
Plutonium-236	0.001	Radon-220	1
Plutonium-237	100	Radon-222	1
Plutonium-238	0.001	Rhenium-177	1,000
Plutonium-239	0.001	Rhenium-178	1,000
Plutonium-240	0.001	Rhenium-181	1,000
Plutonium-241	0.01	Rhenium-182 (12.7h)	1,000
Plutonium-242	0.001	Rhenium-182 (64.0h)	100
Plutonium-243	1,000	Rhenium-184	100
Plutonium-244	0.001	Rhenium-184m	10
Plutonium-245	100	Rhenium-186	100
Polonium-203	1,000	Rhenium-186m	10
Polonium-205	1,000	Rhenium-187	1,000
Polonium-207	1,000	Rhenium-188	100
Polonium-210	0.1	Rhenium-188m	1,000
Potassium-40	100	Rhenium-189	100
Potassium-42	1,000	Rhodium-100	100
Potassium-43	1,000	Rhodium-101	10
Potassium-44	1,000	Rhodium-101m	1,000
Potassium-45	1,000	Rhodium-102	10
Praseodymium-136	1,000	Rhodium-102m	10
Praseodymium-137	1,000	Rhodium-103m	1,000
Praseodymium-138m	1,000	Rhodium-105	100
Praseodymium-139	1,000	Rhodium-106m	1,000
Praseodymium-142	100	Rhodium-107	1,000
Praseodymium-142m	1,000	Rhodium-99	100
Praseodymium-143	100	Rhodium-99m	1,000
Praseodymium-144	1,000	Rubidium-79	1,000
Praseodymium-145	100	Rubidium-81	1,000
Praseodymium-147	1,000	Rubidium-81m	1,000
Promethium-141	1,000	Rubidium-82m	1,000
Promethium-143	100	Rubidium-83	100
Promethium-144	10	Rubidium-84	100
Promethium-145	10	Rubidium-86	100
Promethium-146	1	Rubidium-87	100
Promethium-147	10	Rubidium-88	1,000
Promethium-148	10	Rubidium-89	1,000
Promethium-148m	10	Ruthenium-103	100
Promethium-149	100	Ruthenium-105	1,000
Promethium-150	1,000	Ruthenium-106	1
Promethium-151	100	Ruthenium-94	1,000
Protactinium-227	10	Ruthenium-97	1,000
Protactinium-228	1	Samarium-141	1,000
Protactinium-230	0.1	Samarium-141m	1,000
Protactinium-231	0.001	Samarium-142	1,000
Protactinium-232	1	Samarium-145	100
Protactinium-233	100	Samarium-146	1
Protactinium-234	100	Samarium-147	100
Radium-223	0.1	Samarium-151	10
Radium-224	0.1	Samarium-153	100

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

# APPENDIX C

## QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity ( $\mu$ Ci) *	Radionuclide Quantity	Quantity ( $\mu$ Ci) *
Samarium-154	1,000	Tantalum-182m	1,000
Samarium-156	1,000	Tantalum-183	100
Scandium-43	1,000	Tantalum-184	100
Scandium-44	100	Tantalum-185	1,000
Scandium-44m	100	Tantalum-186	1,000
Scandium-46	10	Technetium-101	1,000
Scandium-47	100	Technetium-104	1,000
Scandium-48	10	Technetium-93	1,000
Scandium-49	1,000	Technetium-93m	1,000
Selenium-70	1,000	Technetium-94	1,000
Selenium-73	100	Technetium-94m	1,000
Selenium-73m	1,000	Technetium-96	100
Selenium-75	100	Technetium-96m	1,000
Selenium-79	100	Technetium-97	1,000
Selenium-81	1,000	Technetium-97m	100
Selenium-81m	1,000	Technetium-98	10
Selenium-83	1,000	Technetium-99	100
Silicon-2	1	Technetium-99m	1,000
Silicon-31	1,000	Tellurium-116	1,000
Silver-102	1,000	Tellurium-121	100
Silver-103	1,000	Tellurium-121m	10
Silver-104	1,000	Tellurium-123	100
Silver-104m	1,000	Tellurium-123m	10
Silver-105	100	Tellurium-125m	10
Silver-106	1,000	Tellurium-127	1,000
Silver-106m	100	Tellurium-127m	10
Silver-108m	1	Tellurium-129	1,000
Silver-111	100	Tellurium-129m	10
Silver-112	100	Tellurium-131	100
Silver-115	1,000	Tellurium-131m	10
Silver-110m	10	Tellurium-132	10
Sodium-22	10	Tellurium-133	1,000
Sodium-24	100	Tellurium-133m	100
Strontium-80	100	Tellurium-134	1,000
Strontium-81	1,000	Terbium-147	1,000
Strontium-83	100	Terbium-149	100
Strontium-85	100	Terbium-150	1,000
Strontium-85m	1,000	Terbium-151	100
Strontium-87m	1,000	Terbium-153	1,000
Strontium-89	10	Terbium-154	100
Strontium-90	0.1	Terbium-155	1,000
Strontium-91	100	Terbium-156	100
Strontium-92	100	Terbium-156m(5.0h)	1,000
Sulfur-35	100	Terbium-156m(24.4h)	1,000
Tantalum-172	1,000	Terbium-157	10
Tantalum-173	1,000	Terbium-158	1
Tantalum-174	1,000	Terbium-160	10
Tantalum-175	1,000	Terbium-161	100
Tantalum-176	100	Thallium-194	1,000
Tantalum-177	1,000	Thallium-194m	1,000
Tantalum-178	1,000	Thallium-195	1,000
Tantalum-179	100	Thallium-197	1,000
Tantalum-180	100	Thallium-198	1,000
Tantalum-180m	1,000	Thallium-198m	1,000
Tantalum-182	10	Thallium-199	1,000

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

APPENDIX C

QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity (μCi)*	Radionuclide Quantity	Quantity (μCi)*
Thallium-200	1,000	Uranium-231	100
Thallium-201	1,000	Uranium-232	0.001
Thallium-202	100	Uranium-233	0.001
Thallium-204	100	Uranium-234	0.001
Thorium-226	10	Uranium-235	0.001
Thorium-227	0.01	Uranium-236	0.001
Thorium-228	0.001	Uranium-237	100
Thorium-229	0.001	Uranium-238	100
Thorium-230	0.001	Uranium-239	1,000
Thorium-231	100	Uranium-240	100
Thorium-232	100	Uranium-natural	100
Thorium-234	10	Vanadium-47	1,000
Thorium-natural	100	Vanadium-48	100
Thulium-162	1,000	Vanadium-49	1,000
Thulium-166	100	Xenon-120	1,000
Thulium-167	100	Xenon-121	1,000
Thulium-170	10	Xenon-122	1,000
Thulium-171	10	Xenon-123	1,000
Thulium-172	100	Xenon-125	1,000
Thulium-173	100	Xenon-127	1,000
Thulium-175	1,000	Xenon-129m	1,000
Tin-110	100	Xenon-131m	1,000
Tin-111	1,000	Xenon-133	1,000
Tin-113	100	Xenon-133m	1,000
Tin-117m	100	Xenon-135	1,000
Tin-119m	100	Xenon-135m	1,000
Tin-121	1,000	Xenon-138	1,000
Tin-121m	100	Ytterbium-162	1,000
Tin-123	10	Ytterbium-166	100
Tin-123m	1,000	Ytterbium-167	1,000
Tin-125	10	Ytterbium-169	100
Tin-126	10	Ytterbium-175	100
Tin-127	1,000	Ytterbium-177	1,000
Tin-128	1,000	Ytterbium-178	1,000
Titanium-44	1	Yttrium-86	100
Titanium-45	1,000	Yttrium-86m	1,000
Tungsten-176	1,000	Yttrium-87	100
Tungsten-177	1,000	Yttrium-88	10
Tungsten-178	1,000	Yttrium-90	10
Tungsten-179	1,000	Yttrium-90m	1,000
Tungsten-18	100	Yttrium-91	10
Tungsten-181	1,000	Yttrium-91m	1,000
Tungsten-187	100	Yttrium-92	100
Tungsten-188	10	Yttrium-93	100
Uranium-230	0.01	Yttrium-94	1,000
		Yttrium-95	1,000

\* To convert μCi to kBq, multiply the μCi value by 37.



APPENDIX C

QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide Quantity	Quantity ( $\mu$ Ci)*	Radionuclide Quantity	Quantity ( $\mu$ Ci)*
Zinc-62	100		
Zinc-63	1,000		
Zinc-65	10		
Zinc-69	1,000		
Zinc-69m	100		
Zinc-71m	1,000		
Zinc-72	100		
Zirconium-86	100		
Zirconium-88	10		
Zirconium-89	100		
Zirconium-93	1		
Zirconium-95	10		
Zirconium-97	100		

Any alpha-emitting  
radionuclide not  
listed above or  
mixtures of alpha  
emitters of unknown  
composition

0.001

Any radionuclide  
other than alpha-  
emitting radionuclides  
not listed above, or  
mixtures of beta  
emitters of unknown  
composition

0.01

\* To convert  $\mu$ Ci to kBq, multiply the  $\mu$ Ci value by 37.

APPENDIX C

QUANTITIES<sup>1</sup> OF LICENSED OR REGISTERED MATERIAL REQUIRING LABELING

Radionuclide	Quantity	Radionuclide
Quantity	( $\mu\text{Ci}$ )*	( $\mu\text{Ci}$ )*

NOTE: For purposes of RH 4.28.5, 4.31.1, and 4.51.1 where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

<sup>1</sup>The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to Part 4, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000  $\mu\text{Ci}$ ). Values of 3.7 MBq (100  $\mu\text{Ci}$ ) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000  $\mu\text{Ci}$ ), to take into account their low specific activity.

\* To convert  $\mu\text{Ci}$  to kBq, multiply the  $\mu\text{Ci}$  value by 37.

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## APPENDIX D

### REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

#### I. Manifest

The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in Section I of Appendix E shall be clearly identified as such in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest required by this paragraph may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.

#### II. Certification

The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Department. An authorized representative of the waste generator shall sign and date the manifest.

#### III. Control and Tracking

a) Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in (a)(1) through (8). Any radioactive waste generator who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of (a)(4) through (8). A licensee shall:

- 1) Prepare all wastes so that the waste is classified according to Section I of Appendix E and meets the waste characteristics requirements in Section II of Appendix E;
- 2) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I of Appendix E;
- 3) Conduct a quality control program to ensure compliance with Section I and II of Appendix E; the program shall include management evaluation of audits;

- 4) Prepare shipping manifests to meet the requirements of Section I and II;
- 5) Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;
- 6) Include one copy of the manifest with the shipment;
- 7) Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by RH 3.22 of these regulations; and
- 8) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with Section III. (e).

b) Any waste collector licensee who handles only prepackaged waste shall:

- 1) Acknowledge receipt of the waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;
- 2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in Section I. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;
- 3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;
- 4) Include the new manifest with the shipment to the disposal site;
- 5) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by RH 3.22 of these regulations, and retain information from generator manifest until disposition is authorized by the Department; and
- 6) For any shipments or any portion of a shipment for which acknowledgement of receipt is not received within the times set forth in this section, conduct an investigation in accordance with Section III. (e).

c) Any licensed waste processor who treats or repackages wastes shall:

- 1) Acknowledge receipt of the waste from the generator within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation;
- 2) Prepare a new manifest that meets the requirements of Section I and II. Preparation of the new manifest reflects that the processor is responsible for the waste;

- 3) Prepare all wastes so that the waste is classified according to Section I of Appendix E and meets the waste characteristics requirements in Section II of Appendix E;
  - 4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Section I and III of Appendix E;
  - 5) Conduct a quality control program to ensure compliance with Section I and II of Appendix E. The program shall include management evaluation of audits;
  - 6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;
  - 7) Include the new manifest with the shipment;
  - 8) Retain copies of original manifests and new manifests and documentation of acknowledgement of receipt as the record of transfer of licensed material required by RH 3.22 of these regulations; and
  - 9) For any shipment or portion of a shipment for which acknowledgement is not received within the times set forth in this section, conduct an investigation in accordance with Section III. (e).
- d) The land disposal facility operator shall:
- 1) Acknowledge receipt of the waste within 1 week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;
  - 2) Maintain copies of all completed manifests or equivalent documentation until the Department authorizes their disposition; and
  - 3) Notify the shipper, that is, the generator, the collector, or processor, and the Department when any shipment or portion of a shipment has not arrived within 60 days after the advance manifest was received.
- e) Any shipment or portion of a shipment for which acknowledgement is not received within the times set forth in this section shall:
- 1) Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
  - 2) Be traced and reported to whom. The investigation shall include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation shall file a written report with the Department within 2 weeks of completion of the investigation.



## APPENDIX E

### CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

#### I. Classification of Radioactive Waste for Land Disposal

- a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.
- b) Classes of waste.
- 1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II. (a). If Class A waste also meets the stability requirements set forth in Section II. (b), it is not necessary to segregate the waste for disposal.
  - 2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.
  - 3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.
- c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:
- 1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.
  - 2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.
  - 3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.
  - 4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I. (g) of this Appendix.

TABLE I

Radionuclide	Concentration	
	curie/cubic meter <sup>a</sup> (Ci/m <sup>3</sup> )	nanocurie/gram <sup>b</sup> (nCi/g)
C-14 in activated metal	80	
C-14	8	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
I-129	0.08	
Tc-99	3	
Alpha emitting transuranic radionuclides with half- life greater than five years		100
Cm-242		20,000
Ra-226		100
Pu-241		3,500

<sup>a</sup>To convert the Ci/m<sup>3</sup> values to gigabecquerel (GBq) per cubic meter, multiply the Ci/m<sup>3</sup> value by 37.

<sup>b</sup>To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f) of this Appendix, if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

- 1) If the concentration does not exceed the value in Column 1, the waste is Class A.
- 2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.
- 3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.
- 4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
- 5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE II

Radionuclide	Concentration, Column 1	curie/cubic meter*	
		Column 2	Column 3
Total of all radio- nuclides with less than 5-year half- life	700	*	*
Co-60	700	*	*
Cs-137	1	44	4600
H-3	40	.*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000

\*Department NOTE: To convert the Ci/m<sup>3</sup> value to gigabecquerel (GBq) per cubic meter, multiply the Ci/m<sup>3</sup> value by 37. There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

- e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:
- 1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.
  - 2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.
- f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

- g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m<sup>3</sup> (50 Ci/m<sup>3</sup>) and Cs-137 in a concentration of 814 GBq/m<sup>3</sup> (22 Ci/m<sup>3</sup>). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction,  $50/150 = 0.33$ , for Cs-137 fraction,  $22/44 = 0.5$ ; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.
- h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

## II. Radioactive Waste Characteristics

- a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.
- 1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of Part 4, the site license conditions shall govern.
  - 2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.
  - 3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.
  - 4) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.
  - 5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.
  - 6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

- 7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.\*
  - 8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20°C. Total activity shall not exceed 3.7 TBq (100 Ci) per container.
  - 9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.
- b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.
- 1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.
  - 2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.
  - 3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

### III. Labeling

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

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\*See RH 1.4 of these regulations for definition of pyrophoric.

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APPENDIX F

QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115	100
Cadmium-115m	10
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134	1
Cesium-134m	100
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58	10
Cobalt-58m	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100

\* To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.



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QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Erbium-169	100
Erbium-171	100
Europium-152 (13 yr)	1
Europium-152 (9.2 h)	100
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115	10
Indium-115m	100
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197	100
Mercury-197m	100
Mercury-203	10

\* To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.

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QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191	100
Osmium-191m	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193	100
Platinum-193m	100
Platinum-197	100
Platinum-197m	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Ruthenium-97	100
Samarium-151	10
Samarium-153	100

\* To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.

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QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-111	100
Silver-110m	1
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur -35	100
Tantalum-182	10
Technetium-96	10
Technetium-97	100
Technetium-97m	100
Technetium-99	10
Technetium-99m	100
Tellurium-125m	10
Tellurium-127	100
Tellurium-127m	10
Tellurium-129	100
Tellurium-129m	10
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10

\* To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.

\*\* Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

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APPENDIX F

QUANTITIES FOR USE WITH DECOMMISSIONING

<u>Material</u>	<u>Microcurie*</u>
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)***	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69	1,000
Zinc-69m	100
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

\* To convert  $\mu\text{Ci}$  to  $\text{kBq}$ , multiply the  $\mu\text{Ci}$  value by 37.

\*\*\* Based on alpha disintegration rate of U-238, U-234, and U-235.

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QUANTITIES FOR USE WITH DECOMMISSIONING

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" -- that is, unity.]

Part 4

APPENDIX G

REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE  
FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable forms 540, uniform low-level radioactive waste manifest (shipping paper), and 541, uniform low-level radioactive waste manifest (container and waste description), and, if necessary, on an applicable Form 542, Uniform Low-Level Radioactive Waste Manifest (manifest index and regional compact tabulation). Forms 540 and 540a must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between the shipper and consignee, Forms 541 and 541a and 542 and 542a may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate and complete records on the respective forms.

Licensees are not required by this department to comply with manifesting requirements of this part when they ship:

- a) Low-level radioactive waste for processing and expect its return (that is, for storage under their license) prior to disposal at a licensed land disposal facility;
- b) Low-level radioactive waste that is being returned to the licensee who is the "waste generator" or "generator" as defined in this Appendix; or
- c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste".

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this Appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

As used in this Appendix, the following definitions apply:

"Chelating agent" means amine polycarboxylic acids, gluconic acid, hydroxycarboxylic acids, and polycarboxylic acids.

"Chemical description" means a description of the principal chemical characteristics of the low-level radioactive waste.

"Consignee" means the designated receiver of the shipment of low-level radioactive waste.



"Decontamination facility" means a facility operating under a Nuclear Regulatory Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for the purposes of this Part, is not considered to be a consignee for low-level radioactive waste shipments.

"Disposal container" means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

"EPA identification number" means the number received by a transporter following application to the administrator of the U.S. Environmental Protection Agency as required by 40 CFR Part 263.

Forms 540, 540a, 541, 541a, 542, and 542a are official forms referenced in this Appendix. Licensees need not use originals of these forms so long as any substitute form are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, Form 541 (and 541a) and Form 542 (and 542a) may be completed, transmitted and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

"Generator" means a licensee operating under a Nuclear Regulatory Commission or Agreement State license who (1) is a waste generator as defined in this Appendix or (2) is a licensee to whom waste can be attributed (for example, waste generated as a result of decontamination or recycle activities).

"High integrity container" (HIC) means a container commonly designed to meet the applicable Nuclear Regulatory Commission structural stability requirements and to meet U.S. Department of Transportation requirements for a type a package.

"Land disposal facility" means the same as in Part 14 of these Regulations.

"Physical description" means the items called for on Form 541 to describe a low-level radioactive waste.

"Residual waste" means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

"Shipper" means the licensed entity (that is, the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

"Shipping paper" means Form 540 and, if required, Form 540a which includes the information required by the U.S. Department of Transportation in 49 CFR Part 172.

"Uniform low-level radioactive waste manifest" or "uniform manifest" means the combination of Nuclear Regulatory Commission Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

"Waste collector" means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

"Waste description" means the physical, chemical and radiological description of a low-level radioactive waste as called for in Form 541.

"Waste generator" means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer low-level radioactive waste from the facility is defined as "residual waste".

"Waste processor" means an entity, operating under a Nuclear Regulatory Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

"Waste type" means a waste within a disposal container having a unique physical description (that is, a specific waste descriptor code or description, or a waste sorbed on or solidified in a specifically defined media).

#### Information requirements

##### a) General information

The shipper of the radioactive waste shall provide the following information on the uniform manifest:

- 1) The name, facility address, and telephone number of the licensee shipping the waste;
- 2) An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and
- 3) The name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number for the carrier transporting the waste.

##### b) Shipment information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

- 1) The date of the waste shipment;
- 2) The total number of packages/disposal containers;
- 3) The total disposal volume and disposal weight of the shipment;
- 4) The total radionuclide activity in the shipment;
- 5) The activity of each of the radionuclides H-3, C-14, TC-99, and I-129 contained in the shipment; and
- 6) The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

c) Disposal container and waste information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

- 1) An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
- 2) A physical description of the disposal container, including the manufacturer and model of any high integrity container;
- 3) The volume displaced by the disposal container;
- 4) The gross weight of the disposal container, including the waste;
- 5) For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;
- 6) A physical and chemical description of the waste;
- 7) The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agents by weight, plus the identity of the principal chelating agent;
- 8) The approximate volume of waste within the container;
- 9) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;
- 10) The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;
- 11) The total radioactivity within each container; and

- 12) For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix E. Waste not meeting the structural stability requirements of Appendix E shall be identified.

d) Uncontainerized waste information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

- 1) The approximate volume and weight of the waste;
- 2) A physical and chemical description of the waste;
- 3) The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;
- 4) For wastes consigned to a disposal facility, the classification as Class A, Class B, or Class C pursuant to Section I of Appendix E. Waste not meeting the structural stability requirements of Appendix E shall be identified.
- 5) The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material.
- 6) For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

e) Multi-generator disposal container information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. The origin of the low-level radioactive waste resulting from a processor's activities may be attributable to one or more "generators", including "waste generators", as defined in this Part. This section also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

- 1) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.
- 2) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (that is, activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container.

For each generator, provide the following:

- 1) The volume of waste within the container
- 2) A physical and chemical description of the waste, including the solidification agent, if any;
- 3) The total weight percentage of chelating agent for any disposal container containing more than 0.1% chelating agents by weight, plus the identity of the principal chelating agent;
- 4) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Appendix E of this Part;
- 5) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

## II. Certification

An authorized representative of the waste generator, collector or processor shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

## III. Control and tracking

- a) Any license who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in (a) (1) through (9) of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of (a) (4) through (9) of this section. A licensee shall:
  - 1) Prepare all wastes so that the waste is classified according to Section I of Appendix E and meets the waste characteristics requirements in Section II of Appendix E;
  - 2) Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is class A waste, class B waste, or class C waste, in accordance with Section I of appendix E;
  - 3) Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix E; the program shall include management evaluation of audits;
  - 4) Prepare the uniform manifest as required by this Appendix;



- 5) Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level radioactive waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
  - 6) Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in (a)(5) of this section;
  - 7) Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;
  - 8) Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by RH 3.22 of these regulations; and
  - 9) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Section III.(e).
- b) -Any waste collector licensee who handles only prepackaged waste shall:
- 1) Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;
  - 2) Prepare a new manifest to reflect consolidated shipments that meet the requirements of this Appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;
  - 3) Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level radioactive waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
  - 4) Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in (b)(3) of this section;
  - 5) Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;
  - 6) Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by RH 3.22 of these regulations; and



- 7) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Section III. (e).
  - 8) Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.
- c) Any licensed waste processor who treats or repackages wastes shall:
- 1) Acknowledge receipt of the waste from the shipper within 1 week of receipt by returning a signed copy of Form 540;
  - 2) Prepare a new manifest that meet the requirements of this Appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information required in Section I. (e) of this Appendix;
  - 3) Prepare all wastes so that the waste is classified according to Appendix E of Part 4 and meets the waste characteristics requirements in Section I of Appendix E;
  - 4) Label each package of waste to identify whether is Class A waste, Class B waste, or Class C waste in accordance with Appendix E;
  - 5) Conduct a quality assurance program to ensure compliance with Sections I and II of Appendix E; the program shall include management evaluation of audits;
  - 6) Forward a copy or electronically transfer the uniform manifest to the intended consignee so that either: (i) receipt of the manifest precedes the low-level radioactive waste shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;
  - 7) Include Form 540 (and Form 540a, if required) with the shipment regardless of the option chosen in (c) (6) of this section;
  - 8) Receive acknowledgement of the receipt of the shipment in the form of a signed copy of Form 540;

- 9) Retain a copy of or electronically store the uniform manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by RH 3.22 of these regulations; and
  - 10) For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this Appendix, conduct an investigation in accordance with Section III. (e).
  - 11) Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.
- d) The land disposal facility operator shall:
- 1) Acknowledge receipt of the waste within 1 week of receipt by returning, as a minimum, a signed copy of Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the uniform manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;
  - 2) Maintain copies of all completed manifests and electronically store the information required by Part 14 of these Regulations until license termination;
  - 3) Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.
- e) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section shall:
- 1) Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
  - 2) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the Department. Each licensee who conducts a trace investigation shall file a written report with the Department within 2 weeks of completion of the investigation.

- 3) Notify the shipper and the Department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

## PART 5

### RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

- RH 5.1 Purpose. The regulations in this part establish radiation safety requirements for persons using sources of radiation for industrial radiography. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.
- RH 5.2 Scope. The regulations in this part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those regulations of this part clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this part.
- RH 5.3 Definitions. As used in this part, the following definitions apply:
- "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in RH 4.14 of these regulations.
- "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.
- "Certified cabinet x-ray system" means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.
- "Collimator" means a device used to limit the size, shape, and direction of the Primary Radiation Beam.
- "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of radiation to produce radiographic images.
- "Lixiscope" means a portable light-intensified imaging device using a sealed source.

"Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed.

"Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Radiographer" means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these regulations and all license and/or certificate of registration conditions.

"Radiographer instructor" means any radiographer who has been authorized by the Department to provide on-the-job training to radiographer trainees in accordance with RH 5.16.2.2.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartment, condominiums, and garages.

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in RH 4.14 of these regulations.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.



"Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a device in which sealed sources are secured or stored.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

RH 5.4     Exemptions.

5.4.1     Except for the requirements of RH 5.25.2 and 5.25.3, certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part.

5.4.2     Industrial uses of lixisopes are exempt from the requirements in this part.

RH 5.5     Performance Requirements for Radiographic Equipment.     Equipment used in industrial radiographic operations must meet the following minimum criteria.

5.5.1     Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", (published as NBS Handbook 136, issued January 1981).<sup>1</sup>

5.5.2     In addition to the requirements specified in RH 5.5.1, the following requirements apply to radiographic exposure devices and associated equipment.

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<sup>1</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, CO, 80222-1530.



- 5.5.2.1 Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the:
- 5.5.2.1.1 Chemical symbol and mass number of the radionuclide in the device;
  - 5.5.2.1.2 Activity and the date on which this activity was last measured;
  - 5.5.2.1.3 Model number and serial number of the sealed source;
  - 5.5.2.1.4 Manufacturer of the sealed source; and
  - 5.5.2.1.5 Licensee's name, address, and telephone number.
- 5.5.2.2 Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of Part 17 of these regulations.
- 5.5.2.3 Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes would not compromise the design safety features of the system.
- 5.5.3 In addition to the requirements in RH 5.5.1 and 5.5.2, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operations.
- 5.5.3.1 The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
  - 5.5.3.2 The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.
  - 5.5.3.3 The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.
  - 5.5.3.4 Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "Danger - Radioactive". The label must not interfere with the safe operation of the exposure device or associated equipment.

- 5.5.3.5 The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.
- 5.5.3.6 Guide tubes must be used when moving the source out of the device.
- 5.5.3.7 An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.
- 5.5.3.8 The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.
- 5.5.3.9 Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
- 5.5.4 All newly manufactured radiographic exposure devices and associated equipment purchased by licensees after the effective date of this regulation must comply with the requirements of this section.
- 5.5.5 All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this section.

#### Equipment Control

- RH 5.6 Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers.
- 5.6.1 Radiographic exposure devices measuring less than 4 inches (10 cm) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens ( $1.29 \times 10^{-5}$  C/kg) per hour at 6 inches (15 cm) from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 4 inches (10 cm) from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens ( $5.16 \times 10^{-5}$  C/kg) per hour at any exterior surface, and 10 milliroentgens ( $2.58 \times 10^{-6}$  C/kg) per hour at 39.4 inches (1 m) from any exterior surface. The radiation levels specified are with the sealed source in the shielded position.

- 5.6.2 The requirements in RH 5.6.1 of this section apply to all equipment manufactured prior to June 1, 1994. After June 1, 1994, radiographic equipment other than storage containers and source changers must meet the requirements of RH 5.5, and RH 5.6 applies only to storage containers (source changers).
- RH 5.7 Locking of Sources of Radiation.
- 5.7.1 Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer trainee, or as may be otherwise authorized pursuant to RH 5.20. Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer trainee.
- 5.7.2 Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.
- 5.7.3 The sealed source shall be secured in its shielding position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to RH 5.22.2.
- RH 5.8 Storage Precautions.
- 5.8.1 Locked radiographic exposure devices, source changers, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.
- 5.8.2 Radiographic exposure devices, source changers, or transport containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with RH 5.8.3, and if the vehicle does not constitute a permanent storage location as described in RH 5.8.4.
- 5.8.3 If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in RH 4.14.1 of these regulations at the exterior surface of the vehicle.

5.8.4 A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

5.8.4.1 Telephone service is established by the licensee;

5.8.4.2 Industrial radiographic services are advertised for or from the location;

5.8.4.3 Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

RH 5.9 Radiation Survey Instruments.

5.9.1 The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and RH 4.9 of these regulations. Instrumentation required by this section shall have a range such that 2 milliroentgens ( $5.16 \times 10^{-7}$  C/kg) per hour through 1 roentgen ( $2.58 \times 10^{-4}$  C/kg) per hour can be measured.

5.9.2 Each radiation survey instrument shall be calibrated:

5.9.2.1 at energies appropriate for use and at intervals not to exceed 3 months and after each instrument servicing;

5.9.2.2 such that accuracy within plus or minus 20 percent can be demonstrated; and

5.9.2.3 at 2 points located approximately 1/3 and 2/3 of full-scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at appropriate points for digital instruments.

5.9.3 Records of these calibrations shall be maintained for 2 years after the calibration date for inspection by the Department.

5.9.4 Each radiation safety instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

RH 5.10 Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources.

5.10.1 The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

- 5.10.2 Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6-month period prior to the transfer, the sealed source shall not be put into use until tested.
- 5.10.3 The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to RH 3.10.5.5 of these regulations. Records of leak test results shall be kept in units of microcuries (becquerels) and maintained for inspection by the Department for 6 months after the next required leak test is performed or until the sealed source is transferred or disposed.
- 5.10.4 Any test conducted pursuant to RH 5.10.2 and 5.10.3 which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with regulations of the Department. Within 5 days after obtaining results of the test, the licensee shall file a report with the Department describing the equipment involved, the test results, and the corrective action taken.
- 5.10.5 Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found".
- RH 5.11 Quarterly Inventory. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and radiography exposure devices received or possessed by him. The records of the inventories shall be maintained for 2 years from the date of the inventory for inspection by the Department and shall include the quantities and kinds of radioactive material, the location of sealed sources, the date of the inventory, the manufacturer, the model number and the serial number.
- RH 5.12 Utilization Logs. Each licensee or registrant shall maintain current logs which shall be kept available for inspection by the Department for 2 years from the date of the recorded event, showing for each source of radiation the following information:
- 5.12.1 a unique identification, such as a serial number, of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;
- 5.12.2 the identity of the radiographer to whom assigned;



- 5.12.3 locations where used and dates of use; and
- 5.12.4 the date(s) each source of radiation is removed from storage and returned to storage.
- RH 5.13 Inspection and Maintenance.
- 5.13.1 Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day or shift of use.
- 5.13.2 Each licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the Department for 2 years from the date of the recorded event.
- 5.13.3 If any inspection conducted pursuant to RH 5.13.1 or 5.13.2 reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.
- RH 5.14 Permanent Radiographic Installations. Permanent radiographic installations having high radiation area entrance controls of the type described in RH 4.19.1.2 and 4.19.1.3 of these regulations shall also meet the following requirements:
- 5.14.1 Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.
- 5.14.2 The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the Department for 2 years from the date of the event.
- RH 5.15 Reporting Requirements
- 5.15.1 In addition to the reporting requirements of Part 4 of these regulations, each licensee shall provide a written report to the Department, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:



- 5.15.1.1 Unintentional disconnection of the source assembly from the control cable.
- 5.15.1.2 Inability to retract the source assembly to its fully shielded position and secure it in this position.
- 5.15.1.3 Failure of any component (critical to safe operation of the device) to properly perform its intended function.
- 5.15.2 The licensee shall include the following information in each report submitted under RH 5.15.1:
  - 5.15.2.1 A description of the equipment problem.
  - 5.15.2.2 Cause of each incident, if known.
  - 5.15.2.3 Manufacturer and model number of equipment involved in the incident.
  - 5.15.2.4 Place, time and date of the incident.
  - 5.15.2.5 Actions taken to establish normal operations.
  - 5.15.2.6 Corrective actions taken or planned to prevent recurrence.
  - 5.15.2.7 Qualifications of personnel involved in the incident.
- 5.15.3 Reports of overexposure submitted under RH 4.31 of these regulations which involve failure of safety components of radiography equipment must also include the information specified in RH 5.15.2.

**Personal Radiation Safety Requirements for  
Radiographic Personnel**

- RH 5.16 Training and Testing.
  - 5.16.1 No licensee or registrant shall permit any individual to act as a radiographer trainee unless such individual has received copies of, instructions in, and has demonstrated an understanding of:
    - 5.16.1.1 the subjects outlined in Appendix A of this part;
    - 5.16.1.2 the regulations contained in this part and the applicable sections of Parts 4, 10 and 17 of these regulations;
    - 5.16.1.3 the appropriate license or certificate of registration; and
    - 5.16.1.4 the licensee's or registrant's operating and emergency procedures.

- 5.16.2 No licensee or registrant shall permit any individual to act as a radiographer, as defined in this part, until such individual:
- 5.16.2.1 has met the requirements of RH 5.16.1;
  - 5.16.2.2 has provided the Department with documentation on Department Form RCD 57 or equivalent showing completion of at least 30 days of on-the-job training by a radiographer instructor as a radiographer trainee following completion of the requirements of RH 5.16.1.<sup>2</sup>
  - 5.16.2.3 has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments; and
  - 5.16.2.4 has demonstrated an understanding of the instructions in RH 5.16.1 by successful completion of a written test and a field examination on the subjects covered.
- 5.16.3 Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the licensee or registrant for inspection by the Department for 3 years following termination of employment.
- 5.16.4 Each licensee or registrant shall conduct an internal audit program to ensure that the Department's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the Department for 2 years from the date of the audit.
- RH 5.17 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:
- 5.17.1 handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Part 4 of these regulations;
  - 5.17.2 methods and occasions for conducting radiation surveys;
  - 5.17.3 methods for controlling access to radiographic areas;
  - 5.17.4 methods and occasions for locking and securing sources of radiation;

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<sup>2</sup>This requirement does not apply to individuals designated as radiographers prior to March 1, 1991.

- 5.17.5 personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
  - 5.17.6 transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;
  - 5.17.7 minimizing exposure of individuals in the event of an accident;
  - 5.17.8 the procedure for notifying proper personnel in the event of an accident;
  - 5.17.9 maintenance of records; and
  - 5.17.10 the inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines.
- RH 5.18 Personnel Monitoring.
- 5.18.1 The licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer trainee unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD), except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters shall have a range from zero to at least 200 milliroentgens ( $5.16 \times 10^{-5}$  C/kg) and shall be recharged daily or at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one individual.
  - 5.18.2 Pocket dosimeters shall be read and exposures recorded at least once daily.
  - 5.18.3 Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the Department for 2 years from the date of the event.
  - 5.18.4 If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made.
  - 5.18.5 Each alarm ratemeter must:
    - 5.18.5.1 be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

- 5.18.5.2 be set to give an alarm signal at a preset dose rate of 500 mr/hr;
- 5.18.5.3 require special means to change the preset alarm function; and
- 5.18.5.4 be calibrated at periods not to exceed one year for correct response to radiation. Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.
- 5.18.6 Reports received from the film badge or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the Department until the Department authorizes disposition.
- 5.18.7 If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.
- RH 5.19 Supervision of Radiographer Trainee. Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools, or conducts radiation surveys required by RH 5.22.2 and 5.22.3 to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor.

#### Precautionary Procedures in Radiographic Operations

- RH 5.20 Security. During each radiographic operation, the radiographer, radiographer instructor, or radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part 1 of these regulations, except:
- 5.20.1 where the high radiation area is equipped with a control device or alarm system as described in RH 4.19.1 of these regulations, or
- 5.20.2 where the high radiation area is locked to protect against unauthorized or accidental entry.
- RH 5.21 Posting. Notwithstanding any provisions in RH 4.29.1 of these regulations, areas in which radiography is being performed shall be conspicuously posted as required by RH 4.28.1 and 4.28.2 of these regulations.
- RH 5.22 Radiation Surveys and Survey Records.
- 5.22.1 No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in RH 5.9, is available and used at each site where radiographic exposures are made.

- 5.22.2 A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube.
- 5.22.3 A survey shall be made of the storage area as defined in RH 5.3 whenever a radiographic exposure device is being placed in storage.
- 5.22.4 A physical radiation survey, as specified in RH 5.7, shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area as defined in RH 5.3.
- 5.22.5 A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".
- 5.22.6 Records shall be kept of the surveys required by RH 5.22.3 and 5.22.4. Such records shall be maintained for inspection by the Department for 2 years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the Department authorizes their disposition.
- RH 5.23 Documents and Records Required at Temporary Jobsites. Each licensee or registrant conducting industrial radiography at a temporary jobsite shall have the following records available at that site for inspection by the Department:
- 5.23.1 appropriate license or certificate of registration or equivalent document;
- 5.23.2 operating and emergency procedures;
- 5.23.3 applicable regulations;
- 5.23.4 survey records required pursuant to RH 5.22 and area survey records required pursuant to RH 4.42 of these regulations for the period of operation at the site;
- 5.23.5 daily pocket dosimeter records for the period of operation at the site; and
- 5.23.6 the latest instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter.



- RH 5.24 Specific Requirements for Radiographic Personnel Performing Industrial Radiography.
- 5.24.1 At a jobsite, the following shall be supplied by the licensee or registrant:
- 5.24.1.1 at least one operable, calibrated survey instrument;
  - 5.24.1.2 a current whole body personnel monitor (TLD or film badge) for each individual;
  - 5.24.1.3 An alarm ratemeter for each individual;
  - 5.24.1.4 an operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens ( $5.16 \times 10^{-5}$  C/kg) for each worker; and
  - 5.24.1.5 the appropriate barrier ropes and signs.
- 5.24.2 Industrial radiographic operations shall not be performed if any of the items in RH 5.24.1 are not available at the jobsite or are inoperable.
- 5.24.3 Reserved.
- 5.24.4 No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.
- 5.24.5 No individual shall act as a radiographer instructor unless such individual:
- 5.24.5.1 has met the requirements of RH 5.16.2;
  - 5.24.5.2 has 1 year of documented experience as a radiographer; and
  - 5.24.5.3 has been designated as a radiographer instructor by the licensee or registrant.
  - 5.24.5.4 The licensee or registrant shall maintain documentation of the designation and the training and experience of radiographer instructors.
- 5.24.6 During an inspection by the Department, the Department inspector may terminate an operation if any of the items in RH 5.24.1 are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.
- RH 5.25 Special Requirements and Exemptions for Cabinet Radiography.
- 5.25.1 Systems for cabinet radiography designed to allow admittance of individuals shall:



- 5.25.1.1 comply with all applicable requirements of this part and RH 4.14 of these regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this part and 21 CFR 1020.40.
- 5.25.1.2 be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements as specified in RH 5.25.1.1. Records of these evaluations shall be maintained for inspection by the Department for a period of 2 years after the evaluation.
- 5.25.2 Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part except that:
- 5.25.2.1 Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results must be maintained for inspection by the Department.
- 5.25.2.2 No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the Department until disposition is authorized by the Department.
- 5.23.2.3 Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with RH 5.14.
- 5.25.2.4 The registrant shall perform an evaluation, at intervals not to exceed 1 year, to determine conformance with RH 4.14 of these regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Department for a period of 2 years after the evaluation.
- 5.25.3 Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Department pursuant to RH 1.5.1 of these regulations.
- RH 5.26 Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device, known as fishpole radiography, is prohibited unless specifically authorized in a license issued by the Department.

Part 5

APPENDIX A

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER TRAINEES

Training provided to qualify individuals as radiographer trainees in compliance with RH 5.16.1 shall be presented on a formal basis. The training shall include the following subjects:

- I. Fundamentals of Radiation Safety
  - A. Characteristics of radiation
  - B. Units of radiation dose and quantity of radioactivity
  - C. Significance of radiation dose
    1. Radiation protection standards
    2. Biological effects of radiation
    3. Case histories of radiography accidents
  - D. Levels of radiation from sources of radiation
  - E. Methods of controlling radiation dose
    1. Working time
    2. Working distances
    3. Shielding
- II. Radiation Detection Instrumentation to be Used
  - A. Use of radiation survey instruments
    1. Operation
    2. Calibration
    3. Limitations
  - B. Survey techniques
  - C. Use of personnel monitoring equipment
    1. Film badges
    2. Thermoluminescent dosimeters (TLD's)
    3. Pocket dosimeters
    4. Alarm ratemeters
- III. The Requirements of Pertinent Federal and State Regulations
- IV. The Licensee's or Registrant's Written Operating and Emergency Procedures
- V. Radiographic Equipment to be Used
  - A. Remote handling equipment
  - B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed)
  - C. Storage and transport containers, source changers
  - D. Operation and control of x-ray equipment
  - E. Collimators
- VI. Case Histories of Radiography Accidents

## PART 6

### X-RAYS IN THE HEALING ARTS

RH 6.1 Scope. This Part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these Regulations. The effective date of this Part is September 1, 1992.

RH 6.2 Definitions. As used in this Part, the following definitions apply:

"Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy<sup>1</sup> affording the same attenuation, under specified conditions, as the material in question.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, or his or her employee or agent, who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy<sup>1</sup>, or other materials having equivalent attenuation.

"Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

"Barrier" (See "Protective barrier").

"Beam axis" means a line from the source through the centers of the x-ray fields.

"Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

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<sup>1</sup>The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

"Certified system" means any x-ray system which has one or more certified component(s).

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process under operator control.

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[ \sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where

$s$	=	Estimated standard deviation of the population.
$\bar{X}$	=	Mean value of observations in sample.
$X_i$	=	$i^{\text{th}}$ observation in sample.
$n$	=	Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (See "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (See "Radiation detector").

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed and used for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment").

"Facility" means the location at which one or more radiation machines are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to absorb preferentially selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.



"Healing arts screening" means the diagnostic irradiation of human beings using x-ray machines when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

"Heat unit" means, for single phase systems, a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e.,  $kVp \times mA \times second$ ; and for 3-phase systems,  $kVp \times mA \times seconds \times 1.35$ .

"HVL" (See "Half-value layer").

"Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor perpendicular to the beam axis during a mammographic examination.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Irradiation" means the exposure of matter to ionizing radiation.

"Kilovolts peak" (See "Peak tube potential").

"kV" means kilovolts.

"kVp" (See "Peak tube potential").

"kWs" means kilowatt second. It is equivalent to  $10^3 \text{ kV} \cdot \text{mA} \cdot \text{s}$ , i.e.,

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{10^3 kV \times mA \times s} = \frac{XYZ \text{ kWs}}{10^3}$$

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

- (1) the useful beam, and
- (2) radiation produced when the exposure switch or timer is not activated.



"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for that potential.

"Light field" means that area of the intersection of the light beam from the beam-limiting device, and one of the set of planes parallel to, and including, the plane of the image receptor, whose perimeter is the locus of points, at which the illumination is one-fourth of the maximum in the intersection.

"Linear attenuation coefficient" or " $\mu$ " means the quotient of  $dN/N$  divided by  $dl$  when  $dN/N$  is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance  $dl$  in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

$V_n$  = No-load line potential and

$V_l$  = Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

"Mobile x-ray equipment" (See "X-ray equipment").

"Optical Density" (OD) =  $\text{Log } (1/\text{Transmittance})$ , where the transmittance of the film is the fraction of incident light transmitted by the film.

"Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

"Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

"Phantom" means a volume of material behaving in a manner similar to human tissues with respect to the attenuation and scattering of radiation.

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

"PID" (See "Position indicating device").

"Portable x-ray equipment" (See "X-ray equipment").

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

"Primary protective barrier" (See "Protective barrier").

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure to the wearer.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- (1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
- (2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

"Qualified expert" means:

(a) For radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in an appropriate field by the American Board of Radiology, or the American Board of Medical Physics, or by the American Board of Health Physics or the American Board of Nuclear Medicine Science, or persons who can demonstrate equivalent education, training, experience and knowledge).

(b) For radiation therapy calibrations, a person having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics, X-ray and Radium Physics, or Therapeutic Radiological Physics by the American Board of Radiology, or the American Board of Medical Physics, or persons who can demonstrate equivalent education, training, experience and knowledge)."

"Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

"Radiographic Imaging System" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from x-ray photons.

"Registrant" means a person responsible for ensuring that the requirements of the Regulations are complied with at a given facility.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

"Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

"Secondary protective barrier" (See "Protective barrier").

"Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (See "Source-image receptor distance").

"Source" means the focal spot of the x-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph. It is not to be confused with other subsystems used for "spot film" recording.

"SSD" means the distance between the source and the skin of the patient.

"Stationary x-ray equipment" (See "X-ray equipment").

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique chart" means a chart which specifies, for common examinations performed with a specific system, the following information:

- (1) technique factors to be utilized versus patient's anatomical size;
- (2) type and size of the film or film-screen combination to be used;
- (3) type and focal distance of the grid to be used, if any; and
- (4) source to image receptor distance to be used.

"Technique factors" means the following conditions of operation:

- (1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (2) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;
- (3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- (4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
- (5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

"Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

"Tube" means an x-ray tube, unless otherwise specified.

"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors. These curves are typically displayed on a graph.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.



"Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

- (1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
- (2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.
- (3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray subsystem" means any combination of two or more components of an x-ray system.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.



## General Regulatory Provisions

- RH 6.3      General Requirements.      Effective July 1, 1995, all human use radiation machines used in Colorado shall meet the Federal Performance Standards, Subchapter J - Radiological Health, 21 CFR 1020.30 through 1020.33, effective April 1, 1991. The Department may grant exemptions to machines manufactured prior to August 4, 1974, provided the registrant can demonstrate that the exemption will not result in undue risk from excessive exposure and will benefit the patient.
- 6.3.1      Administrative Controls
- 6.3.1.1      Registrant.      The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of RH 6.3.1 are met in the operation of the x-ray system(s).
- 6.3.1.1.1      An x-ray system which does not meet the provisions of these Regulations, and is determined to be unsafe for use, shall not be operated for diagnostic or therapeutic purposes.
- 6.3.1.1.2      Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.
- 6.3.1.1.2.1      In addition to RH 6.3.1.1.2, individuals, except for the licensed practitioners, shall meet the training requirements, if any, of the appropriate licensing board.
- 6.3.1.1.2.2      In addition to RH 6.3.1.1.2 and 6.3.1.1.2.1, individuals operating x-ray machine systems in mammography facilities shall meet the requirements in RH 6.12.3.7.2.
- 6.3.1.1.3      A technique chart shall be provided in the vicinity of the diagnostic x-ray system's control panel for all common procedures performed with that system.
- 6.3.1.1.4      Written safety procedures shall be provided to each individual operating x-ray equipment. These procedures shall include any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.
- 6.3.1.1.5      Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
- 6.3.1.1.5.1      All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

- 6.3.1.1.5.2 Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent, or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
- 6.3.1.1.5.3 Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
- 6.3.1.1.6 Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not passed beyond the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- 6.3.1.1.7 Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
- 6.3.1.1.7.1 exposure of an individual for training, demonstration, or other non-healing arts purposes; and
- 6.3.1.1.7.2 exposure of an individual for the purpose of healing arts screening except as authorized by RH 6.3.1.1.11.
- 6.3.1.1.8 When a patient or film must be provided with auxiliary support during a radiation exposure:
- 6.3.1.1.8.1 mechanical holding devices shall be used when the technique permits. The written safety procedures, required by RH 6.3.1.1.4, shall list individual projections where holding devices cannot be utilized;
- 6.3.1.1.8.2 written safety procedures, as required by RH 6.3.1.1.4, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
- 6.3.1.1.8.3 the human holder shall be protected as required by RH 6.3.1.1.5;

- 6.3.1.1.8.4 no individual shall be used routinely to hold film or patients; and
- 6.3.1.1.8.5 in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.
- 6.3.1.1.9 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
- 6.3.1.1.9.1 The speed of film or screen and film combinations shall be the highest speed consistent with the diagnostic objective of the examinations.
- 6.3.1.1.9.1.1 The replacement of existing screens shall be with screens utilizing rare earth phosphors or with screen utilizing phosphor materials providing equivalent speed and image quality. For general purpose radiographic imaging, screens of nominal speed class less than 200 shall not be used.
- 6.3.1.1.9.2 The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
- 6.3.1.1.9.3 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation, or when the practitioner determines that portable equipment is most suitable for the diagnostic procedure.
- 6.3.1.1.9.4 X-ray systems subject to RH 6.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
- 6.3.1.1.10 All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18 of these Regulations. In addition:
- 6.3.1.1.10.1 When protective clothing or devices are worn, personnel monitoring devices shall be worn, such that the requirements of RH 4.6, 4.10, 4.12, 4.13, 4.14, and 4.18 shall be met.
- 6.3.1.1.10.2 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

- 6.3.1.1.11 Healing Arts Screening. With the exception of ACR accredited or HCFA approved facilities which are registered with the Department for the use of dedicated mammographic equipment, any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix C of this Part. If any information submitted to the Department becomes invalid or outdated, the Department shall be immediately notified.
- 6.3.1.1.12 Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Department:
- 6.3.1.1.12.1 maximum technique factors for which the machine has been rated;
- 6.3.1.1.12.2 model and serial numbers of each tube housing assembly and control panel;
- 6.3.1.1.12.2.1 The facility registrant shall assign a unique identification number to each tube housing assembly and/or control panel which lacks a clearly visible serial number from the manufacturer. The tube housing assembly and/or control panel shall be labeled or stenciled with this number. This number shall be used by the registrant to identify this machine in all correspondence with the Department.
- 6.3.1.1.12.3 tube rating charts and cooling curves;
- 6.3.1.1.12.4 records of survey measurements, calibrations, maintenance, and modifications performed on the x-ray system(s) after September 1, 1992 with the names of persons who performed such services;
- 6.3.1.1.12.5 Except for single occupancy rooms using only dental intraoral or panoramic machines, a dimensional drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
- 6.3.1.1.12.5.1 the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or
- 6.3.1.1.12.5.2 the type and thickness of materials, or lead equivalency, of each protective barrier; and
- 6.3.1.1.12.6 a copy of all correspondence with this Department regarding that x-ray system.



- 6.3.1.1.13      Procedures for Collimation.      The registrant shall provide written policy and procedures to all operators regarding collimation. The policy shall specify for each tube with variable collimation whether positive beam limitation (pbl) shall be used or whether manual collimation shall be used.
- 6.3.1.1.13.1      If manual collimation is used, then there shall be positive indication of collimation on all films except as provided in RH 6.12.1.10.1, or when contra indicated and diagnosis could be compromised. Tubes collimated manually need not comply with PBL requirements.
- 6.3.1.1.13.2      Regardless of the method of collimation, the beam size shall be limited to the smallest area which is clinically necessary.
- 6.3.1.1.14      Process QA Program.      Every human use facility which is required to be inspected on an annual basis must have an active film processing QA program. The QA program must address the following issues:
- 6.3.1.1.14.1      The x-ray film must be developed following the recommendations of the film manufacturer for development time and temperature. Those manufacturers recommendations must be posted in the film processing area.
- 6.3.1.1.14.1.1      In lieu of the requirements of RH 6.3.1.1.14.1, the facility may adopt a continuous, documented sensitometric quality control program.
- 6.3.1.1.14.2      If manual processing of films is done the temperature of the developer must be measured and logged each day the processing system is used.
- 6.3.1.1.14.3      If an automatic film processor is used then its developer temperature must be monitored and logged at least once per week.
- 6.3.1.1.14.4      For both manual and automated processing there must be an adequate method used to monitor and/or determine processing time.
- 6.3.1.1.14.5      An adequate developer replenishment system must be functional to meet the manufacturer's recommendations for automated film processors. For manual developing procedures the developer chemicals must be changed at least every month and documented in a written log.
- 6.3.1.1.14.6      The darkroom lighting must be such that exposure of a film to the darkroom safelight for 1 minute does not increase the optical density of that film by more than 0.1 optical density units when the test film has a latent image sufficient to produce a density between 1.0 and 2.0 optical density units prior to safe light exposure.

- 6.3.1.1.14.7 The base plus fog of an unexposed film must not exceed 0.25 optical density units when developed by the routine procedure used by the facility.

6.3.2 Plan Review and Shielding Design

- 6.3.2.1 Prior to the construction of a new x-ray facility, the floor plans and equipment arrangement shall be submitted to a qualified expert for the determination of shielding requirements. Prior to the modification or renovation of an existing x-ray facility, or installation of a new x-ray machine in an existing x-ray facility, the plans and equipment arrangements shall be submitted to a qualified expert for determination of shielding requirements when there is a change in primary beam orientation, or a change in primary shielding due to the modification or renovation of a facility, or there is a projected increase in the x-ray workload from that which was used for the original x-ray shielding design. In such cases shielding shall meet the criteria in Appendix B and the recommendations of the qualified expert. The required information is denoted in Appendices A and B of this Part.

- 6.3.2.1.1 Facilities using only dental intraoral or panoramic machines in single occupancy rooms are exempt from the requirements of RH 6.3.2.1.

- 6.3.2.2 The review of such plans, and determination of shielding requirements, shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in RH 4.6, 4.12, 4.13, and 4.14 of these Regulations.

- 6.3.3 General Requirements for Certified Diagnostic X-Ray Systems. Certified diagnostic x-ray systems or any components thereof which are certified according to Title 21, Code of Federal Regulations, Chapter I, Subchapter J<sup>2</sup>, shall be maintained to remain in compliance with those regulations, except as noted in RH 6.3.1.1.13.1.

**Diagnostic X-Ray Systems**

- RH 6.4 General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

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<sup>2</sup>A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, B-1, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80220-1530.



- 6.4.1 Warning Label. The control panel containing the main power switch shall bear this or an equivalent warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
- 6.4.2 Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery needs to be changed, or the battery is in a state of charge adequate for proper operation.
- 6.4.3 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens ( $25.8 \mu\text{C/kg}$ ) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- 6.4.4 Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens ( $0.516 \mu\text{C/kg}$ ) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- 6.4.5 Beam Quality
- 6.4.5.1 Half-Value Layer
- 6.4.5.1.1 The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I			
Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)	
		Other Systems	Dental Systems
Below 50	30	0.3	1.5
	40	0.4	1.5
	49	0.5	1.5
50 to 70	50	1.2	1.5
	60	1.3	1.5
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	140	3.8	3.8
	150	4.1	4.1

6.4.5.1.2

The requirements of RH 6.4.5.1.1 will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

Table II			
Filtration Required vs. Operating Voltage			
Operating Voltage (kVp)	Total Filtration (inherent plus added) (mm aluminum equivalent)	Other Systems	Dental Systems
Below 50 . . . . .		0.5	1.5
50 - 70 . . . . .		1.5	1.5
Above 70 . . . . .		2.5	2.5

6.4.5.1.3

Beryllium window tubes, except those used for mammography, shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

6.4.5.1.4

For capacitor energy storage equipment, compliance with the requirements of RH 6.4.5 shall be determined with the maximum quantity of charge per exposure.

- 6.4.5.1.5 The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.
- 6.4.5.2 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RH 6.4.5.1 is in the useful beam for the given kVp which has been selected.
- 6.4.6 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.
- 6.4.7 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- 6.4.8 Technique Indicators
- 6.4.8.1 The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
- 6.4.8.2 The requirement of RH 6.4.8.1 may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except for spot films and cineradiography.
- RH 6.5 Fluoroscopic X-Ray Systems Except for Computed Tomography X-Ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:
- 6.5.1 Limitation of Useful Beam
- 6.5.1.1 Primary Barrier
- 6.5.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
- 6.5.1.1.2 The x-ray tube used for fluoroscopy shall not produce x rays unless the barrier is in position to intercept the entire useful beam.
- 6.5.1.2 X-Ray Field
- 6.5.1.2.1 Non-Intensified Fluoroscopic Equipment.

6.5.1.2.1.1 The use of non-image-intensified fluoroscopic equipment is prohibited after June 30, 1993.

6.5.1.2.1.2 The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

6.5.1.2.1.2.1 means shall be provided for stepless adjustment of the field size;

6.5.1.2.1.2.2 the minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters;

6.5.1.2.1.2.3 for equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

6.5.1.2.1.2.4 compliance with RH 6.5.1.2.1.2 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

6.5.1.2.2 For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

6.5.1.2.2.1 means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

6.5.1.2.2.2 all equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less;

6.5.1.2.2.3

for equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

6.5.1.2.2.4

compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

6.5.1.2.3

Spot-film devices which are certified components shall meet the following additional requirements:

6.5.1.2.3.1

means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

6.5.1.2.3.2

it shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters  $\pm$  5 centimeters;

6.5.1.2.3.3

the center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

6.5.1.2.3.4

on spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.



6.5.1.2.4 If a means exists to override any of the automatic x-ray field size adjustments required in RH 6.5.1.2, that means:

6.5.1.2.4.1 shall be designed for use only in the event of system failure;

6.5.1.2.4.2 shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

6.5.1.2.4.3 shall be clearly and durably labeled as follows:

FOR X-RAY FIELD  
LIMITATION SYSTEM FAILURE

6.5.2 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time.

6.5.3 Exposure Rate Limits

6.5.3.1 Entrance Exposure Rate Allowable Limits

6.5.3.1.1 The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC/kg) per minute, except during recording of fluoroscopic images or when provided with optional high level control.

6.5.3.1.2 When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

6.5.3.1.2.1 Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.

6.5.3.1.2.2 A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.



- 6.5.3.1.3 In addition to the other requirements of RH 6.5, certified systems which do not incorporate an automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient except during recording of fluoroscopic images or when an optional high level control is activated.
- 6.5.3.1.4 Compliance with the requirements of RH 6.5.3 shall be determined as follows:
- 6.5.3.1.4.1 Movable grids and compression devices shall be removed from the useful beam during the measurement.
- 6.5.3.1.4.2 If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.
- 6.5.3.1.4.3 If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- 6.5.3.1.4.4 All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in RH 6.5.3.1.1, 6.5.3.1.2, and 6.5.3.1.3, 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- 6.5.3.1.4.5 All lateral type fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in RH 6.5.3.1.1, 6.5.3.1.2, and 6.5.3.1.3; measured at a point 15 centimeters from the centerline of the table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the table.
- 6.5.3.1.5 Periodic measurement of entrance exposure rate shall be performed as follows:

- 6.5.3.1.5.1 Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
- 6.5.3.1.5.2 Conditions of periodic measurement of entrance exposure rate are as follows:
- 6.5.3.1.5.2.1 the measurement shall be made under the conditions that satisfy the requirements of RH 6.5.3.1.4;
- 6.5.3.1.5.2.2 the kVp shall be the maximum kVp which can be produced by the x-ray system;
- 6.5.3.1.5.2.3 the x-ray system(s) that incorporates automatic exposure rate control shall have the beam collimated to the size of the detector and have sufficient material placed in the useful beam to intercept the entire beam so that output of the machine is a maximum for the x-ray system; and
- 6.5.3.1.5.2.4 x-ray system(s) that do not incorporate an automatic exposure rate control shall utilize the maximum milliamperage typical of the clinical use of the x-ray system.<sup>3</sup>

6.5.4 Barrier Transmitted Radiation Rate Limits

- 6.5.4.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516  $\mu\text{C/kg}$ ) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

6.5.4.2 Measuring Compliance of Barrier Transmission

- 6.5.4.2.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

- 6.5.4.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

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<sup>3</sup>Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

- 6.5.4.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
- 6.5.4.2.4 Movable grids and compression devices shall be removed from the useful beam during the measurement.
- 6.5.4.2.5 The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- 6.5.5 Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated on certified units.
- 6.5.6 Source-to-Skin Distance. The SSD shall not be less than:
- 6.5.6.1 38 centimeters on stationary fluoroscopes installed after September 1, 1992,
- 6.5.6.2 35.5 centimeters on stationary fluoroscopes which were in operation on or before September 1, 1992,
- 6.5.6.3 30 centimeters on all mobile fluoroscopes, and
- 6.5.6.4 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of these systems.
- 6.5.7 Fluoroscopic Timer
- 6.5.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
- 6.5.7.2 A signal to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.
- 6.5.8 Mobile Fluoroscopes. In addition to the other requirements of RH 6.5, mobile fluoroscopes shall be equipped with image intensifiers.

6.5.9 Control of Scattered Radiation

6.5.9.1 Conventional fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

6.5.9.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities or head, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

6.5.9.2.1 is at least 120 centimeters from the center of the useful beam, or

6.5.9.2.2 the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RH 6.3.1.1.5.

6.5.9.3 The Department may grant exemptions to RH 6.5.9.2. where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department shall not permit such exemption.

6.5.10 Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of RH 6.5.1, 6.5.3, 6.5.4, and 6.5.7 provided that:

6.5.10.1 such systems are designed and used in such a manner that no individual other than the patient, required staff and ancillary personnel are in the x-ray room during periods of time when the system is producing x-rays; and

6.5.10.2 systems which do not meet the requirements of RH 6.5.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

RH 6.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinary, Computed Tomography, or Mammography X-Ray Systems

6.6.1 Beam Limitation. The useful beam shall be limited to the area of clinical interest.

6.6.1.1

General Purpose Stationary and Mobile X-Ray Systems

6.6.1.1.1

There shall be provided a means for stepless adjustment of the size of the x-ray field.

6.6.1.1.2

A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

6.6.1.1.3

The Department may grant an exemption on non-certified x-ray systems to RH 6.6.1.1.1 and 6.6.1.1.2 provided the registrant makes a written application for such exemption and in that application:

6.6.1.1.3.1

demonstrates it is impractical to comply with RH 6.6.1.1.1 and 6.6.1.1.2; and

6.6.1.1.3.2

the purpose of RH 6.6.1.1.1 and 6.6.1.1.2 will be met by other methods.

6.6.1.2

Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of RH 6.6.1.1, stationary general purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

6.6.1.2.1

A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

6.6.1.2.2

The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

6.6.1.2.3

Indication of field size dimensions and S.A. shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.



6.6.1.3

X-Ray Systems Designed for One Image Receptor Size.

Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.1.4

X-Ray Systems Other Than Those Described in RH 6.6.1.1, 6.6.1.2 and 6.6.1.3.

6.6.1.4.1

Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

6.6.1.4.2

Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6.6.1.4.3

RH 6.6.1.5.1 and 6.6.1.5.2 may be met with a system that meets the requirements for a general purpose x-ray system as specified in RH 6.6.1.1 or, when alignment means are also provided, may be met with either:

6.6.1.4.3.1

an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

6.6.1.4.3.2

a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.



6.6.2 Radiation Exposure Control Devices

6.6.2.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

6.6.2.2 X-Ray Control

6.6.2.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

6.6.2.2.1.1 exposure of one-half (½) second or less, or

6.6.2.2.1.2 during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

6.6.2.2.2 Except for bone mineral analyzers and similar machines, each x-ray control shall be located in such a way as to meet the following requirements:

6.6.2.2.2.1 Stationary x-ray systems, and mobile or portable systems used routinely in one location, shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

6.6.2.2.2.2 mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 6 feet (1.83 m) from the patient, the x-ray tube and the useful beam. Mobile and portable x-ray systems used in surgery are considered to be not routinely used in one location.

6.6.2.2.2.3 The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

6.6.2.3 Automatic Exposure Controls. When an automatic exposure control is provided:

6.6.2.3.1 indication shall be made on the control panel when this mode of operation is selected;

- 6.6.2.3.2 if the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;
- 6.6.2.3.3 the minimum exposure time for all equipment other than that specified in RH 6.6.2.3.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
- 6.6.2.3.4 either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
- 6.6.2.3.5 a visible signal shall indicate when an exposure has been terminated at the limits required by RH 6.6.2.3.4, and manual resetting shall be required before further automatically timed exposures can be made.

- 6.6.2.4 Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ( $\bar{T}$ ) shall be greater than or equal to 5 times the maximum exposure period ( $T_{max}$ ) minus the minimum exposure period ( $T_{min}$ ) when 4 timer tests are performed:

$$\bar{T} \geq 5(T_{max} - T_{min}).$$

- 6.6.3 Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.
- 6.6.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. The facility registrant may request a variance for any machines manufactured prior to 1974, which cannot meet this requirement. The variance request must verify that this exposure reproducibility variation will not result in unnecessary patient radiation exposure due to the need for repeat examinations.
- 6.6.5 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516  $\mu$ C/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6.6.6 Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

6.6.6.1 Reproducibility. The estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

6.6.6.2 Linearity. When the equipment allows a choice of x-ray tube current or mAs settings for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratio of exposure to the indicated milliamperereconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$- |\bar{X}_1 - \bar{X}_2| \leq 0.10 (\bar{X}_1 + \bar{X}_2),$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the mR/mAs (microcoulomb/kilogram per mAs) values obtained at each of 2 consecutive tube current settings.

6.6.6.3 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. If manufacturer specifications are not available, the following criteria shall be used:

6.6.6.3.1 The kVp shall not deviate from indicated values by more than 10%.

6.6.6.3.2 The timer accuracy shall not deviate from indicated values by more than:

6.6.6.3.2.1 10% for an indicated time of greater than 20 ms; or

6.6.6.3.2.2 50% for an indicated time of 20 ms or less."

6.6.6.4 Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

6.6.6.4.1 There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

6.6.6.4.2 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

- 6.6.6.5 Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of RH 6.6.1.1 and 6.6.6.4.
- 6.6.6.6 Field Limitation and Alignment on Stationary General Purpose X-Ray Systems. For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c):
- 6.6.6.6.1 Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:
- 6.6.6.6.1.1 The image receptor is inserted into a permanently mounted cassette holder;
- 6.6.6.6.1.2 The image receptor length and width are each less than 50 centimeters;
- 6.6.6.6.1.3 The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;
- 6.6.6.6.1.4 The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;
- 6.6.6.6.1.5 Neither tomographic nor stereoscopic radiography is being performed;
- 6.6.6.6.1.6 Manual collimation is not used pursuant to RH 6.3.1.1.13.1.
- 6.6.6.6.1.7 The machine is used for procedures other than therapy simulation.
- 6.6.6.6.1.8 The PBL system has not been intentionally overridden. This override provision is subject to RH 6.6.6.6.3.
- 6.6.6.6.2 PBL shall prevent the production of x-rays when:
- 6.6.6.6.2.1 Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by RH 6.6.6.6.5, from the corresponding image receptor dimensions by more than 3 percent of the SID; or
- 6.6.6.6.2.2 The sum of the length and width differences as stated in RH 6.6.6.6.2.1, without regard to sign, exceeds 4 percent of the SID.

- 6.6.6.6.3 If a means of overriding the PBL system exists, that means:
- 6.6.6.6.3.1 Shall be designed for use only in the event of PBL system failure, or if the system is being serviced; and
- 6.6.6.6.3.2 If in a position that the operator would consider it part of the operational controls, or if it is referenced in the operator's manual, or in other materials intended for the operator,
- 6.6.6.6.3.2.1 shall require that a key be utilized to defeat the PBL;
- 6.6.6.6.3.2.2 shall require that the key remain in place during the entire time the PBL system is overridden; and
- 6.6.6.6.3.2.3 shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

- 6.6.6.6.4 Compliance with RH 6.6.6.6.2 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of RH 6.6.6.6.1 are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.
- 6.6.6.6.5 The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
- 6.6.6.6.6 The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in RH 6.6.6.6.2, then any change of image receptor size or SID must cause the automatic return.
- 6.6.6.7 Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting, or to "zero".

- RH 6.7 Intraoral Dental Radiographic Systems. In addition to the provisions of RH 6.3 and RH 6.4, the requirements of RH 6.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in RH 6.6.



- 6.7.1 Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:
- 6.7.1.1 18 centimeters if operable above 50 kVp, or
  - 6.7.1.2 10 centimeters if not operable above 50 kVp.
- 6.7.2 Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
- 6.7.2.1 if the minimum SSD is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and
  - 6.7.2.2 if the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.
- 6.7.3 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:
- 6.7.3.1 It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
  - 6.7.3.2 Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ( $\bar{T}$ ) shall be greater than or equal to 5 times the maximum exposure period ( $T_{max}$ ) minus the minimum exposure period ( $T_{min}$ ) when 4 timer tests are performed:

$$\bar{T} \geq 5(T_{max} - T_{min})$$

6.7.4 X-Ray Control

- 6.7.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.
- 6.7.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:
  - 6.7.4.2.1 stationary x-ray systems, and mobile or portable systems used routinely in one location, shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure, or the exposure control shall be such that the operator can stand at least 2 meters from the patient, the x-ray tube and the useful beam; and



- 6.7.4.2.2 mobile and portable x-ray systems not routinely used in one location shall be required to have an exposure switch so arranged that the operator can stand at least 2 meters from the patient, the x-ray tube and the useful beam.
- 6.7.4.3 The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced.
- 6.7.5 Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure ( $\bar{E}$ ) is greater than or equal to 5 times the maximum exposure ( $E_{\max}$ ) minus the minimum exposure ( $E_{\min}$ ):

$$\bar{E} \geq 5(E_{\max} - E_{\min})$$

6.7.6 Administrative Controls

- 6.7.6.1 Patient and film holding devices shall be used when the techniques permit.
- 6.7.6.2 The tube housing and the PID shall not be hand-held during an exposure.
- 6.7.6.3 The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of RH 6.7.2.1.
- 6.7.6.4 Dental fluoroscopy without image intensification shall not be used.
- 6.7.7 Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).
- 6.7.7.1 Reproducibility. The estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

- 6.7.7.2 Linearity. When the equipment allows choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10 (\bar{X}_1 + \bar{X}_2),$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

- 6.7.7.3 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
- 6.7.7.4 Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
- 6.7.7.5 Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of RH 6.4.5.1.

#### Therapeutic X-Ray Systems

#### RH 6.8 Therapeutic X-Ray Systems of Less Than One MeV

##### 6.8.1 Equipment Requirements

- 6.8.1.1 Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.
- 6.8.1.1.1 Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8  $\mu\text{C/kg}$ ) per hour at 5 centimeters from the surface of the tube housing assembly.
- 6.8.1.1.2 0-150 kVp Systems. Systems which were manufactured or installed prior to September 1, 1992 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.
- 6.8.1.1.3 0-150 kVp Systems. Systems which are manufactured on or after September 1, 1992 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8  $\mu\text{C/kg}$ ) in 1 hour at 1 meter from the source.

- 6.8.1.1.4      151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam 1 meter from the source.
- 6.8.1.2      Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.
- 6.8.1.3      Removable and Adjustable Beam Limiting Devices
- 6.8.1.3.1      Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and with filtration installed which produces the highest energy beam. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
- 6.8.1.3.2      Adjustable beam limiting devices installed after September 1, 1992 shall meet the requirements of RH 6.8.1.3.1.
- 6.8.1.3.3      Adjustable beam limiting devices installed before September 1, 1992 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and with filtration installed which produces the highest energy beam.
- 6.8.1.4      Filter System. The filter system shall be so designed that:
- 6.8.1.4.1      the filters cannot be accidentally displaced at any possible tube orientation;
- 6.8.1.4.2      the radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and
- 6.8.1.4.3      each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- 6.8.1.5      Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.
- 6.8.1.6      Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

- 6.8.1.7      Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- 6.8.1.8      Beam Monitor System. Systems of greater than 150 kVp manufactured after September 1, 1992 shall be provided with a beam monitor system which:
- 6.8.1.8.1      shall have the detector of the monitor system interlocked to prevent incorrect positioning;
- 6.8.1.8.2      shall not allow irradiation until a pre-selected value of exposure has been made at the treatment control panel;
- 6.8.1.8.3      shall independently terminate irradiation when the pre-selected exposure has been reached;
- 6.8.1.8.4      shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
- 6.8.1.8.5      shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
- 6.8.1.8.6      shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and
- 6.8.1.8.7      shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
- 6.8.1.9      Timer
- 6.8.1.9.1      A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator or a time remaining indicator.
- 6.8.1.9.2      The timer shall be a total treatment timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
- 6.8.1.9.3      The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

- 6.8.1.9.4 The timer shall permit accurate presetting and determination of exposure times as short as 10% of the prescribed dose.
- 6.8.1.9.5 The timer shall not permit an exposure if set at zero.
- 6.8.1.9.6 The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- 6.8.1.10 Control Panel Functions. The control panel, in addition to the displays required in other provisions of RH 6.8, shall have:
- 6.8.1.10.1 an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
- 6.8.1.10.2 an indication of whether x-rays are being produced;
- 6.8.1.10.3 means for indicating x-ray tube potential and current;
- 6.8.1.10.4 means for terminating an exposure at any time;
- 6.8.1.10.5 a locking device which will prevent unauthorized use of the x-ray system; and
- 6.8.1.10.6 for x-ray systems manufactured after September 1, 1992, a positive display of specific filter(s) in the beam.
- 6.8.1.11 System Security. Therapeutic systems which can be secured to prevent unauthorized use by the use of a locking device not located on the control panel shall be exempt from the requirement of RH 6.8.1.10.5.
- 6.8.1.12 Multiple Tubes. When a control panel may energize more than one x-ray tube:
- 6.8.1.12.1 It shall be possible to activate only one x-ray tube at any time.
- 6.8.1.12.2 There shall be an indication at the control panel identifying which x-ray tube is energized.
- 6.8.1.12.3 There shall be an indication at the tube housing assembly when that tube is energized.
- 6.8.1.13 Source-to-Skin Distance. There shall be means of determining the SSD to within 1 centimeter.
- 6.8.1.14 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,



- 6.8.1.14.1 After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
- 6.8.1.14.2 an indication of shutter position shall appear at the control panel.
- 6.8.1.15 Low-Filtration X-Ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
- 6.8.2 Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp
- 6.8.2.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.
- 6.8.2.2 Viewing Systems
- 6.8.2.2.1 Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
- 6.8.2.2.2 Treatment shall not be allowed unless a viewing system is available and in use.
- 6.8.2.3 Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp
- 6.8.2.3.1 All protective barriers shall be fixed except for entrance doors or beam interceptors.
- 6.8.2.3.2 The control panel shall be located outside the treatment room.
- 6.8.2.3.3 Entrance Interlocks.
- 6.8.2.3.3.1 Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.



6.8.2.3.3.2 In maze type facilities without doors, optical beam interlocks shall be provided such that all optical beam interlocks must be functioning before treatment can be initiated or continued. If the optical beam is interrupted it shall not be possible to restore the machine to operation without first clearing the person from the beam and reinitiating irradiation by manual action at the control panel.

6.8.2.3.3.3 When any door referred to in RH 6.8.2.3.3.1 is opened or any optical beam referred to in RH 6.8.2.3.3.2 is interrupted while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8  $\mu\text{C/kg}$ ) per hour.

### 6.8.3 Surveys, Calibrations, Spot Checks, and Operating Procedures

#### 6.8.3.1 Surveys

6.8.3.1.1 All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.8.3.1.2 The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Department within 30 days of receipt of the report.

6.8.3.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

#### 6.8.3.2 Calibrations

6.8.3.2.1 The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.

6.8.3.2.2 The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.

6.8.3.2.3 Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be in accordance with RH 9.4.3 of the Regulations.

- 6.8.3.2.4 The calibrations shall be such that the exposure at a reference point in air can be calculated to within an uncertainty of 5 percent.
- 6.8.3.2.5 The calibration of the x-ray system shall include, but not be limited to, the following determinations:
- 6.8.3.2.5.1 verification that the x-ray system is operating in compliance with the design specifications;
- 6.8.3.2.5.2 the exposure rates as a function of field size, technique factors, filter, and treatment distance used;
- 6.8.3.2.5.3 the degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
- 6.8.3.2.5.4 an evaluation of the uniformity of the largest radiation field used.
- 6.8.3.2.6 Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.
- 6.8.3.2.7 A copy of the most recent x-ray system calibration results shall be readily available.
- 6.8.3.3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:
- 6.8.3.3.1 The spot-check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedure shall be maintained for a period of 5 years by the registrant.
- 6.8.3.3.2 If a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.
- 6.8.3.3.3 The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in RH 6.8.3.2. The acceptable range of tolerances for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in RH 6.8.3.2. shall be stated. The lower value of the range will be an investigational level and the upper value of the range will be maximum acceptable level for routine use.

- 6.8.3.3.4 When the lower value of the range of tolerances is exceeded, the qualified expert shall investigate the cause of the exceedance, and when the higher value of the range of tolerances is exceeded, the system shall not be used until the qualified expert has investigated the cause and either brought the system within the specified range or authorized, in writing, the system to continue in use at the higher level either permanently or temporarily.
- 6.8.3.3.5 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as determined by the qualified expert.
- 6.8.3.3.6 Records of spot-check measurements shall be maintained by the registrant for 2 years after completion of the spot-check measurements and any necessary corrective actions.
- 6.8.3.3.7 Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RH 6.8.3.2. or which has been intercompared with a system meeting those requirements within the previous year.
- 6.8.3.4 Operating Procedures
- 6.8.3.4.1 X-ray systems shall not be left unattended unless the system is secured against unauthorized use.
- 6.8.3.4.2 When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
- 6.8.3.4.3 The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.
- 6.8.3.4.4 No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of RH 4.6 of these Regulations. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.
- 6.8.3.4.5 The x-ray system shall not be used in the administration of radiation therapy unless the requirements of RH 6.8.3.2. and RH 6.8.3.3.5 have been met.

RH 6.9      X-Ray and Electron Therapy Systems with Energies of One MeV and Above.

6.9.1      Definitions. In addition to the definitions provided in RH 6.2, the following definitions shall be applicable to RH 6.9:

"Applicator" means a structure which determines the extent of the field to be treated with electrons at a given distance from the virtual source.

"Beam scattering filter" means a filter used in order to scatter a beam of electrons.

"Central axis of the beam" means a line passing through the virtual source and the center of the plane figure, formed by the edge of the first beam limiting device.

"Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

"Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

"Existing equipment" means therapy systems subject to RH 6.9 which were manufactured before September 1, 1992.

"Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

"Field size" means the dimensions along the major axis of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axis and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

"Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

"Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

"New equipment" means systems subject to RH 6.9 which were manufactured after September 1, 1992.

"Normal treatment distance" means:

- (1) for electron irradiation, the nominal source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
- (2) for x-ray irradiation, the nominal source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

"Radiation head" means the structure from which the useful beam emerges.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

"Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

"Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

"Virtual source" means a point from which radiation appears to originate.

#### 6.9.2 Requirements for Equipment

##### 6.9.2.1 Leakage Radiation to the Patient Area

6.9.2.1.1 New equipment shall meet the following requirements:

6.9.2.1.1.1 For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.



6.9.2.1.1.2

For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in RH 6.9.2.1.1.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Department.

6.9.2.1.2

Existing equipment shall meet the following requirements:

6.9.2.1.2.1

For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

6.9.2.1.2.2

For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in RH 6.9.2.1.2.1 for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Department.

6.9.2.2

Leakage Radiation Outside the Patient Area for New Equipment

6.9.2.2.1

The absorbed dose in rads (grays) due to leakage radiation except in the area specified in RH 6.9.2.1.1.1 when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.20 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in RH 6.9.2.1.1.1.

6.9.2.2.2

The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in RH 6.9.2.2.1 for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over the smallest practical area.



- 6.9.2.3 Beam Limiting Devices. With the exception of secondary custom blocks, adjustable or interchangeable beam limiting devices shall be provided, and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.
- 6.9.2.4 Filters
- 6.9.2.4.1 Each filter which is removable from the system shall be clearly marked with a means of identification. Documentation available at the control panel shall contain a description of the filter. For standard wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- 6.9.2.4.2 If the absorbed dose rate data required by RH 6.9.2.16 relates exclusively to operation with a field-flattening or beam scattering filter in place, such filter shall be removable only by the use of tools or by specific commands entered at the control.
- 6.9.2.4.3 For new equipment which utilizes a system of standard wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering filters:
- 6.9.2.4.3.1 irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
- 6.9.2.4.3.2 an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- 6.9.2.4.3.3 an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
- 6.9.2.5 Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
- 6.9.2.5.1 The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

Table III

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

- 6.9.2.5.2 Compliance with RH 6.9.2.5.1 shall be determined using:
- 6.9.2.5.2.1 a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
- 6.9.2.5.2.2 the largest field size available which does not exceed 15 by 15 centimeters; and
- 6.9.2.5.2.3 a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.
- 6.9.2.5.3 The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.
- 6.9.2.6 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
- 6.9.2.6.1 New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
- 6.9.2.6.2 Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
- 6.9.2.6.3 The detector and the system into which that detector is incorporated shall meet the following requirements:
- 6.9.2.6.3.1 Each detector shall be removable only with tools.
- 6.9.2.6.3.2 Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

- 6.9.2.6.3.3 Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.
- 6.9.2.6.3.4 For new equipment, the design of the dose monitoring systems shall assure that:
- 6.9.2.6.3.4.1 The malfunctioning of one system shall not affect the correct functioning of the second system; and
- 6.9.2.6.3.4.2 The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.
- 6.9.2.6.3.5 Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:
- 6.9.2.6.3.5.1 maintain a reading until intentionally reset to zero;
- 6.9.2.6.3.5.2 have only one scale and no scale multiplying factors;
- 6.9.2.6.3.5.3 utilize a design such that increasing dose is displayed by increasing numbers; and
- 6.9.2.6.3.5.4 in the event of power failure, the dose monitoring information required in RH 6.9.2.6.3.5 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.
- 6.9.2.7 Beam Symmetry. In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.
- 6.9.2.8 Selection and Display of Dose Monitor Units
- 6.9.2.8.1 Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
- 6.9.2.8.2 The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

- 6.9.2.8.3 After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.
- 6.9.2.8.4 For new equipment after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.
- 6.9.2.9 Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy
- 6.9.2.9.1 Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
- 6.9.2.9.2 If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
- 6.9.2.9.3 For equipment manufactured after September 1, 1992, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
- 6.9.2.9.4 For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
- 6.9.2.10 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
- 6.9.2.11 Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

6.9.2.12

Timer

6.9.2.12.1

A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

6.9.2.12.2

The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.9.2.12.3

For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

6.9.2.12.4

The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

6.9.2.13

Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

6.9.2.13.1

Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

6.9.2.13.2

An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

6.9.2.13.3

An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.9.2.13.4

An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

6.9.2.13.5

An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6.9.2.13.6

The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

6.9.2.14

Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

6.9.2.14.1

Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.



- 6.9.2.14.2 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- 6.9.2.14.3 The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
- 6.9.2.14.4 For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.
- 6.9.2.15 Selection of Stationary Beam Therapy or Moving Beam Therapy.  
Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- 6.9.2.15.1 Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
- 6.9.2.15.2 An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
- 6.9.2.15.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
- 6.9.2.15.4 The mode of operation shall be displayed at the treatment control panel.
- 6.9.2.15.5 For new equipment, an interlock system shall be provided to terminate irradiation if:
- 6.9.2.15.5.1 movement of the gantry occurs during stationary beam therapy; or
- 6.9.2.15.5.2 movement of the gantry stops during moving beam therapy unless such stoppage is a pre-planned function.
- 6.9.2.15.6 Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
- 6.9.2.15.6.1 For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.



- 6.9.2.15.6.2 For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.
- 6.9.2.15.7 Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by RH 6.9.2.9.
- 6.9.2.16 Absorbed Dose Rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.\* In addition:
- 6.9.2.16.1 The dose monitor unit rate shall be displayed at the treatment control panel.
- 6.9.2.16.2 If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.
- 6.9.2.17 Location of Nominal Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
- 6.9.2.17.1 The x-ray target or the nominal source of x-rays; and
- 6.9.2.17.2 The electron window or the nominal source of electrons if the system has electron beam capabilities.
- 6.9.3 Facility and Shielding Requirements. In addition to Part 4 of these Regulations, the following design requirements shall apply:
- 6.9.3.1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.
- 6.9.3.2 Control Panel. The control panel shall be located outside the treatment room.

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\*The radiation detectors specified in Subparagraph RH 6.9.2.6 may form part of this system.

6.9.3.3            Viewing Systems

6.9.3.3.1            Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.

6.9.3.3.2            Treatment shall not be allowed unless a viewing system is available and in use.

6.9.3.4            Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

6.9.3.5            Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".

6.9.3.6            Entrance Interlocks.

6.9.3.6.1            Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.9.3.6.2            In maze type facilities without doors, optical beam interlocks shall be provided such that all optical beam interlocks must be functioning before treatment can be initiated or continued. If the optical beam is interrupted it shall not be possible to restore the machine to operation without first clearing the person from the beam and reinitiating irradiation by manual action at the control panel.

6.9.4            Surveys, Calibrations, Spot Checks, and Operating Procedures

6.9.4.1            Surveys

6.9.4.1.1            All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.9.4.1.2            The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the Department within 30 days of receipt of the report.

6.9.4.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations.

6.9.4.2 Calibrations and Spot Checks

6.9.4.2.1 Calibrations and spot checks shall be performed in accordance with Part 9 of the Regulations.

6.9.4.3 Operating Procedures

6.9.4.3.1 No individual other than the patient shall be in the treatment room during treatment of a patient.

6.9.4.3.2 If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

6.9.4.3.3 The system shall not be used in the administration of radiation therapy unless the requirements of RH 6.9.4.1, 6.9.4.2, and 6.9.4.3. have been met.

Other Diagnostic X-Ray Systems

RH 6.10 Veterinary Medicine Radiographic Installations

6.10.1 Equipment

6.10.1.1 The protective tube housing shall be equivalent to the requirements of RH 6.4.3.

6.10.1.2 Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

6.10.1.3 The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

6.10.1.4 A device shall be provided to terminate the exposure after a preset time or exposure.

6.10.1.5 A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all x-ray exposures.

6.10.2 Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with RH 4.6, 4.12, 4.13, and 4.14 of these Regulations.

6.10.2.1 Vet facilities are exempt from the requirements of Appendix B, provided that the operator is adequately protected by distance and/or shielding.

6.10.3 Operating Procedures

6.10.3.1 Whenever possible, the operator shall stand well away from the useful beam and the animal during radiographic exposures.

6.10.3.2 No individual, other than the operator, shall be in the x-ray room while exposures are being made, unless such individual's assistance is required or the person is adequately protected by shielding and/or distance.

6.10.3.3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he/she shall be so positioned that no part of his/her body will be struck by the useful beam. The exposure of any individual used for this purpose shall be maintained below the limits specified in RH 4.6.

RH 6.11 Computed Tomography X-Ray Systems

6.11.1 Definitions. In addition to the definitions provided in RH 1.4 and RH 6.2 of these Regulations, the following definitions shall be applicable to RH 6.11:

"Computed tomography dose index" means the integral from  $-7T$  to  $+7T$  of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

$z$  = Position along a line perpendicular to the tomographic plane.  
 $D(z)$  = Dose at position  $z$ .  
 $T$  = Nominal tomographic section thickness.  
 $n$  = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around  $z=0$  and that, for a multiple tomogram system, the scan increment between adjacent scans is  $nT$ .

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

$\mu_x$  = Linear attenuation coefficient of the material of interest.

$\mu_w$  = Linear attenuation coefficient of water.

$(CTN)_x$  = CTN of the material of interest.

$(CTN)_w$  = CTN of water.

"CS" (See "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in RH 6.2.

"CTDI" (See "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (See "CT number").

"CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

$k$  = A constant<sup>1</sup>

$\mu_x$  = Linear attenuation coefficient of the material of interest.

$\mu_w$  = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

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<sup>1</sup>The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.



"Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate ( $S_n$ ) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

where:

CS = Contrast scale

$\mu_w$  = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.



6.11.2 Requirements for Equipment

6.11.2.1 Termination of Exposure

6.11.2.1.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

6.11.2.1.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by RH 6.11.2.1.1.

6.11.2.1.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

6.11.2.2 Tomographic Plane Indication and Alignment

6.11.2.2.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

6.11.2.2.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

6.11.2.2.3 If a device using a light source is used to satisfy RH 6.11.2.2.1 or 6.11.2.2.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux (46 footcandles).

6.11.2.3 Beam-On and Shutter Status Indicators and Control Switches

6.11.2.3.1 The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

6.11.2.3.2 Each emergency button or switch shall be clearly labeled as to its function.

- 6.11.2.4 Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
- 6.11.2.5 Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by RH 6.4.3.
- 6.11.2.6 Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
- 6.11.2.7 Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 2, 1992
- 6.11.2.7.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
- 6.11.2.7.2 If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
- 6.11.2.7.3 The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.
- 6.11.2.7.4 Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.
- 6.11.3 Facility Design Requirements
- 6.11.3.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- 6.11.3.2 Viewing Systems

- 6.11.3.2.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
- 6.11.3.2.2 Scanner operation shall not be allowed unless a viewing system is available and in use.
- 6.11.4 Surveys, Calibrations, Spot Checks, and Operating Procedures
- 6.11.4.1 Surveys
- 6.11.4.1.1 All CT x-ray systems installed after September 1, 1992 and those systems not previously surveyed shall have a shielding survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- 6.11.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Department upon request.
- 6.11.4.2 Radiation Calibrations
- 6.11.4.2.1 The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.
- 6.11.4.2.2 The calibration of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.
- 6.11.4.2.3 The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.
- 6.11.4.2.4 CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

- 6.11.4.2.4.1 CT dosimetry phantom(s) shall be right circular cylinders of water or polymethyl methacrylate. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.
- 6.11.4.2.4.2 CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.
- 6.11.4.2.4.3 All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.
- 6.11.4.2.5 The calibration shall be required for each common type of head, body, or whole-body scan performed at the facility.
- 6.11.4.2.6 Calibration shall meet the following requirements:
- 6.11.4.2.6.1 The CTDI<sup>6</sup> along the two axes specified in RH 6.11.1.2.4.2 shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.
- 6.11.4.2.6.2 The spot checks specified in RH 6.11.4.3 shall be made.
- 6.11.4.2.7 Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for a period of 3 years for inspection by the Department.
- 6.11.4.3 Spot Checks
- 6.11.4.3.1 The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

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<sup>6</sup>For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

6.11.4.3.2 The spot-check procedures shall incorporate the use of a CT performance phantoms which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

6.11.4.3.3 All spot checks shall be included in the calibration required by RH 6.11.4.2. and at time intervals and under system conditions specified by a qualified expert.

6.11.4.3.4 Spot checks shall include acquisition of images obtained with the CT performance phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by RH 6.11.4.2. The images shall be retained, until a new calibration is performed, as follows:

6.11.4.3.4.1 photographic copies of the images obtained from the image recording device; or

6.11.4.3.4.2 images stored in digital form on a storage medium compatible with the CT x-ray system.

6.11.4.3.5 Written records of the spot checks performed shall be maintained for inspection by the Department.

6.11.4.4 Operating Procedures

6.11.4.4.1 The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

6.11.4.4.2 Information shall be available at the control panel regarding the operation of the system. Information regarding calibration of the system shall be readily available. Such information shall include the following:

6.11.4.4.2.1 dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

6.11.4.4.2.2 instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

6.11.4.4.2.3 the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and



6.11.4.4.2.4

when operators must select technique factors, a current technique chart shall be available at the control panel which specifies for each routine examination the CT conditions of operation and the typical number of scans per examination.

6.11.4.4.3

If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

RH 6.12     Mammography.

6.12.1     Equipment Standards.

6.12.1.1     The x-ray system shall be specifically designed for mammography.

6.12.1.2     The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography.

6.12.1.3     The x-ray equipment must provide kVp-target-filter combinations appropriate to image receptors meeting the requirements of RH 6.12.1.2 of this section, and those appropriate combinations must be used in performing mammography.

6.12.1.4     Beam Quality.

6.12.1.4.1     When used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam shall have a half-value layer (HVL) between the values of: measured kVp/100 and measured kVp/100 + 0.1 millimeters aluminum equivalent.

6.12.1.4.2     For Xeroradiography using a kVp in the range of 35-50, the HVL of the useful beam with the compression device in place shall be at least 1.2 mm aluminum equivalent.

6.12.1.4.3     For all other imaging systems, the HVL shall not be less than that specified in RH 6.4.5.

6.12.1.5     Resolution. The focal spot size and source-to-image receptor distance combinations shall be limited to those appropriate for mammography.

6.12.1.6     Compression. Devices parallel to the imaging plane must be available to immobilize and compress the breast.

6.12.1.7     A mammographic x-ray system utilizing screen-film image receptors shall have the capability of using anti-scatter grids which are available for all image receptor sizes.



- 6.12.1.7.1 All mammographic x-ray systems installed on or after September 1, 1992 shall have the capability of automatic exposure control.
- 6.12.1.8 All mammographic x-ray systems installed on or after September 1, 1992 shall indicate, or provide the means of determining, the mAs resulting from each exposure made with automatic exposure control.
- 6.12.1.9 Transmission. For x-ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
- 6.12.1.10 Collimation.
- 6.12.1.10.1 The mammographic system shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designed SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.
- 6.12.1.10.2 Each image receptor support intended for use on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- 6.12.1.10.3 The mis-alignment of the chest-wall edge of the collimator light field with the chest-wall edge of the x-ray beam shall not exceed 2% of the SID. The edge of the x-ray beam on the other three sides shall not exceed the edge of the light field on those sides.
- 6.12.1.11 The actual kVp shall be within  $\pm 10\%$  of the indicated kVp.

- 6.12.1.11.1 Automatic Systems Performance. See Part RH 6.6.4. In addition, those mammographic systems, installed on or after September 1, 1992, operating with automatic exposure control shall be able to maintain constant film density to within  $\pm 0.3$  OD of the average OD over the range of clinically used kVps, for a specific phantom. The phantom thicknesses shall be of 2 centimeters to 6 centimeters. All mammographic machines shall meet these requirements by July 1, 1995.
- 6.12.1.11.2 Radiation Output Minimum. At a kVp of 28, the mammographic system shall be capable of generating at least 8 mR/mAs and at least 500 mR/second, measured at a point 4.5 centimeters from the surface of the patient support device when the SID is at its maximum.
- 6.12.1.12 Screen-film Contact. Cassettes shall not be used for mammography if one or more large areas ( $>1$  cm) or 2-3 small areas ( $<1$  cm) of poor contact can be seen in a 30-40 mesh test.
- 6.12.1.13 The minimum image quality at a mammographic facility shall be the ability to observe the image of a 0.75 mm fiber, 0.32 mm speck, and a 0.75 mm mass from an ACR phantom (or equivalent) on the standard mammographic film at use in a facility.
- 6.12.1.14 Timer reproducibility. Timers shall meet the reproducibility standards in RH 6.6.2.4.
- 6.12.1.15 Exposure reproducibility. The exposure reproducibility shall meet the standards in RH 6.6.6.1.
- 6.12.1.16 Linearity. Mammographic systems shall meet the linearity standards in RH 6.6.6.2.
- 6.12.2 Quality Assurance
- 6.12.2.1 The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. For each value tested for which a standard is not stated in these Regulations, the Registrant shall establish acceptable ranges of values for each of the parameters tested to aid in the evaluation. These ranges must have a firm scientific and medical basis. Responsibilities under this requirement include:
- 6.12.2.1.1 Conducting or training others to conduct equipment performance monitoring functions;
- 6.12.2.1.2 Analyzing the monitoring results to determine if there are problems requiring correction;

- 6.12.2.1.3 Carrying out or arranging for the necessary corrective actions when results of quality control test results including those specified in RH 6.12.2.3 indicate the need; and
- 6.12.2.1.4 Maintenance of records documenting RH 6.12.2.3 for a period of two years from the date of the evaluation.
- 6.12.2.2 At intervals not to exceed three months, the registrant shall conduct a review of the effectiveness of the quality assurance program required in RH 6.12.2.10.5.1 and maintain a written report of such review. The eight most recent copies of such reports shall be available for inspection by the Department.
- 6.12.2.3 The registrant shall ensure that the following quality control tests are performed when applicable equipment is initially installed and according to the frequency specified, and that applicable tests are performed after major changes or replacement of parts:
- 6.12.2.3.1 Processor performance by sensitometric means - daily, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement.
- 6.12.2.3.2 Resolution and/or focal spot size - upon tube installation or replacement only.
- 6.12.2.3.3 Half-value-layer - 12 months.
- 6.12.2.3.4 kVp accuracy - 12 months.
- 6.12.2.3.5 Output reproducibility, mA linearity, timer linearity, and mR/mAs - 12 months.
- 6.12.2.3.6 Automatic exposure control reproducibility, including kVp response and thickness response - 12 months.
- 6.12.2.3.7 Screen-film contact - 6 months.
- 6.12.2.3.8 Screen cleaning - weekly.
- 6.12.2.3.9 Compression device performance (releases, level of force, etc.) - 6 months.
- 6.12.2.3.10 Collimator alignment - 12 months.
- 6.12.2.3.11 Primary/secondary barrier transmission - upon initial x-ray system installation only.
- 6.12.2.3.12 Image quality using a test "phantom," which simulates the composition of the breast and includes normal and pathological breast structures - weekly for stationary systems and prior to performing mammography at each new location for mobile systems.

- 6.12.2.3.13 Dark dusting of Xerographic plates in positive mode - monthly.
- 6.12.2.3.14 For receptor speed uniformity and artifact detection, blank or clear-block imaging for each:
  - 6.12.2.3.14.1 Xerographic plate, in the most commonly used mode - monthly
  - 6.12.2.3.14.2 Screen-film cassette - quarterly for artifacts and annually for screen uniformity of speed.
- 6.12.2.4 The registrant shall perform the following observations according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two year period.
  - 6.12.2.4.1 Retake analysis - 3 months.
  - 6.12.2.4.2 Mechanical checks - 6 months.
  - 6.12.2.4.3 Viewbox uniformity - 6 months.
  - 6.12.2.4.4 Darkroom integrity - 6 months.
  - 6.12.2.4.5 Adequacy of film storage (including storage after exposure if processing does not occur immediately) - 12 months.
- 6.12.3 Additional Facility Requirements
  - 6.12.3.1 Masks shall be provided on the viewboxes to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the film size or area of clinical interest.
  - 6.12.3.2 Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.
  - 6.12.3.3 An image quality phantom and calibrated sensitometer, densitometer and thermometer must be available to each facility in order to comply with the quality control test frequencies specified in RH 6.12.2 of this section. The calibration of the instruments must be checked every 12 months.
  - 6.12.3.4 A program to analyze retakes must be established as a further aid in detecting and correcting problems affecting image quality or exposure.
  - 6.12.3.5 Darkroom fog levels shall not exceed 0.05 OD when sensitized film is exposed to darkroom conditions with safelight on for 2 minutes.

- 6.12.3.6 All films shall be processed within 12 hours of the exposure of the film.
- 6.12.3.7 Requirements for Mammographers
- 6.12.3.7.1 Effective January 1, 1994, no person shall perform a mammography exam nor shall anyone employ a person to perform a mammography exam unless said person has been approved by the Department as meeting the qualifications for mammographers.
- 6.12.3.7.2 All mammography machines used in the conduct of a mammography exam shall be operated only by:
- 6.12.3.7.2.1 Radiographic technologists who are currently registered in mammography by the American Registry of Radiologic Technologists (ARRT).
- 6.12.3.7.2.2 Additionally, radiographic technologists who are currently registered by the ARRT in diagnostic radiology may perform mammography exams under a provisional certificate pursuant to RH 2.4.4 for a time period of up to one (1) year as part of a structured training program in mammography, while under the direct supervision of a radiologic technologist who is ARRT registered in mammography.
- 6.12.3.7.2.3 Subsequent to successfully completing the training period described in RH 6.12.3.7.2.2, an individual may perform mammography exams under a provisional certificate pursuant to RH 2.4.4 for a period of up to six (6) months while awaiting the administration of, and the results of the test given by the ARRT.
- 6.12.3.7.3 The mammography facility shall post on or near each mammography machine, a list of the qualified mammographers operating the machine.
- 6.12.3.7.4 Copies of registration certificates of mammographers shall be available for inspection by patients and the Department upon request.
- RH 6.13 Requests for Materials Incorporated by Reference. Requests for public inspection of materials incorporated by reference in this Regulation should be made to Robert Quillin, Director, at the Colorado Department of Health, Radiation Control Division, RCD-DO-B1, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530. The Regulation incorporates the materials as they exist at the date of the promulgation of this Regulation and does not include later amendments to or editions of the incorporated material.



RE 6.14

Severability. The provisions of this Regulation are severable, and if any provisions or the application of the provisions to any circumstances is held invalid, the application of such provision to other circumstances, and the remainder of this Regulation shall not be affected thereby.



Part 6

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information shall be submitted to the qualified expert.

1. The plans shall show, as a minimum, the following:
  - (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
  - (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
  - (c) The dimensions of the room(s) concerned and inter-floor distances if occupied.
  - (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
  - (e) The type of examination(s) or treatment(s) which will be performed with the equipment.
2. Information on the anticipated workload of the x-ray system(s).

Part 6

APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH<sup>7</sup>

1. Space Requirements:

- (a) The operator shall be allotted not less than 7.5 square feet (0.697 m<sup>2</sup>) of unobstructed floor space in the booth.
- (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).
- (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's location within the booth.

2. Structural Requirements:

- (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.
- (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- (c) Shielding shall be provided to meet the requirements of Part 4 of these Regulations.

3. X-Ray Control Placement:

The x-ray control for the system shall be fixed within the control booth such that when the operator is at the x-ray control:

- (a) the operator will not be exposed to the useful x-ray beam or to primary x-ray scattered radiation such that the levels in Part 4 could be exceeded; and

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<sup>7</sup>Variances from the above design requirements may be granted by the Department. To apply for such a variance, the facility registrant must submit a facility design review from a Qualified Expert to the Department. The review must specify the reason for the variance and it must demonstrate that the operator will have equivalent protection from radiation by use of the proposed shielding design.

- (b) The operator can use the majority of the available viewing window(s) or device(s).

4. Viewing System Requirements:

- (a) Each booth shall have at least one viewing device which will:
  - (1) be so placed that the operator can view the patient during any exposure, and
  - (2) the device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have either an interlock controlling the exposure which will prevent the exposure if the door is not closed; or a warning light must be activated at the control panel when the door is opened.
- (b) When the viewing system is a window, the following requirements also apply:
  - (1) The viewing area shall be at least 1 square foot (0.0929 m<sup>2</sup>).
  - (2) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457 m) from the edge of the booth.
  - (3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.
- (c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of paragraph 4.(a) of this Appendix.
- (d) When the viewing system is by electronic means:
  - (1) the camera shall be so located as to accomplish the general requirements of paragraph 4.(a) of this Appendix.
  - (2) there shall be an alternate viewing system as a backup for the primary system.

Part 6

APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS  
PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.
2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
3. A detailed description of the x-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.
6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program prior to being placed into operation. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these Regulations.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the x-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the x-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

Part 7

USE OF RADIONUCLIDES IN THE HEALING ARTS

RH 7.1 Purpose and Scope. This part establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to this part unless specifically exempted.

RH 7.2 Definitions. As used in this part, the following definitions apply:

"Area of Use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

- (1) Consistent with the purpose for which the licensed activity is undertaken;
- (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations; and
- (3) In relation to utilization of nuclear energy in the public interest.

"Authorized user" means a practitioner of the healing arts who is identified as an authorized user on a Department, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

"Misadministration" means the administration of:

- (1) A radiopharmaceutical or radiation from a sealed source other than the one intended;
- (2) A radiopharmaceutical or radiation to the wrong patient;
- (3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;
- (4) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;
- (5) A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or
- (6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on a Department license.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

#### GENERAL REGULATORY REQUIREMENTS

##### RH 7.3 License Required.

- 7.3.1 No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these regulations.



- 7.3.2 Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this part under the supervision of an authorized user as provided in RH 7.10.
- RH 7.4 License Amendments. A licensee shall apply for and receive a license amendment:
- 7.4.1 Before using radioactive material for a method or type of medical use not permitted by the license issued under this part;
- 7.4.2 Before permitting anyone, except a visiting authorized user described in RH 7.11, to work as an authorized user under the license;
- 7.4.3 Before changing a Radiation Safety Officer or Teletherapy Physicist;
- 7.4.4 Before receiving radioactive material in excess of the amount authorized on the license;
- 7.4.5 Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and
- 7.4.6 Before changing statements, representations, and procedures which are incorporated into the license.
- RH 7.5 Notifications. A licensee shall notify the Department in writing within 30 days when the authorized user, Radiation Safety Officer, or Teletherapy Physicist, permanently discontinues performance of duties under the license.

#### **Additional Requirements**

- RH 7.6 ALARA Program.
- 7.6.1 Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with RH 4.5.2 of these regulations.
- 7.6.2 To satisfy the requirement of RH 7.6.1:
- 7.6.2.1 The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulation or the Radiation Safety Committee;  
or
- 7.6.2.2 For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

- 7.6.3 The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.
- 7.6.4 The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:
- 7.6.4.1 A commitment by management to keep occupational doses as low as reasonably achievable;
  - 7.6.4.2 A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;
  - 7.6.4.3 Personnel exposure investigational levels as established in accordance with RH 7.8.2.8 that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and
  - 7.6.4.4 Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

RH 7.7 Radiation Safety Officer.

- 7.7.1 A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.
- 7.7.2 The Radiation Safety Officer shall:
- 7.7.2.1 Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;
  - 7.7.2.2 Implement written policy and procedures for:
    - 7.7.2.2.1 Authorizing the purchase of radioactive material;

- 7.7.2.2.2 Receiving and opening packages of radioactive material;
- 7.7.2.2.3 Storing radioactive material;
- 7.7.2.2.4 Keeping an inventory record of radioactive material;
- 7.7.2.2.5 Using radioactive material safely;
- 7.7.2.2.6 Taking emergency action if control of radioactive material is lost;
- 7.7.2.2.7 Performing periodic radiation surveys;
- 7.7.2.2.8 Performing checks and calibrations of survey instruments and other safety equipment;
- 7.7.2.2.9 Disposing of radioactive material;
- 7.7.2.2.10 Training personnel who work in or frequent areas where radioactive material is used or stored; and
- 7.7.2.2.11 Keeping a copy of all records and reports required by the Department regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and
- 7.7.2.3 For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Department for licensing action; or
- 7.7.2.4 For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.
- RH 7.8 Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.
- 7.8.1 The Committee shall meet the following administrative requirements:
  - 7.8.1.1 Membership must consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

- 7.8.1.2 The Committee shall meet at least once each calendar quarter.
- 7.8.1.3 To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.
- 7.8.1.4 The minutes of each Radiation Safety Committee meeting shall include:
  - 7.8.1.4.1 The date of the meeting;
  - 7.8.1.4.2 Members present;
  - 7.8.1.4.3 Members absent;
  - 7.8.1.4.4 Summary of deliberations and discussions;
  - 7.8.1.4.5 Recommended actions and the numerical results of all ballots; and
  - 7.8.1.4.6 Document any reviews required in RH 7.6.3 and 7.8.2.
- 7.8.1.5 The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Department authorizes its disposition.
- 7.8.2 To oversee the use of licensed material, the Committee shall:
  - 7.8.2.1 Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
  - 7.8.2.2 Review, on the basis of safety and with regard to the training and experience standards of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;
  - 7.8.2.3 Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
  - 7.8.2.4 Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Department for licensing action;
  - 7.8.2.5 Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

- 7.8.2.6 Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;
- 7.8.2.7 Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and
- 7.8.2.8 Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

RH 7.9 Statement of Authorities and Responsibilities.

- 7.9.1 A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:
  - 7.9.1.1 Identify radiation safety problems;
  - 7.9.1.2 Initiate, recommend, or provide solutions; and
  - 7.9.1.3 Verify implementation of corrective actions.
- 7.9.2 A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

RH 7.10 Supervision.

- 7.10.1 A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by RH 7.3 is responsible for the acts and omissions of the supervised individual and shall:
  - 7.10.1.1 Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;
  - 7.10.1.2 Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;
  - 7.10.1.3 Reserved.
  - 7.10.1.4 Require that an authorized user be able to communicate with the supervised individual on 1 hours notice; 1/ and

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1/ The supervising authorized user need not be present for each use of radioactive material.

- 7.10.1.5            Require that only those individuals specifically designated by an authorized user be permitted to administer radionuclides or radiation to patients.
- 7.10.2            A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under RH 7.3 to:
- 7.10.2.1           Follow the instructions of the supervising authorized user;
- 7.10.2.2           Follow the procedures established by the Radiation Safety Officer; and
- 7.10.2.3           Comply with these regulations and the license conditions with respect to the use of radioactive material.

RH 7.11           Visiting Authorized User.

- 7.11.1           A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:
- 7.11.1.1           The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;
- 7.11.1.2           The licensee has a copy of a Department, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; and
- 7.11.1.3           Only those procedures for which the visiting authorized user is specifically authorized by the Department, Agreement State, Licensing State or U.S. Nuclear Regulatory Commission license are performed by that individual.
- 7.11.2           A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in RH 7.11.1.
- 7.11.3           A licensee shall retain copies of the records specified in RH 7.11.1 for 5 years from the date of the last visit.

RH 7.12           Mobile Nuclear Medicine Service Administrative Requirements.

- 7.12.1           The Department will only license mobile nuclear medicine services in accordance with this part and other applicable requirements of these regulations to serve clients who do not have a Department license.



7.12.2 Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.

7.12.3 A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

RH 7.13 Records and Reports of Misadministrations.

7.13.1 When a misadministration involves any therapy procedure, the licensee shall notify the Department. The licensee shall also notify the referring physician of the affected patient and the patient, or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

7.13.2 Within 15 days after an initial therapy misadministration report to the Department, the licensee shall report, in writing, to the Department and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee as required by RH 7.13.1. The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.

- 7.13.3 When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for Department review, and retain the record as directed in RH 7.13.4. The licensee shall also notify the referring physician and the Department in writing on Department Form RCD 56 - Report of Misadministration within 15 days if the misadministration involved the use of radioactive material not intended for medical use, administration of dosage five-fold different from the intended dosage, or administration of radioactive material such that the patient is likely to receive an organ dose greater than 2 rems (0.02 Sv) or whole body dose greater than 500 millirems (5 mSv). Licensees shall use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.
- 7.13.4 Each licensee shall retain a record of each misadministration for 10 years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.
- 7.13.5 Aside from the notification requirements, nothing in RH 7.13.1 through RH 7.13.4 shall affect any rights or duties of licensees, and physicians in relation to each other, patients, or responsible relative or guardians.
- RH 7.14 Suppliers. A licensee shall use for medical use only:
- 7.14.1 Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission; and
- 7.14.2 Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration.
- 7.14.3 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing state, or the U.S. Nuclear Regulatory Commission.

## SPECIFIC REQUIREMENTS

- RH 7.15      Quality Control of Nuclear Medicine Imaging and Uptake Quantifying Equipment. Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies for equipment used for quantifying radionuclide uptake. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the Department. The licensee shall conduct quality control procedures in accordance with written procedures.
- RH 7.16      Possession, Use, Calibration, and Check of Dose Calibrators.
- 7.16.1      A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient.
- 7.16.2      A licensee shall:
- 7.16.2.1      Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;
- 7.16.2.2      Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
- 7.16.2.3      Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 10 microcuries (370 kBq) and the highest dosage that will be assayed; and
- 7.16.2.4      Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

- 7.16.3 A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
- 7.16.4 A licensee shall also perform checks and tests required by RH 7.16.2 following adjustment or repair of the dose calibrator.
- 7.16.5 A licensee shall retain a record of each check and test required by RH 7.16 for 3 years. The records required by RH 7.16.2 shall include:
- 7.16.5.1 For RH 7.16.2.1, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;
- 7.16.5.2 For RH 7.16.2.2, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the Radiation Safety Officer or their designee;
- 7.16.5.3 For RH 7.16.2.3, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer or their designee; and
- 7.16.5.4 For RH 7.16.2.4 the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the Radiation Safety Officer or their designee.
- RH 7.17 Calibration and Check of Survey Instruments.
- 7.17.1 A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, annually, and following repair.
- 7.17.2 To satisfy the requirements of RH 7.17.1 the licensee shall:
- 7.17.2.1 Calibrate all required scale readings up to 1000 millirems (10mSv) per hour with a radiation source. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour;



- 7.17.2.2 For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and
- 7.17.2.3 Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.
- 7.17.3 To satisfy the requirements of RH 7.17.2, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.
- 7.17.4 A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.
- 7.17.5 The licensee shall retain a record of each calibration required in RH 7.17.1 for 3 years. The record shall include:
- 7.17.5.1 A description of the calibration procedure; and
- 7.17.5.2 A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.
- 7.17.6 To meet the requirements of RH 7.17.1, 7.17.2 and 7.17.3, the licensee may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by RH 7.17.5 shall be maintained by the licensee.
- RH 7.18 Assay of Radiopharmaceutical Dosages. A licensee shall:
- 7.18.1 Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 microcuries (370 kBq) of a photon-emitting radionuclide;
- 7.18.2 Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries (370 kBq); and
- 7.18.3 Retain a record of the assays required by RH 7.18.1 and 7.18.2 for 3 years. To satisfy this requirement, the record shall contain the:
- 7.18.3.1 Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

- 7.18.3.2 Patient's name, and identification number if one has been assigned;
- 7.18.3.3 Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 microcuries (370 kBq);
- 7.18.3.4 Date and time of the assay and administration; and
- 7.18.3.5 Initials of the individual who performed the assay.
- RH 7.19 Authorization for Calibration and Reference Sources. Any person authorized by RH 7.3 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:
  - 7.19.1 Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part 3 of these regulations or equivalent provisions of the U.S. Nuclear Regulatory commission, Agreement State or Licensing State and that do not exceed 15 millicuries (555 MBq) each;
  - 7.19.2 Any radioactive material listed in RH 7.30 or 7.32 with a half-life not longer than 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);
  - 7.19.3 Any radioactive material listed in RH 7.30 or RH 7.32 with a half life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and
  - 7.19.4 Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).
- RH 7.20 Requirements for Possession of Sealed Sources and Brachytherapy Sources.
  - 7.20.1 A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department and shall maintain the instructions for the duration of source use in a legible form convenient to users.
  - 7.20.2 A licensee in possession of a sealed source shall assume that:
    - 7.20.2.1 The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and
    - 7.20.2.2 The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the Department, another Agreement State, a Licensing State or the U.S Nuclear Regulatory Commission.



- 7.20.3 To satisfy the leak test requirements of RH 7.20.2, the licensee shall assure that:
- 7.20.3.1 Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;
- 7.20.3.2 Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
- 7.20.3.3 Test samples are taken when the source is in the "off" position.
- 7.20.4 A licensee shall retain leak test records for 5 years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.
- 7.20.5 If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:
- 7.20.5.1 Immediately withdraw the sealed source from use and store it in accordance with the requirements of these regulations; and
- 7.20.5.2 File a report with the Department within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.
- 7.20.6 A licensee need not perform a leak test on the following sources:
- 7.20.6.1 Sources containing only radioactive material with a half-life of less than 30 days;
- 7.20.6.2 Sources containing only radioactive material as a gas;
- 7.20.6.3 Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material;
- 7.20.6.4 Encased seeds of iridium-192 in nylon ribbon; and
- 7.20.6.5 Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

- 7.20.7 A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed 3 months. The licensee shall retain each inventory record for 5 years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.
- 7.20.8 A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.
- 7.20.9 A licensee shall retain a record of each survey required in RH 7.20.8 for 3 years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer
- RH 7.21 Syringe Shields.
- 7.21.1 A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.
- 7.21.2 A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for the patient.
- RH 7.22 Syringe Labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's name.
- RH 7.23 Vial Shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.
- RH 7.24 Vial Shield Labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of radiopharmaceutical with the radiopharmaceutical name or its abbreviation.
- RH 7.25 Surveys for Contamination and Ambient Radiation Dose Rate.
- 7.25.1 A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

- 7.25.2 A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.
- 7.25.3 A licensee shall conduct the surveys required by RH 7.25.1 and RH 7.25.2 so as to be able to measure dose rates as low as 0.1 millirem (1 uSv) per hour.
- 7.25.4 A licensee shall establish dose rate action levels for the surveys required by RH 7.25.1 and 7.25.2 and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.
- 7.25.5 A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.
- 7.25.6 A licensee shall conduct the surveys required by RH 7.25.5 so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).
- 7.25.7 A licensee shall establish removable contamination action levels for the surveys required by RH 7.25.5 and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.
- 7.25.8 A licensee shall retain a record of each survey required by RH 7.25.1, 7.25.2, and 7.25.5 for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.
- RH 7.26 Release of Patients Containing Radiopharmaceuticals or Permanent Implants.
- 7.26.1 A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:
- 7.26.1.1 The dose rate from the patient is less than 5 millirems (50 uSv) per hour at a distance of 1 meter; or
- 7.26.1.2 The activity in the patient is less than 30 millicuries (1.11 GBq).

- 7.26.2 A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 5 millirems (50 uSv) per hour at a distance of 1 meter.
- RH 7.27 Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:
- 7.27.1 Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;
- 7.27.2 Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- 7.27.3 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;
- 7.27.4 Check survey instruments and dose calibrators as required in RH 7.16.2.1, 7.16.4, 7.16.5, and 7.17.4, and check all other transported equipment for proper function before medical use at each location of use;
- 7.27.5 Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and
- 7.27.6 Retain a record of each survey required by RH 7.27.5 for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.
- RH 7.28 Storage of Volatiles and Gases.
- 7.28.1 A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.
- 7.28.2 A licensee shall store and use a multidose container in a properly functioning fume hood.



RH 7.29     Decay-In-Storage.

- 7.29.1     A licensee shall hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of RH 4.33 of these regulations if the licensee:
- 7.29.1.1     Holds radioactive material for decay a minimum of 10 half-lives;
- 7.29.1.2     Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
- 7.29.1.3     Removes or obliterates all radiation labels; and
- 7.29.1.4     Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.
- 7.29.2     For radioactive material disposed in accordance with RH 7.29.1, the licensee shall retain a record of each disposal for 3 years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

**SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS FOR UPTAKE, DILUTION, OR EXCRETION STUDIES**

RH 7.30     Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

- 7.30.1     A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:
- 7.30.1.1     Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;
- 7.30.1.2     Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA);
- 7.30.1.3     Cobalt-57 as labeled cyanocobalamin;
- 7.30.1.4     Cobalt-58 as labeled cyanocobalamin;
- 7.30.1.5     Cobalt-60 as labeled cyanocobalamin;

- 7.30.1.6 Chromium-51 as sodium chromate or labeled human serum albumin;
- 7.30.1.7 Iron-59 as citrate;
- 7.30.1.8 Technetium-99m as pertechnetate;
- 7.30.1.9 Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).
- 7.30.2 A licensee using a radiopharmaceutical specified in RH 7.30.1 for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.
- RH 7.31 Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 uSv) per hour to 50 millirems (50 uSv) per hour. The instrument shall be operable and calibrated in accordance with RH 7.17.

**SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS, GENERATORS, AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES**

- RH 7.32 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.
- 7.32.1 A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:
  - 7.32.1.1 Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;
  - 7.32.1.2 Technetium-99m as pertechnetate;
  - 7.32.1.3 Prepare radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:
    - 7.32.1.3.1 Sulfur colloid,
    - 7.32.1.3.2 Pentetate sodium,
    - 7.32.1.3.3 Human serum albumin microspheres,
    - 7.32.1.3.4 Polyphosphate,



7.32.1.3.5	Macroaggregated human serum albumin,
7.32.1.3.6	Etidronate sodium,
7.32.1.3.7	Stannous pyrophosphate,
7.32.1.3.8	Human serum albumin,
7.32.1.3.9	Medronate sodium,
7.32.1.3.10	Glucaptate sodium,
7.32.1.3.11	Oxidronate sodium,
7.32.1.3.12	Disofenin, and
7.32.1.3.13	Succimer;
7.32.1.4	Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (macroaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;
7.32.1.5	Iodine-125 as sodium iodide or fibrinogen;
7.32.1.6	Chromium-51 as human serum albumin;
7.32.1.7	Gold-198 in colloidal form;
7.32.1.8	Mercury-197 as chlormerodrin;
7.32.1.9	Selenium-75 as selenomethionine;
7.32.1.10	Strontium-85 as nitrate;
7.32.1.11	Ytterbium-169 as pentetate sodium;
7.32.1.12	Gallium-67 as citrate;
7.32.1.13	Indium-111 as chloride or DTPA;
7.32.1.14	Tin-113/indium-113m generators for the elution of indium-113m as chloride;
7.32.1.15	Yttrium-87/strontium-87m generators for the elution of strontium-87m;
7.32.1.16	Thallium-201 as chloride;
7.32.1.17	Iodine-123 as sodium iodide or iodohippurate;

- 7.32.1.18 Any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).
- 7.32.2 A licensee using radiopharmaceuticals specified in RH 7.32.1 for clinical procedures shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.
- 7.32.3 A licensee shall elute generators in compliance with RH 7.33 and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.
- 7.32.4 Technetium-99m pentetate as an aerosol for lung function studies is not subject to the restrictions in RH 7.32.2.
- 7.32.5 Provided the conditions of RH 7.34 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Department.
- RH 7.33 Permissible Molybdenum-99 Concentration.
- 7.33.1 A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).
- 7.33.2 A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.
- 7.33.3 A licensee who must measure molybdenum concentration shall retain a record of each measurement for 3 years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicuries of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.
- 7.33.4 A licensee shall report immediately to the Department each occurrence of molybdenum-99 concentration exceeding the limits specified in RH 7.33.1.

RH 7.34 Control of Aerosols and Gases.

- 7.34.1 A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by RH 4.4 and RH 4.7 of these regulations.
- 7.34.2 The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- 7.34.3 A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- 7.34.4 Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix A of Part 4 of these regulations. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- 7.34.5 A licensee shall post the time calculated in RH 7.34.4 at the area of use, and the safety measures to be instituted in case of a spill in the area of use.
- 7.34.6 A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.
- 7.34.7 A copy of the calculations required in RH 7.34.4 shall be recorded and retained for the duration of the license.
- RH 7.35 A licensee authorized to use radioactive materials for imaging and localization studies shall possess the capability of detecting dose rates over the range of 0.1 millirem (1 uSv) per hour to 1000 millirems (10 mSv) per hour. The portable radiation detection survey instruments shall be operable and calibrated in accordance with RH 7.17. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour.

**SPECIFIC REQUIREMENTS FOR THE USE OF RADIOPHARMACEUTICALS FOR THERAPY**

- RH 7.36 Use of Radiopharmaceuticals for Therapy. A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

RH 7.37     Safety Instruction.

7.37.1     A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed 1 year.

7.37.2     To satisfy RH 7.37.1, the instruction shall describe the licensee's procedures for:

7.37.2.1     Patient control;

7.37.2.2     Visitor control;

7.37.2.3     Contamination control;

7.37.2.4     Waste control;

7.37.2.5     Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency; and

7.37.2.6     Part 10 training requirements.

7.37.3     A licensee shall keep a record of individuals receiving instruction required by RH 7.37.1, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Department for 3 years.

RH 7.38     Safety Precautions.

7.38.1     For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with RH 7.26, a licensee shall:

7.38.1.1     Provide a private room with a private sanitary facility;

7.38.1.2     Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

7.38.1.3     Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

- 7.38.1.4 Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of RH 4.14 and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems per hour, the instrument used to make the survey, and the initials of the individual who made the survey. A survey of contiguous restricted and unrestricted areas need not be repeated provided the patient's dose is no greater than that for which a previous survey of contiguous areas was completed, determined to be in compliance with RH 4.6 and a record maintained;
- 7.38.1.5 Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;
- 7.38.1.6 Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;
- 7.38.1.7 Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and
- 7.38.1.8 Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within 3 days after administering the dosage, and retain for the period required by RH 4.42.2 of these regulations a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.
- 7.38.2 A licensee shall notify the Radiation Safety Officer or the authorized user immediately if the patient dies or has a medical emergency.



- RH 7.39 A licensee authorized to use radioactive materials for radiopharmaceutical therapy shall possess the capability of detecting dose rates over the range of 0.1 millirem (1 uSv) per hour to 1000 millirems (10 mSv) per hour. The portable radiation detection survey instruments shall be operable and calibrated in accordance with RH 7.17. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour.

#### SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS

- RH 7.40 Use of Sealed Sources for Diagnosis. A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:
- 7.40.1 Iodine-125 as a sealed source in a device for bone mineral analysis;
  - 7.40.2 Americium-241 as a sealed source in a device for bone mineral analysis;
  - 7.40.3 Gadolinium-153 as a sealed source in a device for bone mineral analysis; and
  - 7.40.4 Iodine-125 as a sealed source in a portable device for imaging.
- RH 7.41 A licensee authorized to use radioactive material as a sealed source for diagnosis shall possess the capability of detecting dose rates over the range of 0.1 millirem (1 uSv) per hour to 1000 millirem (10 mSv) per hour. The portable radiation detection survey instruments shall be operable and calibrated in accordance with RH 7.17. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour.

#### SPECIFIC REQUIREMENTS FOR THE USE OF SOURCES FOR BRACHYTHERAPY

- RH 7.42 Use of Sources for Brachytherapy. A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:
- 7.42.1 Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
  - 7.42.2 Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
  - 7.42.3 Gold-198 as a sealed source in seeds for interstitial treatment of cancer;



- 7.42.4 Iodine-125 as a sealed source in seeds for interstitial treatment of cancer or as an applicator cell for topical treatment of cancer;
- 7.42.5 Iridium-192 as encased seeds for the interstitial treatment of cancer;
- 7.42.6 Reserved.
- 7.42.7 Reserved.
- 7.42.8 Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions ; and
- 7.42.9 Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.
- RH 7.43 Safety Instruction.
- 7.43.1 The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training shall be provided at intervals not to exceed 1 year.
- 7.43.2 To satisfy RH 7.43.1, the instruction shall describe:
- 7.43.2.1 Size and appearance of the brachytherapy sources;
- 7.43.2.2 Safe handling and shielding instructions in case of a dislodged source;
- 7.43.2.3 Procedures for patient control;
- 7.43.2.4 Procedures for visitor control;
- 7.43.2.5 Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency; and
- 7.43.2.6 Part 10 training requirements.
- 7.43.3 A licensee shall maintain a record of individuals receiving instruction required by RH 7.43.1, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 2 years.
- RH 7.44 Safety Precautions.
- 7.44.1 For each patient receiving implant therapy a licensee shall:
- 7.44.1.1 Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of RH 4.14 of these regulations at a distance of 1 meter from the implant.

- 7.44.1.2 Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;
- 7.44.1.3 Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
- 7.44.1.4 Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with RH 4.14 of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey. A survey of contiguous restricted and unrestricted areas need not be repeated provided the patient's dose is no greater than that for which a previous survey of contiguous areas was completed, determined to be in compliance with RH 4.14 and a record maintained; and
- 7.44.1.5 Provide the patient with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.
- 7.44.2 A licensee shall notify the Radiation Safety Officer or authorized user immediately if the patient dies or has a medical emergency.
- RH 7.45 Brachytherapy Sources Inventory.
- 7.45.1 Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.
- 7.45.2 A licensee shall make a record of brachytherapy source utilization which includes:
- 7.45.2.1 The names of the individuals permitted to handle the sources;
- 7.45.2.2 The number and activity of sources removed from storage, the room number of use or patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

- 7.45.2.3 The number and activity of sources returned to storage, the room number of use or patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.
- 7.45.3 Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
- 7.45.4 A licensee shall maintain the records required in RH 7.45.2 and 7.45.3 for 3 years.
- RH 7.46 Release of Patients Treated with Temporary Implants.
- 7.46.1 Immediately after removing the last temporary implant source from a patient, the licensee shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.
- 7.46.2 A licensee shall maintain a record of patient surveys which demonstrate compliance with RH 7.46.1 for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.
- RH 7.47 A licensee authorized to use radioactive material for implant therapy shall possess the capability of detecting dose rates over the range of 0.1 millirem (1 uSv) per hour to 1000 millirems (10 mSv) per hour. The portable radiation detection survey instruments shall be operable and calibrated in accordance with RH 7.17. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour.

#### **SPECIFIC REQUIREMENTS FOR THE USE OF A SEALED SOURCE IN TELETHERAPY**

- RH 7.48 Use of a Sealed Source in a Teletherapy Unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

- RH 7.49     Maintenance and Repair Restrictions. Only a person specifically licensed by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.
- RH 7.50     Amendments. In addition to the requirements specified in RH 7.4, a licensee shall apply for and receive a license amendment before:
- 7.50.1     Making any change in the treatment room shielding;
  - 7.50.2     Making any change in the location of the teletherapy unit within the treatment room;
  - 7.50.3     Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
  - 7.50.4     Relocating the teletherapy unit; or
  - 7.50.5     Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.
- RH 7.51     Safety Instruction.
- 7.51.1     A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:
    - 7.51.1.1     The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;
    - 7.51.1.2     The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and
    - 7.51.1.3     The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.
  - 7.51.2     A licensee shall provide instruction in the topics identified in RH 7.51.1 to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed 1 year.

- 7.51.3 A licensee shall maintain a record of individuals receiving instructions required by RH 7.51.2, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 2 years.
- RH 7.52 Doors, Interlocks, and Warning Systems.
- 7.52.1 A licensee shall control access to the teletherapy room by a door at each entrance.
- 7.52.2 A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
- 7.52.2.1 Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;
- 7.52.2.2 Turn the beam of radiation "off" immediately when an entrance door is opened; and
- 7.52.2.3 Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.
- 7.52.3 A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.
- RH 7.53 A licensee authorized to use radioactive material in a teletherapy unit shall possess the capability of detecting dose rates over the range of 0.1 millirem (1 uSv) per hour to 1000 millirems (10 mSv) per hour. The portable radiation detection survey instruments shall be operable and calibrated in accordance with RH 7.17. Licensees with specified limited authorized quantities of radioactive material may specify a different dose rate range, however, in no case will the lower level be higher than 0.1 millirem (1 uSv) per hour.
- RH 7.54 Radiation Monitoring Device.
- 7.54.1 A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.
- 7.54.2 Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.
- 7.54.3 Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.



- 7.54.4 A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.
- 7.54.5 A licensee shall maintain a record of the check required by RH 7.54.4 for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.
- 7.54.6 If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in RH 7.54.5.
- 7.54.7 A licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- RH 7.55 Viewing System. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.
- RH 7.56 Dosimetry Equipment.
- 7.56.1 A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:
- 7.56.1.1 The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or



7.56.1.2 The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

7.56.2 The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with RH 7.56.1. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in RH 7.56.1.

7.56.3 The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by RH 7.56.1 and RH 7.56.2, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

RH 7.57 Full Calibration Measurements.

7.57.1 A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

7.57.1.1 Before the first medical use of the unit;

7.57.1.2 Before medical use under the following conditions:

- 7.57.1.2.1 Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
- 7.57.1.2.2 Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
- 7.57.1.2.3 Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- 7.57.1.3 At intervals not exceeding 1 year.
- 7.57.2 To satisfy the requirement of RH 7.57.1, full calibration measurements shall include determination of:
  - 7.57.2.1 The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
  - 7.57.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing device;
  - 7.57.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;
  - 7.57.2.4 Timer accuracy, constancy, and linearity;
  - 7.57.2.5 "On-off" error; and
  - 7.57.2.6 The accuracy of all distance measuring and localization devices in medical use.
- 7.57.3 A licensee shall use the dosimetry system described in RH 7.56 to measure the output for one set of exposure conditions. The remaining radiation measurements required in RH 7.57.2.1 may then be made using a dosimetry system that indicates relative dose rates.

- 7.57.4 A licensee shall make full calibration measurements required by RH 7.57.1 in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213.<sup>2</sup>
- 7.57.5 A licensee shall correct mathematically the outputs determined in RH 7.57.2.1 for physical decay for intervals not exceeding 1 month for cobalt-60 and intervals not exceeding 6 months for cesium-137.
- 7.57.6 Full calibration measurements required by RH 7.57.1 and physical decay corrections required by RH 7.57.5 shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such service.
- 7.57.7 A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.
- RH 7.58 Periodic Spot Checks.
- 7.58.1 A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed 1 month.

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2 A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.

- 7.58.2 To satisfy the requirement of RH 7.58.1, spot checks shall include determination of:
- 7.58.2.1 Timer constancy and timer linearity over the range of use;
  - 7.58.2.2 "On-off" error;
  - 7.58.2.3 The coincidence of the radiation field and the field indicated by the light beam localizing device;
  - 7.58.2.4 The accuracy of all distance measuring and localization devices used for medical use;
  - 7.58.2.5 The output for one typical set of operating conditions; and
  - 7.58.2.6 The difference between the measurement made in RH 7.58.2.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).
- 7.58.3 A licensee may use the dosimetry system described in RH 7.56 to make the spot check required in RH 7.58.2.5.
- 7.58.4 A licensee shall perform spot checks required by RH 7.58.1 in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.
- 7.58.5 A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for 3 years.
- 7.58.6 A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed 1 month.
- 7.58.7 To satisfy the requirement of RH 7.58.6, safety spot checks shall assure proper operation of:
- 7.58.7.1 Electrical interlocks at each teletherapy room entrance;
  - 7.58.7.2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;
  - 7.58.7.3 Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
  - 7.58.7.4 Viewing systems;

- 7.58.7.5 Treatment room doors from inside and outside the treatment room; and
- 7.58.7.6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".
- 7.58.8 A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the Department.
- 7.58.9 A licensee shall promptly repair any system identified in RH 7.58.7 that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.
- 7.58.10 A licensee shall maintain a record of each spot check required by RH 7.58.1 and 7.58.6 for 3 years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door, electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.
- RH 7.59 Radiation Surveys for Teletherapy Facilities.
- 7.59.1 Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by RH 7.50.1 through RH 7.50.4, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with RH 7.17 to verify that:
- 7.59.1.1 The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 uSv) per hour and 2 millirems (20 uSv) per hour, respectively; and
- 7.59.1.2 With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:



- 7.59.1.2.1 Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in RH 4.6 of these regulations; and
- 7.59.1.2.2 Radiation levels in unrestricted areas do not exceed the limits specified in RH 4.14.1 of these regulations.
- 7.59.2 If the results of the surveys required in RH 7.59.1 indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:
- 7.59.2.1 Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
- 7.59.2.2 Until the licensee has received a specific exemption from the Department.
- 7.59.3 A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.
- RH 7.60 Safety Spot Check for Teletherapy Facilities.
- 7.60.1 A licensee shall promptly check all systems listed in RH 7.58.7 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by RH 7.50.
- 7.60.2 If the result of the safety spot checks required in RH 7.60.1 indicate the malfunction of any system specified in RH 7.58, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- 7.60.3 A licensee shall maintain a record of the safety spot checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.



- RH 7.61 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by RH 7.59 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by RH 4.14.1 of these regulations, before beginning the treatment program the licensee shall:
- 7.61.1 Either equip the unit with stops or add additional radiation shielding to ensure compliance with RH 4.6.1 of these regulations;
  - 7.61.2 Perform the survey required by RH 7.59 again; and
  - 7.61.3 Include in the report required by RH 7.62 the results of the initial survey, a description of the modification made to comply with RH 7.61.1, and the results of the second survey; or
  - 7.61.4 Request and receive a license amendment under RH 4.14.3 of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by RH 4.14.1 of these regulations.
- RH 7.62 Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in RH 7.59, 7.60, 7.61 and the output from the teletherapy source expressed as rads (Grays) per hour at 1 meter from the source as determined during the full calibration required in RH 7.57 to the Department within 30 days following completion of the action that initiated the record requirement.
- RH 7.63 Five-Year Inspection.
- 7.63.1 A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
  - 7.63.2 This inspection and servicing shall only be performed by persons specifically licensed to do so by the Department, an Agreement State, or the U.S. Nuclear Regulatory Commission.
  - 7.63.3 A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

SPECIFIC REQUIREMENTS FOR TRAINING

- RH 7.64     Radiation Safety Officer. Except as provided in RH 7.65, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in RH 7.7 shall:
- 7.64.1     Be certified by the:
    - 7.64.1.1     American Board of Health Physics in Comprehensive Health Physics;
    - 7.64.1.2     American Board of Radiology;
    - 7.64.1.3     American Board of Nuclear Medicine;
    - 7.64.1.4     American Board of Science in Nuclear Medicine; or
    - 7.64.1.5     Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or
  - 7.64.2     Have had 200 hours of classroom and laboratory training as follows:
    - 7.64.2.1     Radiation physics and instrumentation;
    - 7.64.2.2     Radiation protection;
    - 7.64.2.3     Mathematics pertaining to the use and measurement of radioactivity;
    - 7.64.2.4     Radiation biology;
    - 7.64.2.5     Radiopharmaceutical chemistry; and
    - 7.64.2.6     1 year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Department, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or
  - 7.64.3     Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.
- RH 7.65     Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on a Department, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on the effective date of this rule who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of RH 7.64.

- PH 7.66     Training for Uptake, Dilution, or Excretion Studies.     Except as provided in RH 7.74 and 7.75, the licensee shall require the authorized user of a radiopharmaceutical listed in RH 7.30 to be a physician who:
- 7.66.1     Is certified in:
- 7.66.1.1     Nuclear medicine by the American Board of Nuclear Medicine;
- 7.66.1.2     Diagnostic radiology by the American Board of Radiology; or
- 7.66.1.3     Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or
- 7.66.1.4     Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
- 7.66.2     Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.
- 7.66.2.1     To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:
- 7.66.2.1.1     Radiation physics and instrumentation;
- 7.66.2.1.2     Radiation protection;
- 7.66.2.1.3     Mathematics pertaining to the use and measurement of radioactivity;
- 7.66.2.1.4     Radiation biology; and
- 7.66.2.1.5     Radiopharmaceutical chemistry.
- 7.66.2.2     To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:
- 7.66.2.2.1     Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
- 7.66.2.2.2     Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
- 7.66.2.2.3     Administering dosages to patients and using syringe radiation shields;
- 7.66.2.2.4     Collaborating with the authorized user in the interpretation of radionuclide test results; and

- 7.66.2.2.5 Patient follow-up; or
- 7.66.3. Has successfully completed a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all topics identified in RH 7.66.2.
- RH 7.67 Training for Imaging and Localization Studies. Except as provided in RH 7.74 and RH 7.75, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in RH 7.32 to be a physician who:
  - 7.67.1 Is certified in:
    - 7.67.1.1 Nuclear medicine by the American Board of Nuclear Medicine;
    - 7.67.1.2 Diagnostic radiology by the American Board of Radiology; or
    - 7.67.1.3 Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or
    - 7.67.1.4 Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
  - 7.67.2 Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.
    - 7.67.2.1 To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:
      - 7.67.2.1.1 Radiation physics and instrumentation;
      - 7.67.2.1.2 Radiation protection;
      - 7.67.2.1.3 Mathematics pertaining to the use and measurement of radioactivity;
      - 7.67.2.1.4 Radiopharmaceutical chemistry; and
      - 7.67.2.1.5 Radiation biology.
    - 7.67.2.2 To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
      - 7.67.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- 7.67.2.2.2      Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
- 7.67.2.2.3      Calculating and safely preparing patient dosages;
- 7.67.2.2.4      Using administrative controls to prevent the misadministration of radioactive material;
- 7.67.2.2.5      Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- 7.67.2.2.6      Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.
- 7.67.2.3        To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
  - 7.67.2.3.1      Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
  - 7.67.2.3.2      Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
  - 7.67.2.3.3      Administering dosages to patients and using syringe radiation shields;
  - 7.67.2.3.4      Collaborating with the authorized user in the interpretation of radionuclide test results; and
  - 7.67.2.3.5      Patient follow-up; or
- 7.67.3        Has successfully completed a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in RH 7.67.2.
- RH 7.68        Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in RH 7.74, the licensee shall require the authorized user of a radiopharmaceutical listed in RH 7.36 for therapy to be a physician who:
  - 7.68.1        Is certified by:
    - 7.68.1.1        The American Board of Nuclear Medicine; or



- 7.68.1.2 The American Board of Radiology in radiology or therapeutic radiology or radiation oncology; or
- 7.68.2 Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.
  - 7.68.2.1 To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:
    - 7.68.2.1.1 Radiation physics and instrumentation;
    - 7.68.2.1.2 Radiation protection;
    - 7.68.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and
    - 7.68.2.1.4 Radiation biology;
  - 7.68.2.2 To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
    - 7.68.2.2.1 Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism and related cardiac dysfunction in ten individuals;
    - 7.68.2.2.2 Use of iodine-131 for treatment of thyroid carcinoma in three individuals; and
- RH 7.69 Training for Therapeutic Use of Brachytherapy Sources.  
 Except as provided in RH 7.74, the licensee shall require the authorized user using a brachytherapy source specified in RH 7.42 for therapy to be a physician who:
  - 7.69.1 Is certified in:
    - 7.69.1.1 Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
    - 7.69.1.2 Radiation oncology by the American Osteopathic Board of Radiology;
    - 7.69.1.3 Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
    - 7.69.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or



- 7.69.2 Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of 3 years of supervised clinical experience.
- 7.69.2.1 To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:
- 7.69.2.1.1 Radiation physics and instrumentation;
- 7.69.2.1.2 Radiation protection;
- 7.69.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and
- 7.69.2.1.4 Radiation biology.
- 7.69.2.2 To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:
- 7.69.2.2.1 Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- 7.69.2.2.2 Checking survey meters for proper operation;
- 7.69.2.2.3 Preparing, implanting, and removing sealed sources;
- 7.69.2.2.4 Using administrative controls to prevent the misadministration of radioactive material; and
- 7.69.2.2.5 Using emergency procedures to control radioactive material.
- 7.69.2.3 To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
- 7.69.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
- 7.69.2.3.2 Selecting the proper brachytherapy sources, dose, and method of administration;
- 7.69.2.3.3 Calculating the dose; and

- 7.69.2.3.4 Post-administration follow-up and review of case histories in collaboration with the authorized user.
- RH 7.70 Training for Ophthalmic Use of Strontium-90. Except as provided in RH 7.74, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:
- 7.70.1 Is certified in radiology or therapeutic radiology by the American Board of Radiology; or
- 7.70.2 Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.
- 7.70.2.1 To satisfy the requirement for instruction, the classroom and laboratory training shall include:
- 7.70.2.1.1 Radiation physics and instrumentation;
- 7.70.2.1.2 Radiation protection;
- 7.70.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and
- 7.70.2.1.4 Radiation biology.
- 7.70.2.2 To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
- 7.70.2.2.1 Examination of each individual to be treated;
- 7.70.2.2.2 Calculation of the dose to be administered;
- 7.70.2.2.3 Administration of the dose; and
- 7.70.2.2.4 Followup and review of each individual's case history.
- RH 7.71 Training for Use of Sealed Sources for Diagnosis. Except as provided in RH 7.74 the licensee shall require the authorized user using a sealed source in a device specified in RH 7.40 to be a physician, dentist, or podiatrist who:
- 7.71.1 Is certified in:
- 7.71.1.1 Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

- 7.71.1.2 Nuclear medicine by the American Board of Nuclear Medicine; or
- 7.71.1.3 Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- 7.71.2 Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device.
  - 7.71.2.1 To satisfy the requirement for instruction, the training shall include:
    - 7.71.2.1.1 Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
    - 7.71.2.1.2 Radiation biology; and
    - 7.71.2.1.3 Radiation protection and training in the use of the device for the purposes authorized by the license.
- RH 7.72 Training for Teletherapy. Except as provided in RH 7.74, the licensee shall require the authorized user of a sealed source specified in RH 7.48 in a teletherapy unit to be a physician who:
  - 7.72.1 Is certified in:
    - 7.72.1.1 Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;
    - 7.72.1.2 Radiation oncology by the American Osteopathic Board of Radiology;
    - 7.72.1.3 Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
    - 7.72.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons ; or
  - 7.72.2 Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.
    - 7.72.2.1 To satisfy the requirement for instruction, the classroom and laboratory training shall include:
      - 7.72.2.1.1 Radiation physics and instrumentation;
      - 7.72.2.1.2 Radiation protection;
      - 7.72.2.1.3 Mathematics pertaining to the use and measurement of radioactivity; and

- 7.72.2.1.4 Radiation biology.
- 7.72.2.2 To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:
  - 7.72.2.2.1 Review of the full calibration measurements and periodic spot checks;
  - 7.72.2.2.2 Preparing treatment plans and calculating treatment times;
  - 7.72.2.2.3 Using administrative controls to prevent misadministrations;
  - 7.72.2.2.4 Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
  - 7.72.2.2.5 Checking and using survey meters.
- 7.72.2.3 To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
  - 7.72.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
  - 7.72.2.3.2 Selecting the proper dose and how it is to be administered;
  - 7.72.2.3.3 Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
  - 7.72.2.3.4 Post-administration follow-up and review of case histories.
- RH 7.73 Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to:
  - 7.73.1 Be certified by the American Board of Radiology in:
    - 7.73.1.1 Therapeutic radiological physics;

- 7.73.1.2 Roentgen-ray and gamma-ray physics;
- 7.73.1.3 X-ray and radium physics; or
- 7.73.1.4 Radiological physics; or
- 7.73.2 Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in RH 7.20, 7.57, 7.58, and 7.59 under the supervision of a teletherapy physicist during the year of work experience.

RH 7.74 Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on a Department, NRC, Agreement State or Licensing State license on December 30, 1990, who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of RH 7.64 through RH 7.76.

RH 7.75 Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a 3-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of RH 7.66 or RH 7.67.

RH 7.76 Recentness of Training. The training and experience specified in RH 7.64 through RH 7.73 shall have been obtained within the 5 years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.



## PART 8

### RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RH 8.1 Purpose and Scope. This part provides special requirements for analytical x-ray equipment. The requirements of this part are in addition to, and not in substitution for, applicable requirements in other parts of these regulations.

RH 8.2 Definitions. As used in this part, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x or gamma rays to determine the elemental composition, or to examine the microstructure of materials.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

#### General Regulatory Provisions and Specific Requirements

RH 8.3 Equipment Requirements.

8.3.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path, or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:



- 8.3.1.1 a description of the various safety devices that have been evaluated;
- 8.3.1.2 the reason each of these devices cannot be used; and
- 8.3.1.3 a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.
- 8.3.2 Warning Devices.
  - 8.3.2.1 Open-beam configurations shall be provided with a readily discernible indication of:
    - 8.3.2.1.1 x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or
    - 8.3.2.1.2 shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
  - 8.3.2.2 An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:
    - 8.3.2.2.1 near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or
    - 8.3.2.2.2 in the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.
  - 8.3.2.3 Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after October 1, 1978, warning devices shall have fail-safe characteristics.
- 8.3.3 Ports. Unused ports on radiation source housings shall be secured in the closed position, in a manner which will prevent casual opening.
- 8.3.4 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:
  - 8.3.4.1 "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and
  - 8.3.4.2 "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

- 8.3.4.3 "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with RH 4.30 of these regulations if the radiation source is a radionuclide.
- 8.3.5 Shutters. On open-beam configurations installed after October 1, 1978, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.
- 8.3.6 Reserved.
- 8.3.7 Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:
- 8.3.7.1 Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing, or if the housing is disassembled.
- 8.3.7.2 Each radioactive source housing, or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.
- 8.3.8 Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 uSv) in one hour.
- RH 8.4 Area Requirements.
- 8.4.1 Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding, or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RH 4.14 of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
- 8.4.2 Surveys.
- 8.4.2.1 Radiation surveys, as required by RH 4.17 of these regulations, of all analytical x-ray systems sufficient to show compliance with RH 8.4.1 shall be performed:
- 8.4.2.1.1 upon installation of the equipment, and at least once every 12 months thereafter;
- 8.4.2.1.2 following any change in the initial arrangement, number, or type of local components in the system;

- 8.4.2.1.3 following any maintenance requiring the disassembly, or removal of a local component in the system;
- 8.4.2.1.4 during the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled, or removed;
- 8.4.2.1.5 any time a visual inspection of the local components in the system reveals an abnormal condition; and
- 8.4.2.1.6 whenever personnel monitoring devices show a significant increase over the previous monitoring period, or the readings are approaching the limits specified in RH 4.6 of these regulations.
- 8.4.2.2 Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with RH 8.4.1 to the satisfaction of the Department.
- 8.4.3 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign, or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with RH 4.28 of these regulations.
- RH 8.5 Operating Requirements.
- 8.5.1 Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.
- 8.5.2 Bypassing. No individual shall bypass a safety device or interlock, unless such individual has obtained the written approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.
- 8.5.3 Repair or Modification of X-Ray Tube Systems. Except as specified in RH 8.5.2, no operation involving removal of covers, shielding materials, or tube housings, or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

8.5.4 Radioactive Source Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

RH 8.6 Personnel Requirements.

8.6.1 Instruction. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction in and demonstrated competence as to:

8.6.1.1 identification of radiation hazards associated with the use of the equipment;

8.6.1.2 significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

8.6.1.3 proper operating procedures for the equipment;

8.6.1.4 recognition of symptoms of an acute localized exposure; and

8.6.1.5 proper procedures for reporting an actual or suspected exposure.

8.6.2 Personnel Monitoring.

8.6.2.1 Finger or wrist dosimetric devices shall be provided to and shall be used by:

8.6.2.1.1 analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

8.6.2.1.2 personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

8.6.2.2 Reported dose values shall not be used for the purpose of determining compliance with RH 4.6 of these regulations unless evaluated by a qualified expert.



## PART 9

### RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

#### RH 9.1 Purpose and Scope.

- 9.1.1 This part establishes procedures for the registration and the use of particle accelerators.
- 9.1.2 In addition to the requirements of this part, all registrants are subject to the requirements of Parts 1, 2, 4, and 10 of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Part 5 of these regulations, and registrants engaged in the healing arts are subject to the requirements of Parts 6 and 7 of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Part 3 of these regulations.

#### Registration Procedure

- RH 9.2 Registration Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Part 2 of these regulations.

- RH 9.3 General Requirements for the Issuance of a Registration for Particle Accelerators. In addition to the requirements of Part 2 of these regulations, a registration application for use of a particle accelerator will be approved only if the Department determines that:

- 9.3.1 the applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and Parts 4 and 10 of these regulations in such a manner as to minimize danger to public health and safety or property;
- 9.3.2 the applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;



- 9.3.3 the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in RH 9.4;
- 9.3.4 the applicant has appointed a radiation safety officer;
- 9.3.5 the applicant and the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;
- 9.3.6 the applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Department; and
- 9.3.7 the applicant has an adequate training program for operators of particle accelerators.

RH 9.4 Human Use of Accelerators.

- 9.4.1 In addition to the requirements of Part 2 of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:
  - 9.4.1.1 the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator whenever deemed necessary by the Department. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation;
  - 9.4.1.2 the individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and
  - 9.4.1.3 the individual designated on the application as the user is a physician.

9.4.2 Viewing System. A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

9.4.3 Dosimetry Equipment.

9.4.3.1 A registrant shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

9.4.3.1.1 The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

9.4.3.1.2 The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the registrant's system had not changed by more than 2 percent. The registrant shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems used for calibrating accelerators, either an accelerator or a cobalt-60 source may be used.

9.4.3.2 The registrant shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with RH 9.4.3.1. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in RH 9.4.3.1.

9.4.3.3 The registrant shall maintain a record of each calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by RH 9.4.3.1 and RH 9.4.3.2, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory.

9.4.4 Full Calibration Measurements.

9.4.4.1 A registrant authorized to use accelerators for medical use shall perform full calibration measurements on each accelerator:

9.4.4.1.1 Before the first medical use of the unit;

9.4.4.1.2 Before medical use under the following conditions:

9.4.4.1.2.1 Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration; and

9.4.4.1.2.2 Following any repair that may potentially result in a change of the accelerator calibration; and

- 9.4.4.1.3 At intervals not exceeding 1 year.
- 9.4.4.2 To satisfy the requirement of RH 9.4.4.1, full calibration measurements shall include determination of:
- 9.4.4.2.1 The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
- 9.4.4.2.2 The coincidence of the radiation field and the field indicated by the light beam localizing device;
- 9.4.4.2.3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- 9.4.4.2.4 Back-up timer accuracy and the back-up secondary system dose monitor;
- 9.4.4.2.5 Dose monitoring system end effect;
- 9.4.4.2.6 The accuracy of all distance measuring and localization devices in medical use; and
- 9.4.4.2.7 The dose monitoring system linearity.
- 9.4.4.3 A registrant shall use the dosimetry system described in RH 9.4.3 to measure the output for one set of exposure conditions. The remaining radiation measurements required in RH 9.4.4.2.1 may then be made using a dosimetry system that indicates relative dose rates.
- 9.4.4.4 A registrant shall make full calibration measurements required by RH 9.4.4.1 in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213, or as amended.<sup>1</sup>

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<sup>1</sup> A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530."

- 9.4.4.5 Full calibration measurements required by RH 9.4.4.1 shall be performed by a teletherapy physicist authorized by the Department to perform such service. A teletherapy physicist must meet the criteria of RH 7.73.
- 9.4.4.6 A registrant shall maintain a record of each calibration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number, the model numbers and serial numbers of the instruments used to calibrate the accelerator, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated end effect error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.
- 9.4.5 Periodic Spot Checks.
- 9.4.5.1 A registrant authorized to use accelerators for medical use shall perform output spot checks on each accelerator unit at intervals not to exceed 1 week.
- 9.4.5.2 To satisfy the requirement of RH 9.4.5.1, spot checks shall include determination of:
- 9.4.5.2.1 The coincidence of the radiation field and the field indicated by the light beam localizing device;
- 9.4.5.2.2 The accuracy of all distance measuring and localization devices used for medical use;
- 9.4.5.2.3 The output for one typical set of operating conditions; and
- 9.4.5.2.4 The output at depth for one typical set of operating conditions.



- 9.4.5.3 A registrant shall use the dosimetry system described in RH 9.4.3 to make the spot check required in RH 9.4.5.2.3.
- 9.4.5.4 A registrant shall perform spot checks required by RH 9.4.5.1 in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot check measurements.
- 9.4.5.5 A registrant shall have the teletherapy physicist review the results of each output spot check within 15 days.
- 9.4.5.6 A registrant authorized to use an accelerator for medical use shall perform safety spot checks of each accelerator facility at intervals not to exceed 1 month.
- 9.4.5.7 For accelerators for medical use, records shall also include the output of the accelerator, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, and the viewing system and doors.

#### Radiation Safety Requirements for the Use of Particle Accelerators

- RH 9.5 A registrant shall use the accelerator in accordance with the manufacturer's radiation safety and operating instructions.
- RH 9.6 Limitations.
- 9.6.1 No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:
- 9.6.1.1 has been instructed in radiation safety and shall have demonstrated an understanding thereof;



9.6.1.2 has received copies of and instruction in this part and the applicable requirements of Parts 4 and 10 of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

9.6.1.3 has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

9.6.2 The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

RH 9.7 Shielding and Safety Design Requirements.

9.7.1 A qualified expert, acceptable to the Department, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. For the purpose of this section, a qualified expert shall:

9.7.1.1 Be certified by the American Board of Radiology in:

9.7.1.1.1 Radiological Physics;

9.7.1.1.2 Therapeutic Radiological Physics; or

9.7.1.2 Be certified by the American Board of Medical Physics in Radiological Oncology Physics; or

9.7.1.3 Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in radiation protection and also 1 year of full time work experience under the supervision of a qualified expert meeting the criteria in this section.

- 9.7.2 Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with RH 4.6 and RH 4.14 of these regulations.

RH 9.8 Particle Accelerator Controls and Interlock Systems.

- 9.8.1 Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.
- 9.8.2 Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.
- 9.8.3 Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.
- 9.8.4 All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.
- 9.8.5 When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator after the condition causing the interrupt has been corrected.
- 9.8.6 A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

RH 9.9 Warning Devices.

- 9.9.1 Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

9.9.2 Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

9.9.3 Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with RH 4.28 of these regulations.

RH 9.10 Operating Procedures.

9.10.1 Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

9.10.2 The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

9.10.3 Safety Checks.

9.10.3.1 All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Department.

To satisfy the requirement of RH 9.10.3, safety checks shall assure, as appropriate, proper operation of:

9.10.3.1.1 Electrical interlocks at each room entrance;

9.10.3.1.2 Timer, dose terminator, emergency off and door interlocks;

9.10.3.1.3 Beam condition indicator lights on the accelerator unit, on the control panel, and in the facility;

9.10.3.1.4 Viewing systems;

- 9.10.3.1.5 Doors from inside and outside the accelerator room; and
- 9.10.3.1.6 Electrically assisted room doors with the accelerator unit electrical power turned off.
- 9.10.3.2 A registrant shall promptly repair any system identified in RH 9.10.3.1 that is not operating properly. The accelerator shall not be used until all repairs are completed.
- 9.10.3.3 Records. A registrant shall maintain a record of each spot check required by RH 9.4.5.1 and RH 9.10.3.1 for 2 years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for the accelerator, and the manufacturer's name, model number, serial number and calibration date of the instrument used to conduct the measurement, notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the individual who performed the periodic spot checks.
- 9.10.3.4 If the result of the safety spot checks required in RH 9.4.5.1 or 9.10.3.1 indicate the malfunction of any system specified in RH 9.4.5.2 or 9.10.3.1, the registrant shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- 9.10.4 Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Department and shall be available to the operator at each accelerator facility.
- 9.10.5 If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
- 9.10.5.1 authorized by the radiation safety committee or radiation safety officer;

- 9.10.5.2 recorded in a permanent log and a notice posted at the accelerator control console; and
- 9.10.5.3 terminated as soon as possible.
- 9.10.6 Safety Instructions.
- 9.10.6.1 A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel. These instructions shall inform the operator of:
- 9.10.6.1.1 The procedure to be followed if the operator is unable to turn the accelerator off with controls at the control panel or any other abnormal operation occurs; and
- 9.10.6.1.2 The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the accelerator or console operates abnormally; and
- 9.10.6.1.3 For human use, the procedure to be followed to ensure that only the patient is in the treatment room before turning the accelerator on to begin a treatment or after a door interlock interruption;
- 9.10.6.2 A registrant shall provide instruction in the topics identified in RH 9.10.6.1 to all individuals who operate an accelerator and shall provide appropriate refresher training to individuals at intervals not to exceed 1 year.
- 9.10.6.3 A registrant shall maintain a record of individuals receiving instructions required by RH 9.10.6.2, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 2 years.



RH 9.11

Radiation Monitoring Requirements.

9.11.1

There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed 1 year and after each servicing and repair.

9.11.2

A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Department, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

9.11.2.1

A registrant shall maintain a record of the radiation measurements made following installation of the accelerator for the duration of the registration. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the accelerator, and the instrument used to measure radiation levels, a plan of the areas surrounding the accelerator that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

9.11.3

For non-medical accelerators, radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

9.11.4

All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.

9.11.5

Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

9.11.6

Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.



- 9.11.7 All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the Department, or the radiation safety officer.
- 9.11.8 Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Department.
- RH 9.12 Ventilation Systems.
- 9.12.1 Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Part 4, Appendix B, Table I of these regulations.
- 9.12.2 A registrant, as required by RH 4.14.1.1 of these regulations, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Part 4, Appendix B, Table II of these regulations, except as authorized pursuant to RH 4.17 or 4.14.3 of these regulations. For purposes of RH 9.12.2, concentrations may be averaged over a period not greater than 1 year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

PART 10

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS

- RH 10.1      Purpose and Scope. This part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The regulations in this part apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with or licensed by the Department pursuant to Parts 2 and 3 of these regulations.

General Regulatory Provisions and Specific Requirements

- RH 10.2      Posting of Notices to Workers.
- 10.2.1      Each licensee or registrant shall post current copies of the following documents:
- 10.2.1.1      the regulations in this part and in Part 4 of these regulations;
- 10.2.1.2      the license, certificate of registration, conditions, or documents incorporated into the license by reference and amendments thereto;
- 10.2.1.3      the operating procedures applicable to activities under the license or registration; and
- 10.2.1.4      any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part 1 of these regulations, and any response from the licensee or registrant.

- 10.2.2 If posting of a document specified in RH 10.2.1.1, 10.2.1.2, or 10.2.1.3 is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- 10.2.3 Department Form OR-RH-15 Notice to Employees shall be posted by each licensee or registrant as required by these regulations.
- 10.2.4 Department documents posted pursuant to RH 10.2.1.4 shall be posted within 5 working days after receipt of the documents from the Department; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.
- 10.2.5 Documents, notices, or forms posted pursuant to RH 10.2 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.
- RH 10.3 Instructions to Workers.
- 10.3.1 All individuals likely to receive an occupational dose:
- 10.3.1.1 shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;
- 10.3.1.2 shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

- 10.3.1.3 shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;
- 10.3.1.4 shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;
- 10.3.1.5 shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
- 10.3.1.6 shall be advised as to the radiation exposure reports which workers shall be furnished—pursuant to RH 10.4.
- 10.3.2 The extent of these instruction shall be commensurate with potential radiological health protection problems in the restricted area.
- RH 10.4 Notification and Reports to Individuals.
- 10.4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in RH 10.4. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to RH 4.46 of these regulations. Each notification and report shall:

- 10.4.1.1 be in writing;
- 10.4.1.2 include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;
- 10.4.1.3 include the individual's exposure information; and
- 10.4.1.4 contain the following statement:
- "This report is furnished to you under the provisions of Colorado Rules and Regulations Pertaining to Radiation Control, Part 10. You should preserve this report for further reference."
- 10.4.2 Each licensee or registrant shall advise each worker annually of the worker's dose as shown in records maintained by the licensee or registrant pursuant to RH 4.46 of these regulations.
- 10.4.3 Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to RH 4.18 of these regulations. Such report shall be furnished within 30 days from the date of the request or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.
- 10.4.4 When a licensee or registrant is required pursuant to RH 4.53 of these regulations to report to the Department any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

- 10.4.5 At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.
- RH 10.5 Presence of Representatives of Licensees or Registrants and Workers During Inspection.
- 10.5.1 Each licensee or registrant shall afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.
- 10.5.2 During an inspection, Department inspectors may consult privately with workers as specified in RH 10.6. The licensee or registrant may accompany Department inspectors during other phases of an inspection.
- 10.5.3 If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
- 10.5.4 Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in RH 10.3.



- 10.5.5 Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.
- 10.5.6 With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.
- 10.5.7 Notwithstanding the other provisions of RH 10.5, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.
- RH 10.6 Consultation with Workers During Inspections.
- 10.6.1 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.
- 10.6.2 During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or cause any violation of the Act, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of RH 10.7.1.

10.6.3 The provisions of RH 10.6.2 shall not be interpreted as authorization to disregard instructions pursuant to RH 10.3.

RH 10.7 Requests by Workers for Inspections.

10.7.1 Any worker or representative of workers believing that a violation of the Act, these regulations, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

10.7.2 If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in RH 10.7.1, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspection pursuant to RH 10.7 need not be limited to matters referred to in the complaint.

10.7.3 No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this part.

RH 10.8

Inspections Not Warranted; Informal Review.

10.8.1

If the Department determines, with respect to a complaint under RH 10.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Department. The Department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Department. The Department will provide the complainant with a copy of such statement by certified mail.

10.8.1.1

Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Department shall affirm, modify, or reverse the determination and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

10.8.2

If the Department determines that an inspection is not warranted because the requirements of RH 10.7.1 have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of RH 10.7.1.

PART 11

Reserved.

## Part 12

### FEES FOR MATERIALS LICENSES AND OTHER RADIATION CONTROL SERVICES

#### RH 12.1 Purpose and Scope

- 12.1.1 The Regulations in this Part establish fees for radiation control services rendered by the Department as authorized by the Act.
- 12.1.2 Except for persons who apply for or hold specific licenses exempted in RH 12.3, the Regulations in this Part apply to radiation control services for a person who is an applicant for, or holder of, a specific radioactive material license or a general radioactive material license, issued pursuant to Part 3 of these Regulations. This Part also applies to a specific request for evaluation of sealed sources and devices containing radioactive material, for a special project review which the Department completes or makes whether or not in conjunction with a license application on file or which may be filed, and for other services as specified in this Part.

#### RH 12.2 Definitions

##### 12.2.1 As used in this Part:

"Anniversary date" means that date upon which annual fees shall be due and payable. Anniversary date is determined as the last day of the month corresponding to the month listed as the licensee's expiration date.

"Application" means any request filed with the Department for a permit, license, approval, exemption, certificate, other permission, or for any other service.

"Full cost fees" mean fees based on reasonable and actual professional staff time and appropriate contractual support services expended for certain radiation control activities as specified in this Part, Appendix A.

"Inspections" (routine or non-routine) means:

(1) "Routine inspections" means inspections designed to evaluate the licensee's activities within the context of the licensee having primary responsibility for protection of the public and environment.



(2) "Non-routine inspections" means inspections in response or reaction to an incident, allegation, follow-up to inspection deficiencies or inspections to determine implementation of safety issues including radioactive waste control services pursuant to Colo. Rev. Stat., Sections 25-11-101--305, (1989 Repl. Vol. 11A) and Sections 24-60-2201--2212 (1988 Repl. Vol. 10B) and these Regulations. A non-routine or reactive inspection has the same purpose as the routine inspection.

"Low-Level Radioactive Waste Access Approval" means those reviews and on-site evaluations necessary to assure waste generator compliance with low-level radioactive waste site access criteria as established by the Rocky Mountain Low-Level Radioactive Waste Board (the Board) or by a compact with which the Board has an agreement to accept low-level radioactive waste from Colorado or by a state with which the Board has an agreement to accept low-level radioactive waste from Colorado or by any state or site to which a Colorado generator ships low-level radioactive waste.

"Open Records Act" means the Colorado Open Records Act, Colo. Rev. Stat., Section 24-72-201 et. seq., (1988 Repl. Vol. 10B)

"Special Projects" means those requests submitted to the Department for review for which fees are not otherwise specified in this chapter. Examples of special projects include, but are not limited to, early site reviews, consultation and financial surety reviews.

#### RH 12.3 Exemptions

12.3.1 No fees pursuant to RH 12.4.1 through 12.4.5 shall be required for:

12.3.1.1 A radioactive materials license authorizing the use of source material as shielding only in devices and containers, provided that all other licensed radioactive material in the device or container will be subject to the fees described in this Part, Appendix A.

12.3.1.2 An application for a new license, a renewal or an amendment to an existing license for possession and use of radioactive material applied for by, or issued to, an agency of Colorado or any political subdivision thereof, except for licenses which authorize distribution of radioactive material or products containing radioactive material or licenses authorizing services to any person other than an agency or political subdivision of the State. This exemption does not apply to fees for inspection of such licensees.

12.3.1.3 A general license for reciprocity. This exemption does not apply to fees for inspection of such licensees.



#### 12.3.2 Application for Exemptions

- 12.3.2.1 The Department may, upon application by an interested person, or upon its own initiative, grant such exemptions from the requirements of this Part for good cause as it determines are authorized by law and are otherwise in the public interest.
- 12.3.2.2 Applications for exemption under this section may include activities such as, but not limited to, the use of licensed materials for educational or noncommercial public displays or scientific collections.

#### RH 12.4 Specific Radioactive Materials Licensees

##### 12.4.1 Application Fees

- 12.4.1.1 Except for licenses subject to full cost, no application for a new license, for the reinstatement of an expired license, or for an amendment to an existing license will be accepted for filing or processed prior to payment of the full amount specified in this Part, Appendix A. Applications for which no remittance is received may be returned to the applicant.
- 12.4.1.2 All licensing fees will be charged irrespective of the Department's disposition of the application or a withdrawal of the application.
- 12.4.1.3 The Department will consider any application abandoned if the Department does not receive a reply within forty-five (45) days to its most recent request for additional information. In such cases the applicant must submit a new application with the application fee specified in this Part, Appendix A.

##### 12.4.2 New License Fees

- 12.4.2.1 Application fees for new radioactive materials licenses not subject to full cost fees must accompany the application when it is filed.
- 12.4.2.2 Application fees for new radioactive materials licenses that are subject to the full cost fees are payable upon notification by the Department.

##### 12.4.3 Amendment Fees and Other Required Approvals

- 12.4.3.1 Application fees for amendments to existing materials licenses and other required approvals not subject to full cost fees must accompany the application when it is filed.
- 12.4.3.2 Application fees for license amendments, other required approvals and requests for dismantling, decommissioning and termination of licensed activities that are subject to full cost fees are payable upon notification by the Department.

12.4.4 Renewal fees

- 12.4.4.1 Application fees for license renewals that are subject to full cost fees are payable upon notification by the Department.
- 12.4.4.2 An application for renewal of a license not subject to full cost fees which has expired and for which a renewal was not timely filed pursuant to RH 3.17.2 shall pay a reinstatement fee of \$400.
- 12.4.4.3 An application fee for renewal of a license not subject to full cost fees, and for which a renewal was timely filed pursuant to RH 3.17.2 shall not be required to submit a separate fee with the application. Renewal fees are paid annually pursuant to RH 12.4.7.1.

12.4.5 Termination fees

- 12.4.5.1 Applications for license termination will not be subject to fees provided that the licensee notifies the Department and requests termination pursuant to RH 3.16.3 and provided that there is no decommissioning or decontamination involved.
- 12.4.5.2 Staff time spent in obtaining information which is not provided by the licensee as required by RH 3.16.6 and 3.16.9 when decontamination is necessary, or in supervising the licensee's decommissioning or decontamination of the site, will be billed at the Department's hourly rate.
- 12.4.5.3 The charges for staff time billed under RH 12.4.5.2 are payable upon notification by the Department.

12.4.6 Inspection fees. Inspection costs include reasonable and actual preparation time, time on site, documentation time, any associated contractual service costs, and time involved in the processing and issuance of a notice of violation or civil penalty.

- 12.4.6.1 Fees for inspection of licensees not subject to full cost fees.
- 12.4.6.1.1 Routine inspections. Fees for routine inspections are included in the annual fee and will not be charged separately.
- 12.4.6.1.2 Non-routine inspections. Fees for all non-routine inspections will be assessed on a per inspection basis, and are payable upon notification by the Department.
- 12.4.6.1.3 Fees for inspection of licenses, authorized under RH 3.5.5 and 3.6, that are based on the full cost of the inspection are payable upon notification by the Department.

12.4.7 Annual Fees

12.4.7.1 Annual Fees for Renewal and Inspection Activities

- 12.4.7.1.1 Except as provided in RH 12.4.7.1.2, licensees not subject to full cost fees shall pay an annual fee based on the fees designated in this Part, Appendix A, and determined according to the following formula:

$$\text{Annual Fee} = \frac{\text{Renewal Fee}}{5} + \frac{\text{Routine Inspection Fee}}{\text{Inspection Frequency}}$$

- 12.4.7.1.2 The annual fee for government licensees exempted from licensing fees in RH 12.3.1.2 shall be based on the following formula:

$$\text{Annual Fee} = \frac{\text{Routine Inspection Fee}}{\text{Inspection Frequency}}$$

12.4.7.2 Annual Fees for Generic and Other Regulatory Costs Not Directly Recoverable.

- 12.4.7.2.1 Persons who hold specific radioactive materials licenses shall pay an annual fee for generic and other regulatory costs not directly recoverable. The licensee shall pay the fee in this Part, Appendix A for each license the person holds on the date the annual fee for renewal and inspection activities is due. If a person holds more than one license, the fee will be the cumulative total of the annual fee for all licenses held by that person. For those licenses that authorize more than one activity (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

- 12.4.7.2.2 The basis for the annual fee is to cover the Department's administrative costs for those generic activities directly related to the regulation of materials licensees; and

- 12.4.7.2.3 Other safety, environmental and emergency response activities.

## 12.4.7.3

A licensee who is required to pay an annual fee under this section may qualify as a small entity. If a licensee qualifies as a small entity and provides the Department with the proper certification, the licensee may pay reduced annual fees as follows:

	Maximum Annual Fee Per Licensed Category
Businesses and not-for-profit organizations (gross annual receipts):	
\$250,000 to \$3.5 million . . . . .	\$1,800
Less than \$250,000 . . . . .	400
Private practice physicians (gross annual receipts):	
\$250,000 to \$1.0 million . . . . .	1,800
Less than \$250,000 . . . . .	400
Small governmental jurisdictions (including publicly supported educational institutions) (population):	
20,000 to 50,000 . . . . .	\$1,800
Less than 20,000 . . . . .	400
Educational institutions that are not state or publicly supported, and have 500 employees or less . . . . .	1,800

## 12.4.7.3.1

A licensee qualifies as a small entity if it meets the following size standards.

## 12.4.7.3.1.1

A small entity business is a business with annual receipts of \$3.5 million or less except private practice physicians for which the standard is annual receipts of \$1 million or less.

## 12.4.7.3.1.2

A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of \$3.5 million or less.

## 12.4.7.3.1.3

Small governmental jurisdictions are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000.

## 12.4.7.3.1.4

A small educational institution is one that is:

- 12.4.7.3.1.4.1 Supported by a qualifying small governmental jurisdiction; or
- 12.4.7.3.1.4.2 One that is not state or publicly supported and has 500 employees or less.
- 12.4.7.3.1.5 A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this section.
- 12.4.7.3.2 The Department shall mail each licensee a copy of RCD Form 62, *Certification of Small Entity Status for Purposes of Annual Fees for Generic and Other Regulatory Costs Not Directly Recoverable*, not later than May 1 of each year. A licensee who seeks to establish status as a small entity for purposes of paying the annual fees required under this section shall file a completed RCD Form 62 with the Department not later than June 15. The licensee shall file the required certification on Department Form RCD-62 for each license under which it is billed.
- 12.4.7.3.3 A completed RCD Form 62, *Certification of Small Entity Status for Purposes of Annual Fees for Generic and Other Regulatory Costs not Directly Recoverable*, must be received by June 15 for a licensee to be billed under a small entity status for the period beginning July 1 of the year which the RCD Form 62 is due and ending June 30 of the following year.
- 12.4.7.4 Payment of annual fees.
- 12.4.7.4.1 The annual fees for renewal and inspection activities, and for generic and other regulatory costs shall be due and payable each year on the anniversary date. The annual fees are not refundable except in those cases where the Department has determined that the fee is not required.
- 12.4.7.4.2 Annual fees shall be charged and payment required for any license that has not been terminated on or before the anniversary date, or for which a request for termination has not been submitted to the Department pursuant to RH 3.16.3 through 3.16.4.2.
- RH 12.5 General Licenses. Fees for persons who hold general licenses under RH 3.5.5 and 3.6 shall pay an annual fee.
- 12.5.1 The basis for the annual fee is to cover the Department's cost associated with the regulation and control of these sources, and to cover the Department's administrative costs for those generic activities directly related to the regulation of materials licensees.
- 12.5.2 Fees for general licenses are listed in Appendix A of this Part and shall be payable every July 1, for as long as the license remains in effect.
- RH 12.6 Special Project Fees. Fees for special projects are payable upon notification by the Department.
- RH 12.7 Low-Level Radioactive Waste Access Approval Fees. Fees for services required for low-level radioactive waste access approval are payable upon notification by the Department.



Search, Review, Duplication  
and Special Service Fees

RH 12.8 Search, Review, Duplication and Special Service Fees

12.8.1 Search, Review, and Special Service Fees

12.8.1.1 The Department charges fees for search, duplication and review.

12.8.1.1.1 The direct costs of searching for Department records. The Department may assess fees even when no Department records are located as a result of the search or when Department records that are located as a result of the search are not disclosed; and

12.8.1.1.2 If the public record is a result of a computer output, other than word processing, the fee for a copy, printout, or other photograph thereof may be based on recovery of the actual incremental costs of providing the electronic services and products together with a reasonable portion of the costs associated with building and maintaining the information system.

12.8.1.1.2.1 The Department shall charge a reasonable fee, if, in response to a specific request, it has performed a manipulation of data so as to generate a record in a form not used by the State. Such fees shall not exceed the actual cost of manipulating the said data and generating the said record in accordance with the request. Persons making subsequent requests for the same or similar records may be charged a fee not in excess of the original fee.

12.8.1.2 The Department shall charge requesters who request the following services for the direct costs of the service:

12.8.1.2.1 Certifying that records are true copies; or

12.8.1.2.2 Sending records by special methods, such as Express Mail, package delivery service, etc.

12.8.2 Duplication Fees

12.8.2.1 The charge for duplicating records shall be computed on the basis of Department's direct costs, including both the cost of staff and the cost of the actual copy.

12.8.2.2 Copyrighted material shall not be reproduced in violation of the copyright laws.



12.8.3 Fees for Search and Review of Department Records by Department Personnel. The Department shall charge the following hourly rates for search and review of Department records by Department personnel:

12.8.3.1 Clerical search, review, and duplication at a rate that is equivalent to the actual cost of an Administrative Assistant III at Step 3;

12.8.3.2 Professional search, review, and duplication at a rate that is equivalent to the actual cost of an Environmental Protection Specialist II at Step 5; and

12.8.3.3 Senior management search, review, and duplication at a rate that is equivalent to the actual cost of an Environmental Protection Specialist V at Step 6.

12.8.4 Search and Duplication Provided Without Charge

12.8.4.1 The Department may not bill any requester for fees if the cost of collecting the fee would be equal to or greater than the fee itself.

12.8.4.2 The Department may aggregate requests in determining search and duplication to be provided without charge as provided in RH 12.8.4.1, if the Department finds a requester, or multiple requestors acting in concert, has filed multiple requests for only portions of a Department record or similar Department records for the purpose of avoiding charges.

12.8.5 Assessment of Fees

12.8.5.1 If the request is expected to require the Department to assess fees in excess of \$25 for search and/or duplication, the Department shall notify the requester that fees will be assessed unless the requester has indicated in advance his or her willingness to pay fees as high as estimated.

12.8.5.2 In the notification, the Department shall include the estimated cost of search fees and the nature of the search required and estimated cost of duplicating fees.

12.8.5.3 The Department will encourage requesters to discuss with the Department the possibility of narrowing the scope of the request with the goal of reducing the cost while retaining the requester's original objective.

12.8.5.4 If the fee is determined to be in excess of \$250, the Department may require payment at the time the information is provided.

12.8.6 Requests for Waiver or Reduction of Fees

- 12.8.6.1 The Department shall collect fees for searching for, reviewing, and duplicating Department records, except as provided in RH 12.8.4, unless a requester submits a request in writing for a waiver or reduction of fees and the Department approves such request. To assure that there will be no delay in the processing of open records act requests, the request for a waiver or reduction of fees should be included in the initial open records act request letter.
- 12.8.6.2 Each request for a waiver or reduction of fees must be addressed to the Director, Radiation Control Division, Colorado Department of Health.
- 12.8.6.3 A person requesting the Department to waive or reduce search, review, or duplication fees shall:
- 12.8.6.3.1 Describe the purpose for which the requester intends to use the requested information;
- 12.8.6.3.2 Explain the extent to which the requester will extract and analyze the substantive content of the Department record;
- 12.8.6.3.3 Describe the nature of the specific activity or research in which the Department records will be used and the specific qualifications the requester possesses to utilize information for the intended use in such a way that it will contribute to public understanding;
- 12.8.6.3.4 Describe the likely impact on the public's understanding of the subject as compared to the level of understanding of the subject existing prior to disclosure;
- 12.8.6.3.5 Describe the size and nature of the public to whose understanding a contribution will be made;
- 12.8.6.3.6 Describe the intended means of dissemination to the general public;
- 12.8.6.3.7 Indicate if public access to information will be provided free of charge or provided for an access fee or publication fee; and
- 12.8.6.3.8 Describe any commercial or private interest the requester or any other party has in the Department records sought.
- 12.8.6.4 The Department may waive or if, from information provided with the request for Department records made under RH 12.8.6.3, the Department determines that disclosure of the information in the Department records is for a public purpose, including public agency program support, nonprofit activities, journalism, and academic research, and is not primarily in the commercial interest of the requester.

- 12.8.6.5 In making a determination regarding a request for a waiver or reduction of fees, the Department may consider the following factors:
- 12.8.6.5.1 If disclosure is likely to contribute significantly to public understanding of government operations or activities;
- 12.8.6.5.2 If, and the extent to which, the requester has a commercial interest that would be furthered by the disclosure of the requested Department records; and
- 12.8.6.5.3 If the magnitude of the identified commercial interests of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester.
- RH 12.9 Partial Payment of Fees. In the case of services which are subject to full cost fees, the Department may bill monthly for any service rendered.
- RH 12.10 Method of Payment. Checks, drafts or money orders for payment of fees shall be payable to the Colorado Department of Health.
- RH 12.11 Schedule of Fees for Materials Licenses and Other Radiation Control Services
- 12.11.1 Applicants for radioactive materials licenses, other regulatory services and holders of materials licenses shall pay fees for the categories of services listed in this Part, Appendix A. License applications received prior to the effective date of this rule shall be billed in accordance with the fee schedule, as updated by the hourly rate in effect at that time the service is performed.
- 12.11.2 For each service provided subject to full cost fees, records will be maintained of time spent, using reasonable accounting procedures by at least 15 minute intervals. A summary of time spent on any activity will be provided upon request.
- 12.11.3 The Department will adjust all fees and the cost per man-hour every six (6) months from the effective date of these regulations based on the Denver Consumer Price Index for All Urban Consumers. An updated version of the fee schedule will be available upon request. Every two (2) years from the effective date of these regulations, the Department will review the fees and the Department's costs. If the adjusted fees and costs for any categories differ by more than ten percent (10%), the Department will propose a revised fee to the Board of Health for those categories.

RH 12.12 Failure by Applicant or Licensee to Pay Prescribed Fee

12.12.1 In any case where the Department finds that an applicant or a licensee has failed to pay a prescribed fee for any licensing or inspection activities required in this Part, the Department will not process any application, may suspend or revoke any license involved pursuant to RH 3.23 and may request action pursuant to Colo. Rev. Stat., Section 25-11-107 (4) (1989 Repl. Vol. 11A). Staff time expended in collection of any fee not paid within sixty (60) days of the date due will be billed at the Department's hourly rate.

12.13 Penalties

12.13.1 A \$15.00 penalty will be assessed for checks returned to the Department due to insufficient funds.

12.13.2 Late Payments

12.13.2.1 A penalty shall be assessed to any person whose fee is collected by a collection agency.

12.13.2.2 The penalty shall be equal to the fee charged by the collection agency.

Rh 12.14 Severability. The provisions of this Regulation are severable, and if any provisions or the application of the provisions to any circumstances is held invalid, the application of such provision to other circumstances, and the remainder of this regulation shall not be affected thereby.

Part 12  
Appendix A

SCHEDULE OF FEES FOR RADIOACTIVE MATERIALS  
LICENSEES AND OTHER REGULATORY SERVICES

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

1. Special Nuclear Material

- \* 1.A. Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.

Annual \$28080

- \* 1.B. Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI).

Annual \$16770

- 1.C. Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems including x-ray fluorescence analyzers.

Application -

New License	\$540
Renewal	\$540
Amendment	\$410
Inspection	
Routine	\$490
Non-routine	\$1400
Annual	\$660

- 1.D. All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combinations that would constitute a critical quantity.

Application -

New License	\$740
Renewal	\$740
Amendment	\$250
Inspection	
Routine	\$740
Non-routine	\$860
Annual	\$900

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

2. Source Material

2.A. Licenses for possession and use of source material in recovery operations such as milling, in situ leaching, heap-leaching, refining uranium mill concentrates to uranium hexafluoride, ore buying stations, ion exchange facilities and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, and licenses authorizing decommissioning, reclamation or restoration activities as well as licenses authorizing the possession and maintenance of a facility in a standby mode.

Application -	
New License	Full Cost
Renewal	Full Cost
Amendment	Full Cost
Inspection	
Routine	Full Cost
Non-routine	Full Cost
<sup>1</sup> Annual- Class I	\$65330
Class II	\$28550
All Other	\$22930

2.B. Licenses for possession and use of a source material for shielding.

Application -	
New License	\$120
Renewal	\$120
Amendment	\$120
Inspection	
Routine	\$310
Non-routine	\$370
Annual	\$170

2.C. All other source material licenses.

Application -	
New License	\$850
Renewal	\$800
Amendment	\$480
Inspection	
Routine	\$860
Non-routine	\$1600
Annual	\$1170

3. Byproduct Material, Naturally Occurring and Accelerator Produced Radioactive Material

3.A. Licenses of broad scope for possession and use of radioactive material issued pursuant to RH 3.11 for processing or manufacturing of items containing radioactive material for commercial distribution.

Application -	
New License	\$2500
Renewal	\$1500
Amendment	\$250
Inspection	
Routine	\$2200
Non-routine	\$2200
Annual	\$3670

<sup>1</sup> A Class I license includes mill licenses issued for the extraction of uranium from uranium ore. A Class II license includes solution mining licenses (in-situ and heap leach) issued for the extraction of uranium from uranium ores including research and development licenses. An "other" license includes licenses for extraction of metals, heavy metals, and rare earths.



Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

- 3.B. Other licenses for possession and use of radioactive material for processing or manufacturing of items containing radioactive material for commercial distribution.

Application -	
New License	\$1400
Renewal	\$2500
Amendment	\$590
Inspection	
Routine	\$1100
Non-routine	\$2100
Annual	\$1790

- 3.C. Licenses authorizing the processing or manufacture and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing radioactive material.

Application -	
New License	\$3600
Renewal	\$1570
Amendment	\$490
Inspection	
Routine	\$1500
Non-routine	\$2000
Annual	\$4250

- 3.D. Licenses authorizing distribution of radio-pharmaceuticals, generators, reagent kits, and/or sources or devices not involving processing of radioactive material.

Application -	
New License	\$1200
Renewal	\$540
Amendment	\$330
Inspection	
Routine	\$860
Non-routine	\$1300
Annual	\$1480

- 3.E. Licenses for possession and use of radioactive material in sealed sources for irradiation of materials where the source is not removed from its shield (self-shielded units).

Application -	
New License	\$540
Renewal	\$510
Amendment	\$270
Inspection	
Routine	\$490
Non-routine	\$740
Annual	\$980

- 3.F. Licenses for possession and use of less than 10,000 curies of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

Application -	
New License	\$1300
Renewal	\$430
Amendment	\$370
Inspection	
Routine	\$620
Non-routine	\$1400
Annual	\$1790

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Category of Materials License  
and Types of Fees<sup>1,2</sup>

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Category of Materials License  
and Types of Fees<sup>1,2</sup>

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- 3.G. Licenses for possession and use of 10,000 curies or more of radioactive material in sealed sources for irradiation of materials where the source is exposed for irradiation purposes.

Application -	
New License	\$4900
Renewal	\$2000
Amendment	\$490
Inspection	
Routine	\$1100
Non-routine	\$1500
Annual	\$6400

- 3.H. Licenses issued to distribute items containing radioactive material which requires device review to persons exempt from the licensing requirements of Part 3.

Application -	
New License	\$2200
Renewal	\$1200
Amendment	\$270
Inspection	
Routine	\$740
Non-routine	\$740
Annual	\$2460

- 3.I. Licenses issued to distribute items containing radioactive material or quantities of radioactive material which do not require device evaluation to persons exempt from the licensing requirements of Part 3, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

Application -	
New License	\$2800
Renewal	\$1300
Amendment	\$370
Inspection	
Routine	\$490
Non-routine	\$740
Annual	\$2960

- 3.J. Licenses issued to distribute items containing radioactive material which require sealed source and/or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

Application -	
New License	\$2700
Renewal	\$620
Amendment	\$420
Inspection	
Routine	\$740
Non-routine	\$740
Annual	\$2930

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

3.K. Licenses issued to distribute items containing radioactive material or quantities of radioactive material which do not require sealed or device review to persons generally licensed, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed by the Nuclear Regulatory Commission or an Agreement State.

Application -	
New License	\$2000
Renewal	\$1000
Amendment	\$310
Inspection	
Routine	\$740
Non-routine	\$740
Annual	\$2340

3.L. Licenses of a broad scope for possession and use of radioactive material for research and development which do not authorize commercial distribution.

Application -	
New License	\$2500
Renewal	\$2100
Amendment	\$540
Inspection	
Routine	\$1000
Non-routine	\$1300
Annual	\$2890

3.M. Other licenses for possession and use of radioactive material for research and development which do not authorize commercial distribution.

Application -	
New License	\$1200
Renewal	\$1200
Amendment	\$670
Inspection	
Routine	\$860
Non-routine	\$1000
Annual	\$1440

3.N. Licenses that authorize services for other licensees, except (1) licenses that authorize calibration and/or leak testing services only are subject to the fees specified in fee Category 3.P., and (2) licensees that authorize waste disposal services are subject to the fees specified in fee Categories 4.A., 4.B., or 4.C.

Application -	
New License	\$1500
Renewal	\$860
Amendment	\$430
Inspection	
Routine	\$740
Non-routine	\$740
Annual	\$1720

3.O. Licenses for possession and use of radioactive material for industrial radiography operations.

Application -	
New License	\$3200
Renewal	\$1900
Amendment	\$520
Inspection	
Routine	\$1300
Non-routine	\$2700
Annual	\$4990

3.P. Licenses for the use of radioactive material in portable gauging devices.

Application -	
New License	\$460
Renewal	\$460
Amendment	\$350
Inspection	
Routine	\$1110
Non-routine	\$1110
Annual	\$700

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

3.Q. All other specific radioactive material licenses, except those in fee Categories 4.A. through 9.D.

Application -	
New License	\$540
Renewal	\$540
Amendment	\$410
Inspection	
Routine	\$1300
Non-routine	\$1300
Annual	\$820

4.A. Licenses specifically authorizing the receipt of waste byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material from other persons for the purpose of commercial disposal by land burial by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for treatment or disposal by incineration and transfer of packages to another person authorized to receive or dispose of waste material.

Application -	
New License	Full Cost
Renewal	Full Cost
Amendment	Full Cost
Inspection	
Routine	Full Cost
Non-routine	Full Cost
Annual	\$32960

4.B. Licenses specifically authorizing the receipt of waste byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

Application -	
New License	\$3000
Renewal	\$2000
Amendment	\$210
Inspection	
Routine	\$2200
Non-routine	\$1700
Annual	\$5380

4.C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material.

Application -	
New License	\$2000
Renewal	\$1000
Amendment	\$250
Inspection	
Routine	\$1700
Non-routine	\$2200
Annual	\$2960

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

5. Well Logging

5.A. Licenses for possession and use of byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material for well logging, well surveys, and tracer studies other than field flooding tracer studies.

Application -	
New License	\$3600
Renewal	\$2100
Amendment	\$580
Inspection	
Routine	\$860
Non-routine	\$860
Annual	\$4020

5.B. Licenses for possession and use of byproduct material for field flooding tracer studies.

Application -	
New License	Full Cost
Renewal	Full Cost
Amendment	Full Cost
Inspection	
Routine	\$740
Non-routine	\$1100
Annual	\$5850

6. Nuclear Laundry

6.A. Licenses for commercial collection and laundry of items contaminated with radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material.

Application -	
New License	\$1500
Renewal	\$1500
Amendment	\$370
Inspection	
Routine	\$1300
Non-routine	\$2000
Annual	\$1990

7. Human Use of Radioactive Material, Source Material, Special Nuclear Material, or Naturally Occurring and Accelerator Produced Material

7.A. Licenses issued for human use of radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material in sealed sources contained in teletherapy devices.

Application -	
New License	\$3600
Renewal	\$850
Amendment	\$460
Inspection	
Routine	\$1300
Non-routine	\$2000
Annual	\$5540

7.B. Licenses of broad scope issued to medical institutions or two or more physicians authorizing research and development including human use of radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material except material in sealed sources contained in teletherapy devices.

Application -	
New License	\$2500
Renewal	\$2200
Amendment	\$390
Inspection	
Routine	\$1700
Non-routine	\$1900
Annual	\$4760

Category of Materials License  
and Types of Fees<sup>1,2</sup>

Category of Materials License  
and Types of Fees<sup>1,2</sup>

7.C. Other licenses issued for human use of radioactive material, source material, and/or naturally occurring and accelerator produced material except material in sealed sources contained in teletherapy devices.

Application -	
New License	\$760
Renewal	\$1100
Amendment	\$460
Inspection	
Routine	\$1100
Non-routine	\$1600
Annual	\$1790

8. Civil Defense

8.A. Licenses for possession and use of radioactive material for civil defense activities.

Application -	
New License	\$620
Renewal	\$430
Amendment	\$330
Inspection	
Routine	\$740
Non-routine	\$740
Annual	\$740

9. Device, Product, or Sealed Source Safety Evaluation

9.A. Safety evaluation of devices or products containing byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material except reactor fuel devices, for commercial distribution.

Evaluation	Full Cost
Amendment	Full Cost
Annual	\$3630

9.B. Safety evaluation of devices or products containing radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material manufactured in accordance with the unique specifications of, and for use by a single applicant, except reactor fuel devices.

Evaluation	Full Cost
Amendment	Full Cost
Annual	\$1760

9.C. Safety evaluation of sealed sources containing byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material, except reactor fuel, for commercial distribution.

Evaluation	Full Cost
Amendment	Full Cost
Annual	\$740

9.D. Safety evaluation of sealed sources containing byproduct material, source material, special nuclear material, or naturally occurring and accelerator produced material, manufactured in accordance with the unique specifications of, and for use by a single applicant, except reactor fuel.

Evaluation	Full Cost
Amendment	Full Cost
Annual	\$390

\*10. Transportation of Radioactive Material

\*11. Review of Standardized Spent Fuel Facilities



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Category of Materials License  
and Types of Fees<sup>1,2</sup>

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Category of Materials License  
and Types of Fees<sup>1,2</sup>

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12. Special Projects

- 12.A. Special Projects and all uses of radioactive material  
which are not included in any other category.

Application Full Cost  
Approval Full Cost  
Amendment Full Cost  
Inspection Full Cost

13. Spent Fuel Storage Costs

14. Byproduct material, source material special nuclear  
material, naturally occurring or accelerator produced  
radioactive material licenses and other approvals  
authorizing decommissioning, decontamination,  
reclamation or site restoration activities.  
Full Cost

15. Emergency Response.

- 15.A. Emergency response requiring over 10 man-hours in  
any 12 consecutive months

Full Cost

- 15.B. Emergency response<sup>3</sup>  
and planning

Full Cost

16. Analytical Procedures<sup>3</sup>

Full Cost

17. General Licenses

- 17.A. General Licenses (Gauges  
and other similar devices)

\$100<sup>4,5</sup>

17.B. General licenses (In-Vitro)

\$50<sup>4,5</sup>

18. Low-Level Radioactive Waste Access Approval

Full Cost

19. Hourly Rate

\$119

20. Transfer of Records to Department Pursuant to RH 4.40.

\$25 per box for indexed paper records submitted  
in state standard file storage boxes.

Full Cost for records not indexed and/or  
requiring repackaging in state standard storage  
boxes.

Footnotes:

1. Separate charges will be assessed for applications for new licenses and approvals, issuance of new licenses and approvals, amendments and renewals to existing licenses and approvals, safety evaluations of sealed sources and devices, and inspections. The following guidelines apply to these charges:
  - (a) Renewal fees - Fees for applications for renewal of materials licenses will be assessed on an annual basis pursuant to RH 12.4.4.1 for each category, except that fees for applications for renewal of licenses subject to full cost fees are due upon notification by the Department.
  - (b) Amendment fees
    - (1) An application for an amendment to a license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment unless the amendment is applicable to two or more fee categories in which case the amendment fee for the highest fee category would apply.
    - (2) An application for amendment to a materials license that would place the license in a higher fee category must be accompanied by the prescribed application fee for the higher fee category.
  - (c) Inspection fees
    - (1) Fees for routine inspections will be assessed on an annual basis pursuant to RH 12.4.6.1.1, except that routine inspections subject to full cost fees are due upon notification by the Department.
    - (2) The inspection fee for licenses covering more than one fee category will be charged only for the highest category assigned to the license, if the inspection of the entire license is done at the same time.
    - (3) Separate charges will be assessed for each non-routine inspection which is performed.
    - (4) For a license authorizing use of material at more than one address, a separate fee will be assessed for inspection of each location, except that if multiple installations are inspected during a single visit, a single inspection fee will be assessed.
    - (5) The frequency of routine inspections are those established in the Radiation Control Division Inspection and Enforcement Manual, and will be in accord with the frequencies established by the U.S. Nuclear Regulatory Commission for similar types of licenses.

2. Applications for new licenses or renewal of existing licenses that cover both special nuclear material and radioactive material and/or naturally occurring and accelerator produced material in sealed sources for use of gauging devices will pay the appropriate processing fee for category 1.C. only.
3. Fees will be charged only when service is requested or required by an authorized person outside of the Department who has legal authority to make such requests, except for analytical procedures required to investigate the loss of control of radioactive material.
4. Fees are for each license at each facility.
5. Fees for general licenses are annual fees, and are due July 1 of each year. Non-routine inspections of general licensees related to 1) exposures to individuals or 2) release of radioactive materials in excess of limits established in Part 4 of these Regulations will be at full cost.

## PART 13

### PENALTIES FOR VIOLATIONS

#### RH 13.1 Purpose and Scope

- 13.1.1 The regulations in this Part set the criteria and specific procedures for notification of violations and the imposition of civil penalties under 25-11-107(5), CRS 1973 as amended.

#### RH 13.2 Definitions

- 13.2.1 "Civil Penalty" means any monetary penalty levied against a licensee or registrant because of violations of statutes, regulations, licenses, registration provision or order issued thereunder. Civil penalty does not include any criminal penalty levied under 25-1-114 or 25-11-107, C.R.S. 1973 as amended.
- 13.2.2 "Material False Statement" means a statement that is false by omission or commission and is relevant to the regulatory process.

#### RH 13.3 Penalties and Severity Levels

- 13.3.1 Any person who violates any license or registration provision of 25-11-103 or 25-11-104, CRS 1973 as amended, regulation, or any license or registration certificate condition, regulation or order issued thereunder shall be subject to these civil penalty regulations except as provided for under 13.4.
- 13.3.2 Violations are categorized in six levels of severity to reflect their public health or worker safety or environmental significance. Severity Level I represents the most significant actual or potential hazard; Severity Level VI represents the least significant actual or potential hazard.
- 13.3.2.1 Examples are provided in Appendix A for determining the appropriate severity level and will be presumptively correct. However, the severity level of a violation will be determined based upon the criteria in 13.3.2, above. The examples are not and do not create new requirements, but are predicated on existing regulatory requirements.
- 13.3.2.2 For violations not listed in Appendix A, the severity of a violation will be characterized at the severity level best-suited to the significance of the particular violation.

#### RH 13.4 Exemptions

- 13.4.1 A civil penalty will not generally be assessed for a violation which was unavoidable to prevent loss of life, personal injury or severe property damage or there were no feasible alternatives, and provided that proper notification was provided to the Department.

- 13.4.2 A civil penalty will not generally be assessed for violations resulting from matters beyond the control of the licensee or registrant, such as equipment failures that were unavoidable by reasonable quality assurance measures or management controls.
- 13.4.3 A civil penalty will not generally be assessed if interlocks are bypassed for short periods for maintenance or for quality control procedures provided that alternative safety procedures are implemented.

RH 13.5 Notification and Imposition

- 13.5.1 If the Department has reason to believe, based upon facts available to the Department, that a person has committed any violation of any licensing or registration provision of 25-11-103 or 25-11-104, CRS 1973 as amended, regulation, any license or registration certificate, or order issued thereunder, it shall notify such person within a reasonable time specifying:
  - 13.5.1.1 The date and factual basis of each act or omission with which such person is charged;
  - 13.5.1.2 The particular provision of the statute, rule, regulation, order, license, or registration certificate violated; and
  - 13.5.1.3 Necessary actions required to bring the licensee or registrant into compliance.
- 13.5.2 The notification required by RH 13.5.1 shall be sent by the Department by certified or registered mail, return receipt requested, to the last known address of the alleged violator. Any notice may be served by the Department by publication in a newspaper of general circulation in the area of the licensed facility or activity that is the subject of the notice, if the Department's efforts to serve by mail are unsuccessful. Service shall not be incomplete due to any refusal to accept service.
- 13.5.3 The alleged violator shall have thirty (30) days following the receipt of publication of the notice to submit a written response containing data, views, and arguments concerning the alleged violations and proposing a reasonable time for abatement. In addition, the alleged violator may request an informal conference with Department personnel to discuss the alleged violations. Such conference is to be held within the thirty (30) days allowed for a written response.
- 13.5.4 Within thirty (30) days after the time allowed for the written response and informal conference, the Department shall issue an order affirming or dismissing or otherwise disposing of the violation and, if the violation is affirmed, setting a time for abatement.
  - 13.5.4.1 The time for abatement shall be that reasonably necessary to achieve compliance given the severity of the violation and the actions necessary to correct the violation.
  - 13.5.4.2 The order may be modified and the time for abatement extended for good cause shown.



13.5.4.3 Immediate abatement may be ordered to the extent necessary to remove an imminent danger to public health, worker safety or the environment.

13.5.5 Any person failing to comply with an order issued pursuant to RH 13.5.4 shall be subject to a civil penalty of not more than five thousand dollars (\$5,000.00) for each violation specified in the order.

13.5.5.1 The amount will be based on the following Severity Level Table as adjusted in the discretion of the Department based on consideration of willfulness of the violation and good faith of the alleged violator in achieving compliance, but in no event may the penalty exceed \$5,000 for a single violation.

Dollar Amounts of Civil Penalties

<u>Severity Level</u>	<u>Penalty</u>
I	\$5,000
II	\$2,500
III	\$1,250
IV	\$ 625
V	\$ 300
VI	NONE

13.5.5.2 The Department may compromise, mitigate, or remit any such civil penalty as justified by written documentation.

13.5.6 Upon determining that a person has failed to comply with an order issued pursuant to RH 13.5.4, the Department shall notify the person within ten (10) days by certified or registered mail, return receipt requested, of the proposed amount of any civil penalty. Such person shall have ten (10) days after receipt of the notification of the proposed penalty within which to request, in writing, an informal conference in which all relevant information concerning the violation and penalty, including all information which the alleged violator may submit, shall be reviewed by the alleged violator and an authorized representative of the Department. If such conference is requested, the alleged violator shall provide the Department with all relevant information, in writing, at least three (3) days prior the conference.

13.5.7 Following the conference pursuant to RH 13.5.6, or upon the expiration of time allowed for requesting the conference if no conference is requested, the Department shall either dismiss the penalty or order the penalty fixed and shall cause the order to be served personally on the alleged violator or his designated agent within forty-five (45) days of the mailing of the proposed penalty pursuant to RH 13.5.1. The order shall notify the alleged violator of the right to request a hearing within thirty (30) days, such hearing to be held in accordance with 24-4-105, C.R.S. 1973 as amended, to determine all of the following:



- 13.5.7.1 Whether the alleged violation exists or did exist;
- 13.5.7.2 Whether the actions taken or to be taken are or will be adequate to correct the violation;
- 13.5.7.3 Whether the time set for abatement was reasonable; and
- 13.5.7.4 Whether the civil penalty is reasonable in light of the statutory criteria upon which it is based.
- 13.5.8 Upon the request for such a hearing, the order shall be stayed pending the results of the hearing and any subsequent judicial review.
- 13.5.9 At the request of the Department, the Attorney General may institute a civil action to collect any civil penalty imposed pursuant to these regulations.

APPENDIX A  
SEVERITY LEVEL EXAMPLES

Severity Level I

1. Single exposure of a worker in excess of 25 rem to the whole body, 150 rem to the skin of the whole body, or 375 rem to the hands, forearms, feet or ankles.
2. Annual whole body exposure of a member of the public in excess of 0.5 rem.
3. Release of radioactive material to an uncontrolled area in excess of ten times the limits of RH 4.35.1.2 of these regulations.
4. Exposure of workers in controlled areas in excess of ten times the limits of RH 4.6.1.1 of these regulations.
5. Violation of Department of Transportation (DOT) requirements pursuant to RH 17.15.10 of these regulations resulting in whole body radiation exposure of a member of the public in excess of 0.5 rem.
6. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times DOT limits.
7. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license.
8. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.
9. A Material False Statement in which the statement made was deliberately false.
10. Deliberate action by management to discriminate against an employee for attempting to communicate or actually communicating with the Department as specified in RH 10.5, RH 10.6, and RH 10.7 of these regulations.

Severity Level II

1. Single exposure of a worker in excess of 5 rem to the whole body, 30 rem to the skin of the whole body, or 75 rem to hands, forearms, feet or ankles.
2. Annual whole body exposure of a member of the public in excess of 0.1 rem.
3. Release of radioactive material to an uncontrolled area in excess of five times the limits of RH 4.35.1.2 of these regulations.
4. Failure to make an immediate notification as required by RH 4.35.1.2 of these regulations.
5. Exposure of a worker in controlled areas in excess of five times the limits of RH 4.6.1.1 of these regulations.

6. Exposure of a worker in controlled areas in excess of five times the limits of RH 4.4 of these regulations.
7. Breach of package integrity resulting in surface contamination or external radiation levels in excess of DOT limits.
8. Surface contamination or external radiation levels in excess of three times DOT limits that did not result from a breach of package integrity.
9. Failure to make required initial notifications associated with Severity Level I or II violations.
10. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license or regulations.
11. A system designed to prevent or mitigate a serious safety event being inoperable.
12. A Material False Statement or a reporting failure, involving information which, had it been available to the Department and accurate at the time the information should have been submitted, would have resulted in the Department seeking further information.
13. A Material False Statement in which the false statement was made with careless disregard.

#### Severity Level III

1. Single exposure of a worker in excess of 3 rem to the whole body, 7.5 rem to the skin of the whole body, or 18.75 rem to the hands, forearms, feet or ankles.
2. A radiation level in an uncontrolled area that exceeds 100 millirem/hour for a one-hour period.
3. Failure to make a 24-hour notification as required by RH 4.52.2 these regulations.
4. Substantial potential for an exposure or release in excess of Part IV of these regulations whether or not such exposure or release occurs.
5. Release of radioactive material to an uncontrolled area in excess of limits of RH 4.35.1.2 these regulations.
6. Improper disposal of licensed material not covered in Severity Levels I or II.
7. Exposure of a worker in controlled areas in excess of limits of RH 4.6.1.1 of these regulations.
8. Release for uncontrolled use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program.

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic rather than an isolated weakness in radiation protection.
10. Conduct of activities by a technically unqualified person.
11. Significant failure to control licensed material.
12. Breach of package integrity.
13. Surface contamination or external radiation levels in excess of, but less than a factor of three above DOT requirements, that did not result from a breach of transport container.
14. Any noncompliance with labeling, placarding, shipping paper, packaging, loading or other requirements that could reasonably result in the following:
  - a. Improper identifications of the type, quantity, or form of material.
  - b. Failure of the carrier or recipient to exercise adequate controls.
  - c. Substantial potential for personnel exposure or contamination, or improper transfer of material.
15. Failure to control access to licensed materials for radiation purposes as specified by Department regulations, license conditions and orders.
16. Possession or use of unauthorized materials or equipment in the conduct of licensee activities.
17. Use of radioactive material on humans where such use is not authorized.
18. Radiation levels, contamination levels, or releases that exceed the limits specified in the license or regulations.
19. Medical therapeutic misadministrations.
20. A Material False Statement not amounting to a Severity Level I or II Violation.

#### Severity Level IV

1. Exposure in excess of the limits of Part 4 of these regulations not constituting Severity Level I, II, or III violations.
2. A radiation level in an uncontrolled area such that an individual could receive greater than 2 millirem in a one hour period or 100 millirem in any seven consecutive days.
3. Failure to make a 30-day notification as required by RH 4.53.1 of these regulations.
4. Failure to make a written report as required by RH 4.54 or 4.59 of these regulations.
5. Package selection or preparation which does not meet DOT requirements, but does not result in a breach of package integrity or surface contamination or external radiation levels in excess of DOT requirements.
6. Failure to maintain patients hospitalized who have had cobalt-60, cesium-137, or iridium-192 implants.
7. Medical diagnostic misadministrations.
8. Failure to conduct required leakage or contamination tests.
9. Failure to use properly calibrated equipment.
10. Other violations that have more than minor safety or environmental significance.

#### Severity Level V

1. Public health or worker safety or environmental items of minor significance.

#### Severity Level VI

1. No public health or worker safety or environmental items of significance.

## PART 14

### LICENSING REQUIREMENTS FOR LAND DISPOSAL OF LOW LEVEL RADIOACTIVE WASTE

#### General Provisions

RH 14.1 Purpose and Scope.

14.1.1 The regulations in this part establish procedure, criteria, and terms and conditions upon which the Department issues licenses for the land disposal of low-level radioactive wastes received from other persons. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.

14.1.2 The regulations in this part do not apply to disposal of byproduct material as defined in the second definition of "byproduct material" in RH 1.4 of these regulations in quantities greater than 10,000 kilograms containing more than 185 MBq (5 millicuries) of radium-226, or disposal of waste as provided for in Part 4 of these regulations.

14.1.3 This part establishes procedural requirements and performance objectives applicable to any method of land disposal. It establishes specific technical requirements for near-surface disposal of low-level radioactive waste which involves disposal in the uppermost portion of the earth, approximately 30 meters. Burial deeper than 30 meters may also be satisfactory.

RH 14.2 Definitions. As used in this part, the following definitions apply:

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in RH 14.18 and 14.19 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general disposal site upkeep such as mowing grass.

"Buffer zone" means a portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid and polycarboxylic acids.



"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

"Custodial Agency" means an agency of the government designated to act on behalf of the federal or state government owner of the disposal site.

"Disposal" means the isolation of radioactive wastes from the biosphere inhabited by man and his food chains by emplacement in a land disposal facility with no intention of retrieval.

"Disposal site" means the portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

"Disposal unit" means a discrete portion of the disposal site into which waste is placed for disposal. For near-surface disposal the unit is usually a trench.

"Engineered barrier" means a man-made structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in this part.

"Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks of flame.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

"Inadvertent intruder" means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

"Intruder barrier" means a sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this part, or engineered structures that provide equivalent protection to the inadvertent intruder.

"Land disposal facility" means the land, buildings and structures, and equipment which are intended to be used for the disposal of low-level radioactive wastes.

"Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

"Near-surface disposal facility" means a land disposal facility in which low-level radioactive waste is disposal of within approximately the upper 30 meters of the earth's surface.

"Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C).

"Pyrophoric solid" means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and which ignited burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

"Site closure and stabilization" means those action that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

"Stability" means structural stability.

"Surveillance" means monitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

"Waste" means radioactive waste other than:

1. Waste generated as a result of the defense activities of the federal government or federal research and development activities;
2. High-level waste such as irradiated reactor fuel, liquid waste from reprocessing irradiated reactor fuel, or solids into which any such liquid waste has been converted;
3. Waste materials containing transuranic elements with contamination levels greater than one hundred nanocuries (3700 bq) per gram of material;
4. Byproduct material as defined in Section 11.e.(2) of the "Atomic Energy Act of 1954", as amended on November 8, 1978;\* or
5. Waste from mining, milling, smelting, or similar processing of ores and mineral-bearing material primarily for minerals other than radium;\*

\* The disposal of these materials is licensed under Part III of the regulations.

- RH 14.3      License Required
- 14.3.1      No person may receive, possess, and dispose of waste received from other persons at a land disposal facility unless authorized by a license issued by the Department pursuant to this Part, and Part III of these regulations.
- 14.3.2      Each person shall file an application with the Department pursuant RH 3.8 of these regulations and obtain a license as provided in this part before commencement of construction of land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.
- RH 14.4      Reserved
- RH 14.5      Content of Application. In addition to the requirements set forth in RH 3.9 of these regulations, an application to receive from others, possess and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in RH 14.6 through 14.10.
- 14.5.1      The licensee shall submit written statements under oath upon request of the Department, to enable the Department to determine the qualifications of individuals, the status of site operators, and whether or not additional actions at the site might be warranted.
- RH 14.6      General Information. The general information shall include each of the following:
- 14.6.1      Identity of the application including:
- 14.6.1.1      The full name, address, telephone number and description of the business or occupation of the applicant;
- 14.6.1.2      If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;
- 14.6.1.3      If the applicant is a corporation or an unincorporated association, (i) the state where it is incorporated or organized and the principal location where it does business, and (ii) the names and addresses of its directors and principal officers; and
- 14.6.1.4      If the applicant is acting as an agent or representative of another person in filing the application, all information required under 14.6.1 must be supplied with respect to the other person.

- 14.6.2       Qualifications of the applicant:
- 14.6.2.1       The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;
- 14.6.2.2       The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 14.6.2.1 must be provided.
- 14.6.2.3       A description of the applicant's personnel training program; and
- 14.6.2.4       The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and disposal operations in a safe manner.
- 14.6.3       A description of:
- 14.6.3.1       The location of the proposed disposal site;
- 14.6.3.2       The general character of the proposed activities;
- 14.6.3.3       The types and quantities of waste to be received, possessed, and disposal of;
- 14.6.3.4       Plans for use of the land disposal facility for purposes other than disposal of wastes; and
- 14.6.3.5       The proposed facilities and equipment.
- 14.6.4       Proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility.
- RH 14.7       Specific Technical Information. The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this part will be met:
- 14.7.1       A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description shall include, but not be limited to, geologic, geotechnical, geochemical, ecologic, archeological, hydrologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

- 14.7.2 A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description shall include those design features related to infiltration of water; integrity of covers for disposal units, structural stability of backfill, wastes, and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measure.
- 14.7.3 A description of the principal design criteria and their relationship to the performance objectives.
- 14.7.4 A description of the design basis natural events or phenomena and their relationship to the principal design criteria.
- 14.7.5 A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facilities.
- 14.7.6 A description of the construction and operation of the land disposal facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedure for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes. The description shall also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives of this part.
- 14.7.7 A description of the disposal site closure plan, including those design features which are intended to facilities disposal site closure and to eliminate the need for ongoing active maintenance.
- 14.7.8 An identification of the known natural resources at the disposal site, whose exploitation could result in inadvertent intrusion into the waste after removal of active institutional control.
- 14.7.9 A description of the kind, amount, classification and specifications of the radioactive materials proposed to be received, possessed, and disposed of at the land disposal facility.
- 14.7.10 A description of the quality assurance program developed and applied by the applicant for the determination of natural disposal site characteristics and for quality control during the design, construction, operation and closure of the land disposal facility and the receipt, handling, and emplacement of waste. Audits and managerial controls must be included.



- 14.7.11 A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in RH 14.19 and occupational radiation exposure to ensure compliance with the requirements of Part IV of these regulations and to control contamination of personnel, vehicles, equipment, buildings, and the disposal site. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.
- 14.7.12 A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration is indicated.
- 14.7.13 A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.
- 14.7.14 A description of the facility electronic recordkeeping system as required in RH 14.33.
- RH 14.8 Technical Analyses. The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of this part will be met:
- 14.8.1 Pathways analyzed in demonstrating protection of the general population from release of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in RH 14.19.
- 14.8.2 Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.
- 14.8.3 Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and disposal of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Part IV of these regulations.
- 14.8.4 Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.



- RH 14.9      Institutional Information. The institutional information submitted by the applicant shall include:
- 14.9.1      A certification by the federal or state custodial agency which owns the disposal site that the federal or state agency is prepared to accept transfer of the license when the provisions of RH 14.16 are met, and will assume responsibility for institutional control after site closure and post-closure observation and maintenance.
- 14.9.2      Where the proposed disposal site is on land not owned by the federal or state government, the applicant shall submit evidence that arrangements have been made for assumption of ownership in fee by the federal or a state agency before the Department issues a license.
- RH 14.10     Financial Information. The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this part.
- RH 14.11     Requirements for Issuance of a License. A license for the receipt, possession, and disposal of waste containing or contaminated with radioactive material will be issued by the Department upon finding that:
- 14.11.1      The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;
- 14.11.2      The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property;
- 14.11.3      The applicant's proposed disposal site, disposal design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in Rh 14.19;
- 14.11.4      The applicant's proposed disposal site, disposal site design, land disposal facility operations, including equipment, facilities, and procedures, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with the performance objective in RH 14.20;
- 14.11.5      The applicant's proposed land disposal facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Part IV of these regulations will be met;

14.11.6 The applicant's proposed disposal site, disposal site design, land disposal facility operations, disposal site closure, and postclosure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure;

14.11.7 The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this part will be met;

14.11.8 The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in Rh 14.11.3 through 14.11.6 and that the institutional control meets the requirements of 14.28; and

14.11.9 The financial or surety arrangement meets the requirements of this part.

RH 14.12 Conditions of Licensure.

14.12.1 A license issued under these regulations for the purpose of near-surface land disposal of low-level radioactive wastes, or any right thereunder, may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, only if the Department finds, after securing full information, that the transfer is in accordance with the provisions of the Act and gives its consent in writing in the form of a license amendment.

14.12.2 The license will be terminated only on the full implementation of the final closure plan as approved by the Department, including postclosure observation and maintenance.

14.12.3 The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the Department. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

14.12.4 Each person licensed by the Department pursuant to the regulations in this part shall confine possession and use of materials to the locations and purposes authorized in the license.

14.12.5 The licensee shall not dispose of waste until the Department has inspected the land disposal facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

- 14.12.6 The Department may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and disposal of waste as it deems appropriate or necessary in order to:
- 14.12.6.1 Protect health or to minimize danger to life or property;
- 14.12.6.2 Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.
- 14.12.7 The authority to dispose of wastes expires on the date stated in the license. Any expiration date on a license applied only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for carrying out site closure, postclosure observation and transfer of the license to the site owner.
- RH 14.13 Application for Renewal or Closure.
- 14.13.1 An application for renewal, or an application for closure under RH 14 must be filed at least one year prior to license expiration.
- 14.13.2 Applications for renewal of a license must be filed in accordance with RH 14.5 through 14.10. Applications for closure must be filed in accordance with RH 14.14. Information contained in previous applications, statements or reports filed with the Department under the license may be incorporate by reference if the references are clear and specific.
- 14.13.3 In any case in which a licensee has filed an application in proper form for renewal of a license, the license does not expire until the Department has taken final action on the application for renewal.
- 14.13.4 In determining whether a license will be renewed, the Department will apply the criteria set forth in RH 14.11.
- RH 14.14 Contents of Application for Site Closure and Stabilization.
- 14.14.1 Prior to final closure of the disposal site, or as otherwise directed by the Department, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under RH 14.7.8 that includes each of the following:
- 14.14.1.1 Any additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced wastes obtained during the operational period.

- 14.14.1.2 The results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to the long-term containment of emplaced waste within the disposal site.
- 14.14.1.3 Any proposed revision of plans for:
- 14.14.1.3.1 Decontamination and/or dismantlement of surface facilities;
- 14.14.1.3.2 Backfilling of excavated areas; or
- 14.14.1.3.3 Stabilization of the disposal site for post closure care.
- 14.14.1.4 Any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.
- 14.14.2 Upon review and consideration of an application to amend the license for closure submitted in accordance with RH 14.14.1, the Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this part will be met.
- RH 14.15 Post-Closure Observation and Maintenance. The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the site closure is complete and the license is transferred by the Department in accordance with RH 14.16. Responsibility for the disposal site must be maintained by the licensee for 5 years following closure. A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.
- RH 14.16 Transfer of License. Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Department finds:
- 14.16.1 That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;
- 14.16.2 That reasonable assurance has been provided by the licensee that the performance objectives of this part are met;
- 14.16.3 That any funds and necessary records for care will be transferred to the disposal site owner;
- 14.16.4 That the post-closure monitoring program is operational for implementation by the disposal site owner; and



14.16.5 That the federal or state agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under RH 14.11.8 will be met.

RH 14.17 Termination of License.

14.17.1 Following any period of institutional control needed to meet the requirements found necessary under RH 14.11, the licensee may apply for an amendment to terminate the license.

14.17.2 This application will be reviewed in accordance with the provisions of RH 3.8 of these regulations.

14.17.3 A license shall be terminated only when the Department finds:

14.17.3.1 That the institutional control requirements found necessary under RH-14.11.8 have been met; and

14.17.3.2 That any additional requirements resulting from new information developed during the institutional control period have been met; and

14.17.3.3 That permanent monuments or markers warning against intrusion have been installed.

Performance Objectives

RH 14.18 General Requirement. Land disposal facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in RH 14.19 through 14.22.

RH 14.19 Protection of the General Population from Releases of Radioactivity. Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 25 millirems (0.25 mSv) to the thyroid, and 25 millirems (0.25 mSv) to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

RH 14.20 Protection of Individuals from Inadvertent Intrusion. Design, operation, and closure of the land disposal facility shall ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

- RH 14.21 Protection of Individuals During Operations. Operations at the land disposal facility shall be conducted in compliance with the standards for radiation protection set out in Part IV of these regulations, except for releases of radioactivity in effluents from the land disposal facility, which shall be governed by RH 14.19. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable.
- RH 14.22 Stability of the Disposal Site After Closure. The disposal facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring, or minor custodial care are required.

Technical Requirements for Land Disposal Facilities

- RH 14.23 Disposal Site Suitability Requirements for Land Disposal.
- 14.23.1 Disposal Site Suitability for Near-Surface Disposal. The primary emphasis in near-surface disposal site suitability is given to isolation of wastes, and to the disposal site features that ensure that the long-term performance objectives are met.
- 14.23.1.1 The disposal site shall be capable of being characterized, modeled, analyzed and monitored.
- 14.23.1.2 Within the region where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of this part.
- 14.23.1.3 Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this part.
- 14.23.1.4 The disposal site shall be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 1988, "Flood plain Management Guidelines."
- 14.23.1.5 Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.
- 14.23.1.6 The disposal site shall provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Department will consider an exception to the requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.



- 14.23.1.7 The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.
- 14.23.1.8 Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part or may preclude defensible modeling and prediction of long-term impacts.
- 14.23.1.9 Area shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of this part, or may preclude defensible modeling and prediction of long-term impacts.
- 14.23.1.10 The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this part or significantly mask the environmental monitoring program.
- 14.23.2 Reserved
- RH 14.24 Disposal Site Design for Land Disposal.
- 14.24.1 Disposal Site Design for Near-Surface Disposal.
- 14.24.1.1 Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.
- 14.24.1.2 The disposal site design and operation shall be compatible with the disposal site closure and stabilization plan and lead to disposal site closure provides reasonable assurance that the performance objectives will be met.
- 14.24.1.3 The disposal site shall be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives will be met.
- 14.24.1.4 Covers shall be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste, and to resist depredation by surface geologic processes and biotic activity.
- 14.24.1.5 Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

- 14.24.1.6 The disposal site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal, and the contact of percolating or standing water with wastes after disposal.
- 14.24.2 Reserved
- RH 14.25 Land Disposal Facility Operation and Disposal Site Closure.
- 14.25.1 Near-Surface Disposal Facility Operation and Disposal Site Closure.
- 14.25.1.1 Wastes designated as Class A pursuant to Part 4, Appendix E of these regulations shall be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this part. This segregation is not necessary for Class A wastes if they meet the stability requirements in Part 4, Appendix E, II(b) of these regulations.
- 14.25.1.2 Wastes designated as Class C pursuant to Part 4, Appendix E, of these regulations shall be disposed of so that the top of the waste is a minimum of sixteen feet (5 meters) below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.
- 14.25.1.3 Except as provided in RH 14.25.1.12 only waste classified as Class A, B, or C shall be acceptable for near-surface disposal. All waste shall be disposed of in accordance with requirements of RH 14.25.1.4 through 14.25.1.11.
- 14.25.1.4 Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.
- 14.25.1.5 Void spaces between waste package shall be filled with earth or other material to reduce future subsidence within the fill.
- 14.25.1.6 Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of RH 4.15.2.2 of these regulations at the time the license is transferred pursuant to RH 14.16.

- 14.25.1.7 The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Near-surface disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.
- 14.25.1.8 A buffer zone of land shall be maintained between any buried waste and the disposal site boundary and beneath the disposal waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in RH 14.26.4 and take mitigative measure if needed.
- 14.25.1.9 Closure and stabilization measures as set forth in the approval site closure plan shall be carried out as each disposal unit is filled and covered.
- 14.25.1.10 Active waste disposal operations shall not have any adverse effect on completed closure and stabilization measures.
- 14.25.1.11 Only wastes containing or contaminated with radioactive material shall be disposed of at the disposal site.
- 14.25.1.12 Proposals for disposal of waste that is not generally acceptable for near-surface disposal because the waste form and disposal methods must be different, and in general more stringent than those specified for Class C waste may be submitted to the Department for approval.
- 14.25.2 Reserved
- RH 14.26 Environmental Monitoring.
- 14.26.1 At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the disposal site. For those characteristics that are subject to seasonal variation, data must cover at least a twelve month period.
- 14.26.2 During the land disposal facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.

- 14.26.3 After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of waste from the disposal site before they leave the site boundary.
- 14.26.4 The licensee shall have plans for taking corrective measures if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.
- RH 14.27 Alternative Requirements for Design and Operations. The Department may, upon request or on its own initiative, authorize provision other than those set forth in RH 14.24 through 14.26 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of this part.
- RH 14.28 Institutional Requirements.
- 14.28.1 Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the federal or a state government.
- 14.28.2 Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer or control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the disposal site, periodic surveillance, minor custodial and other requirements as determined by the Department; and administration of funds to cover the costs for these activities. The period of controls will be determined by the Department, but controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.
- RH 14.29 Alternative Requirements for Waste Classification and Characteristics. The Department may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal site, method of disposal, it finds reasonable assurance of compliance with the performance objectives specified in this part.

#### Financial Assurances

- RH 14.30 Applicant Qualifications and Assurances. Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs construction and disposal.



RH 14.31      Funding for Disposal Site Closure and Stabilization.

- 14.31.1      The applicant shall provide assurance prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including: (1) decontamination or dismantlement of land disposal facility structures; and (2) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurance shall be based on Department-approved cost estimates reflecting the Department-approved plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.
- 14.31.2      In order to avoid unnecessary duplication and expense, the Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of federal or other state agencies for such decontamination, closure and stabilization. The Department will accept these arrangements only if they are considered adequate to satisfy the requirements of RH 14.31 and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.
- 14.31.3      The licensee's financial surety arrangement shall be submitted annually for review by the Department to assure that sufficient funds will be available for completion of the closure plan.
- 14.31.4      The amount of the licensee's financial surety arrangement shall change in accordance with changes in predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include: inflation, increase in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.
- 14.31.5      The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Department, the beneficiary (the site owner), and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation the licensee must submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement acceptable to the Department, the beneficiary may collect on the original surety arrangement.

- 14.31.6 Proof of forfeiture shall not be necessary to collect the surety so that in the event the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. the conditions described above shall be clearly stated on any surety instrument.
- 14.31.7 Financial or surety arrangements generally acceptable to the Department include: surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the Department. Self-insurance, or any arrangement which essentially constitutes self-insurance shall not satisfy the surety requirement for private sector applicant.
- 14.31.8 The licensee's financial surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Department, and the license has been transferred to the site owner.
- RH 14.32 Financial Assurances for Institutional Controls.
- 14.32.1 Prior to the issuance of the license, the applicant shall provide a binding arrangement for Department approval, between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Department to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements.
- 14.32.2 Subsequent changes to the binding arrangement specified in RH 14.32.1 relevant to institutional control shall have prior approval by the Department.

Records, Reports, Tests, and Inspections

- RH 14.33 Maintenance of Records, Reports, and Transfers.
- 14.33.1 Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Department.
- 14.33.2 Records which are required by these regulations or by license conditions shall be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in RH 14.33.4 as a condition of license termination unless the Department otherwise authorizes their disposition.
- 14.33.3 Records which shall be maintained pursuant to this part may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.



- 14.33.4 Notwithstanding RH 14.33.1 through 14.33.3, copies of records of the location and the quantity of wastes contained in the disposal site must be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor and other local, state and federal governmental agencies as designated by the Department at the time of license termination.
- 14.33.5 Following receipt and acceptance of a shipment of radioactive waste, the licensee shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for the disposal of the waste, the location of disposal at the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in the U.S. Department of Transportation and Department regulations. The licensee shall briefly describe any repackaging operations of any of the disposal containers included in the shipment, plus any other information required by the Department as a license condition. The licensee shall retain these records in accordance with RH 3.15.4 until the license that authorizes the activities described in this section is transferred or terminated.
- 14.33.6 Each licensee authorized to dispose of waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Department in order to update the information base for determining financial qualifications.
- 14.33.7 Annual Reports.
- 14.33.7.1 Each licensee authorized to dispose of waste received from other persons, pursuant to this part, shall submit annual reports to the Department. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.
- 14.33.7.2 The reports shall include:
- 14.33.7.2.1 Specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,
- 14.33.7.2.2 the results of the environmental monitoring program,
- 14.33.7.2.3 a summary of licensee disposal unit survey and maintenance activities,
- 14.33.7.2.4 a summary, by waste class, of activities and quantities of radionuclides disposed of,

- 14.33.7.2.5 any instances in which observed site characteristics were significantly different from those described in the application for a license, and
- 14.33.7.2.6 any other information the Department may require.
- 14.33.7.2.7 If the quantities of waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically.
- 14.33.8 In addition to the other requirements of this section, the licensee shall store, or have stored, manifest and other information pertaining to receipt and disposal of radioactive waste in an electronic recordkeeping system.
- 14.33.8.1 The manifest information that must be electronically stored is:
- 14.33.8.1.1 That required in Appendix G of Part 4, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications;
- 14.33.8.1.2 That information required in RH 14.33.5.
- 14.33.8.2 As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer readable medium.
- RH 14.34 Tests of Land Disposal Facilities. Each licensee shall perform, or permit the Department to perform, any tests the Department deems appropriate or necessary for the administration of the regulations in this part, including, but not limited to, tests of:
- 14.34.1 Wastes;
- 14.34.2 Facilities used for the receipt, storage, treatment, handling or disposal of wastes;
- 14.34.3 Radiation detection and monitoring instruments; and
- 14.34.4 Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or disposal of waste.
- RH 14.35 Agency Inspections of Land Disposal Facilities.
- 14.35.1 Each licensee shall afford to the Department at all reasonable times opportunity to inspect radioactive waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed.
- 14.35.2 Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the Department may copy and take away copies of, for the Department's use, any record required to be kept pursuant to these regulations.

PART XV

COLORADO LOW-LEVEL RADIOACTIVE WASTE  
RATE REGULATIONS

- RH 15.1 Authority. These regulations are promulgated in accordance with 24-60-2212 C.R.S. 1982. In the event of conflict between these rules and 24-60-2212, C.R.S. 1982, the latter shall control.
- RH 15.2 Basis and Purpose. The basis and purpose of these regulations is to achieve, in the application of these regulations pursuant to the requirements stated herein, just and reasonable rates for the management of low-level radioactive waste at facilities. The regulations are intended to effect the legislative intent of Section 24-60-2212, C.R.S. 1982, prescribing the powers and duties of the Board of Health as the designated agency responsible for regulating low-level radioactive waste management charges at facilities in the State. The rationale for these regulations as promulgated herein is to establish a regulatory scheme based upon that employed for the regulation of public utilities rates.
- RH 15.3 Amendment of Rules. These rules may be amended at any time by the Board of Health as provided by law.
- RH 15.3 Definitions. As used in these rules, the following words shall have meaning indicated unless context otherwise requires.

"Board" means Board of Health of the State of Colorado.

"Closure" means those actions that are taken upon completion of operations to prepare the facility for custodial care and that assure that the facility will remain stable and will not need ongoing active maintenance as defined in RH 14.2.

"Facility" means a low-level radioactive waste facility capable of serving as a regional disposal or management site in compliance with all pertinent federal and state laws and rules and regulations and which also complies with the provisions of the "Rocky Mountain Low-Level Radioactive Waste Compact" set forth in 24-60-2212, C.R.S. 1982

"Management" means collection, consolidation, storage, treatment, incineration or disposal.

"Normalization" is the requirement that a company reflect in its financial accounting income statement a deferred tax so that the entire federal income tax is equal to that which the company normally would have had to pay if it had chosen to use

straight-line depreciation for tax purposes as well as for financial accounting.

"Reasonable cost" means a cost which in its nature or amount does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost.

"Straight-line basis" is the distribution of the depreciable cost of an asset in equal amounts over its useful life.

#### Rate Review and Approval Process

- RH 15.5 The licensee shall establish a schedule of rates for the management of low-level radioactive waste subject to approval by the Board, pursuant to 24-60-2212(3)(2), C.R.S. 1982 and in accordance with the procedures set forth in these regulations as follows:
- 15.5.1 The licensee shall file with the Board, at least sixty days prior to the proposed effective date, proposed schedules showing all rates, charges, and classifications collected or enforced or to be collected or enforced, and a filing fee in the amount of \$1000. Such rates, when effective, shall be posted and open to public inspection at the facility.
  - 15.5.2 Within ten (10) days of receipt, the Board shall make available for public inspection the filing and supporting information and provide reasonable public notice thereof.
  - 15.5.3 Unless the Board otherwise orders, no change shall be made in any rate, charge, or classification collected or enforced or to be collected or enforced by a facility except after sixty days of filing with the Board. All filings shall be kept open for public inspection with new schedules stating plainly the changes to be made in the schedules then in force and the time when the changes will go into effect.
  - 15.5.4 The Board shall not approve or disapprove a filing without a public hearing. If the Board does not disapprove or schedule a hearing on a filing within sixty (60) days of receipt by the Board, the filing shall automatically become effective.

- 15.5.5 During the sixty-day (60) review period, the Board may conclude that it is in the public interest to hold a public hearing, or any interested person may request a public hearing by written petition to the Board.
- 15.5.6 Whenever the Board after a hearing upon its own motion or upon petition finds, based upon the record and investigation by the Board, that the rates or charges, enforced or to be enforced by any facility are unjust, unreasonable, discriminatory, or violative of any provision of law or that such rates, charges, or classifications are insufficient, the Board shall determine the just, reasonable, or sufficient rates, charges, classifications, rules, regulations, or practices to be thereafter observed and in force and shall fix the same by order of the Board.
- 15.5.7 The Board has the authority, after a hearing upon its own motion or upon complaint, to investigate a single rate, charge, classification, or practice of any facility and to establish new rates, charges, classifications or practices in lieu thereof.
- 15.5.8 Within ten (10) days of Board approval of the rate schedules or within 10 days after becoming automatically effective, the rate schedules shall be forwarded to the Rocky Mountain Low-Level Radioactive Waste Board for approval pursuant to 24-60-2212, (3)(D), C.R.S. 1982.
- RH 15.6 The rates for managing low-level radioactive waste at facilities shall remain in effect until modified by the Board upon application by the licensee or upon the Board's own motion or until a new rate application becomes effective automatically pursuant to RH 15.5.
- RH 15.7 Initial rates for the facility shall be based on a forecasted twelve (12) month test year which shall include an estimate of the revenues expected to be derived from the projected volume of waste to managed at the facility and the cost projected to be incurred to provide such service associated with the estimated volume of waste to be disposed. If the revenue derived from the actual volume of waste managed differs from the initial projections by 15% after twelve (12) months, the licensee shall petition the Board to adjust the rates to correct for the error in projection.
- RH 15.8 Two (2) years after the facility has been operated, the licensee shall petition the Board to determine the rates using a historic test period of no less than twelve (12) continuous months,



adjusted for known and certain future expenditures that will be incurred by the licensee which are reasonable and necessary for the operation of the facility.

RH 15.9 In the event the licensee or the board determines that various classes of low-level radioactive waste will be managed at the facility which will impact upon the cost of service, rates shall be designated which best reflect the actual costs incurred in order to manage a particular class of low-level radioactive waste, so that the various classes do not subsidize costs associated with the management of another class of waste.

RH 15.10 When applying for approval of a proposed rate schedule by the Board, the licensee shall submit the following:

15.10.1 Identification including name, location of business, and licensee number;

15.10.2 Proposed rate schedules according to waste classes which may be characterized by chemical, physical form, container type, or by radiation quantity and concentration; and

15.10.3 Estimated allowable expenses and proposed rate of return in accordance with RH 15.17 through 15.20.

RH 15.11 Calculation of the Rates

15.11.1 Rates are based upon the licensee's cost of rendering service to the public.

15.11.2 The two components of cost of service are allowable expenses and return on invested capital.

RH 15.12 Allowable expenses. Only those expenses which are reasonable and necessary to provide service shall be included in allowable expenses. Allowable expenses may include, but are not limited to the following general categories:

15.12.1 Site operating costs incurred during the daily operation of the facility (labor, supplies, and maintenance costs).

15.12.2 Depreciation expense based on original cost of all buildings and equipment used on the facility computed on a straight line basis for a period extending from the date of purchase to the expected date of closure.

- 15.12.3 Amortization expense based on the original costs for site acquisition, environmental and geotechnical studies, licensing site development, and administrative and legal expenses incurred prior to the start of site operations, computed on a straight line basis for a period extending from the date such costs and expenses are incurred to the expected date of closure.
- 15.12.4 Assessments and taxes other than income taxes.
- 15.12.5 Federal and state income taxes normalized to reflect the taxes that would have been paid had the licensee elected to use straight line depreciation.
- 15.12.6 Cost of financial assurance required by the Department for facility closure and post-closure monitoring and maintenance pursuant to Parts III and XIV.
- 15.12.7 State surcharge of one percent of gross revenue and local surcharge of up to two percent of annual gross revenue as provided in 24-60-2212, C.R.S. 1982.
- 15.12.8 Compact surcharge as authorized in 24-60-2212, C.R.S. 1982
- 15.12.9 Annual license fee and attendant legal fees pursuant to regulations.
- 15.12.10 Cost of liability insurance for both sudden and accidental or slow and gradual contamination to people and/or property off site.
- 15.12.11 Legal fees necessary to the safe operation and management of the facility.

RH 15.13 Costs Not Allowed. The following expenses shall never be allowed as a component of cost of service:

- 15.13.1 Legislative advocacy expenses, whether made directly or indirectly, including but not limited to legislative advocacy expenses included in professional or trade association dues.
- 15.13.2 Funds expended in support of political candidates, any political movement or in the promotion of political or religious causes.

- 15.13.3 Funds expended in support of or membership in social, recreational, fraternal, or religious clubs or organizations.
- 15.13.4 Funds expended to mail any material containing any of the items mentioned in RH 15.13 through 15.13.3.
- 15.13.5 Criminal penalties or fines, and civil penalties or fines.
- 15.13.5 Any other expenditure found by the Board to be unreasonable, unnecessary, or not in the public interest, including but not limited to executive salaries, advertising expenses, legal expenses incurred in suits initiated against the State of Colorado, or the Rocky Mountain Low-Level Radioactive Waste Board, or penalties and interest on overdue taxes.

RH 15.14 Return on invested capital. The return on invested capital is the rate of return multiplied by invested capital (also known as rate base). Invested capital includes the original cost of plant, property and equipment, less accumulated depreciation authorized under these rules and the accumulated amortization expenses associated with start up costs incurred prior to the start of site operations, which were prudently incurred and are used and useful in rendering service to the public. Components to be included in determining the overall rate base are as follows:

- 15.14.1 Costs incurred prior to the start of site operations, less accumulated amortization expenses associated with such costs which shall include:
  - 15.14.1.1 Site acquisition costs including but not limited to costs incurred to acquire the site for low-level radioactive waste management.
  - 15.14.1.2 Licensing costs and costs associated with site selection, and the development of any plans, reports, design, manuals or schedules.
  - 15.14.1.3 Site development costs including but not limited to the costs for grading, development of roads, installation of fencing and lighting.
  - 15.14.1.4 Administrative costs and legal fees.
- 15.14.2 Plant in service, less accumulated depreciation actually incurred and as reported on federal and state income tax returns.

15.14.3 Working capital, which shall include:

15.14.3.1 Reasonable inventories of materials, and supplies held specifically for purposes of permitting efficient operation of the facility.

15.14.3.2 Reasonable prepayments for operating expenses.

RH 15.15 Rate of Return. The Board shall allow the licensee an opportunity to earn a reasonable return on its invested capital and shall fix the rate of return in accordance with the following principles:

15.15.1 The return should be sufficient to assure confidence in the financial soundness of the facility and should be adequate, under efficient management, to maintain and support its credit and enable it to raise the money necessary for proper discharge of its public duties. A rate of return may be reasonable at one time and become too high or too low by changes affecting opportunities for investment, the money market, inflation, deflation, the growth rate of the service area, business conditions generally and the need for the facility to attract necessary capital.

15.15.2 The Board shall consider the risks associated with the unique character of this facility and the risks which the licensee must incur in order to establish, operate and maintain the facility. In evaluating these risks, the Board may consider such factors as the amount of capital expended and required to establish the facility, the potential liability which the licensee incurs while operating the facility, the potential liability the licensee may incur after closure, and whether the licensee is a small business which is not a public corporation or whether the licensee is a public corporation, and whether the licensee operates the facility as its sole business rather than a portion of a larger business.

#### Rate Review Documentation

RH 15.16 For purpose of verifying the rate base upon which rates have been proposed or established, including any rate base changes affecting the calculation of proposed rates, the licensee shall supply the following reports and records to the Department.

- 15.16.1 Semiannual reports of all allowable costs to operate the facility.
  - 15.16.2 Semiannual reports on the quantity of waste managed at the facility.
  - 15.16.3 An annual financial report which includes complete data on the rates charged for each type of waste managed at the facility, all surcharges collected and paid by the licensee, the actual return on invested capital received by the licensee, and the data used or proposed to be used by the licensee in the calculation of the rate base and/or rates for the facility. This report shall be due within three months after the close of the licensee's fiscal year.
- RH 15.17 All contracts made by the licensee which require payments by the licensee of five percent or more of the latest annual reported gross revenue shall require that an independent audit report be made available to the Board.
- RH 15.18 The books and records supporting the reports referred to in this part shall be maintained in a form capable of review and audit by the Board or its staff, and the Board or its staff shall have the right to inspect these books and records.
- RH 15.19 All documents submitted pursuant to these rules which are proprietary, private or confidential shall be so identified by the applicant or licensee or any parties who apply to become the licensee of the facility. The Board may issue such protective orders as are necessary to protect such proprietary, private or confidential material, subject to the provisions of 24-72-204, C.R.S. 1982.



## PART 16

### RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

- RH 16.1 Purpose. The regulations in this part establish radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this part are in addition to, and not in substitution for, the requirements of Parts 1, 2, 3, 4, and 10 of these regulations.
- RH 16.2 Scope. The regulations in this part apply to all licensees or registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.
- RH 16.3 Definitions. As used in this part, the following definitions apply:
- "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.
- "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
- "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by RH 16.22
- "Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.
- "Logging tool" means a device used subsurface to perform well-logging.
- "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Temporary jobsite" means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

"Well-logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

#### Prohibition

RH 16.4 Prohibition. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well-operator, well-owner, drilling contractor, or land owner that:

16.4.1 in the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

16.4.2 in the event a decision is made to abandon the sealed source downhole, the requirements of RH 16.25 and of any other State Agency having applicable regulations shall be met.

#### Equipment Control

RH 16.5 Limits on Levels of Radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Part 17 and the dose limitation requirements of Part 4 of these regulations are met.

RH 16.6 Storage Precautions.

16.6.1 Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

16.6.2 Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

RH 16.7 Transport Precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

RH 16.8     Radiation Survey Instruments.

- 16.8.1     The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this part and by RH 4.9 of these regulations. Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour. Survey instruments acquired before the effective date of this part and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 20 milliroentgens (5.16 microcoulombs/kg) per hour also satisfies this requirement.
- 16.8.2     Each radiation survey instrument shall be calibrated:
- 16.8.2.1     at intervals not to exceed 6 months and after each instrument servicing;
- 16.8.2.2     for linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and
- 16.8.2.3     so that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.
- 16.8.3     Calibration records shall be maintained for a period of 2 years for inspection by the Department.

RH 16.9     Leak Testing of Sealed Sources.

- 16.9.1     Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the Department for 6 months after the next required leak test is performed or until transfer or disposal of the sealed source.

16.9.2 Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

16.9.3 Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

16.9.4 Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these regulations. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the Department within 5 days of receiving the test results.

16.9.5 Exemptions. The following sources are exempted from the periodic leak test requirements of RH 16.9.1 through 16.9.4:

16.9.5.1 hydrogen-3 sources;

16.9.5.2 sources of radioactive material with a half-life of 30 days or less;



- 16.9.5.3 sealed sources of radioactive material in gaseous form;
- 16.9.5.4 sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and
- 16.9.5.5 sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.
- RH 16.10 Quarterly Inventory. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the Department and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.
- RH 16.11 Utilization Records. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the Department for 2 years from the date of the recorded event, showing the following information for each source of radiation:
- 16.11.1 make, model number, and a serial number or a description of each source of radiation used;
- 16.11.2 the identity of the well-logging supervisor or field unit to whom assigned;
- 16.11.3 locations where used and dates of use; and
- 16.11.4 in the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

- RH 16.12      Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.
- 16.12.1      Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after December 30, 1986 shall be certified by the manufacturer, or other testing organization acceptable to the Department, to meet the following minimum criteria:
- 16.12.1.1      be of doubly encapsulated construction;
- 16.12.1.2      contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and
- 16.12.1.3      has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m<sup>2</sup>) without failure.
- 16.12.2      For sealed sources, except those containing radioactive material in gaseous form, acquired after December 30, 1986, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of RH 16.12.1, the sealed source shall not be put into use until such determinations and testing have been performed.
- 16.12.3      Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after December 30, 1986 shall be certified by the manufacturer, or other testing organization acceptable to the Department, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N43.6 "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on December 30, 1985.
- 16.12.4      Certification documents shall be maintained for inspection by the Department for a period of 2 years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the Department authorizes disposition.

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<sup>1</sup> A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Creek Drive South, Building B, First Floor, Denver, Colorado. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80222-1530.

RH 16.13 Labeling.

- 16.13.1 Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER 1/  
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment..

- 16.13.2 Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER 1/  
RADIOACTIVE  
NOTIFY CIVIL AUTHORITIES [OR NAME OF COMPANY]

RH 16.14 Inspection and Maintenance.

- 16.14.1 Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the Department.

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1/ or CAUTION

- 16.14.2 If any inspection conducted pursuant to RH 16.14.1 reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.
- 16.14.3 If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform this operation.
- 16.14.4 The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

#### Requirements for Personnel Safety

##### RH 16.15 Training Requirements.

- 16.15.1 No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this part until such individual has:
- 16.15.1.1 received, in a course recognized by the Department, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, instruction in the subjects outlined in Appendix A of this part and demonstrated an understanding thereof;
- 16.15.1.2 read and received instruction in the regulations contained in this part and the applicable sections of Parts 1, 4, and 10 of these regulations or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

- 16.15.1.3 demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- 16.15.2 No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:
- 16.15.2.1 read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and
- 16.15.2.2 demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.
- 16.15.2.3 The licensee or registrant shall maintain employee training records for inspection by the Department for 2 years following termination of the individual's employment.
- RH 16.16 Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:
- 16.16.1 handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Part 4 of these regulations;
- 16.16.2 methods and occasions for conducting radiation surveys;
- 16.16.3 methods and occasions for locking and securing sources of radiation;
- 16.16.4 personnel monitoring and the use of personnel monitoring equipment;
- 16.16.5 transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;



- 16.16.6 minimizing exposure of individuals in the event of an accident;
- 16.16.7 procedure for notifying proper personnel in the event of an accident;
- 16.16.8 maintenance of records;
- 16.16.9 use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;
- 16.16.10 procedure to be followed in the event a sealed source is lodged downhole;
- 16.16.11 procedures to be used for picking up, receiving, and opening packages containing radioactive material;
- 16.16.12 for the use of tracers, decontamination of the environment, equipment, and personnel;
- 16.16.13 maintenance of records generated by logging personnel at temporary jobsites;
- 16.16.14 notifying proper persons in the event of an accident; and
- 16.16.15 actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and indigestion of radioactive material and actions to obtain suitable radiation survey instruments as required by RH 16.8.

RH 16.17 Personnel Monitoring.

- 16.17.1 No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be exchanged at least monthly and TLD's exchanged at least quarterly. After replacement, each replaced film badge or TLD must be promptly processed.

- 16.17.2 Personnel monitoring records shall be maintained for inspection until the Department authorizes disposition.

**Precautionary Procedures in Logging and Subsurface  
Tracer Operations**

- RH 16.18 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Part 1 of these regulations.
- RH 16.19 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources..
- RH 16.20 Subsurface Tracer Studies.
- 16.20.1 Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
- 16.20.2 No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the Department and any other appropriate State Agency.
- RH 16.21 Particle Accelerators. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of RH 4.6 and 4.14 of these regulations, as applicable, are met.

**Radiation Surveys and Records**

- RH 16.22 Radiation Surveys.
- 16.22.1 Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are stored.

- 16.22.2 Radiation surveys or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and calculations shall include each source of radiation or combination of sources to be transported in the vehicle.
- 16.22.3 If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.
- 16.22.4 Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.
- 16.22.5 Records required pursuant to RH 16.22.1 through 16.22.4 shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Department for 2 years after completion of the survey.
- RH 16.23 Documents and Records Required at Field Stations. Each licensee or registrant shall maintain, for inspection by the Department, the following documents and records for the specific devices and sources used at the field station:
- 16.23.1 appropriate license, certificate of registration, or equivalent document(s);
- 16.23.2 operating and emergency procedures;
- 16.23.3 applicable regulations;
- 16.23.4 records of the latest survey instrument calibrations pursuant to RH 16.8;
- 16.23.5 records of the latest leak test results pursuant to RH 16.9;

- 16.23.6 records of quarterly inventories required pursuant to RH 16.10;
- 16.23.7 utilization records required pursuant to RH 16.11;
- 16.23.8 records of inspection and maintenance required pursuant to RH 16.14;
- 16.23.9 survey records required pursuant to RH 16.22; and
- 16.23.10 training records required pursuant to RH 16.15.
- RH 16.24 Documents and Records Required at Temporary Jobsites. Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the Department:
  - 16.24.1 ~~operating and emergency procedures;~~
  - 16.24.2 survey records required pursuant to RH 16.22 for the period of operation at the site;
  - 16.24.3 evidence of current calibration for the radiation survey instruments in use at the site;
  - 16.24.4 when operating in the State under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and
  - 16.24.5 shipping papers for the transportation of radioactive material.

#### Notification

- RH 16.25 Notification of Incidents, Abandonment, and Lost Sources.
  - 16.25.1 Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of RH 4.52 of these regulations.
  - 16.25.2 Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall;

- 16.25.2.1 monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
- 16.25.2.2 notify the Department immediately by telephone and subsequently within 30 days by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts being planned or taken to mitigate these consequences.
- 16.25.3 When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall
- 16.25.3.1 advise the well-operator of the regulations of the Department regarding abandonment and an appropriate method of abandonment, which shall include:
- 16.25.3.1.1 the immobilization and sealing in place of the radioactive source with a cement plug,
- 16.25.3.1.2 the setting of a whipstock or other deflection device, and
- 16.25.3.1.3 the mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by RH 16.25.4;
- 16.25.3.2 notify the Department by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and
- 16.25.3.3 file a written report with the Department within 30 days of the abandonment. The licensee shall send a copy of the report to the appropriate State Agency that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:



- 16.25.3.3.1 date of occurrence;
- 16.25.3.3.2 a description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;
- 16.25.3.3.3 surface location and identification of the well;
- 16.25.3.3.4 results of efforts to immobilize and seal the source in place;
- 16.25.3.3.5 a brief description of the attempted recovery effort;
- 16.25.3.3.6 depth of the source;
- 16.25.3.3.7 depth of the top of the cement plug;
- 16.25.3.3.8 depth of the well;
- 16.25.3.3.9 any other information, such as a warning statement, contained on the permanent identification plaque; and
- 16.25.3.3.10 the names of State Agencies receiving a copy of this report.
- 16.25.4 Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque 2/ for posting the well or well-bore. This plaque shall:
  - 16.25.4.1 be constructed of long-lasting material, such as stainless steel or monel, and
  - 16.25.4.2 contain the following information engraved on its face:
    - 16.25.4.2.1 the word "CAUTION";

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2/ An example of a suggested plaque is shown in Appendix B of this part.

- 16.25.4.2.2 the radiation symbol without the conventional color requirement;
- 16.25.4.2.3 the date of abandonment;
- 16.25.4.2.4 the name of the well-operator or well-owner;
- 16.25.4.2.5 the well name and well identification number(s) or other designation;
- 16.25.4.2.6 the sealed source(s) by radionuclide and activity;
- 16.25.4.2.7 the source depth and the depth to the top of the plug; and
- 16.25.4.2.8 an appropriate warning, depending on the specific circumstances of each abandonment. 3/
- 16.25.5 The licensee shall immediately notify the Department by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

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3/ Appropriate warnings may include: (a) "Do not drill below plug- back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Colorado Department of Health, Radiation Control Division.

## APPENDIX A

### SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

- I. Fundamentals of Radiation Safety
  - A. Characteristics of radiation
  - B. Units of radiation dose and quantity of radioactivity
  - C. Significance of radiation dose
    - 1. Radiation protection standards
    - 2. Biological effects of radiation dose
  - D. Levels of radiation from sources of radiation
  - E. Methods of minimizing radiation dose
    - 1. Working time
    - 2. Working distances
    - 3. Shielding
  - F. Radiation safety practices including prevention of contamination and methods of decontamination
- II. Radiation Detection Instrumentation to be Used
  - A. Use of radiation survey instruments
    - 1. Operation
    - 2. Calibration
    - 3. Limitations
  - B. Survey techniques
  - C. Use of personnel monitoring equipment
- III. Equipment to be Used
  - A. Handling equipment
  - B. Sources of radiation
  - C. Storage and control of equipment
  - D. Operation and control of equipment

- IV. The Requirements of Pertinent Federal and State Regulations
- V. The Licensee's or Registrant's Written Operating and Emergency Procedures
- VI. The Licensee's or Registrant's Record Keeping Procedures

APPENDIX B

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS  
CONTAINING SEALED SOURCES  
CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

[COMPANY NAME]  
[WELL IDENTIFICATION]



**CAUTION**



ONE 2 CURIE CS-137 RADIOACTIVE SOURCE ABANDONED  
3-3-75 AT 8400 FT. PLUG BACK DEPTH 8200 FT.  
DO NOT RE-ENTER THIS WELL BEFORE CONTACTING  
COLORADO DEPARTMENT OF HEALTH

The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.



PART 17

TRANSPORTATION OF RADIOACTIVE MATERIAL

RH 17.1 Purpose and Scope. The regulations in this part establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

RH 17.2 Definitions. As used in this part, the following definitions apply:

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

"Exclusive use" means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

"Fissile material" means plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only, are not included in this definition.<sup>1</sup>

"Fissile material package" means a fissile material packaging together with its fissile material contents.

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<sup>1</sup>Department jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in Part 1 of these regulations.

"Low specific activity (LSA) material" means radioactive material that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

(1) LSA-I.

- i. Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or
- ii. Solid unirradiated natural uranium, depleted uranium, natural thorium, or their solid or liquid compounds or mixtures; or
- iii. Radioactive material, other than fissile material, for which the  $A_2$  value is unlimited; or
- iv. Mill tailings, contaminated earth, concrete, rubble, other bulk debris, and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed  $10^{-6} A_2/g$ .

(2) LSA-II.

- i. Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or
- ii. Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed  $10^{-4} A_2/g$  for solids and gases, and  $10^{-5} A_2/g$  for liquids.

(3) LSA-III. Solids (e.g., consolidated wastes, activated materials) in which:

- i. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and
- ii. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed  $0.1 A_2$ ; and
- iii. The average specific activity of the solid does not exceed  $2 \times 10^{-3} A_2/g$ .

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates; or alpha emitters with a half-life of less than 10 days.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements 49 CFR Part 173 Subpart I. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189 and Parts 390-397.

"Regulations of the U.S. Nuclear Regulatory Commission" means the regulations in 10 CFR 71 for purposes of this Part.

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

A. SCO-I: a solid object on which:

- I. The non-fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4 Bq/cm<sup>2</sup> (10<sup>-4</sup> microcurie/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters, or 0.4 Bq/cm<sup>2</sup> (10<sup>-5</sup> microcurie/cm<sup>2</sup>) for all other alpha emitters;
- II. The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4x10<sup>4</sup> Bq/cm<sup>2</sup> (1.0 Microcurie/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters, or 4x10<sup>3</sup> Bq/cm<sup>2</sup> (0.1 Microcurie/cm<sup>2</sup>) for all other alpha emitters; and
- iii. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 4x10<sup>4</sup> Bq/cm<sup>2</sup> (1 microcurie/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters, or 4x10<sup>3</sup> Bq/cm<sup>2</sup> (0.1 Microcurie/cm<sup>2</sup>) for all other alpha emitters.

B. SCO-II: a solid object on which the limits for sco-i are exceeded and on which:

- I. The non-fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 400 Bq/cm<sup>2</sup> (10<sup>-2</sup> microcurie/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters or 40 Bq/cm<sup>2</sup> (10<sup>-3</sup> microcurie/cm<sup>2</sup>) for all other alpha emitters;
- II. The fixed contamination on the accessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 8x10<sup>5</sup> Bq/cm<sup>2</sup> (20 microcuries/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters, or 8x10<sup>4</sup> Bq/cm<sup>2</sup> (2 microcuries/cm<sup>2</sup>) for all other alpha emitters; and
- III. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm<sup>2</sup> (or the area of the surface if less than 300 cm<sup>2</sup>) does not exceed 8x10<sup>5</sup> Bq/cm<sup>2</sup> (20 microcuries/cm<sup>2</sup>) for beta, gamma and low toxicity alpha emitters, or 8x10<sup>4</sup> Bq/cm<sup>2</sup> (2 microcuries/cm<sup>2</sup>) for all other alpha emitters.

"Transport index" means the dimensionless number, rounded up the next tenth, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level at 1 meter (3.3 feet) from the external surface of the package in millisievert (mSv) per hour multiplied by 100 (equivalent to the maximum radiation level in millirem per hour at 1 meter).

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A<sub>1</sub> for special form radioactive material or A<sub>2</sub> for normal form radioactive material, where A<sub>1</sub> and A<sub>2</sub> are given in Appendix A of this Part 17 or may be determined by procedures described in Appendix A of this Part 17.

"Type A package" means a packaging that, together with its radioactive contents limited to A<sub>1</sub> OR A<sub>2</sub> as appropriate, meets the requirements of 49 CFR 173.410 and 173.412 and is designed to retain the integrity of containment and shielding under normal conditions of transport as demonstrated by the tests set forth in 173.465 Or 173.466, as appropriate.

"Type B package" means a Type B packaging together with its radioactive contents.<sup>2</sup>

"Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth 10 CFR Part 71.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

#### General Regulatory Provisions

- RH 17.3     Requirement for License. No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Department or as exempted in RH 17.4.
- RH 17.4     Exemptions.
- 17.4.1     Common and contract carriers, freight forwarders, and warehouse workers which are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), are exempt from the requirements of this part to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to RH 17.3 and other applicable requirements of these regulations.
- 17.4.2     Any licensee is exempt from the requirements of this part to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 Bq/g (0.002 microcurie per gram).
- RH 17.5     Transportation of Licensed Material.
- 17.5.1     Each licensee who transports licensed material outside the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

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<sup>2</sup>A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983 was designated only as Type B. Limitations on its use are specified in RH 17.8.



17.5.1.1

Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation, particularly the regulations of U.S. Department of transportation in the following areas:

- (1) Packaging - 49 CFR Part 173: Subparts A and B and I.
- (2) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and Subpart E.
- (3) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.
- (4) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.
- (5) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.
- (6) Hazardous material employee training - 49 CFR Part 172: Subpart H.
- (7) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

17.5.1.2

The licensee shall also comply with applicable U.S. Department of Transportation regulations pertaining to the following modes of transportation:

- (1) Rail - 49 CFR Part 174: Subparts A through D and K.
- (2) Air - 49 CFR Part 175.
- (3) Vessel - 49 CFR Part 176: Subparts A through F and M.
- (4) Public highway - 49 CFR Part 177 and Parts 390 through 397.

17.5.1.3

Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

17.5.2

If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

## General Licenses

### RH 17.6 General Licenses for Carriers.

- 17.6.1 A general license is hereby issued to any common or contract carrier not exempt under RH 17.4 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.<sup>3</sup>
- 17.6.2 A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.<sup>3</sup>
- 17.6.3 Persons who transport radioactive material pursuant to the general licenses in RH 17.6.1 or 17.6.2 are exempt from the requirements of Parts 4 and 10 of these regulations to the extent that they transport radioactive material.

### RH 17.7 General License: Nuclear Regulatory Commission-Approved Packages.

- 17.7.1 A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the Nuclear Regulatory Commission.
- 17.7.2 This general license applies only to a licensee who:
- 17.7.2.1 Has a copy of the specific license, certificate of compliance, or other approval by the Nuclear Regulatory Commission of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the action to be taken prior to shipment;
- 17.7.2.2 Complies with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of this Part 17;

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<sup>3</sup>Notification of an incident shall be filed with, or made to, the Department as prescribed in 49 CFR, regardless of and in addition to the notification made to the U.S. Department of Transportation or other agencies.

- 17.7.2.3 Prior to the licensee's first use of the package, has registered with the Nuclear Regulatory Commission; and
- 17.7.2.4 Has a quality assurance program required by RH 17.20.
- 17.7.3 The general license in RH 17.7.1 applies only when the package approval authorizes use of the package under this general license.
- 17.7.4 For a Type B or fissile material package, the design of which was approved by Nuclear Regulatory Commission before April 1, 1996, the general license is subject to additional restrictions of RH 17.8.
- RH 17.8 General License: Previously Approved Type B Packages.
- 17.8.1 A Type B package previously approved by the Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of RH 17.7 with the following additional conditions:
- 17.8.1.1 Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);
- 17.8.1.2 A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. Department of Transportation regulations at 49 CFR 173.403; and
- 17.8.1.3 A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.
- 17.8.2 A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the Nuclear Regulatory Commission but without the designation "-85" in the identification number of the Nuclear Regulatory Commission certificate of compliance, may be used under the general license of RH 17.7 with the following additional conditions:
- 17.8.2.1 Fabrication of the package is satisfactorily completed by April 1, 1996, as demonstrated by application of its model number in accordance with Nuclear Regulatory Commission regulations at 10 CFR 71.85(c);
- 17.8.2.2 A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with U.S. Department of Transportation regulations at 49 CFR 173.403; and

- 17.8.2.3 A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.
- RH 17.9 General License: U.S. Department of Transportation Specification Container.
- 17.9.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.
- 17.9.2 This general license applies only to a licensee who:
- 17.9.2.1 Has a copy of the specification;
- 17.9.2.2 Complies with the terms and conditions of the specification and the applicable requirements of this Part 17; and
- 17.9.2.3 Has a quality assurance program required by 17.20.
- 17.9.3 The general license in RH 17.9.1 is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.
- RH 17.10 General License: Use of Foreign Approved Package.
- 17.10.1 A general license is issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate and revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.
- 17.10.2 This general license applies only to international shipments.
- 17.10.3 This general license applies only to a licensee who:
- 17.10.3.1 Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;
- 17.10.3.2 Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements of this Part 17; and
- 17.10.3.3 Has a quality assurance program approved by the Nuclear Regulatory Commission.

- RH 17.11     General License: Fissile Material, Limited Quantity per Package.
- 17.11.1     A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section.
- 17.11.2     This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:
- 17.11.2.1     Up to 40 grams of uranium-235; or
- 17.11.2.2     Up to 30 grams of uranium-233; or
- 17.11.2.3     Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A<sub>1</sub> quantity of plutonium may be present; or
- 17.11.2.4     A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amount in RH 17.11.2.1, 17.11.2.2, and 17.11.2.3 does not exceed unity.
- 17.11.3     Except as specified in RH 17.11.3.2, this general license applies:
- 17.11.3.1     only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:
- Minimum Transport Index =  

$$(0.40x + 0.67y + z) (1 - 15/(x+y+z))$$
where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium;
- 17.11.3.2     For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.
- 17.11.3.3     In all cases, the transport index must be rounded up to one decimal place and shall not exceed 10.0.
- RH 17.12     General License: Fissile Material, Limited Moderator per Package.
- 17.12.1     A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section.
- 17.12.2     This general license applies only when all of the following requirements are met.



- 17.12.2.1 The package contains no more than a Type A quantity of radioactive material.
- 17.12.2.2 Neither beryllium nor hydrogenous material enriched in deuterium is present.
- 17.12.2.3 The total mass of graphite present does not exceed 7.7 times the total mass of uranium-235 plus plutonium.
- 17.12.2.4 Substances having a higher hydrogen density than water, for example certain hydrocarbon oils, are not present, except that polyethylene may be used for packing or wrapping.
- 17.12.2.5 Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium-235.
- 17.12.2.6 The amount of uranium-235 is limited as follows:
- 17.12.2.6.1 If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in the following Table 1:
- 17.12.2.6.2 If the fissile radionuclides are distributed uniformly, for example, cannot form a lattice arrangement within the packaging, the maximum amount of uranium-235 per package may not exceed the value given in the following Table 2:
- 17.12.2.7 The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or 2 of this section as applicable.

TABLE 1: PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE  
[NONUNIFORM DISTRIBUTION]

<u>Uranium enrichment in weight percent of uranium-235 not exceeding</u>	<u>Permissible maximum grams of uranium-235 per package</u>
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680*
0.92	1200*

TABLE 2: PERMISSIBLE MASS OF URANIUM-235 PER FISSILE MATERIAL PACKAGE  
[UNIFORM DISTRIBUTION]

<u>Uranium enrichment in weight percent of uranium-235 not exceeding</u>	<u>Permissible maximum grams of uranium-235 per package</u>
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

\* Pursuant to the Department's agreement with the Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium-235.

## Operating Controls and Procedures

- RH 17.13 Fissile Material: Assumptions as to Unknown Properties of Fissile Material. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum neutron multiplication.
- Rh 17.14 Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:
- 17.14.1 The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;
  - 17.14.2 Where the maximum normal operating pressure will exceed 35 kilopascal (5 pounds per square inch) gauge, the licensee shall test the containment systems at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;
  - 17.14.3 The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Nuclear Regulatory Commission; and
  - 17.14.4 The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number as assigned by the Nuclear Regulatory Commission.
- RH 17.15 Routine Determinations. Prior to each shipment of licensed material, the licensee shall determine that:
- 17.15.1 The package is proper for the contents to be shipped;
  - 17.15.2 The package is in unimpaired physical condition except for superficial defects such as marks or dents;
  - 17.15.3 Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;
  - 17.15.4 Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;
  - 17.15.5 Any pressure relief device is operable and set in accordance with written procedures;
  - 17.15.6 The package has been loaded and closed in accordance with written procedures;
  - 17.15.7 Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for the purpose unless it satisfies design requirements specified in 10 CFR 71.45;

- 17.15.8 The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable.
- 17.15.8.1 The level of non-fixed (removable) radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in RH 17.15.8.2, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken in account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table 3.
- 17.15.8.2 In the case of packages transported as exclusive use shipments by rail or highway only, the non-fixed (removable) radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in RH 17.15.8.1. The levels at the beginning of transport must not exceed the levels in RH 17.15.8.1.
- 17.15.9 External radiation levels around the package and around the vehicle, if applicable will not exceed 2 mSv/h (200 millirems per hour) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.0;

TABLE 3: NON-FIXED (REMOVABLE) EXTERNAL RADIOACTIVE CONTAMINATION WIPE LIMITS

Contaminant	Maximum Permissible Limits		
	Bq/cm <sup>2</sup>	uCi/cm <sup>2</sup>	dpm/cm <sup>2</sup>
Beta and gamma emitters and low toxicity alpha emitters . . . . .	0.4	10 <sup>-5</sup>	22
All other alpha emitting radionuclides . . . . .	0.04	10 <sup>-6</sup>	2.2

- 17.15.10 For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in RH 17.15.9 but shall not exceed any of the following:

- 17.15.10.1 2 mSv/h (200 millirems per hour) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 mSv/h (1000 millirems per hour);
- 17.15.10.1.1 The shipment is made in a closed transport vehicle,
- 17.15.10.1.2 Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and
- 17.15.10.1.3 There are no loading or unloading operations between the beginning and end of the transportation.
- 17.15.10.2 2 mSv/h (200 millirems per hour) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier\*, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used), and on the lower external surface of the vehicle;
- 17.15.10.3 0.1 mSv/h (10 millirems per hour) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and
- 17.15.10.4 0.02 mSv/h (2 millirems per hour) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with RH 10.3 of these regulations; and
- 17.15.11 A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 180 degrees Fahrenheit (82 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.
- 17.15.12 A package may not incorporate a feature intended to allow continuous venting during transport.

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\* A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier is in place, the package cannot exceed 2 mSv/h (200 millirems per hour) at any accessible surface.



- RH 17.16 Air Transport of Plutonium. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this part or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:
- 17.16.1 The plutonium is contained in a medical device designed for individual human application; or
  - 17.16.2 The plutonium is contained in a material in which the specific activity is not greater than 70 Bq/g (0.002 microcuries per gram) of material and in which the radioactivity is essentially uniformly distributed; or
  - 17.16.3 The plutonium is shipped in a single package containing no more than an A<sub>1</sub> quantity of plutonium in any isotope or form and is shipped in accordance with RH 17.5; or
  - 17.16.4 The plutonium is shipped in a package specifically authorized (in the certificate of compliance issued by the Nuclear Regulatory Commission for that package) for the shipment of plutonium by air and the licensee requires, through special arrangement with the carrier, compliance with 49 CFR 175.704, the U.S. Department of Transportation regulations applicable to the air transport of plutonium.
- RH 17.17 Shipment Records. Each licensee shall maintain, for a period of 2 years after shipment, a record of each shipment of licensed material not exempt under RH 17.4 showing, where applicable:
- 17.17.1 Identification of the packaging by model number and serial number;
  - 17.17.2 Verification that the packaging, as shipped, had no significant defect;
  - 17.17.3 Volume and identification of coolant;
  - 17.17.4 Type and quantity of licensed material in each package, and the total quantity of each shipment;
  - 17.17.5 Date of the shipment;
  - 17.17.6 Name and address of the transferee;
  - 17.17.7 Address to which the shipment was made; and
  - 17.17.8 Results of the determinations required by RH 17.15 and by the conditions of the package approval.
- RH 17.18 Reports. The licensee shall report to the Department within 30 days:
- 17.18.1 Any instance in which there is significant reduction in the effectiveness of any packaging during use; and

- 17.18.2 Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence; or
- 17.18.3 Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.
- RH 17.19 Advance Notification of Transport of Nuclear Waste.
- 17.19.1 Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee, of each state through which the waste will be transported.
- 17.19.2 Advance notification is required only when:
- 17.19.2.1 The nuclear waste is required to be in Type B packaging for transportation;
- 17.19.2.2 The nuclear waste is being transported into, within, or through, a state enroute to a disposal facility or to a collection point for transport to a disposal facility; and
- 17.19.2.3 The quantity of licensed material in a single package exceeds;
- 17.19.2.3.1 3000 times the  $A_1$  value of the radionuclides as specified in Appendix A, Table A-1 for special form radioactive material;
- 17.19.2.3.2 3000 times the  $A_2$  value of the radionuclides as specified in Appendix A, Table A-1 for normal form radioactive material;
- 17.19.2.3.3 1000 TBq (27,000 Ci);
- 17.19.3 Each advance notification required by RH 17.19.1 shall contain the following information:
- 17.19.3.1 The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

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'A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

- 17.19.3.2 A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);
- 17.19.3.3 The point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;
- 17.19.3.4 The 7-day period during which arrival of the shipment at state boundaries is estimated to occur;
- 17.19.3.5 The destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and
- 17.19.3.6 A point of contact with a telephone number for current shipment information.
- 17.19.4 The notification required by RH 17.19.1 shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Department. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.
- 17.19.5 The licensee shall notify each appropriate governor, or governor's designee, and the Department of any changes to schedule information provided pursuant to RH 17.19.1. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for 1 year a record of the name of the individual contacted.
- 17.19.6 Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the Department. A copy of the notice shall be retained by the licensee for 1 year.

#### Quality Assurance

- RH 17.20 Quality Assurance Requirements.
- 17.20.1 Unless otherwise authorized by the agency, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.
- 17.20.2 The licensee shall identify the material and components to be covered by the quality assurance program.

- 17.20.3 Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.
- 17.20.4 Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Department of its quality assurance program.
- 17.20.5 The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of 3 years after shipment.
- 17.21 Referenced Materials
- 17.21.1 This Part 17 of these regulations incorporates by reference material originally published elsewhere. Certified copies of the complete text of incorporated materials referenced are available for public inspection during regular business hours at the radiation control division. Copies of referenced material will be provided at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from:
- Director, Radiation Control Division (RCD-DO-B1)  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, Colorado 80222-1530
- 17.21.2 Any material that has been incorporated by reference may be examined in any state publications depository library. Copies of the incorporated materials have been sent to the state publications depository and distribution center, and are available for interlibrary loan.
- 17.21.3 Material referenced in this Part 17 of the regulations does not include amendments to or revised editions of the material published later than the effective date of the relevant section.

# Appendix A to Part 17 - Determination of $A_1$ and $A_2$

- I. Values of  $A_1$  and  $A_2$  for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of  $A_1$  or  $A_2$  are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.
- II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of  $A_1$  and  $A_2$  requires Department approval, except that the values of  $A_1$  and  $A_2$  in Table A-2 may be used without obtaining Agency approval.
- III. In the calculations of  $A_1$  and  $A_2$  for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the  $A_1$  or  $A_2$  value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.
- IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:
  - (a) For special form radioactive material, the maximum quantity transported in a Type A package:
 
$$\sum_I \frac{B(i)}{A_1(i)} \text{ less than or equal to } 1$$
  - (b) For normal form radioactive material, the maximum quantity transported in a Type A package:
 
$$\sum_I \frac{B(i)}{A_2(i)} \text{ less than or equal to } 1$$

where  $B(i)$  is the activity of radionuclide  $I$  and  $A_1(i)$  and  $A_2(i)$  are the  $A_1$  and  $A_2$  values for radionuclide respectively.

Alternatively, an  $A_1$  value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_I \frac{f(i)}{A_1(i)}}$$

where  $f(i)$  is the fraction of activity of nuclide  $I$  in the mixture and  $A_1(i)$  is the appropriate  $A_1$  value for nuclide  $I$ .



An  $A_2$  value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_I \frac{f(i)}{A_2(i)}}$$

where  $f(i)$  is the fraction of activity of nuclide  $I$  in the mixture and  $A_2(i)$  is the appropriate  $A_2$  value for nuclide  $I$ .

- V. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest  $A_1$  or  $A_2$  value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest  $A_1$  or  $A_2$  values for the alpha emitters and beta/gamma emitters.

Table A-1:  $A_1$  and  $A_2$  Values for Radionuclides

Symbol of Radionuclide	Element and Atomic No.	$A_1$ (TBq)	$A_1$ (Ci)	$A_2$ (TBq)	$A_2$ (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Ac-225	Actinium(89)	0.6	16.2	$1 \times 10^{-2}$	0.270	$2.1 \times 10^3$	$5.8 \times 10^4$
Ac-227		40	1080	$2 \times 10^{-5}$	$5.41 \times 10^{-4}$	2.7	$7.2 \times 10^1$
Ac-228		0.6	16.2	0.4	10.8	$8.4 \times 10^4$	$2.2 \times 10^6$
Ag-105	Silver(47)	2	54.1	2	54.1	$1.1 \times 10^3$	$3.0 \times 10^4$
Ag-108m		0.6	16.2	0.6	16.2	$9.7 \times 10^{-1}$	$2.6 \times 10^1$
Ag-110m	Aluminum(13)	0.4	10.8	0.4	10.8	$1.8 \times 10^2$	$4.7 \times 10^3$
Ag-111		0.6	16.2	0.5	13.5	$5.8 \times 10^3$	$1.6 \times 10^5$
Al-26		0.4	10.8	0.4	10.8	$7.0 \times 10^{-4}$	$1.9 \times 10^{-2}$
Am-241		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$1.3 \times 10^{-1}$	3.4
Am-242m		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$3.6 \times 10^{-1}$	$1.0 \times 10^1$
Am-243	Argon(18)	2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$7.4 \times 10^{-3}$	$2.0 \times 10^{-1}$
Ar-37		40	1080	40	1080	$3.7 \times 10^3$	$9.9 \times 10^4$
Ar-39		20	541	20	541	1.3	$3.4 \times 10^1$
Ar-41		0.6	16.2	0.6	16.2	$1.5 \times 10^6$	$4.2 \times 10^7$
Ar-42		0.2	5.41	0.2	5.41	9.6	$2.6 \times 10^2$
As-72	Arsenic(33)	0.2	5.41	0.2	5.41	$6.2 \times 10^4$	$1.7 \times 10^6$
As-73		40	1080	40	1080	$8.2 \times 10^2$	$2.2 \times 10^4$
As-74		1	27.0	0.5	13.5	$3.7 \times 10^3$	$9.9 \times 10^4$
As-76		0.2	5.41	0.2	5.41	$5.8 \times 10^4$	$1.6 \times 10^6$
As-77		20	541	0.5	13.5	$3.9 \times 10^4$	$1.0 \times 10^6$
At-211	Astatine(85)	30	811	2	54.1	$7.6 \times 10^4$	$2.1 \times 10^6$
Au-193	Gold(79)	6	162	6	162	$3.4 \times 10^4$	$9.2 \times 10^5$
Au-194		1	27.0	1	27.0	$1.5 \times 10^4$	$4.1 \times 10^5$
Au-195		10	270	10	270	$1.4 \times 10^2$	$3.7 \times 10^3$
Au-196		2	54.1	2	54.1	$4.0 \times 10^3$	$1.1 \times 10^5$
Au-198		3	81.1	0.5	13.5	$9.0 \times 10^3$	$2.4 \times 10^5$
Au-199	Barium(56)	10	270	0.9	24.3	$7.7 \times 10^3$	$2.1 \times 10^5$
Ba-131		2	54.1	2	54.1	$3.1 \times 10^3$	$8.4 \times 10^4$
Ba-133m		10	270	0.9	24.3	$2.2 \times 10^4$	$6.1 \times 10^5$
Ba-133		3	81.1	3	81.1	9.4	$2.6 \times 10^2$
Ba-140		0.4	10.8	0.4	10.8	$2.7 \times 10^3$	$7.3 \times 10^4$
Be-7	Beryllium(4)	20	541	20	541	$1.3 \times 10^4$	$3.5 \times 10^5$
Be-10		20	541	0.5	13.5	$8.3 \times 10^{-4}$	$2.2 \times 10^{-2}$
Bi-205	Bismuth(83)	0.6	16.2	0.6	16.2	$1.5 \times 10^3$	$4.2 \times 10^4$
Bi-206		0.3	8.11	0.3	8.11	$3.8 \times 10^3$	$1.0 \times 10^5$
Bi-207	Berkelium(97)	0.7	18.9	0.7	18.9	1.9	$5.2 \times 10^1$
Bi-210m		0.3	8.11	$3 \times 10^{-2}$	0.811	$2.1 \times 10^{-5}$	$5.7 \times 10^{-4}$
Bi-210		0.6	16.2	0.5	13.5	$4.6 \times 10^3$	$1.2 \times 10^5$
Bi-212		0.3	8.11	0.3	8.11	$5.4 \times 10^5$	$1.5 \times 10^7$
Bk-247		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$3.8 \times 10^{-2}$	1.0

Table A-1 (Cont.)

Sym. of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Bk-249	Bromine(35)	40	1080	8x10 <sup>-2</sup>	2.16	6.1x10 <sup>1</sup>	1.6x10 <sup>3</sup>
Br-76		0.3	8.11	0.3	8.11	9.4x10 <sup>4</sup>	2.5x10 <sup>6</sup>
Br-77		3	81.1	3	81.1	2.6x10 <sup>4</sup>	7.1x10 <sup>5</sup>
Br-82		0.4	10.8	0.4	10.8	4.0x10 <sup>4</sup>	1.1x10 <sup>6</sup>
C-11	Carbon(6)	1	27	0.5	13.5	3.1x10 <sup>7</sup>	8.4x10 <sup>8</sup>
C-14	Calcium(20)	40	1080	2	54.1	1.6x10 <sup>-1</sup>	4.5
Ca-41		40	1080	40	1080	3.1x10 <sup>-3</sup>	8.5x10 <sup>-2</sup>
Ca-45		40	1080	0.9	24.3	6.6x10 <sup>-2</sup>	1.8x10 <sup>4</sup>
Ca-47		0.9	24.3	0.5	13.5	2.3x10 <sup>4</sup>	6.1x10 <sup>5</sup>
Cd-109	Cadmium(48)	40	1080	1	27.0	9.6x10 <sup>1</sup>	2.6x10 <sup>3</sup>
Cd-113m	Cerium(58)	20	541	9x10 <sup>-2</sup>	2.43	8.3x10 <sup>4</sup>	2.2x10 <sup>2</sup>
Cd-115m		0.3	8.11	0.3	8.11	9.4x10 <sup>2</sup>	2.5x10 <sup>4</sup>
Cd-115		4	108	0.5	13.5	1.9x10 <sup>4</sup>	5.1x10 <sup>5</sup>
Ce-139		6	162	6	162	2.5x10 <sup>2</sup>	6.8x10 <sup>3</sup>
Ce-141		10	270	0.5	13.5	1.1x10 <sup>3</sup>	2.8x10 <sup>4</sup>
Ce-143	Californium(98)	0.6	16.2	0.5	13.5	2.5x10 <sup>4</sup>	6.6x10 <sup>5</sup>
Ce-144		0.2	5.41	0.2	5.41	1.2x10 <sup>2</sup>	3.2x10 <sup>3</sup>
Cf-248		30	811	3x10 <sup>-3</sup>	8.11x10 <sup>-2</sup>	5.8x10 <sup>1</sup>	1.6x10 <sup>3</sup>
Cf-249		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	1.5x10 <sup>-1</sup>	4.1
Cf-250		5	135	5x10 <sup>-4</sup>	1.35x10 <sup>-2</sup>	4.0	1.1x10 <sup>2</sup>
Cf-251	Chlorine(17)	2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	5.9x10 <sup>-2</sup>	1.6
Cf-252		0.1	2.70	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	2.0x10 <sup>1</sup>	5.4x10 <sup>2</sup>
Cf-253		40	1080	6x10 <sup>-2</sup>	1.62	1.1x10 <sup>3</sup>	2.9x10 <sup>4</sup>
Cf-254		3x10 <sup>-3</sup>	8.11x10 <sup>-2</sup>	6x10 <sup>-4</sup>	1.62x10 <sup>-2</sup>	3.1x10 <sup>2</sup>	8.5x10 <sup>3</sup>
Cl-36		20	541	0.5	13.5	1.2x10 <sup>-3</sup>	3.3x10 <sup>-2</sup>
Cl-38	Curium(96)	0.2	5.41	0.2	5.41	4.9x10 <sup>6</sup>	1.3x10 <sup>8</sup>
Cm-240		40	1080	2x10 <sup>-2</sup>	0.541	7.5x10 <sup>2</sup>	2.0x10 <sup>4</sup>
Cm-241		2	54.1	0.9	24.3	6.1x10 <sup>2</sup>	1.7x10 <sup>4</sup>
Cm-242		40	1080	1x10 <sup>-2</sup>	0.270	1.2x10 <sup>2</sup>	3.3x10 <sup>3</sup>
Cm-243		3	81.1	3x10 <sup>-4</sup>	8.11x10 <sup>-3</sup>	1.9	5.2x10 <sup>1</sup>
Cm-244		4	108	4x10 <sup>-4</sup>	1.08x10 <sup>-2</sup>	3.0	8.1x10 <sup>5</sup>
Cm-245		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	6.4x10 <sup>-3</sup>	1.7x10 <sup>-1</sup>
Cm-246		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	1.1x10 <sup>-2</sup>	3.1x10 <sup>-1</sup>
Cm-247		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	3.4x10 <sup>-6</sup>	9.3x10 <sup>-5</sup>
Cm-248		4x10 <sup>-2</sup>	1.08	5x10 <sup>-5</sup>	1.35x10 <sup>-3</sup>	1.6x10 <sup>-4</sup>	4.2x10 <sup>-3</sup>
Co-55	Cobalt(27)	0.5	13.5	0.5	13.5	1.1x10 <sup>5</sup>	3.1x10 <sup>6</sup>
Co-56		0.3	8.11	0.3	8.11	1.1x10 <sup>3</sup>	3.0x10 <sup>4</sup>
Co-57		8	216	8	216	3.1x10 <sup>2</sup>	8.4x10 <sup>3</sup>
Co-58m		40	1080	40	1080	2.2x10 <sup>5</sup>	5.9x10 <sup>6</sup>
Co-58		1	27.0	1	27.0	1.2x10 <sup>3</sup>	3.2x10 <sup>4</sup>
Co-60	Chromium(24)	0.4	10.8	0.4	10.8	4.2x10 <sup>1</sup>	1.1x10 <sup>3</sup>
Cr-51		30	811	30	811	3.4x10 <sup>3</sup>	9.2x10 <sup>4</sup>
Cs-129	Cesium(55)	4	108	4	108	2.8x10 <sup>4</sup>	7.6x10 <sup>5</sup>

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Cs-131		40	1080	40	1080	3.8x10 <sup>3</sup>	1.0x10 <sup>5</sup>
Cs-132		1	27.0	1	27.0	5.7x10 <sup>3</sup>	1.5x10 <sup>5</sup>
Cs-134m		40	1080	9	243	3.0x10 <sup>5</sup>	8.0x10 <sup>6</sup>
Cs-134		0.6	16.2	0.5	13.5	4.8x10 <sup>1</sup>	1.3x10 <sup>3</sup>
Cs-135		40	1080	0.9	24.3	4.3x10 <sup>-5</sup>	1.2x10 <sup>-3</sup>
Cs-136		0.5	13.5	0.5	13.5	2.7x10 <sup>3</sup>	7.3x10 <sup>4</sup>
Cs-137		2	54.1	0.5	13.5	3.2	8.7x10 <sup>1</sup>
Cu-64	Copper(29)	5	135	0.9	24.3	1.4x10 <sup>5</sup>	3.9x10 <sup>6</sup>
Cu-67		9	243	0.9	24.3	2.8x10 <sup>4</sup>	7.6x10 <sup>5</sup>
Dy-159	Dysprosium(66)	20	541	20	541	2.1x10 <sup>-2</sup>	5.7x10 <sup>-3</sup>
Dy-165		0.6	16.2	0.5	13.5	3.0x10 <sup>5</sup>	8.2x10 <sup>6</sup>
Dy-166		0.3	8.11	0.3	8.11	8.6x10 <sup>3</sup>	2.3x10 <sup>5</sup>
Er-169	Erbium(68)	40	1080	0.9	24.3	3.1x10 <sup>3</sup>	8.3x10 <sup>4</sup>
Er-171		0.6	16.2	0.5	13.5	9.0x10 <sup>4</sup>	2.4x10 <sup>6</sup>
Es-253	Einsteinium(99)*	200	5400	2.1x10 <sup>-2</sup>	5.4x10 <sup>-1</sup>	--	--
Es-254		30	811	3x10 <sup>-3</sup>	8.11x10 <sup>-2</sup>	--	--
Es-254m		0.6	16.2	0.4	10.8	--	--
Es-255		--	--	--	--	--	--
Eu-147	Europium(63)	2	54.1	2	54.1	1.4x10 <sup>3</sup>	3.7x10 <sup>4</sup>
Eu-148		0.5	13.5	0.5	13.5	6.0x10 <sup>2</sup>	1.6x10 <sup>4</sup>
Eu-149		20	541	20	541	3.5x10 <sup>-2</sup>	9.4x10 <sup>-3</sup>
Eu-150		0.7	18.9	0.7	18.9	6.1x10 <sup>4</sup>	1.6x10 <sup>6</sup>
Eu-152m		0.6	16.2	0.5	13.5	8.2x10 <sup>4</sup>	2.2x10 <sup>6</sup>
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8x10 <sup>2</sup>
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6x10 <sup>2</sup>
Eu-155		20	541	2	54.1	1.8x10 <sup>1</sup>	4.9x10 <sup>2</sup>
Eu-156		0.6	16.2	0.5	13.5	2.0x10 <sup>3</sup>	5.5x10 <sup>4</sup>
F-18	Fluorine(9)	1	27.0	0.5	13.5	3.5x10 <sup>6</sup>	9.5x10 <sup>7</sup>
Fe-52	Iron(26)	0.2	5.41	0.2	5.41	2.7x10 <sup>5</sup>	7.3x10 <sup>6</sup>
Fe-55		40	1080	40	1080	8.8x10 <sup>1</sup>	2.4x10 <sup>3</sup>
Fe-59		0.8	21.6	0.8	21.6	1.8x10 <sup>3</sup>	5.0x10 <sup>4</sup>
Fe-60		40	1080	0.2	5.41	7.4x10 <sup>-4</sup>	2.0x10 <sup>-2</sup>

\*International shipments of Einsteinium require multilateral approval of A<sub>1</sub> and A<sub>2</sub> values.

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g) (Ci/g)	
Fm-255	Fermium(100) <sup>b</sup>	40	1080	0.8	21.6	--	--
Fm-257		10	270	8x10 <sup>-3</sup>	21.6x10 <sup>-1</sup>	--	--
Ga-67	Gallium(31)	6	162	6	162	2.2x10 <sup>4</sup>	6.0x10 <sup>5</sup>
Ga-68		0.3	8.11	0.3	8.11	1.5x10 <sup>6</sup>	4.1x10 <sup>7</sup>
Ga-72		0.4	10.8	0.4	10.8	1.1x10 <sup>5</sup>	3.1x10 <sup>6</sup>
Gd-146	Gadolinium(64)	0.4	10.8	0.4	10.8	6.9x10 <sup>2</sup>	1.9x10 <sup>4</sup>
Gd-148		3	81.1	3x10 <sup>-4</sup>	8.11x10 <sup>-3</sup>	1.2	3.2x10 <sup>1</sup>
Gd-153		10	270	5	135	1.3x10 <sup>2</sup>	3.5x10 <sup>3</sup>
Gd-159		4	108	0.5	13.5	3.9x10 <sup>4</sup>	1.1x10 <sup>6</sup>
Ge-68	Germanium(32)	0.3	8.11	0.3	8.11	2.6x10 <sup>2</sup>	7.1x10 <sup>3</sup>
Ge-71		40	1080	40	1080	5.8x10 <sup>3</sup>	1.6x10 <sup>5</sup>
Ge-77	Hydrogen(1) Hafnium(72)	0.3	8.11	0.3	8.11	1.3x10 <sup>5</sup>	3.6x10 <sup>6</sup>
H-3		See T-Tritium					
Hf-172		0.5	13.5	0.3	8.11	4.1x10 <sup>1</sup>	1.1x10 <sup>3</sup>
Hf-175		3	81.1	3	81.1	3.9x10 <sup>2</sup>	1.1x10 <sup>4</sup>
Hf-181	Mercury(80)	2	54.1	0.9	24.3	6.3x10 <sup>2</sup>	1.7x10 <sup>4</sup>
Hf-182		4	108	3x10 <sup>-2</sup>	0.811	8.1x10 <sup>-6</sup>	2.2x10 <sup>-4</sup>
Hg-194		1	27.0	1	27.0	1.3x10 <sup>-1</sup>	3.5
Hg-195m		5	135	5	135	1.5x10 <sup>4</sup>	4.0x10 <sup>5</sup>
Hg-197m		10	270	0.9	24.3	2.5x10 <sup>4</sup>	6.7x10 <sup>5</sup>
Hg-197	Holmium(67)	10	270	10	270	9.2x10 <sup>3</sup>	2.5x10 <sup>5</sup>
Hg-203		4	108	0.9	24.3	5.1x10 <sup>2</sup>	1.4x10 <sup>4</sup>
Ho-163		40	1080	40	1080	2.7	7.6x10 <sup>1</sup>
Ho-166m		0.6	16.2	0.3	8.11	6.6x10 <sup>-2</sup>	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6x10 <sup>4</sup>	7.0x10 <sup>5</sup>
I-123	Iodine(53)	6	162	6	162	7.1x10 <sup>4</sup>	1.9x10 <sup>6</sup>
I-124		0.9	24.3	0.9	24.3	9.3x10 <sup>3</sup>	2.5x10 <sup>5</sup>
I-125		20	541	2	54.1	6.4x10 <sup>2</sup>	1.7x10 <sup>4</sup>
I-126		2	54.1	0.9	24.3	2.9x10 <sup>3</sup>	8.0x10 <sup>4</sup>
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5x10 <sup>-6</sup>	1.8x10 <sup>-4</sup>
I-131		3	81.1	0.5	13.5	4.6x10 <sup>3</sup>	1.2x10 <sup>5</sup>
I-132		0.4	10.8	0.4	10.8	3.8x10 <sup>5</sup>	1.0x10 <sup>7</sup>
I-133		0.6	16.2	0.5	13.5	4.2x10 <sup>4</sup>	1.1x10 <sup>6</sup>
I-134		0.3	8.11	0.3	8.11	9.9x10 <sup>5</sup>	2.7x10 <sup>7</sup>
I-135		0.6	16.2	0.5	13.5	1.3x10 <sup>5</sup>	3.5x10 <sup>6</sup>

<sup>b</sup>International shipments of Fermium require multilateral approval of A<sub>1</sub> and A<sub>2</sub> values.



Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
In-111	Indium(49)	2	54.1	2	54.1	1.5x10 <sup>4</sup>	4.2x10 <sup>5</sup>
In-113m		4	108	4	108	6.2x10 <sup>5</sup>	1.7x10 <sup>7</sup>
In-114m		0.3	8.11	0.3	8.11	8.6x10 <sup>2</sup>	2.3x10 <sup>4</sup>
In-115m		6	162	0.9	24.3	2.2x10 <sup>5</sup>	6.1x10 <sup>6</sup>
Ir-189	Iridium(77)	10	270	10	270	1.9x10 <sup>3</sup>	5.2x10 <sup>4</sup>
Ir-190		0.7	18.9	0.7	18.9	2.3x10 <sup>3</sup>	6.2x10 <sup>4</sup>
Ir-192		1	27.0	0.5	13.5	3.4x10 <sup>2</sup>	9.2x10 <sup>3</sup>
Ir-193m		10	270	10	270	2.4x10 <sup>3</sup>	6.4x10 <sup>4</sup>
Ir-194	Potassium(19)	0.2	5.41	0.2	5.41	3.1x10 <sup>4</sup>	8.4x10 <sup>5</sup>
K-40		0.6	16.2	0.6	16.2	2.4x10 <sup>-7</sup>	6.4x10 <sup>-6</sup>
K-42		0.2	5.41	0.2	5.41	2.2x10 <sup>5</sup>	6.0x10 <sup>6</sup>
K-43		1.0	27.0	0.5	13.5	1.2x10 <sup>5</sup>	3.3x10 <sup>6</sup>
Kr-81	Krypton(36)	40	1080	40	1080	7.8x10 <sup>-4</sup>	2.1x10 <sup>-2</sup>
Kr-85m		6	162	6	162	3.0x10 <sup>5</sup>	8.2x10 <sup>6</sup>
Kr-85		20	541	10	270	1.5x10 <sup>1</sup>	3.9x10 <sup>2</sup>
Kr-87		0.2	5.41	0.2	5.41	1.0x10 <sup>6</sup>	2.8x10 <sup>7</sup>
La-137	Lanthanum(57)	40	1080	2	54.1	1.6x10 <sup>-3</sup>	4.4x10 <sup>-2</sup>
La-140		0.4	10.8	0.4	10.8	2.1x10 <sup>4</sup>	5.6x10 <sup>5</sup>
Lu-172	Lutetium(71)	0.5	13.5	0.5	13.5	4.2x10 <sup>5</sup>	1.1x10 <sup>5</sup>
Lu-173		8	216	8	216	5.6x10 <sup>1</sup>	1.5x10 <sup>3</sup>
Lu-174m		20	541	8	216	2.0x10 <sup>2</sup>	5.3x10 <sup>3</sup>
Lu-174		8	216	4	108	2.3x10 <sup>1</sup>	6.2x10 <sup>2</sup>
Lu-177		30	811	0.9	24.3	4.1x10 <sup>3</sup>	1.1x10 <sup>5</sup>
MFP	For mixed fission products, use formula for mixtures or Table A-2.						
Mg-28	Magnesium(12)	0.2	5.41	0.2	5.41	2.0x10 <sup>5</sup>	5.4x10 <sup>6</sup>
Mn-52	Manganese(25)	0.3	8.11	0.3	8.11	1.6x10 <sup>4</sup>	4.4x10 <sup>5</sup>
Mn-53	Molybdenum(42)	Unlimited	Unlimited	Unlimited	Unlimited	6.8x10 <sup>-5</sup>	1.8x10 <sup>-3</sup>
Mn-54		1	27.0	1	27.0	2.9x10 <sup>2</sup>	7.7x10 <sup>3</sup>
Mn-56		0.2	5.41	0.2	5.41	8.0x10 <sup>5</sup>	2.2x10 <sup>7</sup>
Mo-93		40	1080	7	189	4.1x10 <sup>-2</sup>	1.1
Mo-99		0.6	16.2	0.5	13.5 <sup>e</sup>	1.8x10 <sup>4</sup>	4.8x10 <sup>5</sup>
N-13	Nitrogen(7)	0.6	16.2	0.5	13.5	5.4x10 <sup>7</sup>	1.5x10 <sup>9</sup>
Na-22	Sodium(11)	0.5	13.5	0.5	13.5	2.3x10 <sup>2</sup>	6.3x10 <sup>3</sup>
Na-24		0.2	5.41	0.2	5.41	3.2x10 <sup>5</sup>	8.7x10 <sup>6</sup>
Nb-92m	Niobium(41)	0.7	18.9	0.7	18.9	5.2x10 <sup>3</sup>	1.4x10 <sup>5</sup>
Nb-93m		40	1080	6	162	8.8	2.4x10 <sup>2</sup>

<sup>e</sup>20 Ci for Mo<sup>99</sup> for domestic use.

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Nb-94	Neodymium(60)	0.6	16.2	0.6	16.2	6.9x10 <sup>-3</sup>	1.9x10 <sup>-1</sup>
Nb-95		1	27.0	1	27.0	1.5x10 <sup>3</sup>	3.9x10 <sup>4</sup>
Nb-97		0.6	16.2	0.5	13.5	9.9x10 <sup>5</sup>	2.7x10 <sup>7</sup>
Nd-147		4	108	0.5	13.5	3.0x10 <sup>3</sup>	8.1x10 <sup>4</sup>
Nd-149		0.6	16.2	0.5	13.5	4.5x10 <sup>5</sup>	1.2x10 <sup>7</sup>
Ni-59	Nickel(28)	40	1080	40	1080	3.0x10 <sup>-3</sup>	8.0x10 <sup>-2</sup>
Ni-63		40	1080	30	811	2.1	5.7x10 <sup>1</sup>
Ni-65	Neptunium(93)	0.3	8.11	0.3	8.11	7.1x10 <sup>5</sup>	1.9x10 <sup>7</sup>
Np-235		40	1080	40	1080	5.2x10 <sup>1</sup>	1.4x10 <sup>3</sup>
Np-236		7	189	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	4.7x10 <sup>-4</sup>	1.3x10 <sup>-2</sup>
Np-237		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	2.6x10 <sup>-5</sup>	7.1x10 <sup>-4</sup>
Np-239	Osmium(76)	6	162	0.5	13.5	8.6x10 <sup>3</sup>	2.3x10 <sup>5</sup>
Os-185		1	27.0	1	27.0	2.8x10 <sup>2</sup>	7.5x10 <sup>3</sup>
Os-191m		40	1080	40	1080	4.6x10 <sup>4</sup>	1.3x10 <sup>6</sup>
Os-191		10	270	0.9	24.3	1.6x10 <sup>3</sup>	4.4x10 <sup>5</sup>
Os-193	Phosphorus(15)	0.6	16.2	0.5	13.5	2.0x10 <sup>4</sup>	5.3x10 <sup>5</sup>
Os-194		0.2	5.41	0.2	5.41	1.1x10 <sup>1</sup>	3.1x10 <sup>2</sup>
P-32		0.3	8.11	0.3	8.11	1.1x10 <sup>4</sup>	2.9x10 <sup>5</sup>
P-33	Protactinium(91)	40	1080	0.9	24.3	5.8x10 <sup>3</sup>	1.6x10 <sup>5</sup>
Pa-230		2	54.1	0.1	2.70	1.2x10 <sup>3</sup>	3.3x10 <sup>4</sup>
Pa-231	Lead(82)	0.6	16.2	6x10 <sup>-5</sup>	1.62x10 <sup>-3</sup>	1.7x10 <sup>-3</sup>	4.7x10 <sup>-2</sup>
Pa-233		5	135	0.9	24.3	7.7x10 <sup>2</sup>	2.1x10 <sup>4</sup>
Pb-201		1	27.0	1	27.0	6.2x10 <sup>4</sup>	1.7x10 <sup>6</sup>
Pb-202		40	1080	2	54.1	1.2x10 <sup>-4</sup>	3.4x10 <sup>-3</sup>
Pb-203		3	81.1	3	81.1	1.1x10 <sup>4</sup>	3.0x10 <sup>5</sup>
Pb-205	Palladium(46)	Unlimited	Unlimited	Unlimited	Unlimited	4.5x10 <sup>-6</sup>	1.2x10 <sup>-4</sup>
Pb-210		0.6	16.2	9x10 <sup>-3</sup>	0.243	2.8	7.6x10 <sup>1</sup>
Pb-212		0.3	8.11	0.3	8.11	5.1x10 <sup>4</sup>	1.4x10 <sup>6</sup>
Pd-103		40	1080	40	1080	2.8x10 <sup>3</sup>	7.5x10 <sup>4</sup>
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9x10 <sup>-5</sup>	5.1x10 <sup>-4</sup>
Pd-109	Promethium(61)	0.6	16.2	0.5	13.5	7.9x10 <sup>4</sup>	2.1x10 <sup>6</sup>
Pm-143		3	81.1	3	81.1	1.3x10 <sup>2</sup>	3.4x10 <sup>3</sup>
Pm-144		0.6	16.2	0.6	16.2	9.2x10 <sup>1</sup>	2.5x10 <sup>3</sup>
Pm-145		30	811	7	189	5.2	1.4x10 <sup>2</sup>
Pm-147		40	1080	0.9	24.3	3.4x10 <sup>1</sup>	9.3x10 <sup>2</sup>

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	$A_1$ (TBq)	$A_1$ (Ci)	$A_2$ (TBq)	$A_2$ (Ci)	Specific Activity (TBq/g) (Ci/g)	
Pm-148m	Polonium(84)	0.5	13.5	0.5	13.5	$7.9 \times 10^2$	$2.1 \times 10^4$
Pm-149		0.6	16.2	0.5	13.5	$1.5 \times 10^4$	$4.0 \times 10^5$
Pm-151		3	81.1	0.5	13.5	$2.7 \times 10^4$	$7.3 \times 10^5$
Po-208		40	1080	$2 \times 10^{-2}$	0.541	$2.2 \times 10^1$	$5.9 \times 10^2$
Po-209		40	1080	$2 \times 10^{-2}$	0.541	$6.2 \times 10^{-1}$	$1.7 \times 10^1$
Po-210	Praseodymium(59)	40	1080	$2 \times 10^{-2}$	0.541	$1.7 \times 10^2$	$4.5 \times 10^3$
Pr-142		0.2	5.41	0.2	5.41	$4.3 \times 10^4$	$1.2 \times 10^6$
Pr-143	Platinum(78)	4	108	0.5	13.5	$2.5 \times 10^3$	$6.7 \times 10^4$
Pt-188		0.6	16.2	0.6	16.2	$2.5 \times 10^3$	$6.8 \times 10^4$
Pt-191		3	81.1	3	81.1	$8.7 \times 10^3$	$2.4 \times 10^5$
Pt-193m		40	1080	9	243	$5.8 \times 10^3$	$1.6 \times 10^5$
Pt-193		40	1080	40	1080	1.4	$3.7 \times 10^1$
Pt-195m		10	270	2	54.1	$6.2 \times 10^3$	$1.7 \times 10^5$
Pt-197m		10	270	0.9	24.3	$3.7 \times 10^5$	$1.0 \times 10^7$
Pt-197		20	541	0.5	13.5	$3.2 \times 10^4$	$8.7 \times 10^5$
Pu-236	Plutonium(94)	7	189	$7 \times 10^{-4}$	$1.89 \times 10^{-2}$	$2.0 \times 10^1$	$5.3 \times 10^2$
Pu-237		20	541	20	541	$4.5 \times 10^2$	$1.2 \times 10^4$
Pu-238		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$6.3 \times 10^{-1}$	$1.7 \times 10^1$
Pu-239		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$2.3 \times 10^{-3}$	$6.2 \times 10^{-2}$
Pu-240		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$8.4 \times 10^{-3}$	$2.3 \times 10^{-1}$
Pu-241	Radium(88)	40	1080	$1 \times 10^{-2}$	0.270	3.8	$1.0 \times 10^2$
Pu-242		2	54.1	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$1.5 \times 10^{-4}$	$3.9 \times 10^{-3}$
Pu-244		0.3	8.11	$2 \times 10^{-4}$	$5.41 \times 10^{-3}$	$6.7 \times 10^{-7}$	$1.8 \times 10^{-5}$
Ra-223		0.6	16.2	$3 \times 10^{-2}$	0.811	$1.9 \times 10^3$	$5.1 \times 10^4$
Ra-224		0.3	8.11	$6 \times 10^{-2}$	1.62	$5.9 \times 10^3$	$1.6 \times 10^5$
Ra-225	Rubidium(37)	0.6	16.2	$2 \times 10^{-2}$	0.541	$1.5 \times 10^3$	$3.9 \times 10^4$
Ra-226		0.3	8.11	$2 \times 10^{-2}$	0.541	$3.7 \times 10^{-2}$	1.0
Ra-228		0.6	16.2	$4 \times 10^{-2}$	1.08	$1.0 \times 10^1$	$2.7 \times 10^2$
Rb-81		2	54.1	0.9	24.3	$3.1 \times 10^5$	$8.4 \times 10^6$
Rb-83		2	54.1	2	54.1	$6.8 \times 10^{-2}$	$1.8 \times 10^4$
Rb-84	Rhenium(75)	1	27.0	0.9	24.3	$1.8 \times 10^3$	$4.7 \times 10^4$
Rb-86		0.3	8.11	0.3	8.11	$3.0 \times 10^3$	$8.1 \times 10^4$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2 \times 10^{-9}$	$8.6 \times 10^{-8}$
Rb (natural)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7 \times 10^6$	$1.8 \times 10^8$
Re-183		5	135	5	135	$3.8 \times 10^2$	$1.0 \times 10^4$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Re-184m		3	81.1	3	81.1	1.6x10 <sup>2</sup>	4.3x10 <sup>3</sup>
Re-184		1	27.0	1	27.0	6.9x10 <sup>2</sup>	1.9x10 <sup>4</sup>
Re-186		4	108	0.5	13.5	6.9x10 <sup>3</sup>	1.9x10 <sup>5</sup>
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4x10 <sup>-9</sup>	3.8x10 <sup>-8</sup>
Re-188		0.2	5.41	0.2	5.41	3.6x10 <sup>4</sup>	9.8x10 <sup>5</sup>
Re-189		4	108	0.5	13.5	2.5x10 <sup>4</sup>	6.8x10 <sup>5</sup>
Re (natural)		Unlimited	Unlimited	Unlimited	Unlimited	--	2.4x10 <sup>-8</sup>
Rh-99	Rhodium(45)	2	54.1	2	54.1	3.0x10 <sup>3</sup>	8.2x10 <sup>4</sup>
Rh-101		4	108	4	108	4.1x10 <sup>1</sup>	1.1x10 <sup>3</sup>
Rh-102m		2	54.1	0.9	24.3	2.3x10 <sup>2</sup>	6.2x10 <sup>3</sup>
Rh-102		0.5	13.5	0.5	13.5	4.5x10 <sup>1</sup>	1.2x10 <sup>3</sup>
Rh-103m		40	1080	40	1080	1.2x10 <sup>6</sup>	3.3x10 <sup>7</sup>
Rh-105		10	270	0.9	24.3	3.1x10 <sup>4</sup>	8.4x10 <sup>5</sup>
Rn-222	Radon(86)	0.2	5.41	4x10 <sup>-3</sup>	0.108	5.7x10 <sup>3</sup>	1.5x10 <sup>5</sup>
Ru-97	Ruthenium(44)	4	108	4	108	1.7x10 <sup>4</sup>	4.6x10 <sup>5</sup>
Ru-103		2	54.1	0.9	24.3	1.2x10 <sup>3</sup>	3.2x10 <sup>4</sup>
Ru-105		0.6	16.2	0.5	13.5	2.5x10 <sup>5</sup>	6.7x10 <sup>6</sup>
Ru-106		0.2	5.41	0.2	5.41	1.2x10 <sup>2</sup>	3.3x10 <sup>3</sup>
S-35	Sulfur(16)	40	1080	2	54.1	1.6x10 <sup>3</sup>	4.3x10 <sup>4</sup>
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	1.5x10 <sup>4</sup>	4.0x10 <sup>5</sup>
Sb-124		0.6	16.2	0.5	13.5	6.5x10 <sup>2</sup>	1.7x10 <sup>4</sup>
Sb-125		2	54.1	0.9	24.3	3.9x10 <sup>1</sup>	1.0x10 <sup>3</sup>
Sb-126		0.4	10.8	0.4	10.8	3.1x10 <sup>3</sup>	8.4x10 <sup>4</sup>
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	6.7x10 <sup>5</sup>	1.8x10 <sup>7</sup>
Sc-46		0.5	13.5	0.5	13.5	1.3x10 <sup>3</sup>	3.4x10 <sup>4</sup>
Sc-47		9	243	0.9	24.3	3.1x10 <sup>4</sup>	8.3x10 <sup>5</sup>
Sc-48		0.3	8.11	0.3	8.11	5.5x10 <sup>4</sup>	1.5x10 <sup>6</sup>
Se-75	Selenium(34)	3	81.1	3	81.1	5.4x10 <sup>2</sup>	1.5x10 <sup>4</sup>
Se-79		40	1080	2	54.1	2.6x10 <sup>-3</sup>	7.0x10 <sup>-2</sup>
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	1.4x10 <sup>6</sup>	3.9x10 <sup>7</sup>
Si-32		40	1080	0.2	5.41	3.9	1.1x10 <sup>2</sup>
Sm-145	Samarium(62)	20	541	20	541	9.8x10 <sup>1</sup>	2.6x10 <sup>3</sup>
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5x10 <sup>-10</sup>	2.3x10 <sup>-8</sup>
Sm-151		40	1080	4	108	9.7x10 <sup>-1</sup>	2.6x10 <sup>1</sup>
Sm-153		4	108	0.5	13.5	1.6x10 <sup>4</sup>	4.4x10 <sup>5</sup>

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Sn-113	Tin(50)	4	108	4	108	3.7x10 <sup>2</sup>	1.0x10 <sup>4</sup>
Sn-117m		6	162	2	54.1	3.0x10 <sup>3</sup>	8.2x10 <sup>4</sup>
Sn-119m		40	1080	40	1080	1.4x10 <sup>2</sup>	3.7x10 <sup>3</sup>
Sn-121m		40	1080	0.9	24.3	2.0	5.4x10 <sup>1</sup>
Sn-123		0.6	16.2	0.5	13.5	3.0x10 <sup>2</sup>	8.2x10 <sup>3</sup>
Sn-125	Strontium(38)	0.2	5.41	0.2	5.41	4.0x10 <sup>3</sup>	1.1x10 <sup>5</sup>
Sn-126		0.3	8.11	0.3	8.11	1.0x10 <sup>-3</sup>	2.8x10 <sup>-2</sup>
Sr-82		0.2	5.41	0.2	5.41	2.3x10 <sup>3</sup>	6.2x10 <sup>4</sup>
Sr-85m		5	135	5	135	1.2x10 <sup>6</sup>	3.3x10 <sup>7</sup>
Sr-85		2	54.1	2	54.1	8.8x10 <sup>2</sup>	2.4x10 <sup>4</sup>
Sr-87m		3	81.1	3	81.1	4.8x10 <sup>5</sup>	1.3x10 <sup>7</sup>
Sr-89		0.6	16.2	0.5	13.5	1.1x10 <sup>3</sup>	2.9x10 <sup>4</sup>
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4x10 <sup>2</sup>
Sr-91		0.3	8.11	0.3	8.11	1.3x10 <sup>5</sup>	3.6x10 <sup>6</sup>
Sr-92		0.8	21.6	0.5	13.5	4.7x10 <sup>5</sup>	1.3x10 <sup>7</sup>
T	Tritium(1)	40	1080	40	1080	3.6x10 <sup>2</sup>	9.7x10 <sup>3</sup>
Ta-178	Tantalum(73)	1	27.0	1	27.0	4.2x10 <sup>6</sup>	1.1x10 <sup>8</sup>
Ta-179		30	811	30	811	4.1x10 <sup>1</sup>	1.1x10 <sup>3</sup>
Ta-182	Terbium(65)	0.8	21.6	0.5	13.5	2.3x10 <sup>2</sup>	6.2x10 <sup>3</sup>
Tb-157		40	1080	10	270	5.6x10 <sup>-1</sup>	1.5x10 <sup>1</sup>
Tb-158	Technetium(43)	1	27.0	0.7	18.9	5.6x10 <sup>-1</sup>	1.5x10 <sup>1</sup>
Tb-160		0.9	24.3	0.5	13.5	4.2x10 <sup>2</sup>	1.1x10 <sup>4</sup>
Tc-95m		2	54.1	2	54.1	8.3x10 <sup>2</sup>	2.2x10 <sup>4</sup>
Tc-96m		0.4	10.8	0.4	10.8	1.4x10 <sup>6</sup>	3.8x10 <sup>7</sup>
Tc-96		0.4	10.8	0.4	10.8	1.2x10 <sup>4</sup>	3.2x10 <sup>5</sup>
Tc-97m		40	1080	40	1080	5.6x10 <sup>2</sup>	1.5x10 <sup>4</sup>
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2x10 <sup>-5</sup>	1.4x10 <sup>-3</sup>
Tc-98		0.7	18.9	0.7	18.9	3.2x10 <sup>-5</sup>	8.7x10 <sup>-4</sup>
Tc-99m		8	216	8	216	1.9x10 <sup>5</sup>	5.3x10 <sup>6</sup>
Tc-99		40	1080	0.9	24.3	6.3x10 <sup>-4</sup>	1.7x10 <sup>-2</sup>
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8x10 <sup>3</sup>	1.8x10 <sup>5</sup>
Te-121m		5	135	5	135	2.6x10 <sup>2</sup>	7.0x10 <sup>3</sup>
Te-121		2	54.1	2	54.1	2.4x10 <sup>3</sup>	6.4x10 <sup>4</sup>
Te-123m		7	189	7	189	3.3x10 <sup>2</sup>	8.9x10 <sup>3</sup>
Te-125m		30	811	9	243	6.7x10 <sup>2</sup>	1.8x10 <sup>4</sup>
Te-127m		20	541	0.5	13.5	3.5x10 <sup>2</sup>	9.4x10 <sup>3</sup>
Te-127		20	541	0.5	13.5	9.8x10 <sup>4</sup>	2.6x10 <sup>6</sup>
Te-129m		0.6	16.2	0.5	13.5	1.1x10 <sup>3</sup>	3.0x10 <sup>4</sup>
Te-129		0.6	16.2	0.5	13.5	7.7x10 <sup>5</sup>	2.1x10 <sup>7</sup>
Te-131m		0.7	18.9	0.5	13.5	3.0x10 <sup>4</sup>	8.0x10 <sup>5</sup>



Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	A <sub>1</sub> (TBq)	A <sub>1</sub> (Ci)	A <sub>2</sub> (TBq)	A <sub>2</sub> (Ci)	Specific Activity (TBq/g)	Specific Activity (Ci/g)
Th-232	Thorium(90)	0.4	10.8	0.4	10.8	1.1x10 <sup>4</sup>	3.0x10 <sup>5</sup>
Th-227		9	243	1x10 <sup>-2</sup>	0.270	1.1x10 <sup>3</sup>	3.1x10 <sup>4</sup>
Th-228		0.3	8.11	4x10 <sup>-4</sup>	1.08x10 <sup>-2</sup>	3.0x10 <sup>1</sup>	8.2x10 <sup>2</sup>
Th-229		0.3	8.11	3x10 <sup>-5</sup>	8.11x10 <sup>-4</sup>	7.9x10 <sup>-3</sup>	2.1x10 <sup>-1</sup>
Th-230		2	54.1	2x10 <sup>-4</sup>	5.41x10 <sup>-3</sup>	7.6x10 <sup>-4</sup>	2.1x10 <sup>-2</sup>
Th-231	Titanium(22)	40	1080	0.9	24.3	2.0x10 <sup>4</sup>	5.3x10 <sup>5</sup>
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0x10 <sup>-6</sup>	1.1x10 <sup>-7</sup>
Th-234		0.2	5.41	0.2	5.41	8.6x10 <sup>2</sup>	2.3x10 <sup>4</sup>
Th (natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1x10 <sup>-9</sup>	2.2x10 <sup>-7</sup>
Ti-44		0.5	13.5	0.2	5.41	6.4	1.7x10 <sup>2</sup>
Tl-200	Thallium(81.1)	0.8	21.6	0.8	21.6	2.2x10 <sup>4</sup>	6.0x10 <sup>5</sup>
Tl-201		10	270	10	270	7.9x10 <sup>3</sup>	2.1x10 <sup>5</sup>
Tl-202		2	54.1	2	54.1	2.0x10 <sup>3</sup>	5.3x10 <sup>4</sup>
Tl-204		4	108	0.5	13.5	1.7x10 <sup>1</sup>	4.6x10 <sup>2</sup>
Tm-167	Thulium(69)	7	189	7	189	3.1x10 <sup>3</sup>	8.5x10 <sup>4</sup>
Tm-168	Uranium(92)	0.8	21.6	0.8	21.6	3.1x10 <sup>2</sup>	8.3x10 <sup>3</sup>
Tm-170		4	108	0.5	13.5	2.2x10 <sup>2</sup>	6.0x10 <sup>3</sup>
Tm-171		40	1080	10	270	4.0x10 <sup>1</sup>	1.1x10 <sup>3</sup>
U-230		40	1080	1x10 <sup>-2</sup>	0.270	1.0x10 <sup>3</sup>	2.7x10 <sup>4</sup>
U-232	Uranium(92)	3	81.1	3x10 <sup>-4</sup>	8.11x10 <sup>-3</sup>	8.3x10 <sup>-1</sup>	2.2x10 <sup>1</sup>
U-233		10	270	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	3.6x10 <sup>-4</sup>	9.7x10 <sup>-3</sup>
U-234		10	270	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	2.3x10 <sup>-4</sup>	6.2x10 <sup>-3</sup>
U-235		Unlimited	Unlimited	Unlimited	Unlimited	8.0x10 <sup>-8</sup>	2.2x10 <sup>-6</sup>
U-236		10	270	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	2.4x10 <sup>-6</sup>	6.5x10 <sup>-5</sup>
U-238		Unlimited	Unlimited	Unlimited	Unlimited	1.2x10 <sup>-8</sup>	3.4x10 <sup>-7</sup>
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6x10 <sup>-8</sup>	7.1x10 <sup>-7</sup>
U (enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited	—	(Table A-3)
U (enriched more than 5%)	Vanadium(23)	10	270	1x10 <sup>-3</sup>	2.70x10 <sup>-2</sup>	—	(Table A-3)
U (depleted)		Unlimited	Unlimited	Unlimited	Unlimited	—	(Table A-3)
V-48		0.3	8.11	0.3	8.11	6.3x10 <sup>3</sup>	1.7x10 <sup>5</sup>
V-49	Tungsten(74)	40	1080	40	1080	3.0x10 <sup>3</sup>	8.1x10 <sup>3</sup>
W-178		1	27.0	1	27.0	1.3x10 <sup>3</sup>	3.4x10 <sup>4</sup>
W-181		30	811	30	811	2.2x10 <sup>2</sup>	6.0x10 <sup>3</sup>
W-185		40	1080	0.9	24.3	3.5x10 <sup>2</sup>	9.4x10 <sup>3</sup>
W-187		2	54.1	0.5	13.5	2.6x10 <sup>4</sup>	7.0x10 <sup>5</sup>

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	$A_1$ (TBq)	$A_1$ (Ci)	$A_2$ (TBq)	$A_2$ (Ci)	Specific Activity (TBq/g) (Ci/g)	
W-188	Xenon(54)	0.2	5.41	0.2	5.41	$3.7 \times 10^2$	$1.0 \times 10^4$
Xe-122		0.2	5.41	0.2	5.41	$4.8 \times 10^4$	$1.3 \times 10^6$
Xe-123		0.2	5.41	0.2	5.41	$4.4 \times 10^5$	$1.2 \times 10^7$
Xe-127		4	108	4	108	$1.0 \times 10^3$	$2.8 \times 10^4$
Xe-131m		40	1080	40	1080	$3.1 \times 10^3$	$8.4 \times 10^4$
Xe-133	Yttrium(39)	20	541	20	541	$6.9 \times 10^3$	$1.9 \times 10^5$
Xe-135		4	108	4	108	$9.5 \times 10^4$	$2.6 \times 10^6$
Y-87		2	54.1	2	54.1	$1.7 \times 10^4$	$4.5 \times 10^5$
Y-88		0.4	10.8	0.4	10.8	$5.2 \times 10^2$	$1.4 \times 10^4$
Y-90		0.2	5.41	0.2	5.41	$2.0 \times 10^4$	$5.4 \times 10^5$
Y-91m	Ytterbium(70)	2	54.1	2	54.1	$1.5 \times 10^6$	$4.2 \times 10^7$
Y-91		0.3	8.11	0.3	8.11	$9.1 \times 10^2$	$2.5 \times 10^4$
Y-92		0.2	5.41	0.2	5.41	$3.6 \times 10^5$	$9.6 \times 10^6$
Y-93		0.2	5.41	0.2	5.41	$1.2 \times 10^5$	$3.3 \times 10^6$
Yb-169		3	81.1	3	81.1	$8.9 \times 10^2$	$2.4 \times 10^4$
Yb-175	Zinc(30)	30	811	0.9	24.3	$6.6 \times 10^3$	$1.8 \times 10^5$
Zn-65		2	54.1	2	54.1	$3.0 \times 10^2$	$8.2 \times 10^3$
Zn-69m	Zirconium(40)	2	54.1	0.5	13.5	$1.2 \times 10^5$	$3.3 \times 10^6$
Zn-69		4	108	0.5	13.5	$1.8 \times 10^6$	$4.9 \times 10^7$
Zr-88		3	81.1	3	81.1	$6.6 \times 10^2$	$1.8 \times 10^4$
Zr-93		40	1080	0.2	5.41	$9.3 \times 10^{-5}$	$2.5 \times 10^{-3}$
Zr-95		1	27.0	0.9	24.3	$7.9 \times 10^2$	$2.1 \times 10^4$
Zr-97		0.3	8.11	0.3	8.11	$7.1 \times 10^4$	$1.9 \times 10^6$

Table A-1 (Cont.)

Symbol of Radionuclide	Element and Atomic No.	$A_1$ (TBq)	$A_1$ (Ci)	$A_2$ (TBq)	$A_2$ (Ci)	Specific Activity	
						(TBq/g)	(Ci/g)

Table A-2: General Values for  $A_1$  and  $A_2$ 

Contents	$A_1$		$A_2$	
	(TBq)	(Ci)	(TBq)	(Ci)
Only beta- or gamma-emitting nuclides are known to be present.	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available.	0.10	2.70	$2 \times 10^{-5}$	$5.41 \times 10^{-4}$

Table A-3: Activity-mass Relationships for Uranium

Uranium Enrichment* wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	$1.8 \times 10^{-8}$	$5.0 \times 10^{-7}$
0.72	$2.6 \times 10^{-8}$	$7.1 \times 10^{-7}$
1.0	$2.8 \times 10^{-8}$	$7.6 \times 10^{-7}$
1.5	$3.7 \times 10^{-8}$	$1.0 \times 10^{-6}$
5.0	$1.0 \times 10^{-7}$	$2.7 \times 10^{-6}$
10.0	$1.8 \times 10^{-7}$	$4.8 \times 10^{-6}$
20.0	$3.7 \times 10^{-7}$	$1.0 \times 10^{-5}$
35.0	$7.4 \times 10^{-7}$	$2.0 \times 10^{-5}$
50.0	$9.3 \times 10^{-7}$	$2.5 \times 10^{-5}$
90.0	$2.2 \times 10^{-6}$	$5.8 \times 10^{-5}$
93.0	$2.6 \times 10^{-6}$	$7.0 \times 10^{-5}$
95.0	$3.4 \times 10^{-6}$	$9.1 \times 10^{-5}$

\*The figures for uranium include representative values for the activity of the uranium-235 which is concentrated during the enrichment process.

PART 18

MILLING OF URANIUM, THORIUM AND RELATED RADIOACTIVE MATERIALS

RH 18.1 Purpose and Scope.

- 18.1.1 The regulations in this part establish procedures, criteria, and terms and conditions upon which the Department issues licenses for the operation of source material milling facilities and for the disposition of byproduct material resulting from milling activities. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of these regulations.
- 18.1.2 This part establishes procedural requirements and performance objectives applicable to any source material milling operation and to byproduct material as in definition (2) of RH 1.4. It establishes specific technical and financial requirements for the construction, operation, and decommissioning, decontamination, reclamation and ultimate stabilization, long-term site monitoring and surveillance, license transfer and termination, and ownership and ultimate custody of source material milling facilities and byproduct material impoundments.
- 18.1.3 The regulations in this part do not establish procedures and criteria for the issuance of licenses for materials covered under Title I of the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021) unless that program fails to accomplish remedial action.

RH 18.2 As used in this regulation:

"Active maintenance" means any significant activity needed during the period of long term care. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a site or one-time measures such as replacement of a disposal site's cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal site cover, and general disposal site upkeep such as mowing grass.

"Aquifer" means a geologic formation, group of formations, or part of a formation capable of yielding a significant amount of ground water to wells or springs. Any saturated zone created by uranium or thorium operations would not be considered an aquifer unless the zone is or potentially is:

- (1) hydraulically interconnected to a natural aquifer;
- (2) capable of discharge to surface water; or
- (3) reasonably accessible because of migration beyond the vertical projection of the boundary of the land transferred for long-term government ownership and care in accordance with Criterion 9 of Appendix A to this Part 18.

"As expeditiously as practicable considering technological feasibility", for the purposes of Criterion 6A, means as quickly as possible considering: the physical characteristics of the tailings and the site; the limits of available technology; the need for consistency with mandatory requirements of other regulatory programs; and factors beyond the control of the licensee. The phrase permits consideration of the cost of compliance only to the extent specifically provided for by use of the term available technology.

"Available technology" means technologies and methods for emplacing a final radon barrier on uranium mill tailings piles or impoundments. This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry (or one that is reasonably analogous), (such as, by way of illustration only, unreasonable overtime, staffing, or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils, etc.), provided there is reasonable progress toward emplacement of the final radon barrier. To determine grossly excessive costs, the relevant baseline against which cost shall be compared is the cost estimate for tailings impoundment closure contained in the licensee's approved reclamation plan, but costs beyond these estimates shall not automatically be considered grossly excessive.

"Closure" means the activities following operations to decontaminate and decommission the buildings and site used to produce byproduct materials and reclaim the tailings and/or waste disposal area.

"Closure plan" means the Department approved plan to accomplish closure.

"Compliance period" begins when the Department sets secondary ground-water protection standards and ends when the owner or operator's license is terminated and the site is transferred to the State or Federal agency for long-term care.

"Dike" means an embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids, or other materials.

"Disposal area" means the area containing byproduct materials to which the requirements of Criterion 6 of Appendix A to this Part 18 apply.

"Disposal site" means all land that is subject to transfer to a government agency after termination of the license.

"Existing portion" means that land surface area of an existing surface impoundment on which significant quantities of uranium or thorium byproduct materials had been placed prior to September 30, 1983.

"Factors beyond the control of the licensee" means factors proximately causing delay in meeting the schedule in the applicable reclamation plan for the timely emplacement of the final radon barrier notwithstanding the good faith efforts of the licensee to complete the barrier in compliance with paragraph (1) of Criterion 6A. These factors may include, but are not limited to:

- (1) physical conditions at the site;
- (2) inclement weather or climatic conditions;
- (3) an act of god;
- (4) an act of war;
- (5) a judicial or administrative order or decision, or change to the statutory, regulatory, or other legal requirements applicable to the licensee's facility that would preclude or delay the performance of activities required for compliance;
- (6) labor disturbances;
- (7) any modifications, cessation or delay ordered by state, federal, or local agencies;



- (8) delays beyond the time reasonably required in obtaining necessary government permits, licenses, approvals, or consent for activities described in the reclamation plan proposed by the licensee that result from agency failure to take final action after the licensee has made a good faith, timely effort to submit legally sufficient applications, responses to requests (including relevant data requested by the agencies), or other information, including approval of the reclamation plan; and
- (9) an act or omission of any third party over whom the licensee has no control.

"Final radon barrier" means the earthen cover (or approved alternative cover) over tailings or waste constructed to comply with Criterion 6 of this Appendix (excluding erosion protection features).

"Ground water" means water below the land surface in a zone of saturation. For purposes of Appendix A to this Part 18, ground water is the water contained within an aquifer as defined above.

"Leachate" means any liquid, including any suspended or dissolved components in the liquid, that has percolated through or drained from the byproduct material.

"Licensed site" means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials under a Department license.

"Liner" means a continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment which restricts the downward or lateral escape of byproduct material, hazardous constituents, or leachate.

"Long term care" means the observation and maintenance of a disposal site following the postclosure period and termination of the license.

"Milestone" means an action or event that is required to occur by an enforceable date.

"Monitoring" means observing and making measurements to provide data to evaluate the performance and characteristics of a site.

"Operation" means that a uranium or thorium mill tailings pile or impoundment is being used for the continued placement of byproduct material or is in standby status for such placement. A pile or impoundment is in operation from the day that byproduct material is first placed in the pile or impoundment until the day final closure begins.

"Point of compliance" is the site specific location in the uppermost aquifer where the ground-water protection standard must be met.

"Postclosure" means a period of time from completion of the site closure plan for decontamination, reclamation, and stabilization of the disposal site and disposal area and prior to the termination of the license.

"Reclamation plan", for the purposes of Criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of this Appendix. The reclamation plan must include a schedule for reclamation milestones that are key to the completion of the final radon barrier including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. (Reclamation of tailings must also be addressed in the closure plan; the detailed reclamation plan may be incorporated into the closure plan.)

"Surface impoundment" means a natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

"Surveillance" means the observation of the disposal site for the purposes of visual detection of the need for maintenance, custodial care, evidence of unauthorized access, and compliance with other license and regulatory requirements.

"Third-party contractor" or "Third-party agreement" means a legal or contractual mechanism whereby an applicant or licensee voluntarily agrees to pay for the services, solely selected and supervised by the Department, of qualified persons not Department staff nor under contract directly to the Department.

"Uppermost aquifer" means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

RH 18.3      Special Requirements for Issuance of Specific Licenses For Source Material Milling. In addition to the requirements set forth in RH 3.8 and 3.9, a specific license for source material milling will be issued if the applicant submits to the Department a complete and acceptable application as described herein and meets the other conditions specified below:

18.3.1      An application for a license or to amend or renew an existing license to receive, possess, and use source material for milling or byproduct material as in definition (2) of RH 1.4 shall address the following:

18.3.1.1      Description of the proposed project or action;

18.3.1.2      Area/site characteristics including geology, topography, hydrology and meteorology;

18.3.1.3      Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

- 18.3.1.4 Environmental effects of accidents;
- 18.3.1.5 Tailings disposal and decommissioning;
- 18.3.1.6 Site and project alternatives.
- 18.3.2 The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.
  - 18.3.2.1 Milling operations shall be conducted so that all effluent releases are reduced to as low as is reasonably achievable below the limits of Part 4.
  - 18.3.2.2 The mill operator shall conduct at least daily inspection of any tailings or waste retention systems. The inspection shall be performed by a person who is qualified and approved by the Department. Records of such inspections shall be maintained for review by the Department.
  - 18.3.2.3 The mill operator shall immediately notify the Department of the following:
    - 18.3.2.3.1 Any failure in a tailings or waste retention system which results in a release of tailings or waste into uncontrolled areas; and
    - 18.3.2.3.2 Any unusual conditions which are not contemplated in the design of the retention system and which if not corrected could lead to failure of the system and result in a release of tailings or waste into uncontrolled areas.
- 18.3.3 During any one full year prior to any major site construction, the applicant/licensee shall conduct a preoperational monitoring program to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, the applicant/licensee shall conduct an operational monitoring program to measure or evaluate compliance with applicable standards and regulations, to evaluate performance of control systems and procedures, to evaluate environmental impacts of operation, and to detect potential long-term effects.

18.3.4 Prior to issuance of the license, the mill operator shall (1) establish financial assurance arrangements, as provided by RH 3.9.5, to ensure decontamination and decommissioning of the facility and (2) provide a fund adequate to cover the payment of the cost for long-term care and monitoring as provided by RH 3.9.6. Such fund shall be sufficient to meet the requirements of RH 3.9.6.4. The Department will consider proposals to combine the two types of financial assurance.

18.3.5 An application for a license to receive, possess and use source material for milling or byproduct material as in definition (2) of RH 1.4 shall contain proposed specifications relating to the milling operations and the disposition of tailings or wastes resulting from such milling activities to achieve the requirements and objectives set forth in the criteria listed in Appendix A to this Part 18. Each application for a new license or for license renewal must clearly demonstrate how the requirements and objectives set forth in Appendix A to this Part 18 have been addressed. Failure to clearly demonstrate how the requirements and objectives in Appendix A to this Part 18 have been addressed shall be grounds for refusing to accept an application.

RH 18.4 Environmental Impact Analysis

18.4.1 For each license application or application to amend or renew an existing license to receive, possess, or use source material for uranium or thorium milling or byproduct material as in definition (2) of RH 1.4 which will have a significant impact on the environment, the Department shall prepare a written analysis of the impact of the licensed activity on the environment, which shall be available to the public at the time of public notice of hearing, which analysis shall include:

18.4.1.1 An assessment of the radiological and nonradiological impacts to the public health;

18.4.1.2 An assessment of any impact on any waterway and ground water;

- 18.4.1.3            Consideration of alternatives to the activities to be conducted; and
- 18.4.1.4            Consideration of the long-term impacts of the licensed activities.
- 18.4.2            In preparing the environmental impact analysis, the Department may use and incorporate by reference the environmental report prepared by the applicant as required by RH 3.8.8 and environmental assessments prepared by Federal, State or local agencies..
- 18.4.3            The environmental impact analysis, or any part thereof, shall be prepared directly by the Department or the Department shall utilize the third party method set forth in RH 3.13.
- RH 18.5            Reserved.

RH 18.6      License Hearings

- 18.6.1      There shall be an opportunity for public hearings to be held in accordance with the procedures in 24-4-104 and 24-4-105, C.R.S. 1973, as amended, and RH 18.6, prior to the granting, denial or renewal of a specific license permitting the receipt, possession or use of source material for milling or byproduct material as in definition (2) of RH 1.4.
- 18.6.2      Notice of Hearing
  - 18.6.2.1      All hearings shall be preceded by written notice containing:
    - 18.6.2.1.1      The nature of the hearing and its time and place;
    - 18.6.2.1.2      The legal authority and jurisdiction under which the hearing is to be held;
    - 18.6.2.1.3      The matters of fact and law asserted or to be considered;
    - 18.6.2.1.4      A description of the proposed licensing action and a statement of the availability of its text from the Department;
    - 18.6.2.1.5      A description of the right of any interested person to make written comments to the Department or present oral comments at the hearing;



- 18.6.2.1.6 The procedure for applying to become a party to the hearing; and
- 18.6.2.1.7 A description of the procedures to be followed at the hearing and at a prehearing conference if required.
- 18.6.2.2 The notice of the hearing shall be mailed by the Department to the licensee or applicant and to each person who has filed a written request to receive notice of such proceedings. The licensee or applicant shall cause the notice to be published for three (3) days in a newspaper of statewide circulation and in local newspapers designated by the Department in the area to be affected by the proposed action. The notice shall be mailed and published not less than ninety (90) days prior to the hearing.
- 18.6.2.3 The time and place of hearing will be fixed with due regard for the convenience of the parties or their representatives, and the public interest. The hearing will be held in the locale of the site to be licensed.
- 18.6.2.4 The cost of any licensing action hearing shall be at the expense of the applicant. These costs shall include, but not be limited to, the hearing officer, the meeting room, the court reporter and transcript copies, and the required notices. The costs shall not include the expenses of other parties to the hearing.
- 18.6.3 Party Status
- 18.6.3.1 A person who may be affected or aggrieved by Department action may apply for party status not less than twenty (20) days prior to the hearing. Thereafter, application to be made a party shall not be considered except upon motion for good cause shown.

- 18.6.3.2 Application for party status must identify the individual or group applying, including the address or phone number where they may be contacted, state the nature of their interest in the hearing and the specific ground on which they claim to be affected or aggrieved, and the specific aspects of the hearing which they wish to address.
- 18.6.3.3 The Department, or the hearing officer, will grant or deny party status within five (5) days after receipt of the request for party status based on the nature and extent of the person's property, financial or other interest in the hearing and the possible effect of any order which may be entered as a result of the hearing on the person's interest. Any person applying for or granted party status may, by motion to the hearing officer or Department, as appropriate, challenge the right of any other person to be a party.
- 18.6.3.4 Parties shall have the right to initiate discovery. Parties shall have the right to make motions or objections, present evidence, cross-examine witnesses, and appeal from the decision of the hearing as provided by the Colorado Administrative Procedures Act, 24-4-101 et seq., C.R.S. 1973, as amended.
- 18.6.3.5 A person who is not a party will be permitted to submit written comments to the Department and may be permitted to make an oral presentation at the hearing, but will not have the other rights of a party.
- 18.6.4 Prehearing Conference
- 18.6.4.1 The Department or hearing officer, on its own motion or at the request of any party or any person who has applied to become a party, may direct the parties to appear at a specific time and place for a conference to consider:

- 18.6.4.1.1 The simplification and clarification of the issues;
- 18.6.4.1.2 The obtaining of stipulations and admissions of fact and of the contents and authenticity of documents to avoid unnecessary proof;
- 18.6.4.1.3 Identification of witnesses and the limitation of the number of expert witnesses, and other steps to expedite the presentation of evidence;
- 18.6.4.1.4 The setting of a hearing schedule;
- 18.6.4.1.5 Granting or denying requests for party status, if such decisions have not previously been made;
- 18.6.4.1.6 Such other matters as may aid in the orderly disposition of the hearing.
- 18.6.4.2 At such conference each party or person who has applied to become a party shall present to every other person, party, and the Department a prehearing statement containing the following:
  - 18.6.4.2.1 A brief summary of the nature of the claim of the party and the basis therefore;
  - 18.6.4.2.2 A copy of all exhibits proposed to be introduced; and
  - 18.6.4.2.3 A list of all witnesses who may be called and a brief description of their testimony.
- 18.6.4.3 Except for good cause shown or for evidence or testimony accepted as rebuttal, no witness may testify nor may any exhibits be introduced on behalf of a party who had notice of the prehearing conference unless such witness has been previously listed and/or his written testimony and related exhibits have been presented to opposing parties at the prehearing conference.

- 18.6.4.4           The Department or hearing officer shall issue a written summary of the action taken at the conference and agreements by the parties, which limits the issues or defines the matters in controversy to be determined in the hearing.
- 18.6.5           Discovery
- 18.6.5.1           Any party may initiate discovery in the form of interrogatories to another party, requests for admission to another party, requests for production of documents to another party, or depositions of any persons, or any combination thereof. The Colorado Rules of Civil Procedure, to the extent not inconsistent with the Colorado Administrative Procedure Act, shall apply. Such discovery may be modified by a motion for protective order filed with the Department or hearing officer within seven (7) days of receipt of the notice or request for discovery. Motions for protective order shall set forth the grounds in support thereof and shall be ruled upon immediately. Discovery shall be completed no later than ten (10) days preceding the hearing date, except as otherwise ordered by the Department or hearing officer.
- 18.6.6           Conduct of Hearings
- 18.6.6.1           Hearing presentations will proceed in the following order unless otherwise directed by the Department or hearing officer.
- 18.6.6.1.1          Call to order, introductory remarks, and action on applications for party status, if not already decided.
- 18.6.6.1.2          Presentation of any stipulations or agreements of the parties, and any other matters which were required to be dealt with at the prehearing conference, if held.
- 18.6.6.1.3          Opening statement by the party upon whom the burden of proof rests.
- 18.6.6.1.4          Opening statements by all other parties.

- 18.6.6.1.5 Presentation of case by party upon whom burden of proof rests.
- 18.6.6.1.6 Presentation by all other persons wishing to offer evidence in the order to be determined by the Department or hearing officer.
- 18.6.6.1.7 Rebuttal by the party upon whom the burden of proof rests, followed by rebuttal of other parties.
- 18.6.6.1.8 Closing statements by party upon whom the burden of proof rests, followed by closing statements of all other parties.
- 18.6.6.2 Public participation as provided for in these rules shall be allowed at that time or times during the hearing as determined by the Department or hearing officer in their discretion to be appropriate.
- 18.6.6.3 At the conclusion of any witness's testimony, or at the conclusion of the party's entire presentation, as may be determined by the Department or hearing officer, all parties may then cross-examine such witness or witnesses. The Department or hearing officer may examine and cross-examine any witness. A person who is not a party shall not have the right to cross-examine.
- 18.6.6.4 Any person, not a party to the proceeding, wishing to present testimony may do so by indicating his desire in writing. A form will be available prior to and during the hearing. This form will request the person's name, address, whom he represents, the general nature of his testimony, and the time required for his presentation. This form is to be presented to a representative of the Department during the hearing. Voluntary testimony not specifically requested on or by the written form may also be allowed. Any person presenting testimony shall be under oath and be subject to cross examination.
- 18.6.6.5 The proponent of any motion, order, or license issuance bears the burden of proof.

- 18.6.6.6 No interested person, party, or applicant for party status outside the Department will have any oral or written communication with any Department personnel or hearing officer relevant to the merits of a hearing pending before the Department unless reasonable prior notice is given to all participants in the hearing. This prohibition shall apply after the hearing is noticed. Any Department employee or hearing officer who is involved in such a prohibited communication shall make a written record of it and transmit it to all the parties to the hearing.
- 18.6.7 Department Decision
- 18.6.7.1 Any party to a hearing may, or if so directed by the Department or the hearing officer shall, file proposed findings of fact and conclusions of law and a proposed form of order or decision within twenty (20) days after the record is closed. A party who has the burden of proof may reply within ten (10) days after service of proposed findings of fact and conclusions of law.
- 18.6.7.2 After due consideration of the hearing record, the Department or hearing officer shall issue its findings of fact, conclusions of law, and decision and order.
- RH 18.7 Operational Requirements. Each licensee authorized to receive, possess or use source material for milling or byproduct material as in definition (2) of RH 1.4 shall:
- 18.7.1 Operate in accordance with the requirements of this Part 18, in particular the procedures required by RH 18.3.2, monitoring required by 18.3.3, and the requirements and objectives of Appendix A to this Part 18.



18.7.2 Submit a report to the Department within 60 days after January 1 and July 1 of each year, specifying the quantity of each of the radioactive materials released to unrestricted areas in liquid and in gaseous effluents during the previous six months of operation, and such other information as the Department may require to estimate maximum potential annual radiation doses to the public resulting from effluent releases. If quantities of radioactive materials released during the reporting period are significantly above the licensee's design objectives previously reviewed as part of the licensing action, the report shall cover this specifically. On the basis of such reports and any additional information the Department may obtain from the licensee or others, the Department may from time to time require the licensee to take such action as the Department deems appropriate.

RH 18.8 Decommissioning Requirements.

18.8.1 In addition to the information required under RH 3.16, each licensee authorized to receive, possess or use source material for milling or byproduct material as in definition (2) of RH 1.4 shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning:

18.8.1.1 Have not been previously approved by the Department; and

18.8.1.2 Could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

18.8.1.2.1 Procedures would involve techniques not applied routinely during cleanup or maintenance operations; or

18.8.1.2.2 Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

18.8.1.2.3 Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

- 18.8.1.2.4 Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.
- 18.8.2 Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.
- 18.8.3 The proposed decommissioning plan, if required by RH 18.8.1 or by license condition, must include:
- 18.8.3.1 Description of planned decommissioning activities;
  - 18.8.3.2 Description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;
  - 18.8.3.3 A description of the planned final radiation survey; and
  - 18.8.3.4 An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.
- 18.8.4 The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.
- 18.8.5 Upon approval of the decommissioning plan by the Department, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall submit the information required in RH 3.16.4.1.5 and shall certify the disposition of accumulated wastes from decommissioning.
- 18.8.6 If the information submitted under RH 3.16.4.1.5 or 18.8 does not adequately demonstrate that the premises are suitable for release for unrestricted use, the Department will inform the licensee of the appropriate further actions required for termination of license.

PART 18

APPENDIX A

CRITERIA RELATING TO THE OPERATION OF  
MILLS AND THE DISPOSITION OF RADIOACTIVE TAILINGS  
OR WASTES

Introduction: Every applicant for a license to possess and use radioactive material in conjunction with uranium or thorium milling, or byproduct material at sites formerly associated with such milling, is required by the provisions of RH 18.3 to include in a license application proposed specifications relating to milling operations and the disposition of tailings or wastes resulting from such milling activities. This appendix establishes technical, ownership, and long-term site surveillance criteria relating to the siting, operation, decontamination, decommissioning, and reclamation of mills and tailings or waste systems and sites at which such mills and systems are located.

As used in this appendix, the term "as low as is reasonably achievable" has the same meaning as in RH 4.3.

In many cases, flexibility is provided in the criteria to allow achieving an optimum tailings disposal program on a site-specific basis. However, in such cases the objectives, technical alternatives and concerns which must be taken into account in developing a tailings program are identified. As provided by the provisions of RH 18.3, applications for licenses must clearly demonstrate how the criteria have been addressed.

The specifications shall be developed considering the expected full capacity of tailings or waste systems and the lifetime of mill operations. Where later expansions of systems or operations may be likely (for example, where large quantities of ore now marginally uneconomical may be stockpiled), the amenability of the disposal system to accommodate increased capacities without degradation in long-term stability and other performance factors shall be evaluated.

Licensees or applicants may propose to the Department alternatives to meet the specific requirements in this Appendix. The alternative proposals may take into account local or regional conditions, including geology, topography, hydrology, and meteorology. The Department may find that the proposed alternatives meet the Department's requirements if the alternatives will achieve a level of stabilization and containment of the sites concerned and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with the site, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by the requirements of this Appendix and the standards promulgated by the Environmental Protection Agency in 40 CFR Part 192, Subparts D and E. Proposed alternatives to specific regulations in this Part 18 require notice and opportunity for hearing before the U.S. Nuclear Regulatory Commission.

All site-specific licensing decisions based on the criteria in this Appendix or alternatives proposed by licensees or applicants will take into account the risk to the public health and safety and the environment with due consideration to the economic costs involved and any other factors the Department determines to be appropriate. In implementing this Appendix, the Department will consider "practicable" and "reasonably achievable" as equivalent terms. Decisions involving these terms will take into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest.

#### Criterion 1.

Criterion 1A. The general goal or broad objective in siting and design decisions is permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces, and to do so without ongoing maintenance. For practical reasons, specific siting decisions and design standards must involve finite times (e.g., the longevity design standard in Criterion 6). The following site features which will contribute to such a goal or objective must be considered in selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites:

- (1) Remoteness from populated areas;

- (2) Hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ground-water sources; and
- (3) Potential for minimizing erosion, disturbance, and dispersion by natural forces over the longterm.

Criterion 1B. The site selection process must be an optimization to the maximum extent reasonably achievable in terms of these features.

Criterion 1C. In the selection of disposal sites, primary emphasis must be given to isolation of tailings or wastes, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site and engineering design, overriding consideration must be given to siting features given the long-term nature of the tailings hazards.

Criterion 1D. Tailings should be disposed of in a manner that no active maintenance is required to preserve conditions of the site.

Criterion 2. To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material as in definition (2) of RE 1.4, from in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote above ground extraction operations shall be disposed of at existing large mill tailings disposal sites; unless considering the nature of the wastes, such as their volume and specific activity and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.



Criterion 3. The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where the need for any specially constructed retention structure is eliminated). The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) must reflect serious consideration of this disposal mode. In some instances, below grade disposal may not be the most environmentally sound approach, such as might be the case if a ground-water formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full below grade burial impracticable: For example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternative sites are not available. Where full below grade burial is not practicable, the size of retention structures, and size and steepness of slopes associated with exposed embankments must be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic conditions at a site. In these cases, it must be demonstrated that an above grade disposal program will provide reasonably equivalent isolation of the tailings from natural erosional forces.

Criterion 4. The following site and design criteria must be adhered to whether tailings or wastes are disposed of above or below grade.

Criterion 4A. Upstream rainfall catchment areas must be minimized to decrease erosion potential and the size of the floods which could erode or wash out sections of the tailings disposal area.

Criterion 4B. Topographic features should provide good wind protection.

Criterion 4C. Embankment and cover slopes must be relatively flat after final stabilization to minimize erosion potential and to provide conservation factors of safety assuring long-term stability. The broad objective should be to contour final slopes to grades which are as close as possible to those which would be provided if tailings were disposed of below grade: this could, for example, lead to slopes of about 10 horizontal to 1 vertical (10h:1v) or less steep. In general, slopes should not be steeper than about 5h:1v. Where steeper slopes are proposed, reasons why a slope less steep than 5h:1v would be impracticable should be provided and compensating factors and conditions which make such slopes acceptable should be identified.



Criterion 4D. A full self-sustaining vegetative cover must be established or rock cover employed to reduce wind and water erosion to negligible levels.

- (1) Where a full vegetative cover is not likely to be self-sustaining due to climatic or other conditions, such as in semi-arid and arid regions, rock cover must be employed on slopes of the impoundment system. The Department will consider relaxing this requirement for extremely gentle slopes such as those which may exist on the top of the pile.
- (2) The following factors must be considered in establishing the final rock cover design to avoid displacement of rock particles by human and animal traffic or by natural process, and to preclude undercutting and piping:
  - (a) Shape, size, composition, and gradation of rock particles (excepting bedding material average particles size must be at least cobble size or greater);
  - (b) Rock cover thickness and zoning of particles by size; and
  - (c) Steepness of underlying slopes.
- (3) Individual rock fragments must be dense, sound, and resistant to abrasion, and must be free from cracks, seams, and other defects that would tend to unduly increase their destruction by water and frost actions. Weak, friable, or laminated aggregate may not be used.
- (4) Rock covering of slopes may be unnecessary where top covers are very thick (on the order of 10m or greater); impoundment slopes are very gentle (on the order of 10h:1v or less); bulk cover materials have inherently favorable erosion resistance characteristics; and, there is negligible drainage catchment area upstream of the pile and good wind protection as described in Criteria 4A and 4B.

- (5) Furthermore, all impoundment surfaces must be contoured to avoid areas of concentrated surface runoff or abrupt or sharp changes in slope gradient. In addition to rock cover on slopes, areas toward which surface runoff might be directed must be well protected with substantial rock cover (rip rap). In addition to providing for stability of the impoundment system itself, overall stability, erosion potential, and geomorphology of surrounding terrain must be evaluated to assure that there are not ongoing or potential processes, such as gully erosion, which would lead to impoundment instability.

Criterion 4E. The impoundment may not be located near a capable fault that could cause a maximum credible earthquake larger than that which the impoundment could reasonably be expected to withstand. As used in this criterion, the term "capable fault" has the same meaning as defined in section III(g) of Appendix A of 10 CFR Part 100. The term "maximum credible earthquake" means that earthquake which would cause the maximum vibratory ground motion based upon an evaluation of earthquake potential considering the regional and local geology and seismology and specific characteristics of local subsurface material.

Criterion 4F. The impoundment, where feasible, should be designed to incorporate features which will promote deposition. For example, design features which promote deposition of sediment suspended in any runoff which flows into the impoundment area might be utilized; the object of such a design feature would be to enhance the thickness of cover over time.

Criterion 5. Criteria 5A-5D and new Criterion 10 incorporate the basic ground-water protection standards imposed by the Environmental Protection Agency in 40 CFR Part 192, Subparts D and E (48 FR 45926; October 7, 1983) which apply during operations and prior to the end of closure. Groundwater monitoring to comply with these standards is required by Criterion 7A.

Criterion 5A.

- (1) The primary ground-water protection standard is a design standard for surface impoundments used to manage byproduct material. Unless exempted under paragraph 5A(3) of this criterion, surface impoundments (except for an existing portion) shall have a liner that is designed, constructed, and installed to prevent any migration of wastes out of the impoundment to the adjacent subsurface soil, ground water, or surface water at any time during the active life (including the closure period) of the impoundment. The liner may be constructed of materials that may allow wastes to migrate into the liner (but not into the adjacent subsurface soil, ground water, or surface water) during the active life of the facility, provided that impoundment closure includes removal or decontamination of all waste residues, contaminated containment system components (liners, etc.) contaminated subsoils, and structures and equipment contaminated with waste and leachate. For impoundments that will be closed with the liner material left in place, the liner must be constructed of materials that can prevent wastes from migrating into the liner during the active life of the facility.
- (2) The liner required by paragraph 5A(1) above shall be:
  - (a) Constructed of materials that have appropriate chemical properties and sufficient strength and thickness to prevent failure due to pressure gradients (including static head and external hydrogeologic forces), physical contact with the waste or leachate to which they are exposed, climatic conditions, the stress of installation, and the stress of daily operation;
  - (b) Placed upon a foundation or base capable of providing support to the liner and resistance to pressure gradients above and below the liner to prevent failure of the liner due to settlement, compression, or uplift; and

- (c) Installed to cover all surrounding earth likely to be in contact with the wastes or leachate.
- (3) The applicant or licensee will be exempted from the requirements of paragraph 5A(1) of this criterion if the Department finds, based on a demonstration by the applicant or licensee, that alternate design and operating practices, including the closure plan, together with site characteristics will prevent the migration of any hazardous constituents into ground water or surface water at any future time.

In deciding whether to grant an exemption, the Department will consider:

- (a) The nature and quantity of the wastes;
  - (b) The proposed alternate design and operation;
  - (c) The hydrogeologic setting of the facility, including the attenuative capacity and thickness of the liners and soils present between the impoundment and ground water or surface water; and
  - (d) All other factors which would influence the quality and mobility of the leachate produced and the potential for it to migrate to ground water or surface water.
- (4) A surface impoundment must be designed, constructed, maintained, and operated to prevent overtopping resulting from normal or abnormal operations, overfilling, wind and wave actions, rainfall, or run-on; from malfunctions of level controllers, alarms, and other equipment; and from human error.

- (5) When dikes are used to form the surface impoundment, the dikes must be designed, constructed, and maintained with sufficient structural integrity to prevent massive failure of the dikes. In ensuring structural integrity, it must not be presumed that the liner system will function without leakage during the active life of the impoundment.

Criterion 5B.

- (1) Uranium and thorium byproduct material in definition (2) of RH 1.4 shall be managed to conform to the following secondary ground-water protection standard: hazardous constituents entering the ground water from a licensed site must not exceed the specified concentration limits in the uppermost aquifer beyond the point of compliance during the compliance period. Hazardous constituents are those constituents identified by the Department pursuant to paragraph 5B(2) of this criterion. Specified concentration limits are those limits established by the Department as indicated in paragraph 5B(5) of this criterion. The Department will also establish the point of compliance and compliance period on a site-specific basis through license conditions and orders. The objective in selecting the point of compliance is to provide the earliest practicable warning that the impoundment is releasing hazardous constituents to the ground water. The point of compliance must be selected to provide prompt indication of ground-water contamination on the hydraulically downgradient edge of the disposal area. The Department shall identify hazardous constituents, establish concentration limits, set the compliance period, and may adjust the point of compliance if needed to accord with developed data and site information as to the flow of ground water or contaminants, when the detection monitoring established under Criterion 7A indicates leakage of hazardous constituents from the disposal area.



- (2) A constituent becomes a hazardous constituent subject to paragraph 5B(5) only when the constituent meets all three of the following tests:
- (a) The constituent is reasonably expected to be in or derived from the uranium and thorium byproduct material in the disposal area;
  - (b) The constituent has been detected in the ground water in the uppermost aquifer; and
  - (c) The constituent is listed in Criterion 10 of this appendix.
- (3) Even when constituents meet all three tests in paragraph 5B(2) of this criterion, the Department may exclude a detected constituent from the set of hazardous constituents on a site-specific basis if it finds that the constituent is not capable of posing a substantial present or potential hazard to human health or the environment. In deciding whether to exclude constituents, the Department will consider the following:
- (a) Potential adverse effects on ground-water quality, considering
    - (i) The physical and chemical characteristics of the waste in the licensed site, including its potential for migration;
    - (ii) The hydrogeological characteristics of the facility and surrounding land;
    - (iii) The quantity of ground water and the direction of ground water flow;
    - (iv) The proximity and withdrawal rates of ground-water users;
    - (v) The current and future uses of ground water in the area;



- (vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground water quality;
  - (vii) The potential for health risks caused by human exposure to waste constituents;
  - (viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;
  - (ix) The persistence and permanence of the potential adverse effects.
- (b) Potential adverse effects on hydraulically-connected surface water quality, considering
- (i) The volume and physical and chemical characteristics of the waste in the licensed site;
  - (ii) The hydrogeological characteristics of the facility and surrounding land;
  - (iii) The quantity and quality of ground water and the direction of ground water flow;
  - (iv) The patterns of rainfall in the region;
  - (v) The proximity of the licensed site to surface waters;
  - (vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;
  - (vii) The existing quality of surface water, including other sources of contamination and the cumulative impact on surface water quality;

- (viii) The potential for health risks caused by human exposure to waste constituents;
  - (ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents; and
  - (x) The persistence and permanence of the potential adverse effects.
- (4) In making any determinations under paragraphs 5B(3) and 5B(6) of this criterion about the use of ground water in the area around the facility, the Department will consider any identification of underground sources of drinking water and exempted aquifers made by the Colorado Water Quality Control Commission, as in 5 CCR 1002-8, or other agency having jurisdiction.
- (5) At the point of compliance, the concentration of a hazardous constituent must not exceed:
- (a) The Department-approved background concentration of that constituent in the ground water;
  - (b) The respective value given in the table in paragraph 5C if the constituent is listed in the table and if the background level of the constituent is below the value listed; or
  - (c) An alternate concentration limit established by the Department.

(6) Conceptually, background concentrations pose no incremental hazards and the drinking water limits in Criterion 5C state acceptable hazards but these two options may not be practically achievable at a specific site. Alternate concentration limits that present no significant hazard may be proposed by licensees for Department consideration. Licensees must provide the basis for any proposed limits including consideration of practicable corrective actions, that limits are as low as reasonably achievable, and information on the factors the Department must consider. The Department will establish a site specific alternate concentration limit for a hazardous constituent as provided in paragraph 5B(5) of this criterion if it finds that the proposed limit is as low as reasonably achievable after considering practicable corrective actions, and that the constituent will not pose a substantial present or potential hazard to human health or the environment as long as the alternate concentration limit is not exceeded. In making the present and potential hazard finding, the Department will consider the following factors:

- (a) Potential adverse effects on ground water quality, considering:
  - (i) The physical and chemical characteristics of the waste in the licensed site including its potential for migration;
  - (ii) The hydrogeological characteristics of the facility and surrounding land;
  - (iii) The quantity of ground water and the direction of ground water flow;
  - (iv) The proximity and withdrawal rates of ground water users;
  - (v) The current and future uses of ground water in the area;

- (vi) The existing quality of ground water, including other sources of contamination and their cumulative impact on the ground water quality;
  - (vii) The potential for health risks caused by human exposure to waste constituents;
  - (viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituents;
  - (ix) The persistence and permanance of the potential adverse effects.
- (b) Potential adverse effects on hydraulically-connected surface water quality, considering:
- (i) The volume and physical and chemical characteristics of the waste in the licensed site;
  - (ii) The hydrogeological characteristics of the facility and surrounding land;
  - (iii) The quantity and quality of ground water, and the direction of ground water flow;
  - (iv) The patterns of rainfall in the region;
  - (v) The proximity of the licensed site to surface waters;
  - (vi) The current and future uses of surface waters in the area and any water quality standards established for those surface waters;
  - (vii) The existing quality of surface water including other sources of contamination and the cumulative impact on surface water quality;

- (viii) The potential for health risks caused by human exposure to waste constituents;
- (ix) The potential damage to wildlife, crops, vegetations, and physical structures caused by exposure to waste constituents; and
- (x) The persistence and permanence of the potential adverse effects.

Criterion 5C.

MAXIMUM VALUES FOR GROUND WATER PROTECTION

Constituent or property	Maximum Concentration
	Milligrams per liter:
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chromium	0.05
Lead	0.05
Mercury	0.002
Selenium	0.01
Silver	0.05
Endrin (1,2,3,4,10,10-hexachloro-1,7 -epoxy-1,4,4a,5,6,7,8,9a-octahydro-1, 4-endo, endo-5, 8-dimethano naphthalene)	0.0002
Lindane (1,2,3,4,5,6-hexachloro-cyclohexane, gamma isomer)	0.004
Methoxychlor (1,1,1-Trichloro-2, 2-bis,p-methoxyphenylethane)	0.1
Toxaphene (C <sub>10</sub> H <sub>10</sub> Cl <sub>6</sub> , Technical chlorinated camphene, 67-69 percent chlorine)	0.005
2,4-D (2,4-Dichlorophenoxyacetic acid)	0.1
2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	0.01

Picocuries per liter:

Combined radium-226 and radium-228	5
Gross alpha-particle activity	
(excluding radon and uranium	
when producing uranium byproduct	
material or radon and thorium when	
producing thorium byproduct	
material)	15

Criterion 5D. If the ground water protection standards established under paragraph 5B(1) of this criterion are exceeded at a licensed site, a corrective action program must be put into operation as soon as is practicable, and in no event later than eighteen (18) months after the Department finds that the standards have been exceeded. The licensee shall submit the proposed corrective action program and supporting rationale for Department approval prior to putting the program into operation, unless otherwise directed by the Department. The objective of the program is to return hazardous constituent concentration levels in ground water to the concentration limits set as standards. The licensee's proposed program shall address removing the hazardous constituents that have entered the ground water at the point of compliance or treating them in place. The program shall also address removing or treating in place any hazardous constituents that exceed concentration limits in ground water between the point of compliance and the downgradient facility property boundary. The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the ground water protection standard. The Department will determine when the licensee may terminate corrective action measures based on data from the ground water monitoring program and other information that provide reasonable assurance that the ground water protection standard will not be exceeded.



Criterion 5E. In developing and conducting ground water protection programs, applicants and licensees shall also consider the following:

- (1) Installation of bottom liners (Where synthetic liners are used, a leakage detection system must be installed immediately below the liner to ensure major failures are detected if they occur. This is in addition to the ground water monitoring program conducted as provided in Criterion 7. Where clay liners are proposed or relatively thin, in situ clay soils are to be relied upon for seepage control, tests must be conducted with representative tailings solutions and clay materials to confirm that no significant deterioration of permeability or stability properties will occur with continuous exposure of clay to tailings solutions. Tests must be run for a sufficient period of time to reveal any effects if they are going to occur (in some cases deterioration has been observed to occur rather rapidly after about nine months of exposure)).
- (2) Mill process designs which provide the maximum practicable recycle of solutions and conservation of water to reduce the net input of liquid to the tailings impoundment.
- (3) Dewatering of tailings by process devices and/or in situ drainage systems (At new sites, tailings must be dewatered by a drainage system installed at the bottom of the impoundment to lower the phreatic surface and reduce the driving head of seepage, unless tests show tailings are not amenable to such a system. Where in situ dewatering is to be conducted, the impoundment bottom must be graded to assure that the drains are at a low point. The drains must be protected by suitable filter materials to assure that drains remain free running. The drainage system must also be adequately sized to assure good drainage).
- (4) Neutralization to promote immobilization of hazardous constituents.

Criterion 5F. Where ground water impacts are occurring at an existing site due to seepage, action must be taken to alleviate conditions that lead to excessive seepage impacts and restore ground water quality. The specific seepage control and ground water protection method, or combination of methods, to be used must be worked out on a site-specific basis. Technical specifications must be prepared to control installation of seepage control systems. A quality assurance, testing, and inspection program, which includes supervision by a qualified engineer or scientist, must be established to assure the specifications are met.

Criterion 5G. In support of a tailings disposal system proposal, the applicant/operator shall supply information concerning the following:

- (1) The chemical and radioactive characteristics of the waste solutions.
- (2) The characteristics of the underlying soil and geologic formations particularly as they will control transport of contaminants and solutions. This includes detailed information concerning extent, thickness, uniformity, shape, and orientation of underlying strata. Hydraulic gradients and conductivities of the various formations must be determined. This information must be gathered from borings and field survey methods taken within the proposed impoundment area and in surrounding areas where contaminants might migrate to ground water. The information gathered on boreholes must include both geological and geophysical logs in sufficient number and degree of sophistication to allow determining significant discontinuities, fractures, and channeled deposits of high hydraulic conductivity. If field survey methods are used, they should be in addition to and calibrated with borehole logging. Hydrologic parameters such as permeability may not be determined on the basis of laboratory analysis of samples alone; a sufficient amount of field testing (e.g., pump tests) must be conducted to assure actual field properties are adequately understood. Testing must be conducted to allow estimating chemi-sorption attenuation properties of underlying soil and rock.

- (3) Location, extent, quality, capacity and current uses of any ground water at and near the site.

Criterion 5H. Steps must be taken during stockpiling of ore to minimize penetration of radionuclides into underlying soils; suitable methods include lining and/or compaction of ore storage areas.

Criterion 6.

- (1) In disposing of waste byproduct material, licensees shall place an earthen cover (or approved alternative) over tailings or wastes at the end of milling operations and shall close the waste disposal area in accordance with a design<sup>1</sup> which provides reasonable assurance of control of radiological hazards to (i) be effective for 1,000 years, to the extent reasonably achievable, and, in any case, for at least 200 years, and (ii) limit releases of radon-222 from uranium byproduct materials, and radon-220 from thorium byproduct materials, to the atmosphere so as not to exceed an average<sup>2</sup> release rate of 20 picocuries per square meter per second (pci/m<sup>2</sup>s) to the extent practicable throughout the effective design life determined pursuant to (1)(i) of this criterion. In computing required tailings cover thicknesses, moisture in soils in excess of amounts found normally in similar soils in similar circumstances may not be considered. Direct gamma exposure from the tailings or wastes should be reduced to background levels. The effects of any thin synthetic layer may not be taken into account in determining the calculated radon exhalation level. If non-soil materials are proposed as cover materials, it must be demonstrated that these materials will not crack or degrade by differential settlement, weathering, or other mechanism, over long-term intervals.
- (2) As soon as reasonably achievable after emplacement of the final cover to limit releases of radon-222 from uranium byproduct material and prior to placement of erosion protection barriers or other features necessary for long-term control of the tailings, the licensee shall verify through appropriate testing and analysis that the design and construction of the final radon barrier is effective in limiting releases of radon-222 to a level not exceeding 20 pci/m<sup>2</sup>s averaged over the entire pile or impoundment using the procedures described in 40 CFR Part 61, Appendix B, Method 115, or another method of verification approved by the Department as being at least as effective in demonstrating the effectiveness of the final radon barrier.
- (3) When phased emplacement of the final radon barrier is included in the applicable reclamation plan, the verification of radon-222 release rates required in paragraph (2) of this Criterion must be conducted for each portion of the pile or impoundment as the final radon barrier for that portion is emplaced.

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<sup>1</sup>In the case of thorium byproduct materials, the standard applies only to design. Monitoring for radon emissions from thorium byproduct materials after installation of an appropriately designed cover is not required.

<sup>2</sup>This average applies to the entire surface of each disposal area over a period of at least one year, but a period short compared to 100 years. Radon will come from both byproduct materials and from covering materials. Radon emissions from covering materials should be estimated as part of developing a closure plan for each site. The standard, however, applies only the emissions from byproduct materials to the atmosphere.

- (4) Within ninety days of the completion of all testing and analysis relevant to the required verification in paragraphs (2) and (3) of this Criterion, the uranium mill licensee shall report to the Department the results detailing the actions taken to verify that levels of release of radon-222 do not exceed 20 pci/m's when averaged over the entire pile or impoundment. The licensee shall maintain records until termination of the license documenting the source of input parameters including the results of all measurements on which they are based, the calculations and/or analytical methods used to derive values for input parameters, and the procedure used to determine compliance. These records shall be kept in a form suitable for transfer to the custodial agency at the time of transfer of the site to DOE or a state for long-term care if requested.
- (5) Near surface cover materials (i.e., within the top three meters) may not include waste or rock that contains elevated levels of radium; soils used for near surface cover must be essentially the same, as far as radioactivity is concerned, as that of surrounding surface soils. This is to ensure that surface radon exhalation is not significantly above background because of the cover material itself.
- (6) The design requirements in this Criterion for longevity and control of radon releases apply to any portion of a licensed and/or disposal site unless such portion contains a concentration of radium in land, averaged over areas of 100 square meters, which as a result of byproduct material, does not exceed the background level by more than: (i) 5 picocuries per gram (pci/g) of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over the first 15 centimeters (cm) below the surface, and (ii) 15 pci/g of radium-226, or, in the case of thorium byproduct material, radium-228, averaged over 15-cm thick layers more than 15 cm below the surface.
- (7) The licensee shall also address the nonradiological hazards associated with the wastes in planning and implementing closure. The licensee shall ensure that disposal areas are closed in a manner that minimizes the need for further maintenance. To the extent necessary to prevent threats to human health and the environment, the licensee shall control, minimize, or eliminate post-closure escape of nonradiological hazardous constituents, leachate, contaminated rainwater, or waste decomposition products to the ground or surface waters or to the atmosphere.

Criterion 6A.

- (1) For impoundments containing uranium byproduct materials, the final radon barrier must be completed as expeditiously as practicable considering technological feasibility after the pile or impoundment ceases operation in accordance with a written, Department-approved reclamation plan. (The term as expeditiously as practicable considering technological feasibility as specifically defined in RH 18.2 includes factors beyond the control of the licensee). Deadlines for completion of the final radon barrier and, if applicable, the following interim milestones must be established as a condition of the individual license: windblown tailings retrieval and placement on the pile and interim stabilization including dewatering or the removal of freestanding liquids and recontouring. The placement of erosion protection barriers or other feature necessary for long-term control of the tailings must also be completed in a timely manner in accordance with a written, Department-approved reclamation plan.



- (2) The Department may approve a licensee's request to extend the time for performance of milestones related to emplacement of the final radon barrier if, after providing an opportunity for public participation, the Department finds that the licensee has adequately demonstrated in the manner required in paragraph (2) of Criterion 6 that releases of radon-222 do not exceed an average of 20 pci/m<sup>3</sup>s. If the delay is approved on the basis that the radon releases do not exceed 20 pci/m<sup>3</sup>s, a verification of radon levels, as required by paragraph (2) of Criterion 6, must be made annually during the period of delay. In addition, once the Department has established the date in the reclamation plan for the milestone for completion of the final radon barrier, the Department may extend that date based on cost if after providing an opportunity for public participation the Department finds that the licensee is making good faith efforts to emplace the final radon barrier, the delay is consistent with the definition of available technology, and the radon releases caused by the delay will not result in a significant incremental risk to the public health.
- (3) The Department may authorize by license amendment, upon licensee report, a portion of the impoundment to accept uranium byproduct material or such materials that are similar in physical, chemical, and radiological characteristics to the uranium mill tailings and associated wastes already in the pile or impoundment from other sources, during the closure process. No such authorization will be made if it results in a delay or impediment to emplacement of the final radon barrier over the remainder of the impoundment in a manner that will achieve levels of radon-222 releases not exceeding 20 pci/m<sup>3</sup>s averaged over the entire impoundment. The verification required in paragraph (2) of Criterion 6 may be completed with a portion of the impoundment being used for further disposal if the Department makes a final finding that the impoundment will continue to achieve a level of radon-222 release not exceeding 20 pci/m<sup>3</sup>s averaged over the entire impoundment in this case, after the final radon barrier is complete except for the continuing disposal area, (a) only byproduct material will be authorized for disposal, (b) the disposal will be limited to the specified existing disposal area, and (c) this authorization will only be made after providing opportunity for public participation. Reclamation of the disposal area, as appropriate, must be completed in a timely manner after disposal operations cease in accordance with paragraph (1) of Criterion 6; however, these actions are not required to be complete as part of meeting the deadline for final radon barrier construction.

Criterion 7. The licensee shall establish a detection monitoring program needed for the Department to set the site-specific ground water protection standards in paragraph 5B(1) of this appendix. For all monitoring under this paragraph, the licensee or applicant will propose for Department approval as license conditions which constituents are to be monitored on a site-specific basis. A detection monitoring program has two purposes. The initial purpose of the program is to detect leakage of hazardous constituents from the disposal area so that the need to set ground water protection standards is monitored. If leakage is detected, the second purpose of the program is to generate data and information needed for the Department to establish the standards under Criterion 5B. The data and information must provide a sufficient basis to identify those hazardous constituents which require concentration limit standards and to enable the Department to set the limits for those constituents and the compliance period. They may also need to provide the basis for adjustments to the point of compliance. The detection monitoring programs must be in place when specified by the Department in orders or license conditions. Once ground water protection standards have been established pursuant to paragraph 5B(1), the licensee shall establish and implement a compliance monitoring program. The purpose of the compliance monitoring program is to determine that the hazardous constituent concentrations in ground water continue to comply with the standards set by the Department. In conjunction with a corrective action program, the licensee shall establish and implement a corrective action monitoring program. The purpose of the corrective action monitoring program is to demonstrate the effectiveness of the corrective actions. Any monitoring program required by this paragraph may be based on existing monitoring programs to the extent the existing programs can meet the stated objective for the program.

Criterion 8. Milling operations must be conducted so that all airborne effluent releases are reduced to levels as low as is reasonably achievable. The primary means of accomplishing this must be by means of emission controls. Institutional controls, such as extending the site boundary and exclusion area, may be employed to ensure that offsite exposure limits are met, but only after all practicable measures have been taken to control emissions at the source. Notwithstanding the existence of individual dose standards, strict control of emissions is necessary to assure that population exposures are reduced to the maximum extent reasonably achievable and to avoid site contamination. The greatest potential sources of offsite radiation exposure (aside from radon exposure) are dusting from dry surfaces of the tailings disposal area not covered by tailings solution and emissions from yellowcake drying and packaging operations. During operations and prior to closure, radiation doses from radon emissions from surface impoundments of uranium or thorium byproduct materials must be kept as low as is reasonably achievable.

Checks must be made and logged hourly for all parameters (e.g., differential pressures and scrubber water flow rates) that determine the efficiency of yellowcake stack emission control equipment operation. The licensee shall retain each log as a record for three years after the last entry in the log is made. It must be determined whether or not conditions are within a range prescribed to ensure that the equipment is operating consistently near peak efficiency; corrective action must be taken when performance is outside of prescribed ranges. Effluent control devices must be operative at all times during drying and packaging operations and whenever air is exhausting from the yellowcake stack. Drying and packaging operations must terminate when controls are inoperative. When checks indicate the equipment is not operating within the range prescribed for peak efficiency, actions must be taken to restore parameters to the prescribed range. When this cannot be done without shutdown and repairs, drying and packaging operations must cease as soon as practicable. Operations may not be restarted after cessation due to off-normal performance until needed corrective actions have been identified and implemented. All these cessations, corrective actions, and restarts must be reported to the Department as indicated in Criterion 8A, in writing, within ten days of the subsequent restart.



To control dusting from tailings, that portion not covered by standing liquids must be wetted or chemically stabilized to prevent or minimize blowing and dusting to the maximum extent reasonably achievable. This requirement may be relaxed if tailings are effectively sheltered from wind, such as may be the case where they are disposed of below grade and the tailings surface is not exposed to wind. Consideration must be given in planning tailings disposal programs to methods which would allow phased covering and reclamation of tailings impoundments because this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Milling operations producing or involving uranium and thorium byproduct materials must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive material, radon and its progeny excepted, to the general environment.

Uranium and thorium byproduct materials must be managed so as to conform to the applicable provisions of Title 40 of the Code of Federal Regulations, Part 440, "Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, Subpart C, Uranium, Radium, and Vanadium Ores Subcategory", as codified on January 1, 1983.

Criterion 8A. Inspections of tailings or waste retention systems must be conducted daily during operations, or at an alternate frequency approved by the Department for other conditions. Such inspections shall be conducted by, or under the supervision of, a qualified engineer or scientist, and documented. The licensee shall retain the documentation for each inspection as a record for three years after the documentation is made. The Department must be immediately notified of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or any unusual conditions (conditions not contemplated in the design of the retention system) that if not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

Criterion 9.

Criterion 9A. These criteria relating to ownership of tailings and their disposal sites became effective on November 8, 1981, and apply to all licenses terminated, issued, or renewed after that date.

Criterion 9B. Any uranium or thorium milling license or tailings license must contain such terms and conditions as the U.S. Nuclear Regulatory Commission and Department determine necessary to assure that prior to termination of the license, the licensee will comply with ownership requirements of this criterion for sites used for tailings disposal.

Criterion 9C. Title to the byproduct material licensed under this Part 18 and land, including any interests therein (other than land owned by the United States or by a State), which is used for the disposal of any such byproduct material, or is essential to ensure the long-term stability of such disposal site, must be transferred to the United States or the State in which such land is located, at the option of such State. In view of the fact that physical isolation must be the primary means of long-term control, and Government land ownership is a desirable supplementary measure, ownership of certain severable subsurface interests (for example, mineral rights) may be determined to be unnecessary to protect the public health and safety and the environment. In any case, however, the applicant/operator must demonstrate a serious effort to obtain such subsurface rights, and must in the event that certain rights cannot be obtained, provide notification in local public land records of the fact that the land is being used for the disposal of radioactive material and is subject to either a U.S. Nuclear Regulatory Commission or Department general or specific license prohibiting the disruption and disturbance of the tailings. In some rare cases, such as may occur with deep burial where no ongoing site surveillance will be required, surface land ownership transfer requirements may be waived with the approval of the Department and U.S. Nuclear Regulatory Commission. For licenses issued before November 8, 1981, the Department and U.S. Nuclear Regulatory Commission may take into account the status of the ownership of such land, and interests therein, and the ability of a licensee to transfer title and custody thereof to the United States or a State.

Criterion 9D. If the U.S. Nuclear Regulatory Commission, or Department if title is held by the State, subsequent to title transfer determines that use of the surface or subsurface estates, or both, of the land transferred to the United States or to a State will not endanger the public health, safety, welfare, or environment, the U.S. Nuclear Regulatory Commission, or Department if title is held by the State, may permit the use of the surface or subsurface estates, or both, of such and in a manner consistent with the provisions provided in these criteria. If the U.S. Nuclear Regulatory Commission, or Department permits such use of such land, it will provide the person who transferred such land with the right of first refusal with respect to such use of such land.

Criterion 9E. Material and land transferred to the United States or the State in accordance with this Criterion 9 must be transferred to the United States or the State without cost other than administrative or legal costs incurred in carrying out such transfer.

Criterion 9F. The provisions of this part respecting transfer of title and custody to land and tailings and wastes do not apply in the case of lands held in trust by the United States for any Indian tribe or lands owned by such Indian tribe subject to a restriction against alienation imposed by the United States. In the case of such lands which are used for the disposal of uranium or thorium byproduct material, as defined in Part 1, the licensee shall enter into arrangements with the U.S. Nuclear Regulatory Commission as may be appropriate to assure the long-term surveillance of such lands by the United States.

Criterion 10. Secondary ground-water protection standards required by Criterion 5 of this Appendix are concentration limits for individual hazardous constituents. The following list of constituents identifies the constituents for which standards must be set and complied with if the specific constituent is reasonably expected to be in or derived from the radioactive material and has been detected in ground water. For purposes of this Appendix, the property of gross alpha activity will be treated as if it is a hazardous constituent. Thus, when setting standards under paragraph 5B(5) of Criterion 5, the Department will also set a limit for gross alpha activity. The Department does not consider the following list imposed by 40 CFR Part 192 to be exhaustive and may determine other constituents to be hazardous on a case-by-case basis, independent of those specified by the U.S. Environmental Protection Agency in Part 192.

NOTE: A certified copy of the referenced material is available for public inspection during normal business hours at the Radiation Control Division, 4300 Cherry Creek Drive South, B-1, Denver, Colorado. These rules do not include later amendments of the referenced material. Certified copies of the referenced material will be provided at cost upon request from the Radiation Control Division at the following mailing address: Director, Radiation Control Division, RCD-DO-B1, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado, 80220-1530.

PART 18

APPENDIX A

HAZARDOUS CONSTITUENTS

- Acetonitrile (Ethanenitrile)
- Acetophenone (Ethanone, 1-phenyl)
- 3-(alpha-Acetylbenzyl)-4-hydroxycoumarin and salts (Warfarin)
- 2-Acetylaminofluorene (Acetamide, N-(9H-fluoren-2-yl)-)
- Acetyl chloride (Ethanoyl chloride)
- 1-Acetyl-2-thiourea (Acetamide, N-(aminothioxomethyl)-)
- Acrolein (2-Propenal)
- Acrylamide (2-Propenamide)
- Acrylonitrile (2-Propenenitrile)
- Aflatoxins
- Aldrin (1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a,8b-hexahydro-endo,exo-1,4:5,8-Dimethanonaphthalene)
- Allyl alcohol (2-Propen-1-ol)
- Aluminum phosphide
- 4-Aminobiphenyl ([1,1-Biphenyl])-4-amine)
- 6-Amino-1,1a,2,8,8a,8b-hexahydro-8-(hydroxymethyl)-8a-methoxy-5-methyl-carbamate azirino(2,3:3,4)pyrrolo(1,2-a)indole-4,7-dione, (ester) (Mitomycin C) (Azirino[2,3:3,4]pyrrolo(1,2-a)indole-4,7-dione, 6-amino-8-(((amino-carbonyl)oxy)methyl)-1,1a,2,8,8a,8b-hexahydro-8a methoxy-5-methyl-)
- 5-(Aminomethyl)-3-isoxazolol (3(2H)-Isoxazolone, 5-(aminomethyl)-)-4-Aminopyridine (4-Pyridinamine)
- Amitrole (1H-1,2,4-Triazol-3-amine)
- Aniline (Benzenamine)
- Antimony and compounds, N.O.S.<sup>3</sup>

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Aramite (Sulfurous acid, 2-chloroethyl-, 2-(4-(1,1-dimethylethyl)phenoxy)-1-methylethyl ester)
- Arsenic and compounds, N.O.S.<sup>3</sup>
- Arsenic acid (Orthoarsenic acid)
- Arsenic pentoxide (Arsenic (V) oxide)
- Arsenic trioxide (Arsenic (III) oxide)
- Auramine (Benzenamine, 4,4-carbonimidoylbis (N,N-Dimethyl-, monohydrochloride)
- Azaserine (L-Serine, diazoacetate (ester))
- Barium and compounds, N.O.S.<sup>3</sup>
- Barium cyanide
- Benz(c)acridine (3,4-Benzacridine)
- Benz(a)anthracene (1,2-Benzanthracene)
- Benzene (Cyclohexatriene)
- Benzenearsonic acid (Arsonic acid, phenyl-)
- Benzene, dichloromethyl-(Benzal chloride)
- Benzenethiol (Thiophenol)
- Benzidine ([1,1-Biphenyl]-4,4 diamine)
- Benzo(b)fluoranthene (2,3-Benzofluoranthene)
- Benzo(j)fluoranthene (7,8-Benzofluoranthene)
- Benzo(a)pyrene (3,4-Benzopyrene)
- p-Benzoquinone (1,4-Cyclohexadienedione)
- Benzotrichloride (Benzene, Trichloromethyl)
- Benzyl chloride (Benzene, (chloromethyl)-)
- Beryllium and compounds, N.O.S.<sup>3</sup>
- Bis(2-chloroethoxy)methane (Ethane, 1,1-(methylenebis(oxy))bis[2-chloro-])
- Bis(2-chloroethyl) ether (Ethane, 1,1-oxybis (2-chloro-))
- N,N-Bis(2-chloroethyl)-2-naphthylamine (Chlornaphazine)
- Bis(2-Chloroisopropyl) ether (Propane, 2,2-oxybis[2-chloro-])

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.



# HAZARDOUS CONSTITUENTS (Continued)

- Bis(chloromethyl) ether (methane, oxybis(chloro-))
- Bis(2-ethylhexyl) phthalate (1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester)
- Bromoacetone (2-Propanone, 1-bromo-)
- Bromomethane (Methyl bromide)
- 4-Bromophenyl phenyl ether (Benzene, 1-bromo-4-phenoxy-)
- Brucine (Strychnidin-10-one, 2,3-dimethoxy-)
- 2-Butanone peroxide (Methyl ethyl ketone, peroxide)
- Butyl benzyl phthalate (1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester)
- 2-sec-Butyl-4,6-dinitrophenol (DNBP) (Phenol, 2,4-dinitro-6-(1-methylpropyl)-)
- Cadmium and compounds, N.O.S.<sup>3</sup>
- Calcium chromate (Chromic acid, calcium salt)
- Calcium cyanide
- Carbon disulfide (Carbon disulfide)
- Carbon oxyfluoride (Carbonyl fluoride)
- Chloral (Acetaldehyde, trichloro-)
- Chlorambucil (Butanoic acid, 4-(bis(2-chloroethyl)amino)benzene-)
- Chlordane (alpha and gamma isomers) 4,7-Methanoindan, 1,2,4,5,6,7,8,8-octachloro-3,4,7,7a-tetrahydro- (alpha and gamma isomers)
- Chlorinated benzenes, N.O.S.<sup>3</sup>
- Chlorinated ethane, N.O.S.<sup>3</sup>
- Chlorinated fluorocarbons, N.O.S.<sup>3</sup>
- Chlorinated naphthalene, N.O.S.<sup>3</sup>
- Chlorinated phenol, N.O.S.<sup>3</sup>
- Chloroacetaldehyde (Acetaldehyde, chloro-)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Chloroalkyl ethers N.O.S.<sup>3</sup>
- p-Chloroaniline (Benzeneamine, 4-chloro-)
- Chlorobenzene (Benzene, chloro-)
- Chlorobenzilate (Benzeneacetic acid, 4-chloro-alpha-(4-chlorophenyl)-alpha-hydroxy-, ethyl ester)
- p-Chloro-m-cresol (Phenol, 4-chloro-3-methyl)
- 1-Chloro-2,3-epoxypropane (Oxirane, 2-(chloromethyl)-)
- 2-Chloroethyl vinyl ether (Ethene, (2-chloroethoxy)-)
- Chloroform (Methane, trichloro-)
- Chloromethane (Methyl chloride)
- Chloromethyl methyl ether (Methane, chloromethoxy-)
- 2-Chloronaphthalene (Naphthalene, betachloro-)
- 2-Chlorophenol (Phenol, o-chloro-)
- 1-(o-Chlorophenyl)thiourea (Thiourea, (2-chlorophenyl)-)
- 3-Chloropropionitrile (Propanenitrile, 3-chloro-)
- Chromium and compounds, N.O.S.<sup>3</sup>
- Chrysene (1,2-Benzphenanthrene)
- Citrus red No. 2 (2-Naphthol, 1-((2,5-dimethoxyphenyl)azo)-)
- Coal tars
- Copper cyanide
- Creosote (Creosote, wood)
- Creso's (Cresylic acid) (Phenol, methyl-)
- Crotonaldehyde (2-Butenal)
- Cyanides (soluble salts and complexes), N.O.S.<sup>3</sup>
- Cyanogen (Ethanedinitrile)
- Cyanogen bromide (Bromine cyanide)
- Cyanogen chloride (Chlorine cyanide)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Cycasin (beta-D-Glucopyranoside, (methyl-ONN-azoxy)methyl-)
- 2-Cyclohexyl-4,6-dinitrophenol (phenol, 2-cyclohexyl-4,6-dinitro-)
- Cyclophosphamide (2H-1,3,2-Oxazaphosphorine (bis(2-chloroethyl)amino)-tetrahydro-,2-oxide)
- Daunomycin (5,12-Naphthacenedione, (8S-cis)-8-acetyl-10-((3-amino-2,3,6-trideoxy)-alpha-L-lyxo-hexopyranosyl)oxy)7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-)
- DDD (Dichlorodiphenyldichloroethane) (Ethane, 1,1-dichloro-2,2-bis(p-chlorophenyl)-)
- DDE (Ethylene, 1,1-dichloro-2,2-bis(4-chlorophenyl)-)
- DDT (Dichlorodiphenyltrichloroethane) (Ethane, 1,1,1-trichloro-2,2-bis (p-chlorophenyl)-)
- Diallylate (S-(2,3-dichloroallyl) diisopropylthiocarbamate
- Dibenz(a,h)acridine(1,2,5,6-Dibenzacridine)
- Dibenz(a,j)acridine(1,2,7,8-Dibenzacridine)
- Dibenz(a,h)anthracene (1,2,5,6-Dibenzanthracene
- 7H-Dibenzo(c,g)carbazole (3,4,5,6-Dibenzcarbazole)
- Dibenzo(a,e)pyrene(1,2,4,5-Dibenzpyrene)
- Dibenzo(a,h)pyrene(1,2,5,6-Dibenzpyrene)
- Dibenzo(a,i)pyrene(1,2,7,8-Dibenzpyrene)
- 1,2-Dibromo-3-chloropropane (Propane, 1,2-dibromo-3-chloro-)
- 1,2 Dibromoethane (Ethylene dibromide)
- Dibromomethane (Methylene bromide)
- Di-n-butyl phthalate (1,2-Benzenedicarboxylic acid, dibutyl ester)
- o-Dichlorobenzene (Benzene, 1,2-dichloro-)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- m-Dichlorobenzene (Benzene, 1,3-dichloro-)
- p-Dichlorobenzene (Benzene, 1,4-dichloro-)
- Dichlorobenzene, N.O.S.<sup>3</sup> (Benzene, dichloro-, N.O.S.<sup>3</sup>)
- 3,3-Dichlorobenzidine ([1,1, Biphenyl]-4,4-diamine, 3,3-dichloro-)
- 1,4-Dichloro-2-butene (2-Butene, 1,4-dichloro-)
- Dichlorodifluoromethane (Methane, dichlorodifluoro-)
- 1,1 Dichloroethane (Ethylidene dichloride)
- 1,2 Dichloroethane (Ethylene dichloride)
- trans-1,2-Dichloroethene (1,2-Dichloroethylene)
- Dichloroethylene, N.O.S.<sup>3</sup> (Ethene, dichloro-N.O.S.<sup>3</sup>)
- 1,1-Dichloroethylene (Ethene, 1,1-dichloro-)
- Dichloromethane (Methylene chloride)
- 2,4-Dichlorophenol (Phenol, 2,4-dichloro-)
- 2,6-Dichlorophenol (Phenol, 2,6-dichloro-)
- 2,4-Dichlorophenoxyacetic acid (2,4-D), salts and esters (Acetic acid, 2,4-dichlorophenoxy-, salts and esters)
- Dichlorophenylarsine (Phenyl dichloroarsine)
- Dichloropropane, N.O.S.<sup>3</sup> (Propane, dichloro-N.O.S.<sup>3</sup>)
- 1,2-Dichloropropane (Propylene dichloride)
- Dichloropropanol, N.O.S.<sup>3</sup> (Propanol, dichloro-N.O.S.<sup>3</sup>)
- Dichloropropene, N.O.S.<sup>3</sup> (Propene, dichloro-N.O.S.<sup>3</sup>)
- 1,3-Dichloropropene (1-Propene, 1,3-dichloro-)
- Dieldrin (1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octa-hydro-endo,exo-1,4:5,8-Dimethanonaphthalene)
- 1,2:3,4-Diepoxycyclobutane (2,2,-Bioxirane)
- Diethylarsine (Arsine, diethyl-)
- N,N-Diethylhydrazine (Hydrazine, 1,2-

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- diethyl)
- O,O-Diethyl S-methyl ester of phosphorodithioic acid (Phosphorodithioic acid, O,O-diethyl S-methyl ester)
- O,O-Diethylphosphoric acid, O-p-nitrophenyl ester (Phosphoric acid, diethyl p-nitrophenyl ester)
- Diethyl phthalate (1,2-Benzenedicarboxylic acid, diethyl ester)
- O,O-Diethyl O-2-pyrazinyl phosphorothioate (Phosphorothioic acid, O,O-diethyl O-pyrazinyl ester)
- Diethylstilbesterol (4,4-Stilbenediol, alpha, alpha-diethyl, bis(dihydrogen phosphate, (E)-)
- Dihydrosafrole (Benzene, 1,2-methylenedioxy-4-propyl-)
- 3,4-Dihydroxy-alpha-(methylamino)methyl benzyl alcohol (1,2-Benzenediol, 4-(1-hydroxy-2 (methylamino)ethyl))
- Diisopropylfluorophosphate (DFP) (Phosphorofluoric acid, bis(1-methylethyl) ester)
- Dimethoate (Phosphorodithioic acid, O,O-dimethyl S-(2-(methylamino)-2-oxoethyl) ester)
- 3,3,-Dimethoxybenzidine ((1,1,-Biphenyl)-4,4,-diamine, 3-3,-dimethoxy-)
- p-Dimethylaminoazobenzene (Benzenamine, N,N-dimethyl-4-(phenylazo)-)
- 7,12-Dimethylbenz(a)anthracene(1,2-Benzanthracene, 7,12-dimethyl-)
- 3,3-Dimethylbenzidine (1,1-Biphenyl)-4,4,diamine, 3,3-dimethyl-)
- Dimethylcarbamoyl chloride (Carbamoyl chloride, dimethyl)
- 1,1 Dimethylhydrazine (Hydrazine, 1,1-

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.



# HAZARDOUS CONSTITUENTS (Continued)

- dimethyl-)
- 1,2-Dimethylhydrazine (Hydrazine, 1,2-dimethyl-)
- 3,3-Dimethyl-1-(methylthio)-2-butanone, O-[(methylamino) carbonyl] oxime (Thiofanox)
- alpha, alpha-Dimethylphenethylamine (Ethanamine, 1,1-dimethyl-2-phenyl-)
- 2,4-Dimethylphenol (Phenol, 2,4-dimethyl-)
- Dimethyl phthalate (1,2-Benzenedicarboxylic acid, dimethyl ester)
- Dimethyl sulfate (Sulfuric acid, dimethyl ester)
- Dinitrobenzene, N.O.S.<sup>3</sup> (Benzene, dinitro-N.O.S.<sup>3</sup>)
- 4,6-Dinitro-o-cresol and salts (Phenol, 2,4-dinitro-6-methyl-, and salts)
- 2,4-Dinitrophenol (Phenol, 2,4-dinitro-)
- 2,4-Dinitrotoluene (Benzene, 1-methyl-2,4-dinitro-)
- 2,6-Dinitrotoluene (Benzene, 1-methyl 2,6-dinitro-)
- Di-n-octyl phthalate (1,2-Benzenedicarboxylic acid, dioctyl ester)
- 1,4-Dioxane (1,4-Diethylene oxide)
- Diphenylamine (Benzenamine, N-phenyl-)
- 1,2-Diphenylhydrazine (Hydrazine, 1,2-diphenyl-)
- Di-n-propylnitrosamine (N-Nitroso-di-n-propylamine)
- Disulfoton (O,O-diethyl S-(2-(ethylthio)ethyl) phosphorodithioate)
- 2,4-Dithiobiuret (Thiomidodicarbonic diamide)
- Endosulfan (5-Norbornene, 2,3-dimethanol, 1,4,5,6,7,7-hexachloro-cyclic sulfite)
- Endrin and metabolites (1,2,3,4,10,10-

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-endo, endo-1,4,5,8-dimethanonaphthalene, and metabolites)
- Ethyl carbamate (Urethan) (Carbamic acid, ethyl ester)
- Ethyl cyanide (Propanenitrile)
- Ethylenebisdithiocarbamic acid, salts, and esters (1,2-Ethanediy1-biscarbamodithioic acid, salts and esters)
- Ethyleneimine (Aziridine)
- Ethylene oxide (Oxirane)
- Ethylenethiourea (2-Imidazolidinethione)
- Ethyl methacrylate (2-Propenoic acid, 2-methyl-, ethyl ester)
- Ethyl methanesulfonate (Methanesulfonic acid, ethyl ester)
- Fluoranthene (Benzo[j,k]fluorene)
- Fluorine
- 2-Fluoroacetamide (Acetamide, 2-fluoro-)
- Fluoroacetic acid, sodium salt (Acetic acid, fluoro-sodium salt)
- Formaldehyde (Methylene oxide)
- Formic acid (Methanoic acid)
- Glycidylaldehyde (1-Propanol-2,3 epoxy)
- Halomethane, N.O.S.<sup>3</sup>
- Heptachlor (4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-)
- Heptachlor epoxide (alpha, beta, and gamma isomers) (4,7-Methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-2,3-epoxy-3a,4,7,7-tetrahydro-, alpha, beta, and gamma isomers)
- Hexachlorobenzene (Benzene, hexachloro-)
- Hexachlorobutadiene (1,3-Butadiene, 1,1,2,3,4,4-hexachloro-)
- Hexachlorocyclohexane (all isomers) (Lindane and isomers)

<sup>3</sup> The abbreviation N,O,S, (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Hexachlorocyclopentadiene (1,3-Cyclopentadiene, 1,2,3,4,5,5-hexachloro-)
- Hexachloroethane (Ethane, 1,1,1,2,2,2-hexachloro-)
- 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4,5,8-endo,endo-dimethanonaphthalene (Hexachlorohexahydro-endo,endo-dimethanonaphthalene)
- Hexachlorophene (2,2,-Methylenebis(3,4,6-trichlorophenol))
- Hexachloropropene (1-Propene, 1,1,2,3,3,3-hexachloro-)
- Hexaethyl tetraphosphate (Tetraphosphoric acid, hexaethyl ester)
- Hydrazine (Diamine)
- Hydrocyanic acid (Hydrogen cyanide)
- Hydrofluoric acid (Hydrogen fluoride)
- Hydrogen sulfide (Sulfur hydride)
- Hydroxydimethylarsine oxide (Cacodylic acid)
- Indeno (1,2,3-cd)pyrene(1,10-(1,2-phenylene)pyrene)
- Iodomethane (Methyl iodide)
- Iron dextran (Ferric dextran)
- Isocyanic acid, methyl ester (Methyl isocyanate)
- Isobutyl alcohol (1-Propanol, 2-methyl-)
- Isosafrole (Benzene, 1,2-methylenedioxy-4-allyl-)
- Kepone (decachlorooctahydro-1,3,4-Methano-2H-cyclobuta[cd]pentalen-2-one)
- Lasiocarpine (2-Butenoic acid, 2-methyl-,7-[(2,3-dihydroxy-2-(1-methoxyethyl)-3-methyl-1-oxobutoxy)methyl]2,3,5,7a-tetrahydro-1H-pyrrolizin-1-yl-ester)
- Lead and compounds, N.O.S.<sup>3</sup>
- Lead acetate (Acetic acid, lead salt)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Lead phosphate (Phosphoric acid, lead salt)
- Lead subacetate (Lead, bis(acetato-  
O)tetrahydroxytri-)
- Maleic anhydride (2,5-Furandione)
- Maleic hydrazide (1,2-Dihydro-3,6-  
pyridazinedione)
- Malononitrile (Propanedinitrile)
- Melfalan (Alanine, 3-(p-bis(2-  
chloroethyl)amino)phenyl-L-)
- Mercury fulminate (Fulminic acid, mercury  
salt)
- Mercury and compounds, N.O.S.<sup>3</sup>
- Methacrylonitrile (2-Propenenitrile,  
2-methyl-)
- Methanethiol (Thiomethanol)
- Methapyrilene (Pyridine, 2-[(2-  
dimethylamino)ethyl]-2-thenylamino-)
- Metholmyl (Acetimidic acid, N-  
[(methylcarbamoyl)oxy]thio-,methyl ester)
- Methoxychlor (Ethane, 1,1,1-trichloro-2,2,-  
bis(p-methoxyphenyl)-)
- 2-Methylaziridine (1,2-Propylenimine)
- 3-Methylcholanthrene (Benz[j]aceanthrylene,  
1,2-dihydro-3-methyl-)
- Methyl chlorcarbonate (Carbonochloridic  
acid, methyl ester)
- 4,4-Methylenebis(2-chloroaniline)  
Benzenamine, 4,4-methylenebis-(2-chloro-)
- Methyl ethyl ketone (MEK) (2-Butanone)
- Methyl hydrazine (Hydrazine methyl-)
- 2-Methylactonitrile (Propanenitrile 2-  
hydroxy-2-methyl-)
- Methyl methacrylate (2-Propenoic acid, 2-  
methyl-, methyl ester)
- Methyl methanesulfonate Methanesulfonic  
acid, methyl ester)
- 2-Methyl-2-(methylthio)propionaldehyde-o-

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- (methylcarbonyl) oxime (Propanal, 2-methyl-2(methylthio-0-[(methylamino)carbonyl]oxime)
- N-Methyl-N,-nitro-N-nitrosoguanidine (Guanidine, N-nitroso-N-methyl-N,-nitro-)
- Methyl parathion (O,O-dimethyl O-(40 nitrophenyl) phosphorothioate)
- Methylthiouracil (4-IH-Pyrimidinone, 2,3-dihydro-6-methyl-2-thioxo-)
- Molybdenum and compounds, N.O.S.<sup>3</sup>
- Mustard gas (Sulfide, bis(2-chloroethyl)-)
- Naphthalene
- 1,4-Naphthoquinone (1,4-Naphthalenedione)
- 1-Naphthylamine (alpha-Naphthylamine)
- 2-Naphthylamine (beta-Naphthylamine)
- 1-Naphthyl-2-thiourea (Thiourea, 1-naphthalenyl-)
- Nickel and compounds, N.O.S.<sup>3</sup>
- Nickel carbonyl (Nickel tetracarbonyl)
- Nickel cyanide (Nickel (II) cyanide)
- Nicotine and salts (Pyridine, (S)-3-(1-methyl-2-pyrrolidinyl)-, and salts)
- Nitric oxide (Nitrogen (II) oxide)
- p-Nitroaniline (Benzenamine, 4-nitro-)
- Nitrobenzene (Benzene, nitro-)
- Nitrogen dioxide (Nitrogen (IV) oxide)
- Nitrogen mustard and hydrochloride salt (Ethanamine, 2-chloro-,N-(2-chloroethyl)-N-methyl-, and hydrochloride salt)
- Nitrogen mustard N-Oxide and hydrochloride salt (Ethanamine, 2-chloro-,N-(2-chloroethyl)-N-methyl-and hydrochloride salt)
- Nitroglycerine (1,2,3-Propanetriol, trinitrate)
- 4-Nitrophenol (Phenol, 4-nitro)
- 4-Nitroquinoline-1-oxide (Quinoline, 4-nitro-1-oxide-)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.



# HAZARDOUS CONSTITUENTS (Continued)

- Nitrosamine, N.O.S.<sup>3</sup>
- N-Nitrosodi-n-butylamine (1-Butanamine, N-butyl-N-nitroso-)
- N-Nitrosodiethanolamine (Ethanol, 2,2-(nitrosoimino)bis-)
- N-Nitrosodiethylamine (Ethanamine, N-ethyl-N-nitroso-)
- N-Nitrosodimethylamine (Dimethylnitrosamine)
- N-Nitroso-N-ethylurea (Carbamide, N-ethyl-N-nitroso-)
- N-Nitrosomethylethylamine (Ethanamine, N-methyl-N-nitroso-)
- N-Nitroso-N-methylurea (Carbamide, N-methyl-N-nitroso-)
- N-Nitroso-N-methylurethane (Carbamic acid, methylnitroso-, ethyl ester)
- N-Nitrosomethylvinylamine (Ethenamine, N-methyl-N-nitroso-)
- N-Nitrosomorpholine (Morpholine, -N-nitroso-)
- N-Nitrosornicotine (Nornicotine, -N-nitroso-)
- N-Nitrosopiperidine (Pyridine, hexahydro-, N-nitroso-)
- Nitrosopyrrolidine (Pyrrole, tetrahydro-N-nitroso-)
- N-Nitrososarcosine (Sarcosine, -N-nitroso-)
- 5-Nitro-o-toluidine (Benzenamine, 2-methyl-5-nitro-)
- Octamethylpyrophosphoramidate (Diphosphoramidate, octamethyl-)
- Osmium tetroxide (Osmium(VIII)oxide)
- 7-Oxabicyclo(2,2,1)heptane-2,3-dicarboxylic acid (Endothal)
- Paraldehyde (1,3,5-Trioxane, 2,4,6-trimethyl-)
- Parathion (Phosphorothioic acid O,O-diethyl O-(p-nitrophenyl)ester)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Pentachlorobenzene (Benzene, pentachloro-)
- Pentachloroethane (Ethane, pentachloro-)
- Pentachloronitrobenzene (PCNB) (Benzene, Pentachloronitro-)
- Pentachlorophenol (Phenol, pentachloro-)
- Phenacetin (Acetamide, N-(4-ethoxyphenyl)-)
- Phenol (Benzene, hydroxy-)
- Phenylenediamine (Benzenediamine)
- Phenylmercury acetate (Mercury acetatophenyl-)
- N-Phenylthiourea (Thiourea, phenyl-)
- Phosgene (Carbonyl chloride)
- Phosphine (Hydrogen phosphide)
- Phosphorodithioic acid, O,O-diethyl S- [(ethylthio)methyl]ester (Phorate)
- Phosphorothioic acid, O,O-dimethyl O-(p- [(dimethylamino)sulfonyl]phenyl]ester (Famphur)
- Phthalic acid esters, N.O.S.<sup>3</sup> (Benzene, 1,2-dicarboxylic acid, esters, N.O.S.<sup>3</sup>)
- Phthalic anhydride (1,2-Benzenedicarboxylic acid anhydride)
- 2-Picoline (Pyridine, 2-methyl-)
- Polychlorinated biphenyl, N.O.S.<sup>3</sup>
- Potassium cyanide
- Potassium silver cyanide (Argentate(1-), dicyano-, potassium)
- Pronamide (3,5-Dichloro-N-(1,1-dimethyl-2-propynyl)benzamide)
- 1,3 Propane sultone (1,2-Oxathiolane, 2,2-dioxide)
- n-Propylamine (1-Propanamine)
- Propylthiouracil (Undecamethylenediamine, N,N-bis(2-chlorobenzyl-), dihydrochloride)
- 2-Propyn-1-ol (Propargyl alcohol)
- Pyridine

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- Radium-226 and -228
- Reserpine (Yohimban-16-carboxylic acid, 11,17-dimethoxy-18-[3,4,5-trimethoxybenzoyl)oxy]-,methyl ester)
- Resorcinol (1,3-Benzenediol)
- Saccharin and salts (1,2-Benzoisothiazolin-3-one, 1,1-dioxide, and salts)
- Safrole (Benzene, 1,2-methylenedioxy-4-allyl-)
- Selenious acid (Selenium dioxide)
- Selenium and compounds, N.O.S.<sup>3</sup>
- Selenium sulfide (Sulfur selenide)
- Selenourea (Carbamimidoseleonic acid)
- Silver and compounds, N.O.S.<sup>3</sup>
- Silver cyanide
- Sodium cyanide
- Streptozotocin (D-Glucopyranose, 2-deoxy-2-(3-methyl-3-nitrosoureido)-)
- Strontium sulfide
- Strychnine and salts (Strychnidin-10-one, and salts)
- 1,2,4,5-Tetrachlorobenzene (Benzene,1,2,4,5-tetrachloro-)
- 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) (Dibenzo-p-dioxin, 2,3,7,8-tetrachloro-)
- Tetrachloroethane, N.O.S.<sup>3</sup> (Ethane, tetrachloro-N.O.S.<sup>3</sup>)
- 1,1,1,2-Tetrachlorethane (Ethane, 1,1,1,2-tetrachloro-)
- 1,1,2,2-Tetrachlorethane (Ethane 1,1,2,2-tetrachloro-)
- Tetrachlorethane (Ethene, 1,1,2,2-tetrachloro-)
- Tetrachloromethane (Carbon tetrachloride)
- 2,3,4,6-Tetrachlorophenol (Phenol 2,3,4,6-tetrachloro-)
- Tetraethyldithiopyrophosphate

<sup>3</sup> The abbreviation N,O,S, (not otherwise specified) signifies those members of the general class not specifically listed by name in this list,

HAZARDOUS CONSTITUENTS (Continued)

- (Dithiopyrophosphoric acid, tetraethyl-  
ester)
- Tetraethyl lead (Plumbane, tetraethyl-)
  - Tetraethylpyrophosphate (Pyrophosphoric  
acide, tetraethyl ester)
  - Tetranitromethane (Methane, tetranitro-)
  - Thallium and compounds, N.O.S.<sup>3</sup>
  - Thallous oxide (Thallium (III) oxide)
  - Thallium (I) acetate (Acetic acid, thallium (I)  
salt)
  - Thallium (I) carbonate (Carbonic acid  
dithallium (I) salt)
  - Thallium (I) chloride
  - Thallium (I) nitrate (Nitric acid, thallium (I)  
salt)
  - Thallium selenite
  - Thallium (I) sulfate (Sulfuric acid, thallium (I)  
salt)
  - Thioacetamide (Ethanethioamide)
  - Thiosemicarbazide  
(Hydrazinecarbothioamide)
  - Thiourea (Carbamide thio-)
  - Thiuram (Bis(dimethylthiocarbamoyl)  
disulfide)
  - Thorium and compounds, N.O.S.<sup>3</sup> when  
producing thorium byproduct material
  - Toluene (Benzene, methyl-)
  - Toluenediamine (Diaminotoluene)
  - o-Toluidine hydrochloride (Benzenamine, 2-  
methyl-,hydrochloride)
  - Tolyene diisocyanate (Benzene, 1,3-  
diisocyanatomethyl-)
  - Toxaphene (Camphene, octachloro-)
  - Tribromomethane (Bromoform)
  - 1,2,4-Trichlorobenzene (Benzene, 1,2,4-  
trichloro-)
  - 1,1,1-Trichloroethane (Methyl chloroform)

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.

# HAZARDOUS CONSTITUENTS (Continued)

- 1,1,2-Trichloroethane (Ethane, 1,1,2-trichloro-)
- Trichloroethene (Trichloroethylene)
- Trichloromethanethiol (Methanethiol, trichloro-)
- Trichloromonofluoromethane (Methane, trichlorofluoro-)
- 2,4,5-Trichlorophenol (Phenol, 2,4,5-trichloro-)
- 2,4,6-Trichlorophenol (Phenol, 2,4,6-trichloro-)
- 2,4,5-Trichlorophenoxyacetic acid (2,4,5-T) (Acetic acid, 2,4,5-trichlorophenoxy-)
- 2,4,5-Trichlorophenoxypropionic acid (2,4,5-TP) (Silvex) (Propionic acid, 2-(2,4,5-trichlorophenoxy)-)
- Trichloropropane, N.O.S.<sup>3</sup> (Propane, trichloro-, N.O.S.<sup>3</sup>)
- 1,2,3-Trichloropropane (Propane, 1,2,3-trichloro-)
- O,O,O-Triethyl phosphorothioate (Phosphorothioic acid, O,O,O-triethyl ester)
- sym-Trinitrobenzene (Benzene, 1,3,5-trinitro-)
- Tris(1-aziridinyl) phosphine sulfide (Phosphine sulfide, tris(1-aziridinyl)-)
- Tris(2,3-dibromopropyl) phosphate (1-Propanol, 2,3-dibromo-, phosphate)
- Trypan blue (2,7-Naphthalenedisulfonic acid, 3,3,-((3,3,-dimethyl (1,1,-bi.henyl)-4,4,-diyl)bis(azo))bis(5-amino-4-hydroxy-tetrasodium salt)
- Uracil mustard (Uracil-5-[bis(2-chloroethyl)amino]-)
- Uranium and compounds, N.O.S.<sup>3</sup>
- Vanadic acid, ammonium salt (ammonium vanadate)
- Vanadium pentoxide (Vanadium (V) oxide)
- Vinyl chloride (Ethene, chloro-)
- Zinc cyanide
- Zinc phosphide

<sup>3</sup> The abbreviation N.O.S. (not otherwise specified) signifies those members of the general class not specifically listed by name in this list.



## PART 19

### LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

#### GENERAL PROVISIONS

##### RH 19.1 Purpose and Scope.

19.1.1 Part 19 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. Part 19 also contains requirements for operating irradiators. The requirements of this part are in addition to the requirements of Parts 3, 4, 10, 12, 13, and 17. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

19.1.2 The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

19.1.3 The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

##### RH 19.2 Definitions.

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

"Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in RH 19.18 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

"Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

#### Specific Licensing Requirements

##### RH 19.3      Application For a Specific License.

19.3.1      A person shall file an application for a specific license authorizing the use of sealed sources in an irradiator pursuant to RH 3.8 of the regulations.

##### RH 19.4      Specific Licenses for Irradiators.

19.4.1      The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

19.4.2      The applicant shall satisfy the general requirements specified in

RH 3.9 of the regulations and the requirements contained in this part.

- 19.4.3 The applicant must describe the training provided to irradiator operators including:
  - 19.4.3.1 Classroom training;
  - 19.4.3.2 On-the-job or simulator training;
  - 19.4.3.3 Safety reviews;
  - 19.4.3.4 Means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures; and
  - 19.4.3.5 Minimum training and experience of personnel who may provide training.
- 19.4.4 The application must include an outline of the written operating and emergency procedures listed in RH 19.19 that describes the radiation safety aspects of the procedures.
- 19.4.5 The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.
- 19.4.6 The application must include a description of the access control systems required by RH 19.8, the radiation monitors required by RH 19.11, the method of detecting leaking sources required by RH 19.22 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.
- 19.4.7 If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the:
  - 19.4.7.1 Instruments to be used;
  - 19.4.7.2 Methods of performing the analysis; and
  - 19.4.7.3 Pertinent experience of the individual who analyzes the samples.

19.4.8 If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the U. S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

19.4.9 The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by RH 19.23.

RH 19.5 Start of Construction.

19.5.1 The applicant may not begin construction of a new irradiator prior to the submission to the Department of both the application for a license for the irradiator and the fee required by Part 12 of the regulations. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of The Act, and rules, regulations, and orders issued under The Act.

RH 19.6 Applications for Exemptions.

19.6.1 Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

Design and Performance Requirements for Irradiators

RH 19.7 Performance Criteria for Sealed Sources.

19.7.1 Requirements. Sealed sources installed after January 1, 1997:

19.7.1.1 Must have a certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State;

19.7.1.2 Must be doubly encapsulated;

19.7.1.3 Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

- 19.7.1.4 Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are used in irradiator pools; and
- 19.7.1.5 In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in RH 19.7.1.5.1 through 19.7.1.5.6.
- 19.7.1.5.1 Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
- 19.7.1.5.2 Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.
- 19.7.1.5.3 Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.
- 19.7.1.5.4 Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.
- 19.7.1.5.5 Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
- 19.7.1.5.6 Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.
- RH 19.8 Access Control.
- 19.8.1 Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.



- 19.8.2 In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and be prepared to promptly render or summon assistance.
- 19.8.3 A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in RH 19.8.2. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.
- 19.8.4 Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
- 19.8.5 Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.
- 19.8.6 Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.
- 19.8.7 Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "CAUTION (OR DANGER) RADIOACTIVE MATERIAL". Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA", but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.
- 19.8.8 If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

19.8.9 Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

RH 19.9 Shielding.

19.9.1 The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 2 millirem (0.02 millisieverts) per hour must be locked, roped off, or posted.

19.9.2 The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisieverts (2 millirem) per hour when the sources are in the fully shielded position.

19.9.3 The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirem) per hour.

RH 19.10 Fire Protection.

19.10.1 The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

19.10.2 The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

RH 19.11 Radiation Monitors.

19.11.1 Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

- 19.11.2 Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.
- RH 19.12 Control of Source Movement.
- 19.12.1 The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be used at any time, and only one operator or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.
- 19.12.2 The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.
- 19.12.3 The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.
- 19.12.4 Each control for a panoramic irradiator must be clearly marked as to its function.
- RH 19.13 Irradiator Pools.
- 19.13.1 For licenses initially issued after January 1, 1997, irradiator pools must either:
- 19.13.1.1 Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
- 19.13.1.2 Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.
- 19.13.2 For licenses initially issued after January 1, 1997, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.
- 19.13.3 A means must be provided to replenish water losses from the pool.

- 19.13.4 A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.
- 19.13.5 Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.
- 19.13.6 A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.
- 19.13.7 If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.
- RH 19.14 Source Rack Protection.
- 19.14.1 If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.
- RH 19.15 Power Failures.
- 19.15.1 If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.
- 19.15.2 The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.
- 19.15.3 During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.
- RH 19.16 Design Requirements.
- 19.16.1 Irradiators whose construction begins after January 1, 1997, must meet the design requirements of this section.
- 19.16.1.1 Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of RH 19.9. If the irradiator will use more than  $2 \times 10^{17}$  becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
- 19.16.1.2 Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.



- 19.16.1.3 Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of RH 19.13.2, and that metal components are metallurgically compatible with other components in the pool.
- 19.16.1.4 Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of RH 19.13.5. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.
- 19.16.1.5 Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by RH 19.11.1. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under RH 19.22.2, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.
- 19.16.1.6 Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.
- 19.16.1.7 Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of RH 19.8.
- 19.16.1.8 Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.



- 19.16.1.9 Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if facility power is lost for more than 10 seconds.
- 19.16.1.10 Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as current national standards or local building codes.
- 19.16.1.11 Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.
- RH 19.17 Construction Monitoring and Acceptance Testing.
- 19.17.1 The requirements of this section must be met for irradiators whose construction begins after January 1, 1997. The requirements must be met prior to loading sources.
- 19.17.1.1 Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
- 19.17.1.2 Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.
- 19.17.1.3 Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of RH 19.13.2.
- 19.17.1.4 Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.
- 19.17.1.5 Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by RH 19.11.1. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet RH 19.22.2. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by RH 19.11.2.

- 19.17.1.6 Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading, and testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in RH 19.14 are met for protection of the source rack and the mechanism that moves the rack. Testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
- 19.17.1.7 Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.
- 19.17.1.8 Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.
- 19.17.1.9 Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.
- 19.17.1.10 Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
- 19.17.1.11 Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

#### Operation of Irradiators

- RH 19.18 Training.
- 19.18.1 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:
- 19.18.1.1 The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

- 19.18.1.2 The requirements of Parts 4, 10 and 19 of these regulations that are relevant to the irradiator;
- 19.18.1.3 The operation of the irradiator;
- 19.18.1.4 Those operating and emergency procedures listed in RH 19.19 that the individual is responsible for performing; and
- 19.18.1.5 Case histories of accidents or problems involving irradiators.
- 19.18.2 Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.
- 19.18.3 Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating procedures that he or she is to perform.
- 19.18.4 The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
  - 19.18.4.1 Changes in operating and emergency procedures since the last review, if any;
  - 19.18.4.2 Changes in regulations and license conditions since the last review, if any;
  - 19.18.4.3 Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
  - 19.18.4.4 Relevant results of inspections of operator safety performance;
  - 19.18.4.5 Relevant results of the facility's inspection and maintenance checks; and
  - 19.18.4.6 A drill to practice an emergency or abnormal event procedure.
- 19.18.5 The licensee shall evaluate the safety performance of each irradiator operator at least annually to assure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

- 19.18.6 Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in RH 19.19 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.
- 19.18.7 Individuals who must be prepared to respond to alarms required by RH 19.8.2, 19.8.9, 19.10.1, 19.11.1, 19.11.2, and 19.22.2 shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.
- RH 19.19 Operating and Emergency Procedures.
- 19.19.1 The licensee shall have and follow written operating procedures for:
- 19.19.1.1 Operation of the irradiator, including entering and leaving the radiation room;
  - 19.19.1.2 Use of personnel dosimeters;
  - 19.19.1.3 Surveying the shielding of panoramic irradiators;
  - 19.19.1.4 Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
  - 19.19.1.5 Leak testing of sources;
  - 19.19.1.6 Inspection and maintenance checks required by RH 19.21;
  - 19.19.1.7 Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
  - 19.19.1.8 Inspection of movable shielding required by RH 19.8.8, if applicable.
- 19.19.2 The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:
- 19.19.2.1 Sources stuck in the unshielded position;
  - 19.19.2.2 Personnel overexposures;
  - 19.19.2.3 A radiation alarm from the product exit portal monitor or pool monitor;
  - 19.19.2.4 Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
  - 19.19.2.5 A low or high water level indicator, an abnormal water loss or leakage from the source storage pool;

- 19.19.2.6 A prolonged loss of electrical power;
- 19.19.2.7 A fire alarm or explosion in the radiation room;
- 19.19.2.8 An alarm indicating unauthorized entry into the radiation room, area around the pool, or another alarmed area;
- 19.19.2.9 Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
- 19.19.2.10 The jamming of automatic conveyor systems.
- 19.19.3 The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:
  - 19.19.3.1 The revisions do not reduce the safety of the facility,
  - 19.19.3.2 The revisions are consistent with the outline or summary of procedures submitted with the license application,
  - 19.19.3.3 The revisions have been reviewed and approved by the radiation safety officer, and
  - 19.19.3.4 The users or operators are instructed and tested on the revised procedures before they are put into use.
- RH 19.20 Personnel Monitoring.
  - 19.20.1 Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool or an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accidental dose ranges (see RH 4.17.3). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLD's must be processed at least quarterly.
  - 19.20.2 Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within  $\pm 30$  percent of the true radiation dose.



RH 19.21     Radiation Surveys.

- 19.21.1     A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.
- 19.21.2     If the radiation levels specified in RH 19.9 are exceeded, the facility must be modified to comply with the requirements in RH 19.9.
- 19.21.3     Portable radiation survey meters must be calibrated at least annually to an accuracy of  $\pm 20$  percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
- 19.21.4     Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Part 4, Appendix B, Table I, "Annual Limits on Intakes (ALI's) and Derived Air Concentrations (DAC's), or Table III, "Release to sewers".
- 19.21.5     Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

RH 19.22     Detection of Leaking Sources.

- 19.22.1     Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the U.S. Nuclear Regulatory Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the U.S. Nuclear Regulatory Commission or an Agreement State to perform the test.

19.22.2 For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. This check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

19.22.3 If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a U.S. Nuclear Regulatory Commission or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a U.S. Nuclear Regulatory Commission or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Part 4, Appendix B, Table III. (See RH 4.52 and 4.53 of these regulations for notification and reporting requirements.)

RH 19.23 Inspection and Maintenance.

19.23.1 The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

19.23.1.1 Operability of each aspect of the access control system required by RH 19.8.

19.23.1.2 Functioning of the source position indicator required by RH 19.12.2.

19.23.1.3 Operability of the radiation monitor for radioactive contamination in pool water required by RH 19.22.2, using a radiation check source, if applicable.

19.23.1.4 Operability of the over-pool radiation monitor at underwater irradiators as required by RH 19.11.2.

- 19.23.1.5 Operability of the product exit monitor required by RH 19.11.1.
- 19.23.1.6 Operability of the emergency source return control required by PH 19.12.3.
- 19.23.1.7 Leak-tightness of systems through which pool water circulates (visual inspection).
- 19.23.1.8 Operability of the heat and smoke detectors and extinguisher system required by RH 19.10 (but without turning extinguishers on).
- 19.23.1.9 Operability of the means of pool water replenishment required by RH 19.13.3.
- 19.23.1.10 Operability of the indicators of high and low pool water levels required by RH 19.13.4.
- 19.23.1.11 Operability of the intrusion alarm required by RH 19.8.9, if applicable.
- 19.23.1.12 Functioning and wear of the system, mechanisms and cables used to raise and lower sources.
- 19.23.1.13 Condition of the barrier to prevent products from hitting the sources or source mechanism as required by RH 19.14.
- 19.23.1.14 Amount of water added to the pool to determine if the pool is leaking.
- 19.23.1.15 Electrical wiring on required safety systems for radiation damage.
- 19.23.1.16 Pool water conductivity measurements and analysis as required by RH 19.24.2.
- 19.23.2 Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.
- RH 19.24 Pool Water Purity.
- 19.24.1 Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.
- 19.24.2 The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

- RH 19.25     Attendance During Operations.
- 19.25.1     Both an irradiator operator and at least one individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:
- 19.25.1.1     Whenever the irradiator is operated using an automatic product conveyor system; and
- 19.25.1.2     Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- 19.25.2     At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in RH 19.18.7 must be onsite.
- 19.25.3     At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in RH 19.18.6 and 19.18.7. Static irradiations may be performed without a person present at the facility.
- RH 19.26     Entering and Leaving the Irradiation Room.
- 19.26.1     Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.
- 19.26.2     Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:
- 19.26.2.1     Visually inspect the entire radiation room to verify that no one else is in it; and
- 19.26.2.2     Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.
- 19.26.3     During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by RH 19.11.2 is operating with backup power.

RH 19.27     Irradiation of Explosive or Flammable Materials.

- 19.27.1     Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.
- 19.27.2     Irradiation of more than small quantities of flammable material (flash point below 140°C) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to the sealed sources or safety systems and without radiation overexposures of personnel.

Records

RH 19.28     Records and Retention Periods.

- 19.28.1     The licensee shall maintain the following records at the irradiator for the periods specified:
- 19.28.1.1     A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.
- 19.28.1.2     Records of each individual's training, tests, and safety reviews provided to meet the requirements of RH 19.18.1, 19.18.2, 19.18.3, 19.18.4, 19.18.6, and 19.18.7 until 3 years after the individual terminates work.
- 19.28.1.3     Records of the annual evaluations of the safety performance of irradiator operators required by RH 19.18.5 for 3 years after the evaluation.
- 19.28.1.4     A copy of the current operating and emergency procedures required by RH 19.19 until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by RH 19.19.3.3 retained for 3 years from the date of the change.
- 19.28.1.5     Film badge and TLD results required by RH 19.20 in accordance with RH 4.46 of these regulations.
- 19.28.1.6     Records of radiation surveys required by RH 19.21 for 3 years from the date of the survey.
- 19.28.1.7     Records of radiation survey meter calibrations required by RH 19.21.3 and pool water conductivity meter calibrations required by RH 19.24.2 until 3 years from the date of calibration.



- 19.28.1.8 Records of the results of leak tests required by RH 19.22.1 and the results of contamination checks required by RH 19.22.2 for 3 years from the date of each test.
- 19.28.1.9 Records of inspection and maintenance checks required by RH 19.23 for 3 years.
- 19.28.1.10 Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.
- 19.28.1.11 Records of the receipt, transfer, and disposal of all licensed sealed sources as required by RH 3.22 and RH 4.48 of these regulations.
- 19.28.1.12 Records on the design checks required by RH 19.16 and the construction control checks as required by RH 19.17 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.
- 19.28.1.13 Records related to decommissioning of the irradiator as required by RH 3.16.6.8 of these regulations.
- RH 19.29 - Reports.
- 19.29.1 In addition to the reporting requirements in other parts of the regulations, the licensee shall report the following events:
- 19.29.1.1 Source stuck in an unshielded position.
- 19.29.1.2 Any fire or explosion in a radiation room.
- 19.29.1.3 Damage to the source racks.
- 19.29.1.4 Failure of the cable or drive mechanism used to move the source racks.
- 19.29.1.5 Inoperability of the access control system.
- 19.29.1.6 Detection of radiation source by the product exit monitor.
- 19.29.1.7 Detection of radioactive contamination attributable to licensed radioactive material.
- 19.29.1.8 Structural damage to the pool liner or walls.
- 19.29.1.9 Abnormal water loss or leakage from the source storage pool.
- 19.29.1.10 Pool water conductivity exceeding 100 microsiemens per centimeter.

19.29.2 The report must include a telephone report within 24 hours as described in RH 4.52.2, and a written report within 30 days as described in RH 4.53.1.2 of these regulations.

The effective date of Part 19 is July 1, 1997.