NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Corrected Copy

MATERIALS LICENSE

Amendment No. 02

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Tri-Med Specialties, Inc.	In accordance with letter dated May 1, 1997 3. License number 45-25215-01 is amended in its entirety to read as follows:
2. 1500 Avon Street Extended Charlottesville, Virginia 22901	4. Expiration date **December 31, 2002 (Extended)**
	5. Docket or Reference No 030-32884

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Carbon 14	A. Any	A. 3.7 gigabecquerels (100 millicuries)

9. Authorized Use:

A. For possession and use in:

i. research and development as defined in 10 CFR 30.4;
ii. for the production and analysis of carbon-14 urea diagnostic products;
iii. the production, labeling, and packaging of liquid scintillation counting standards; and,
iv. the handling and analysis of breath samples.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1500 Avon Street Extended, Charlottesville, Virginia, and at 713 B Harris Street, Charlottesville, Virginia.

11. The Radiation Safety Officer for this license is James R. Gilchrist.

12. Licensed material shall be used by, or under the supervision of, Barry J. Marshall, Matthew Combs, or James Gilchrist.

13. This license does not authorize distribution to persons licensed pursuant to 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, or 10 CFR 35.600.

0/1 ML20

NRC FORM 374A (7-94) U.S. NUCLEAR REGULATORY COMMISSION

License Number 45-25215-01

Docket or Refe. 030-32884

Amendment No. 02

MATERIALS LICENSE
SUPPLEMENTARY SHEET
Corrected Copy

(continued) CONDITIONS

14. The licensee shall maintain records of information related to decommissioning at the location in Condition 10, as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A.	Application dated July 28, 1992	
B.	Letter dated November 17, 1992	[Additional information]
C.	Letter dated December 9, 1996	[Addition of C-14 as scintillation counting standard]
D.	Letter dated December 18, 1996	[Facsimile regarding reducing possession limit for C-14 urea and possession limit for C-14 toluene; and Extension of expiration date in accordance with 10 CFR 30.36]
E.	Letter dated December 19, 1996	[Facsimile regarding the labeling of the vials]
F.	**NRC letter dated March 1, 1996**	**[extends expiration date in accordance with 10 CFR 30.36]**
G.	Letter dated May 1, 1997	[Change in authorized form, addition of new authorized place of use, revision of radiation safety training program, and revision of radioactive waste disposal program]
H.	Letter dated May 20, 1997	[additional information]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

for JOHN M. PELCHAT

Date JUN 03 1997

By Earl G. Wright

Region II, Division of Nuclear Materials Safety
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30323

6/6/97

N:\MLICENSE\45-25215.c02

MATERIALS LICENSE

Amendment No. 02

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Tri-Med Specialties, Inc.	In accordance with letter dated May 1, 1997 3. License Number 45-25215-01 is amended in its entirety to read as follows:
2. 1500 Avon Street Extended Charlottesville, Virginia 22901	4. Expiration Date December 31, 2002 (Extended)
	5. Docket or Reference No. 030-32884

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Carbon 14	**A. Any**	**A. 3.7 gigabecquerels (100 millicuries)**

9. Authorized Use:

A. For possession and use in:

i. research and development as defined in 10 CFR 30.4;
ii. for the prototype production and analysis of carbon-14 urea diagnostic products;
iii. the production, labeling, and packaging of liquid scintillation counting standards; and,
iv. the handling and analysis of breath samples.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1500 Avon Street Extended, Charlottesville, Virginia, and at 713 B Harris Street, Charlottesville, Virginia.

11. The Radiation Safety Officer for this license is James R. Gilchrist.

12. Licensed material shall be used by, or under the supervision of, Barry J. Marshall, Matthew Combs, or James Gilchrist.

13. This license does not authorize distribution to persons licensed pursuant to 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, or 10 CFR 35.600.

License Number 45-25215-01

Docket or Reference Number 030-32884

Amendment No. 02

MATERIALS LICENSE
SUPPLEMENTARY SHEET

(continued) CONDITIONS

14. The licensee shall maintain records of information related to decommissioning at the location in Condition 10, as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

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A.	Application dated July 28, 1992	
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E.	Letter dated December 19, 1996	[Facsimile regarding the labeling of the vials]
F.	**Letter dated May 1, 1997**	**[Change in authorized form, addition of new authorized place of use, revision of radiation safety training program, and revision of radioactive waste disposal program]**
G.	Letter dated May 20, 1997	[additional information]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

JOHN M. PELCHAT

Date MAY 23 1997

By _____

Region II, Division of Nuclear Materials Safety
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30323

N:\MLICENSE\45-25215.A02

5/27/97

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
ATLANTA FEDERAL CENTER
61 FORSYTH STREET, SW, SUITE 23T85
ATLANTA, GEORGIA 30303

INFORMATION FOR NRC MATERIAL LICENSEES

MAY 23 1997

Please find enclosed:
____ Your NRC material license
____ Amendment to your NRC material license
____ Amendment renewing your NRC material license
____ Amendment terminating your NRC material license
____ Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 562-4723) so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR 19, "Notice, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:

   a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and

   b. you have notified the U. S. Nuclear Regulatory Commission, Region II, ATTN: Materials Licensing\Inspection Branch, in writing, that activities authorized by the license will be initiated.

   c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering >30 uCi of I-125 or I-131.

3. Notify NRC, in writing, within 30 days:

   a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change; or

   b. when the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. when you decide to terminate all activities involving materials authorized under the license; or

   b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

(Rev. 4/97)

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

May 20, 1997

John Pelchat
Region II, Division of Nuclear Materials Safety
US Nuclear Regulatory Commission
61 Forsyth St.
Suite 23 T-85
Atlanta, GA 30303

Re: Amendment of licenses 45-25215-01 and 45-25215-02MD

Dear Mr. Pelchat,
I am writing to respond to your questions of 5-19-97

1. Regarding Page 3, Table 3, please delete our request to add distribution under 35.300.
2. I am including a copy of our Radiation Safety Training Program. This program is administered by our Radiation Safety Officer. This Training Program takes approximately 3-4 hours to complete. The test is on the last page of the Manual.
3. Waste Management. I spoke with Dr. Matt Combs regarding this question. He stated that if you look at our original applicatic. , it states that we do not produce any wa te. He wanted to clarify the point that we do produce waste, and that we will follow the appropriate regulations to discard this waste.

If you have any additional questions please give me a call.

Sincerely,

Susie Hoffman

Susie R. Hoffman RN BSN

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20021231
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION ~~II~~

1. APPLICATION ATTACHED
   Applicant/Licensee: TRI-MED SPECIALTIES, INC.
   Received Date: 970505
   Docket No: 3032884
   Control No.: 257481
   License No.: 45-25215-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 1130.00
   Check No.: 2647

3. COMMENTS
   2 CONTROLS (257482)

Signed DIANE HEIM
Date 5/5/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /✓/)

1. Fee Category and Amount: 3M $610

2. Correct Fee Paid / Application may be processed for:
   Amendment ✓
   Renewal _____
   License _____

3. OTHER _____

Signed Rita Messier
Date 5/19/97

Log May 2 II
Remitter
Check No 2647
Amount $1130 ($610 applied)
Fee Category 3M
Type of Fee Amd
Date Check Rec'd. 5/19/97
Date Completed 5/19/97
By: Ken

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

May 1, 1997
Earl G. Wright

Region II, Division of Nuclear Materials Safety
US Nuclear Regulatory Commission
61 Forsyth St.
Suite 23 T-85
Atlanta, GA 30303
re: Amendment of licenses 45-25215-01 and 45-25215-02MD

Dear Mr. Wright:

This is a request for amendment of materials possession and use license 45-25215-01 and distribution license 45-25215-02MD. Each of these changes will be described in subsequent sections. Attached is the appropriate license amendment fee. I contacted Rita Messier who instructed me to send a check with this application.

1. **Addresses where licensed material will be used:**

   A) 1500 Avon St. Extd.
   Charlottesville, VA 22902

   B) 713B Harris St.
   Charlottesville, VA 22903

Facility A) is described in our previous license submissions. A sketch of facility B) on Harris St. is shown in Appendix A. The new facility is a 2400 square foot facility zoned for light industrial uses. The facility will be used for two purposes regarding Byproduct Material. The first use is to count breath samples from the ^{14}C-urea diagnostic product we manufacture. The activity associated with those samples is minimal (<100 uCi). The second use of the facility will be for storage and distribution of finished drug product (^{14}C-urea capsules) and the scintillation counting reference standards currently described in our licenses. The material will be appropriately secured since the building will remain locked at all times in addition to our interior security systems.
Liquid scintillation counters which are calibrated each day of use will be used at facility B). If needed, the GM probe from facility A) can be brought to facility B), although this is unlikely since minute amounts of ^{14}C will be open at facility B).

2. **Inclusion of other chemical forms for research and development**:

We wish to update sections 6-9 of our license with the following information shown in Table 1.

Table 1. Preferred data for sections 6-9 of license 45-25215-01.

Item	Radionuclide	Chemical and/or physical form	Maximum amount in possession
A	^{14}C	Any	100 mCi

This format would give us the maximum flexibility in possessing and using ^{14}C for our puroses. It would eliminate the need to amend our license for development of future diagnostics, and the need for sub-inventory of our radiaoctive material. We currently have to break our posession limit into an amount for each form. This scenario would allow us to keep track of only the total amount of ^{14}C at our facilities.

Although the above scenario is preferred an alternative (shown in Table 2) is provided in the event our preferred scenario is not possible:

Table 2. Alternate wording for sections 6-9 of license 45-25215-01.

Item	Radionuclide	Chemical and/or physical form	Maximum amount in posession
A	^{14}C	Urea	90 mCi
B	^{14}C	Toluene	0.1 mCi
C	^{14}C	Carbon Dioxide	0.1 mCi
D	^{14}C	Any	9.8 mCi
		Total	100 mCi
	Authorized Uses: A. Production, analysis and quality control of ^{14}C-urea diagnostic product. B. Possession and use of ^{14}C-toluene for the production, labeling and packaging of liquid scintillation counting standards. C. Trapping and analysis of $^{14}CO_2$ from breath samples D. Research and development of ^{14}C-labeled diagnostic products		

The updated wording of item A will allow a more accurate description of the use of the ^{14}C-urea as we anticipate approval of our New Drug Application very soon which will shift the manufacture of the diagnostic from the realm of prototype to simply manufacturing the product. The addition of item C will account for the small amounts of $^{14}CO_2$ used in analysis of breath samples that are anticipated. The addition of item D will provide us with some flexibility in developing other ^{14}C-labeled diagnostic tests.

At this time we cannot predict exactly what ^{14}C-labeled compounds we will be using, so we would like to have some flexibility in our license to develop them without having to make a license amendment each time we wish to try another radiochemical. We could perform our research and development using exempt quantity materials, but that would not allow us to transfer the material to another licensee for further evaluation. Therefore, we must add the

radiochemicals we want to use to our license and then if the development works well, send small amounts to other licensees (via transfer of material) for further evaluation.

Finally, if the next phase of evaluation is successful, we would need to amend our distribution license for distribution of the radiopharmaceutical for use in large-scale clinical trials as we have done with the ^{14}C-urea product. This raises the question "Would it be possible to have a general item in our distribution license so that we would not need to update it for clinical trials of radiopharmaceuticals we have not developed as of yet?" If items, 6,7,8 were collapsed and item 7 stated "Any" as the chemical form as shown in Table 3, then there would be no need for additional amendments to our license because we will be authorized to distribute material under 10CFR part 35 which mentions that we will need an IND or NDA for the material we wish to distribute (except the scintillation standards, of course).

Table 3. Proposed information for items 6-9 for license 45-25215-02MD.

Item	Radionuclide	Chemical and/or physical form	Maximum amount in possession
A	^{14}C	Any	Not Applicable
	Authorized Uses: A. Pursuant to section 32.72, 10CFR part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.11 and Section 35.100, *35.200, 35.300* 10CFR Part 35, or under equivalent licenses of Agreement States.		

That would provide us with flexibility from the NRC but we would have to have authorization from FDA to distribute the material. The addition of distribution to licensees under 35.200 and 35.300 would prevent licensees who have the other license capabilities from amending their license. Those licensed under 35.200 and 35.300 certainly have sufficient training and experience to perform our simple test and in the event they do not have 35.100 licensing this would allow them to use our product.

3) **Review of other aspects of license**
This section outlines other, primarily administrative updates to the documentation submitted with our license application. This review covers radiation safety training and waste management issues.

Update of the radiation safety training program. At this time we wish to update the radiation safety training of our possession and use license. The radiation safety training is performed by qualified individuals (or equivalently qualified individuals) listed in our original application. In conjunction with several radiation safety consultants, Tri-Med has developed a radiation safety course tailored for the safe handling of ^{14}C. The training program has been approved by the Tri-Med radiation safety committee and is outlined below.

New Employees

Orientation
Read and view radiation and chemical safety training materials
Take and pass written exam
Discuss deficiencies in exam and answer any further questions
(At this time worker can begin working with radioactive materials)
Worker will take next available radiation safety training course at the University of Virginia
Must pass written exam

Retraining (all employees) - annually

Read and view training materials, discuss changes/concerns with supervisors
Attend annual chemical and radiation safety retraining course at the University of Virginia

In addition, license and procedural changes are discussed at weekly staff meetings to ensure workers are aware of changes in licenses and other regulations. Time is given for concerns regarding the safe use of radioactive materials to be discussed and ideas presented. The format of our training program is fixed, although from time to time administrative changes are performed to update and improve the exact content of the program. The training is documented and the procedures and manuals are available to workers at all times.

Waste Management Update/Clarification: Wastes will be released and disposed of in accordance with 10 CFR part 20. Very little waste is generated since our process is very efficient and the vast majority of the material is distributed as finished drug product. Most wastes are liquid aqueous wastes which can be released via sanitary sewer in accordance with 10CFR 20.2003 or are scintillation media which can be disposed of in accordance with 10CFR 20.2005. Other solid and liquid wastes will be disposed at an NRC-licensed disposal facility.

Should you have any questions or comments concerning this application, or need further clarification, please call me at your earliest convenience (804-977-8711) or email me at mcombs@trimed.com. We wish to get the changes made expeditiously, so if any clarification by us would make the process go smoother, we will certainly do our best to help.

Sincerely,

Matthew J. Combs, Ph.D.
Scientific Coordinator of ^{14}C projects
Tri-Med Specialties, Inc.

APPENDIX A. Sketch of Facility B, 713B Harris St.

Radiation Safety Training Handbook

A Radiation Safety Training Handbook for the Handling and Use

of

Radioactive Materials used at Tri-Med Specialties, Inc.

Tri-Med Specialties, Inc.

Revised February 1997

1 INTRODUCTION

1.1 Personnel

The purpose of this handbook is to instruct personnel in the safe and legal use of radioactive materials used at Tri-Med Specialties, Inc. Tri-Med is currently licensed to possess and use only carbon-14 (C-14, ^{14}C), typically in very low levels. Tri-Med also has small amounts of other radionuclides such as tritium (^{3}H) and cesium-137 (^{137}Cs). These radionuclides are in quantities that are exempt from licensing and are used for QC checks and research, but are mentioned for completeness. The radioactive material (RAM) uses fall in the following categories:

1. Breath sample handling and analysis
2. Shipping of PYtest capsules
3. Production of PYtest capsules
4. Laboratory testing

1.2 The C-14 breath test (PYtest)

Carbon-14 labeled urea is used at the Tri-Med facility to produce PYtest capsules for ^{14}C urea breath test. The purpose of the breath test is to detect the presence or absence of the H.pylori bacteria in the stomach. It is this bacteria that is believed to be a major cause of symptoms in patients which exhibit ulcer-like symptoms. To detect the presence of this bacteria, a capsule containing urea is administered to the patient. The urea is identical to normal urea except that some of the urea molecules are "labeled" with carbon-14. The body cannot distinguish between non-radioactive and radioactive urea. Following ingestion of the radiolabeled urea, the patient breathes into a balloon to collect a breath sample. This expired breath may or may not contain C-14, depending on whether the patient's stomach contains the *H. pylori* bacteria. Other Tri-Med documents describe the breath test in greater detail.

1.3 Purpose of this training manual

The purpose of this handbook is to provide instruction on the safe and legal handling of ^{14}C. It also includes procedures thatshould be implemented in the event that unexpected circumstances arise.

The use of ^{14}C as well as other radioactive materials, is regulated by either the U.S. Nuclear Regulatory Commission (NRC) or the state in which the material is used, if that state has entered into an agreement with the NRC to regulate radioactive material use. Regardless of the regulatory authority, users of radioactive material must receive appropriate training and licensure for such use by the NRC, state, and/or the institution under which the use of radioactive material is authorized.

Instructions contained in this handbook contain only limited information regarding ^{14}C. Consult texts (see bibliography) for a more comprehensive discussion of ^{14}C.

1.4 What this handbook is not:

This is not a comprehensive handbook on radiological physics, radiation protection, and regulations. Is also not a handbook covering the use of sources of radioactive materials other than those approved for use at Tri-Med Specialties, Inc.

2. RADIATION PHYSICS

2.1 Sources of Radiation

Exposure to radiation is a part of our daily lives. We are exposed to radiation from space (cosmic radiation), medical exposure (such as medical x-rays), and radiation that comes from materials present in nature, (such as radon from the soil and the naturally radioactive fractions of other elements such as potassium).

The most well known types of ionizing radiation are alpha particles, beta particles , x-rays and gamma rays. With the exception of x-rays, which are usually associated with production by equipment, the other sources of radiation result from the decay (nuclear transformation) of radioactive (unstable) atoms to more stable nuclear states.

Alpha particles consist of two neutrons and two protons This is the same composition of a helium nucleus. They are very large compared to the other radiation types. Due to their large size they do not have much range (penetration distance), but do relatively large damage when they interact with certain types of tissue inside the body. Their range is generally less than 3 inches in air and they can not penetrate the outer layer of a persons skin. Generally alpha particles are a personal risk if ingested or inhaled. C-14 does not emit alpha particles.

Gamma radiation is electromagnetic in nature (similar to light). Gamma rays can penetrate the human body without interacting and do less biological damage per unit emission than either alpha or beta.. A gamma ray emitted from a radioactive material acts exactly like an x-ray produced by a machine. For analogy, if the energy of a gamma ray is similar to that produced by an x-ray machine, most of the radiation would penetrate the body without interacting in the body. This energy will darken an x-ray film except where it hits dense material such as bone. The x-rays that are stopped result in an unexposed area on the film. This shows up as the white area on the x-ray film. Neither gamma radiation nor x-rays are emitted by C-14.

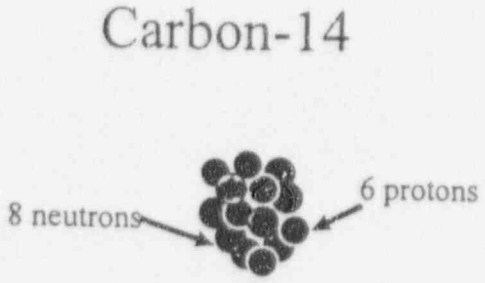
Beta particles are much smaller than alpha particles and are physically the same as electrons. The difference is that a beta particle originates from the nucleus of a radioactive material. Beta particles are charged particles (electrons) and are stopped by a fairly thin amount of material. They have a relatively low penetrating power which is proportional to their energy. In general, less than an inch of dense plastic will stop the higher energy beta particles and even these are only able to penetrate the outer millimeter of body tissue. C-14 emits a low energy beta particle when it decays to stable nitrogen. These beta particles can be stopped by a millimeter thick piece of plastic. Therefore C-14 does not present any external risk to the user unless it gets in one's eye. It presents only a risk if substantial amounts are ingested.

2.2 Carbon 14

The emphasis in this handbook will be on the decay and subsequent beta particle emission of C-14, and the risks associated with its use.

C-14 is a form of radioactive carbon. It is present in nature as a result of cosmic ray interactions in the atmosphere and from nuclear weapons testing and use. Most C-14 that is used for medical purposes is produced in nuclear reactors designed for its production. A diagram of the carbon-14 nucleus is shown in Figure 1.

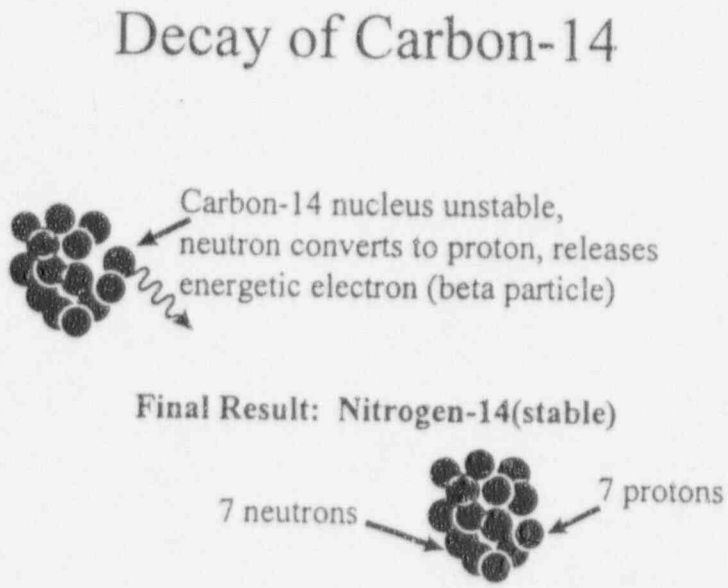
Figure 1. Carbon-14 nucleus



Carbon-14
aka ^{14}C, C-14

The carbon-14 nucleus is unstable and seeks to become stable, or reach a "ground" energy state from its current "excited" energy state. When the ^{14}C nucleus transmutates or decays to its ground state, it does so by beta particle emission to a stable atom of nitrogen as shown in Figure 2.

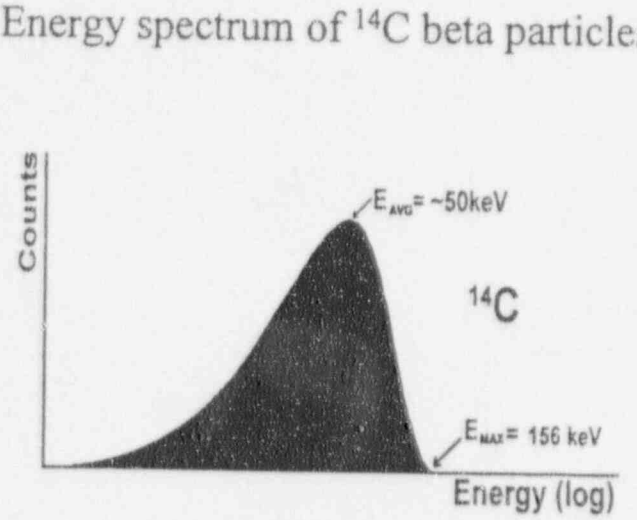
Figure 2. Carbon-14 decay scheme.



In the beta decay, a neutron is converted into a proton. In doing so, it must release energy (conservation of energy), and it releases that energy in the form of a beta-particle. A beta-particle is an electron with kinetic energy. The emission of a beta particle also conserves the net charge on the nucleus since an uncharged neutron is converted into a positively charged proton, so to make the net charge zero, the beta-particle has a negative charge equaling that of the positively charged proton.

The energy associated with the beta particle varies from ^{14}C nucleus to ^{14}C nucleus, ranging from 0 electron-volts to a maximum of 156 kiloelectron-volts (keV) as shown in Figure 3.

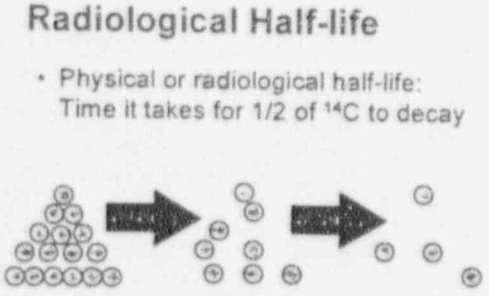
Figure 3. C-14 Energy spectrum



The mean energy of the beta particles for ^{14}C is about 50 keV.

The rate at which radioactive materials transform or decay varies from radionuclide to radionuclide. The time in which a group of radioactive atoms decay to half of their original number is known as the half-life. In other words, the number of radioactive atoms of a particular material will decay to half of that level after one half-life as shown in . Figure 4.

Figure 4: Radiological half-life



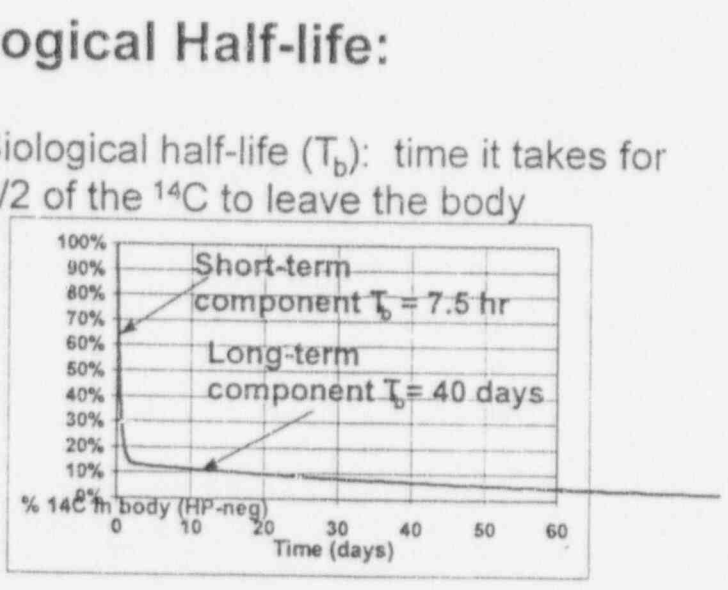
Therefore after two half lives, one quarter of the radioactive atoms will remain and so on. The physical half-life of C-14 is 5730 years and the energy of the beta particle emitted from a C-14 nucleus is 156 kilo electron-volts.

Radioactive material is measured in terms of the Curie. A Curie of radioactive material undergoes 2.22 trillion nuclear transformations per minute. The SI measure of radioactivity is the Becquerel. One Becquerel is equal to one transformation per second. The capsule used in the breath test contains about one microCurie (one millionth of a Curie) and thus emits about 2,220,000 beta particles per minute (37,000Bq)

2.3 Biological and Physical half-life

Radioactivity disappears from the body in two ways, one by elimination, biological loss and the other by radiological decay. Concern with ^{14}C usually arises because of its long half-life. However, the primary radioactive compound used at Tri-Med, C-14 urea, is rapidly lost from the body in the expired breath, and excreted in the urine. The rate at which ingested material is eliminated form the body is expressed by the term biological half-life, which is the time in which ½ of the ingested material exits the body. The biological half-life for ^{14}C-urea (based on experimental data) is described in Figure 5 .

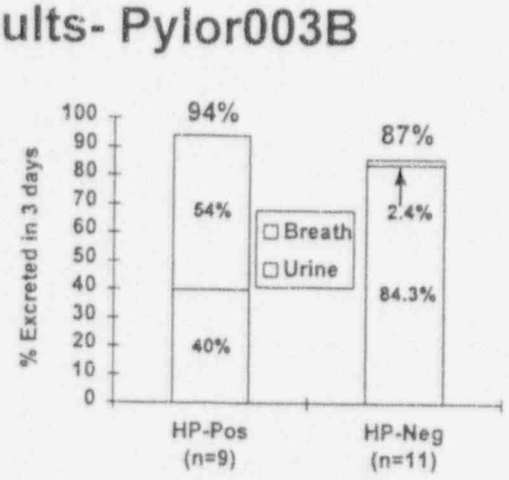
Figure 5. Biological Half-life.



Note that for ^{14}C-urea the biological half-lives are MUCH shorter than the long radiological half-life. The biological half-life is important in determining the radiation dose (a term defined later) that the patient or worked receives when given or working with the radioactive material. In a

study sponsored by Tri-Med (Pylor 003) the distribution of the excretion of C-14 during the first 72 hours after administration of a 1 μCi ^{14}C-urea capsule (PYtest) was demonstrated as shown in Figure 6.

Figure 6 :Distribution of 72-hour ^{14}C excretion between breath and urinary pathways for *HP*-positive and *HP*-negative volunteers.



An interesting finding was that excretion was nearly the same regardless of Helicobacter pylori (*H.pylori* , HP) status: i.e., HP-positive subjects excreted more isotope in breath and less in urine than HP- negative subjects who excreted isotope mostly in the urine. Either way, subjects excreted approximately the same total amount of C-14..
In the study, the biological half-times were 7.46 and 9.16 hours for *HP*-negative and *HP*-positive volunteers, respectively.
The first 90% of the material came out within 72 hours, but what about the remaining 10%? The long-term retention of ingested carbon (C-12 or C-14) is estimated to have a half-life of 40 days as recommended by a body of experts (ICRP). Assuming a 40-day half-life as recommended by the ICRP and used in our dose estimates, after 12.7 months (9.6 half-lives), we would expect to find a tiny 1.4×10^{-4} (0.014%) of the 0.1 μCi sent to the long-term component to be in the body.

2.4 Detection Instrumentation

There are many types of instrumentation used to detect ionizing radiation. All involve the interaction of the radiation with the detector. The interactions result in the release of energy which is converted to electricity or light which can be measured. The amount of light and/or electricity produced by the radiation is proportional to the amount of radiation present.

Detection Efficiency

Radiation is measured in units of activity, or their derivatives. For beta particles, the units used by detection equipment are disintegrations per minute (DPM) or counts per minute (CPM). The detection system will usually yield a number of CPM. This is the number of radiation events recorded by the instrument in one minute. This is not necessarily the number of events (decays) that actually occurred, but the number of events the instrument detected. Some detectors are more efficient at detecting a given amount of radiation than others. By knowing the efficiency of the detection system, or the number of events detected by the instrument compared to the number that actually occurred, one can then convert CPM to DPM. To determine the efficiency of the detection system, a known amount of radioactivity (in DPM) is placed in front of the detector and the detector response is measured (in CPM). The ratio of CPM to DPM is then calculated and that ratio is the efficiency for that detector and that type of radiation. Standardized reference sources are available to perform this type of an efficiency check.

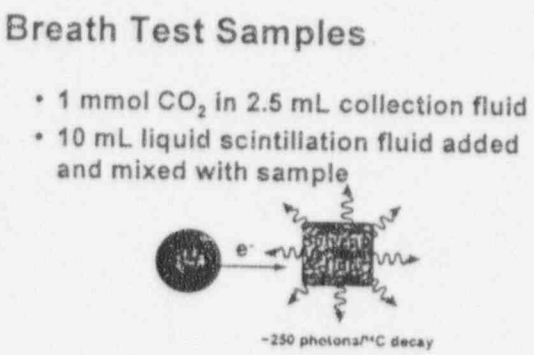
C-14 is usually detected by either of two systems of detection. These are the Geiger-Mueller (GM) detection system or the liquid scintillation spectrometer.

The ionization chamber or GM system consists of a detector which has a very thin cover usually made of mylar, and inside the counting chamber is a gas and high voltage. The radiation enters the chamber and interacts with the gas, causing a shower of electrons with are detected as an electrical pulse. The number of pulses are counted and are proportional to the amount of radioactivity in the sample. The electronics package converts the detected radiation into a readable output. This output is usually seen by the deflection on a needle on the detector. A scale on the detector is used to record the counts per minute (CPM) that are detected. To convert this CPM measurement to a disintegration per minute or amount of radioactivity the efficiency of the detector must be determined. The efficiency of the GM-probe for ^{14}C is very low, less than one percent and therefore it is not very useful for detecting very low levels of C-14 radioactivity. Ionization and proportional flow detectors are based on the same principal as the Geiger counter, but use different gases and voltages. The net result is the same, radiation interacting with a gas that gives an electrical pulse and the pulses are counted and then converted to some display device. Typical counting efficiencies for GM and ionization chambers are less than 10% for ^{14}C, with less than one percent being very common.

The other system to detect C-14 is the liquid scintillation counter (LSC). This method involves collecting the C-14 on a medium such as a filter paper wipe or the liquid converted from the breath expired during a C-14 breath test. The sample is then placed into a vial with scintillation fluid. The beta particles emitted by the C-14 are in immediate contact with the scintillation fluid.

The radioactivity then interacts with the fluorescent compounds in the scintillation fluid (cocktail) and produce light as shown in Figure 7.

Figure 7:Interaction of C-14 with LSF



This light is then measured with light sensors called photomultiplier tubes which convert the light to electrical pulses which are counted. The number of counts collected in a given period of time is proportional to the amount of radioactivity in the vial. By putting a known amount of C-14 into a vial or using a standardized vial containing a known amount of C-14, an efficiency can be obtained by counting the vial and finding the resulting conversion from counts detected per DPM or microCurie in the standard. Typical ^{14}C efficiencies using liquid scintillation counting are greater than 50%, with most samples being greater than 80% efficient. Liquid scintillation counting is the primary method for detection of ^{14}C.

For additional information on liquid scintillation counting refer to Appendix A.

3.0 BIOLOGICAL EFFECTS (DOSIMETRY) OF RADIATION

3.1 General Information

Radiation is capable of causing damage to tissue. The extent of the damage is related to the type of radiation, the energy of the radiation, the amount of radiation present and the dose rate. Radiation interacts with cells and causes ionization and excitation of cells. This in turn creates chemical changes within the cell which may cause mutations and result in the formation of cancerous tumors, leukemia, and a wide variety of cancers.

3.2 Hazards of C-14

The fact that C-14 emits only low energy beta particles makes the hazard of handling the ^{14}C extremely low. The only risk of using C-14 is when it comes in direct contact with sensitive tissues for long periods of time and when significant amounts of C-14 are involved. It is, therefore, not an external risk in the manner it is used at Tri-Med.

The only risk of using C-14 is internal, with the exception of getting it in your eyes. Internally, the damage caused by C-14 is based on the amount ingested, the site of deposition (if any) and the time during which it remains in the body. As described previously, the biological half-life for ^{14}C-urea (the primary radiopharmaceutical used at Tri-Med) is very low, reducing the risk to workers. The amounts used in production of the PYtest™ ^{14}C-urea breath test are not trivial, however, they are not unusually high. Safety measures such as using fume hoods and gloves are employed to ensure that employee exposures are kept to a minimum. Except in the case of accidents, the radiation received from working at Tri-Med should be no different from that received from background radiation.

3.4 Measurement of Radiation Dosimetry

Radiation dose is measured in rads. This is a measure of the amount of energy deposited in the body or organ per unit of mass. Modifying factors based on the type of radiation involved are applied to derive the dose equivalent which is measured in the unit of rems, or more often in millirems (mrem, 1/1000 of a rem).

The U.S. Nuclear Regulatory Commission has set the occupational dose equivalent limit of radiation to adult workers involved with the use of radioactive material at 5,000 mrem per year. The limit for pregnant workers and minors is 10% of this occupational limit, or 500 mrem/yr. See **Appendix B** for additional information on risks from occupational radiation exposure. The annual dose equivalent limit to the general population from regulated uses of radioactive material has been set at 100 mrem. This is in addition to background and medical exposures.

For comparative reasons only, meeting the 5,000 mrem limit would require ingestion of 13,000 µCi ^{14}C-urea in a year. This should be compared to the activity of the PYtest which contains only about 1 microCurie each. It is anticipated that workers will ingest no ^{14}C while working at Tri-Med Specialties.

The radiation dose estimates for the PYtest have been calculated based on the experimental data described previously. The maximum organ doses are to the stomach, with 1.4 mrad per test for *HP*-negatives and 0.82 mrad for *HP*-positives. The effective dose equivalent was calculated as 0.38 mrem for *HP*-negatives and 0.18 for *HP*-positives. A summary of the dosimetry parameters and radiation dose estimates for the PYtest are shown in Table 1. Note that the dose estimates are the total estimates for the entire life of the person ingesting the ^{14}C-urea.

Table 1: Comparison of Dosimetry Parameters for C-14-urea Breath Test

Parameter	HP-	HP+
f_u	84.2%	39.9%
f_B	2.4%[2]	54.3%[2]
T_B	7.46 h	9.16 h
T_{UBC}	2.21 h	1.03 h
T_{RB}	195 h	87.7 h
T_{Lung}	2.86 h	1.29 h
T_{Stom}	2.37 h	1.17 h
D_{Stom} (mrad/μCi)	1.4	0.82
D_{UBW} (mrad/μCi)	0.70	0.32
D_{Lung} (mrad/μCi)	0.30	0.14
D_{other} (mrad/μCi)	0.29	0.13
EDE (mrem/μCi)	0.38	0.18

f_U = simulated percentage of activity excreted in the urine
f_B = measured percentage of activity excreted in the breath
T_B = Biological removal half-time (hours) for activity excreted in urine
EDE = Effective Dose Equivalent
2) Measured values
3) That report assumed all activity not excreted in urine was excreted in breath.

3.3 Dose Equivalent

To allow radiation sources to be compared, the dose arising from differing types of radiation, alpha, beta , gamma are expressed in "*dose equivalence units*",DE. The DE for ^{14}C takes into account the energy of the radiation and the radiosensitivity of the organ or tissue
The dose equivalent received from natural background radiation depends on where you live, but it is usually is between 100 and 300 millirem per year. Exposures from other sources such as medical x-rays add dosage to the general population and the occupationally exposed population.

The radiation dose equivalent received by the patient undergoing the C-14 breath test varies depending on whether the patient tests positive or negative for H.pylori. In the positive patient, C-14 urea is converted to CO_2 and some is exhaled and the remainder metabolized and excreted. In the negative patient the C-14 urea is simply metabolized. In either case the dose equivalent to the patient does not exceed 1 mrem. This is negligible compared to radiation to which

individuals are normally exposed. The dose equivalent received by a person handling capsules under normal conditions is zero. Potential exposures to the person administering or handling the test capsules under abnormal conditions would not exceed that received by the patient.

Comparison of Effective Dose equivalence (EDEs)

The EDE for HP-positives is 0.18 mrem and for *HP*-negatives is 0.38. A comparison of doses from other diagnostic procedures involving radiopharmaceuticals was provided by RIDIC. The comparison is reproduced in Table 2.

Table 2 : Comparison of Effective dose Equivalents of Common FDA-Approved Radiopharmaceuticals with PYtest.

Procedure	Dose Admin	Radiopharmaceutical	Half-life	EDE (mrem)
Lung perfusion*	10,000 μCi	Kr-81 gas	13.3 sec	1
Shilling's Test (vitamin deficiency)	1 μCi	Co-57 cyanocobalamin	270 days	16
Renal function	10,000 μCi	Tc-99m DTPA	6 hr	300
Bone scan	20,000 μCi	Tc-99m MDP	6 hr	540
Brain perfusion*	10,000 μCi	F-18 FDG	110 min	1070
Myocardial perfusion	20,000 μCi	Tc-99m MIBI	6 hr	1100
Myocardial perfusion	2,000 μCi	Tl-201-chloride	73.1 hr	1200
White blood cells (infection imaging)	500 μCi	In-111 WBCs	2.83 days	1250
Tumor imaging	5,000 μCi	Ga-67 citrate	78.3 hr	2300
H. pylori infection (PYtest)*	1 μCi	^{14}C	5730 yr.	0.2-0.4

* Currently not FDA-approved

As Table 2 shows, the radiation dose received from the PYtest is much smaller than most diagnostic nuclear medicine procedures. In fact, the test has a dose 40 times lower than a non-imaging test with the same administered activity (1 μCi) of a much shorter-lived radionuclide (Co-57, 270 days). The dose from the PYtest is also lower, but on the same order of magnitude as a 10,000 μCi inhalation of an inert gas for lung perfusion assessment (Kr-81) with a 13.3 second half-life.

The dose from this procedure is also small in relation to background radiation levels. We normally receive between 88 and 240 mrem annually from background radiation . The annual dose received from naturally occurring ^{40}K (17 mrem) is 42 times higher than that received from the PYtest .

The dosimetry model used in this study is the best available model for ^{14}C-urea dosimetry. It is based on a widely accepted, published method and this study provided a significant improvement in the model. The amount of ^{14}C retained in the body after 3 days is low, averaging 7% for *HP*-positive and 13% for *HP*-negatives. The remaining activity should normally be excreted from the body through the same pathways as naturally-incorporated ^{14}C. The model used is conservative and assumes a rather long (40-day) biological half-life for the activity not recovered

short-term. The dose estimates were verified to be accurate and reasonable by an outside party (RIDIC). This study confirmed the previous safety estimates for the PYtest.

3.5 ALARA

ALARA is an acronym for "as low as is reasonably achievable". This is a practice which licensees must follow with respect to the amount of radiation exposure delivered to workers, the public and the environment. In other words, although regulatory limits are imposed, individuals are expected to use amounts of material which are ALARA, therefore keeping their exposure to radioactivity ALARA. Potential exceptions are discussed in the Emergency Procedures Section (6) of this handbook.

4.0 REGULATORY REQUIREMENTS

The use of radioactive material is regulated and persons using radioactive material at a licensed institution must also be approved for such use by the institution. Please see Appendix C for additional information on regulatory issues.

Regulations require that individuals who use radioactive material must have appropriate training. Testing may also be required depending on individual circumstances If you have questions regarding the information in this handbook you should direct them to your Radiation Safety Officer (RSO), or you may contact other personnel at Tri-Med Specialties, Inc. Since the level of radiation exposure associated with administering or handling the C-14 breath test is little or none, prenatal radiation exposure is not a hazard. However, please review Appendix D *Regulatory Guide, 8.13*, "Instruction Concerning Prenatal Radiation Exposure" issued by the NRC.

Areas where the C-14 breath tests are used or stored must be properly posted and/or labeled. Tri-Med Specialties provides appropriate posting and labeling. Regardless of posting and labeling requirements, all materials associated with the breath tests which contain C-14 must be secured at all times. When no authorized user of the radioactive material is present, all RAM must be secured in a locked room or storage area. Fortunately the Tri-Med facility has automatic locks on every door so that as long as the door is closed, the RAM is secure. Make sure youkeep all doors closed so that we may remain in compliance with this regulation.

It is important that an inventory of all C-14 is maintained. A log of material received and used is kept. The balance of radioactive C-14 in possession must be known at all times. Licenses issued to Tri-Med Specialties limit the total amount of C-14 that may be possessed. You will learn the procedures for maintaining the RAM log by reviewing the Standard Operating Procedures (SOPs) listed elsewhere in this document.

Radiation surveillance of work areas is required to ensure that contamination of equipment, and surfaces is detected and removed should it occur. You may be required to do this daily, weekly,

or at some other frequency. The probability of contamination occurring without your knowledge is unlikely but must be prevented by performing frequent surveys. Surveys can be conducted using a Geiger counter equipped with a thin-window probe sufficiently sensitive to detect the low energy beta particles emitted by C-14. Another acceptable method which can be used in conjunction with, or in lieu of, the Geiger counter is to perform wipe tests of the use areas and equipment. A 100cm^2 wipe of an area with a filter paper (usually about 1½" in diameter) is made and then counted in a liquid scintillation counter to determine the amount of removable contamination. If contamination is detected, it should be reported to the RSO. It is important to note that some areas and equipment are going to be contaminated and are designated as such. It is very important, however, that areas not marked as contaminated always be free of removable radioactivity so that it cannot be spread. You will be required to review the SOPs regarding contamination surveys. Should you have additional questions, contact the RSO.

5.0 GENERAL C14 USE GUIDELINES

When working with C-14, individuals should wear protective clothing such laboratory coats and disposable gloves. No eating, drinking or smoking is allowed in use areas. The areas designated for RAM use are outlined on the maps posted throughout the facility. The use of magenta and yellow tape on the floor designates the threshold from a RAM-use to a non-RAM use area. Individuals should wash their hands after using radioactive material. See Appendix E for practical aspects of radiation protection.

As stated before, no C-14 shall ever be left unattended or unsecured.

Please see SOP # 05-20 for radiation safety training requirements.

6.0 EMERGENCY PROCEDURES

The likelihood of a radiation emergency related to handling the C-14 is extremely low. The small amount of material and the relatively low risk posed by exposure to C-14 makes an "emergency" fairly inconsequential. Emergency procedures are, however, given below.

The only emergency scenario which may be postulated would occur if ^{14}C capsules or ^{14}C-urea drug substance should be spilled. The general procedure for this and all contamination emergencies is (if possible or feasible):

1) With as little spread of contamination as possible, contact the Safety Officer. If she/he is not available, then contact another laboratory worker to assist you in determining the severity of the spill.
2) Clean up the spill, trying to use washable materials to reduce solid radioactive waste.
3) After cleaning up the area, survey for removable contamination.
4) Repeat procedures until area has been thoroughly decontaminated (SOP 40-03).

7.0 STANDARD OPERATING PROCEDURES(SOPS)

7.1 For personnel performing PYtest analysis.

The following SOPS must be read by personnel performing PYtest analysis:
15-10 Operation and Maintenance of the Ludlum LSC
15-11 Operation of the Beckman LS6500 Liquid Scintillation Counter
35-14 Shipping PYtest capsules
40-10 Storage of breath test sample vials
40-14 Breath sampling, Handling and Reporting
40-20 Operation of TM Analytic Liquid Scintillation Counter
05-12 Hazardous Spills
40-03 Performing facility-wide radiation contamination surveys

7.2 For personnel working in PYtest capsule production and analysis

The following additional SOPS must be read by personnel also working in PYtest capsule production and analysis.
25-04 General Manufacturing Procedures
40-03 Radioactivity- contamination surveys
40-21 Performing facility- wide radiation contamination surveys
40-23 Internal Standard and Quench Standard Sample Preparation
40-07 Stability Protocol- Stability Testing Program
05-12 Hazardous Spills

8.0 CONCLUSION

Should you have questions regarding the contents of this handbook, contact the Tri-Med Specialties radiation safety officer or his/her designee.

Appendix A: Liquid Scintillation Counting

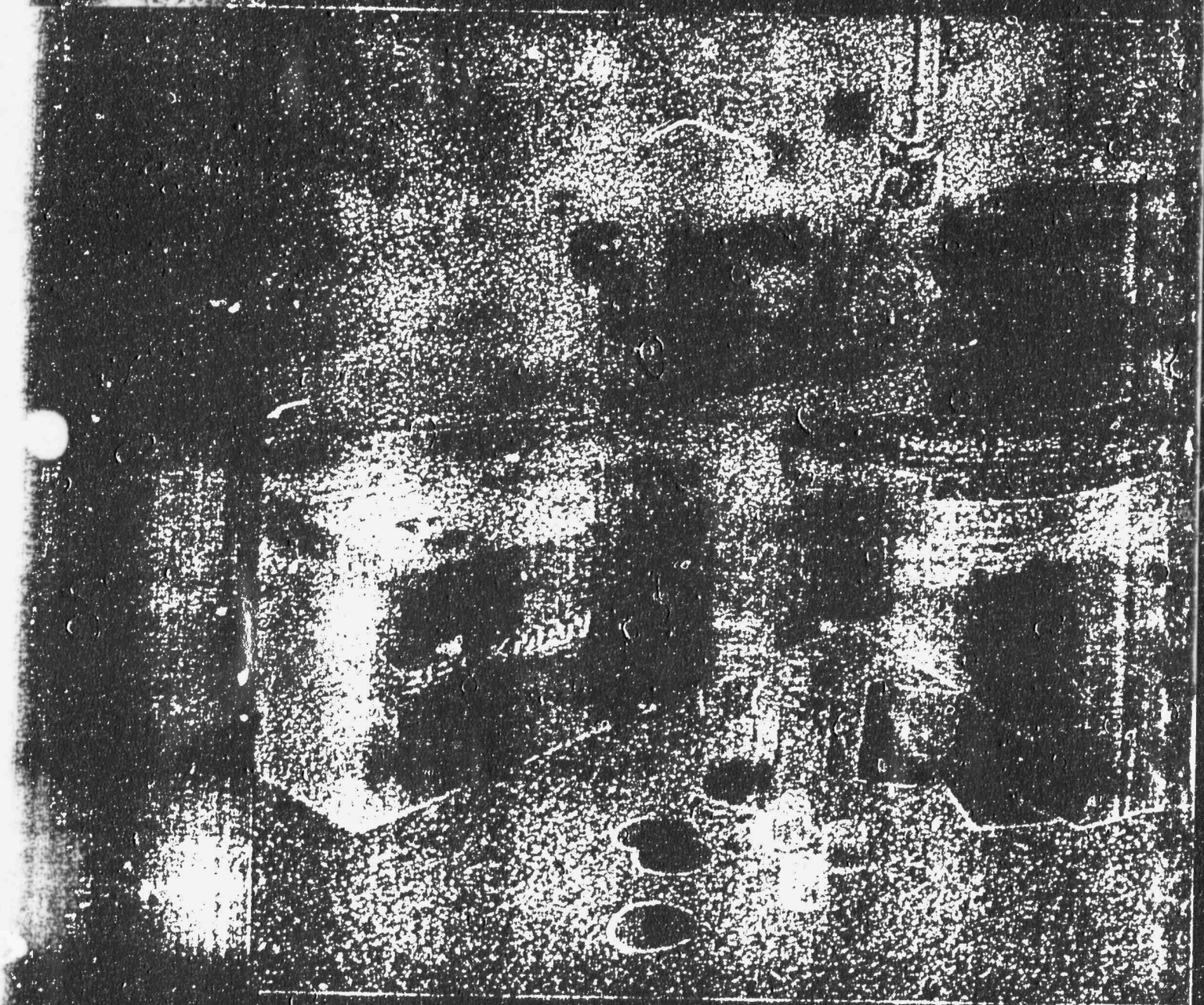
For additional reading on Liquid Scintillation counting please read the following:

Knoche, Herman W. (1991). Liquid Scintillation: Theory of Detection and Instrument Design. In Radioistotopic Methods for Biological and Medical Research (PP 153-176, Chapter 8). New York: Oxford University Press.

Knoche, Herman W. (1991). Liquid Scintillation: Practical Aspects In Radioistotopic Methods for Biological and Medical Research (PP 177-210, Chapter 9). New York: Oxford University Press.

Sample Preparation Guide

LS 6000 Series Scintillation Systems



BECKMAN

Basic Liquid Scintillation Theory

After discussing how the new solid scintillator products from Beckman can be used, here is a summary and brief description of the scintillation process.

Decay Products of Radioisotopes

Radioactivity is the result of an unstable combination of protons and neutrons in the nucleus, and the attempt to arrive at a more stable combination. This stable combination is frequently attained by the emission of an alpha or beta particle.

Alpha Particles are energetic helium nuclei (two protons and two neutrons) and are normally emitted by isotopes of the heavier elements (Z > 82). Alpha particles have discrete energies depending on the radioisotope (see Figure 1).

Beta Particles are energetic electrons emitted from the nucleus (neutron → electron + proton + $\bar{\nu}$) of many radioisotopes. The energy released by this emission is dependent on the radioisotope and is shared between the beta particle and the anti-neutrino ($\bar{\nu}$). Because of this energy sharing, and the fact anti-neutrinos are not detectable, beta spectra are very broad, normally starting at 0 keV (all energy is given to the anti-neutrino) and ending at some E_{max} keV depending on the radioisotope (see Figure 2).

Gamma Rays are electromagnetic radiation (no mass, no charge) and are almost never emitted alone; they are normally emitted accompanying alpha and beta particles. Gamma rays also have discrete energies depending on the radioisotope (see Figure 3).

Fundamental properties of these decay products are easy to predict if one remembers that particles with mass and charge interact with matter. By virtue of their mass and charge, alpha and beta particles interact with their surroundings and, as a result, they transfer energy. Eventually the particles will lose all of their energy and come to rest.

Usually alpha and beta particles do not travel far after emission; they rarely penetrate through the vial in which they are contained. However, gamma rays have no mass or charge and therefore do no interact with matter to a great extent. Gamma rays travel great distances before coming to rest (i.e., more than 100 cm of water is needed to attenuate 1MeV gamma rays) and they can easily penetrate the vial. This is why lead shielding must be used when working with gamma emitters to prevent exposure to

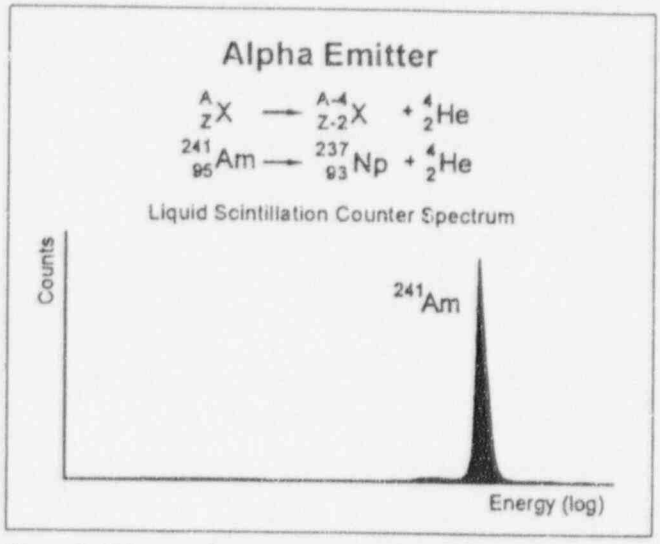


Figure 1. Alpha particles are mono energetic and easily detected in an liquid scintillation system. Z is the atomic number; A is the mass number.

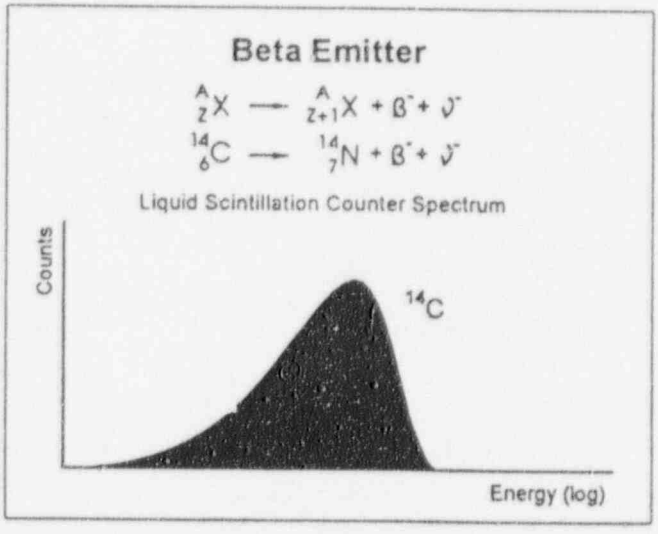


Figure 2. Beta particles vary in energy resulting in broad liquid scintillation spectra (pulse distribution from 0 to max. energy).

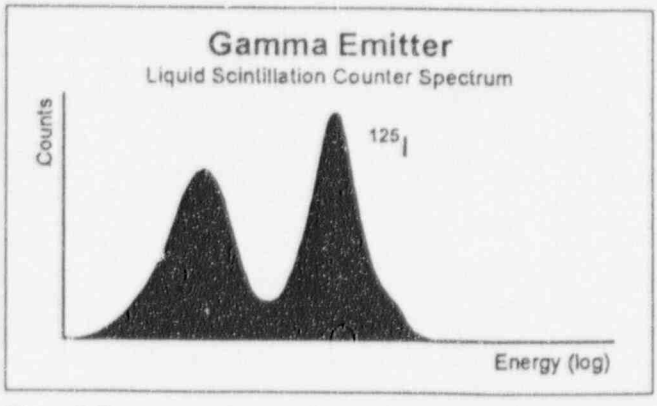


Figure 3. Gamma emissions are frequently accompanied by Auger and/or conversion electrons which can be detected in a LS system.

the radiation. However, with beta emitters, such shielding not necessary; for example, a thin plastic shield is all that is required for ^{32}P. Nevertheless, whatever the nature of the radioisotope, it is important to remember that the material should not be ingested or inhaled nor allowed to come into contact with your skin.

Liquid Scintillation versus Gamma Instrumentation

Since, in contrast with gamma rays, alpha and most beta particles cannot penetrate the sample vial, the method of their detection is different. For alpha and beta particles it is necessary to put the "detector" as close to the decay particle as possible, that is, inside the vial. This detector is the liquid scintillation cocktail. In contrast, for gamma detection the detector may be outside the sample container, so no cocktail is needed with a gamma counter.

This is an important point because no matter how good your liquid scintillation system is, you ... the investigator, actually prepare the primary detector.

Commonly, scintillation instrumentation is blamed for erroneous results when, in fact, it is the sample preparation that is at fault. Understanding the liquid scintillation process, including the nature of the emission and the interaction of the decay particle with the cocktail (or solid scintillator) can help you to avoid mistakes.

Note: *Liquid scintillation counters can be used effectively to analyze gamma emitting radioisotopes (see Chapter 1 and Appendices 5 and 6).*

The Scintillation Process (Liquid)

A scintillation sample vial normally contains the following components:

1. **The radioactive sample.**
2. **A LIQUID scintillation cocktail,** normally consisting of the following components:

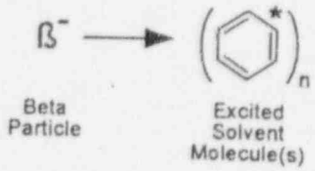
   Solvent: Typically toluene, xylene, pseudocumene or an alkyl benzene (biodegradable) type solvent.

   Emulsifier: A detergent type molecule (like Triton X-100) that ensures proper mixing of aqueous samples in organic solvents.

   Fluor: A fluorescent solute (like PPO).

The function of the scintillation cocktail is to convert the energy of the radioactive decay particle into visible light which can be detected by the scintillation counter. This visible light is the result of the following interactions:

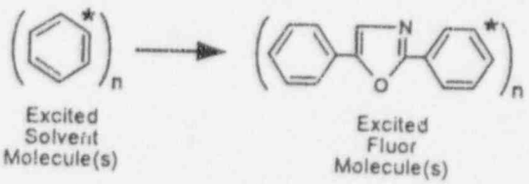
1. The kinetic energy of a single radioactive decay particle is absorbed by many solvent molecules causing them to become excited.



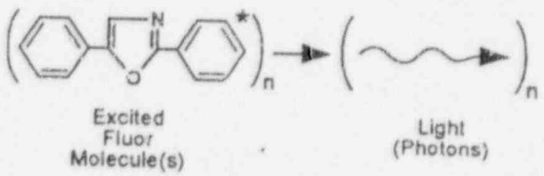
n is the number of solvent molecules in the path of the decay particle.

Excited molecules return to their ground states by losing this excitation energy as either heat or light. All solvents used to date tend to lose most of this excitation energy as heat; the light that is emitted is in the UV region of the spectrum and is not efficiently detected by the LS counter.

2. The addition of a fluor is necessary to ensure emission of detectable light. The excitation energy of the solvent molecule is transferred to a fluor molecule causing it to become excited.



3. The fluor molecules return to their ground states by emitting light.



Regardless of the radioactive isotope, the wavelength of this scintillation light is dependent upon the fluor. PPO normally generates light in the blue (approximately 370 nm) region of the spectrum.

The amount of light being emitted from the vial is proportional to the energy of the particle. That is, the higher the energy of a particle, the more solvent molecules it is able to excite and, therefore, more light is generated (see Figure 4).

This light is emitted from the LS sample vial in all directions and is "directed" into two photomultiplier tubes (PMTs) which convert the light into a measurable electrical pulse. In the case of ^{32}P, a single beta particle can give rise to more than 3,000 photons.

The amplitude (or "height") of the pulse can now be determined as a voltage and is proportional to the amount

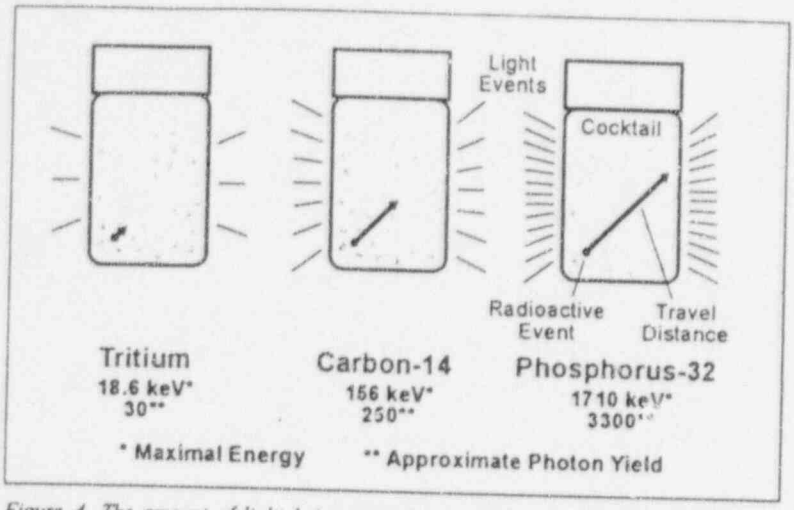


Figure 4. The amount of light being emitted from the vial is proportional to the energy of the particle.

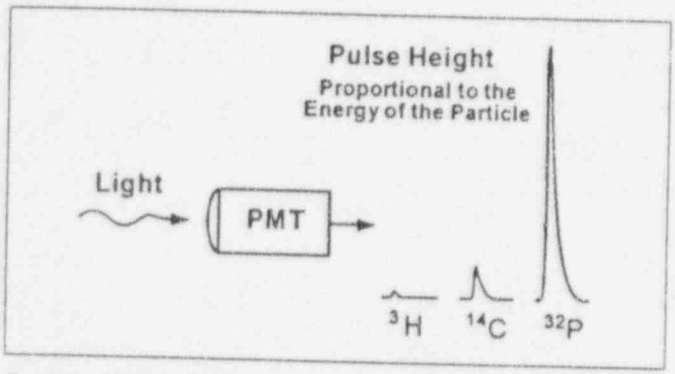
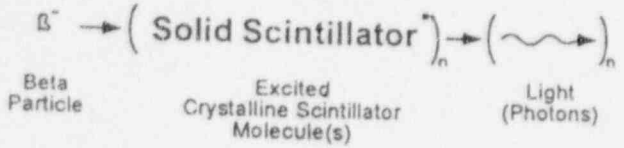


Figure 5. The pulse height is proportional to the energy of the particle.

of light which interacts with the face of the PMT (photocathode). Therefore, the pulse height at the output of the PMT is proportional to the energy of the particle (see Figure 5).

The Scintillation Process (Solid)

The process of solid scintillation is similar to that for liquid cocktails except that no solvent is involved. Instead, the particles transfer their energy directly to the crystalline solid scintillator.



The Beckman solid scintillator Xtalscint is a crystalline solid containing yttrium which acts as a substitute for conventional fluors. Radioactive decay particles from the sample are emitted striking the solid matrix. Kinetic energy from the particle is thus converted to vibrational energy in the matrix. This vibrational energy ultimately excites the yttrium atom. It is this excited yttrium atom which emits light.

The light-emitting properties of solid scintillators differ from those of fluors in cocktail. For more information about solid scintillator properties see the section "Xtalscint, Clean, Dry Scintillation Counting" and "Quench" on page 3 and information on quenching in Appendices 1 & 2.

The Coincidence Gate Circuit

The coincidence gate circuit was introduced in the early 1950's to reduce noise level in liquid scintillation counters. The problem is that all PMT's generate noise pulses that are not the result of the scintillation process. These pulses are referred to as background or noise. Typically the background from a 2-inch (diameter of the face) PMT is greater than 10,000 CPM. A 10,000 CPM background in a counter is, of course, unacceptable especially when investigators are interested in analyzing low activity samples. In order to reduce this background level a second PMT and a "coincidence circuit" were introduced in 1953. This coincidence circuit, in a sense, is able to discriminate between noise pulses and pulses from "real" scintillation events (Figure 6).

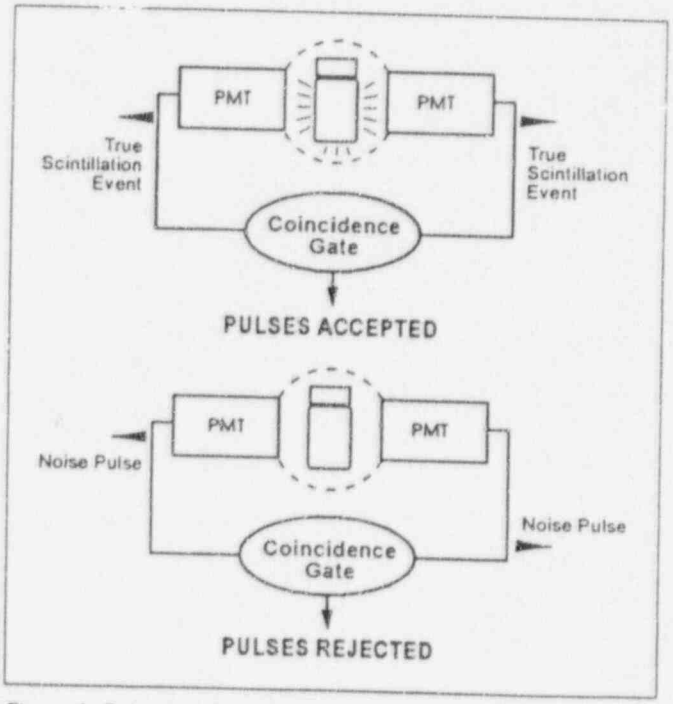


Figure 6. Only when the coincidence circuit detects a pulse from each PMT simultaneously will the counter register a count.

Recall in an actual scintillation event, many photons are emitted isotropically. Thus, light will impinge on both photocathodes simultaneously. This being the case, each

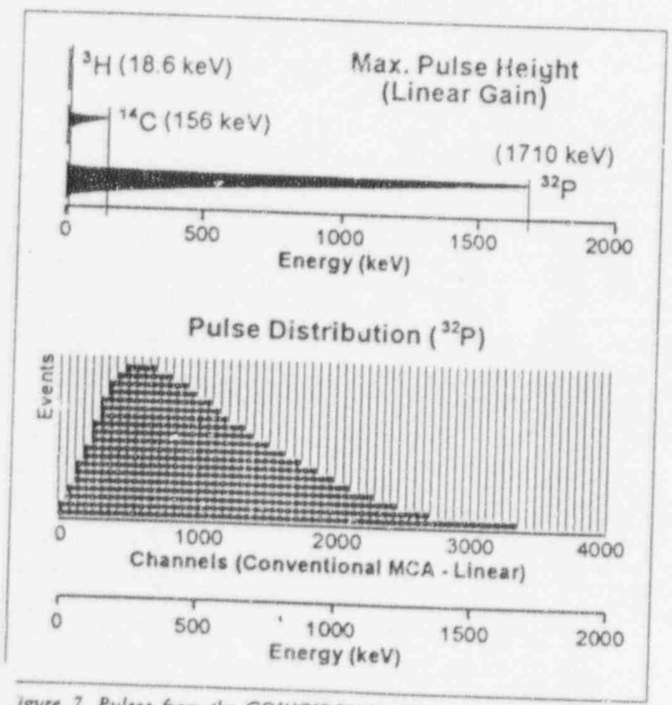
PMT will generate a pulse simultaneously. Only when the coincidence circuit detects a pulse from each PMT simultaneously will the counter register that a beta decay occured.

Unlike scintillation events, noise pulses are generated randomly from each PMT. he chances of a noise pulse being emitted from both PMT's simultaneously are very small. If the coincidence circuit detects a pulse from one PMT and not the other, the counter will disregard the pulse. Figure 6 summarizes the differences between true scintillation events and noise.

In reality, two pulses hitting the coincidence circuit simultaneously is hard to assure, even in a true scintillation process. Therefore upon detecting a pulse from one PMT, the coincidence circuit will wait 10 to 30 nanoseconds for a pulse to arrive from the second PMT. For a true scintillation event this assures "coincidence"; however, it is possible that noise pulses from each PMT could arrive at the coincidence circuit within this "gate". Such an event is called a chance coincidence.

Pulse Processing

The pulses from the coincidence gate are analyzed and sent to an analog-to-digital converter where the pulse is digitized. The digitized pulse is then stored in a multichannel analyzer (MCA) channel corresponding to the particle energy.



igure 7. Pulses from the COINCIDENCE CIRCUIT are digitized and stored in a multichannel analyzer.

The MCA accumulates counts (pulses) representing the spectrum of the radioactive decay particles in the sample (see Figure 7).

The data in the MCA can be analyzed to provide the following information:

1. The energy of the particles in the sample.
2. The rate (CPM) of the radioactive decay in the sample (the total number of pulses in all channels of the MCA divided by the total time in minutes needed to collect them).

Quench

Virtually anything added to a counting vial by an investigator (color, solvents, filters) can reduce the efficiency of the scintillation process and this reduction in counting efficiency is called QUENCH. The three major forms of quench are:

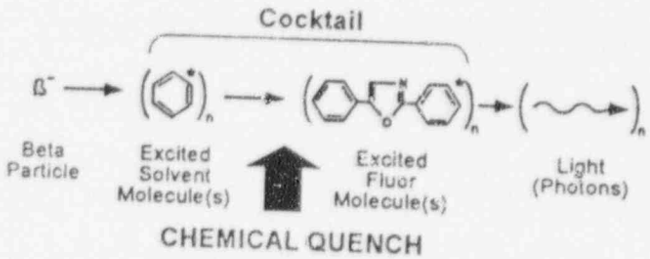
- ❑ Chemical Quench
- ❑ Color Quench
- ❑ Self-Absorption

Since these affect liquid and solid scintillation to different extents, we will review them briefly and suggest some ways for reducing their troublesome effects.

Chemical Quench

Chemical quench occurs with liquid cocktails but not with Xtalscint solid scintillator.

Liquid Scintillation

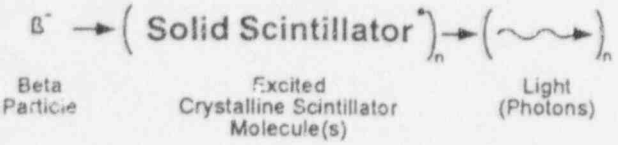


In chemical quench, chemical agents (e.g., dissolved oxygen, water and other solvents) added to the cocktail with the radioactive sample interfere with the transfer of kinetic energy between the solvent and the fluor(s).

The results are:

- ❑ Reduction and loss of light.
- ❑ Reduced efficiency.

Solid Scintillation



Since there is no solvent-mediated energy transfer step, there is *no chemical quench.*

The difference between solid and liquid scintillation is shown in the following table.

Effect of Chemical Quenching on the Counting Efficiencies of Tritiated Inulun with Liquid and Solid Scintillators

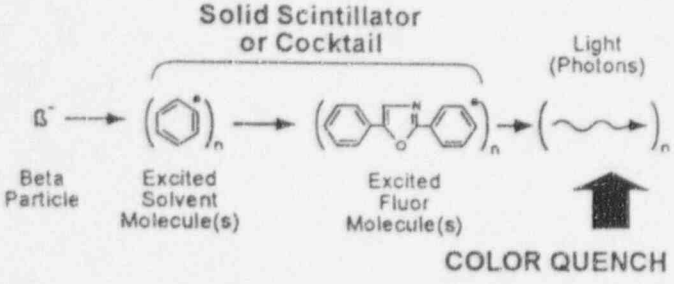
Quench Agent	Volume	Liquid Scintillator	Xtalscint
None	-	45.5%	39.0% (dry)
Isopropanol	100 µL	45.0%	28.5% (wet)
Nitromethane	100 µL	2.9%	28.5% (wet)

Note:

- Liquid (isopropanol) reduced the counting effciency of Xtalscint solid scintillator. This is a self-absorption effect (see below) and not chemical quench (cocktail efficiency was unaffected).
- Nitromethane, a powerful, colorless chemical quench agent, caused severe quenching with cocktail but no additional quench with Xtalscint solid scintillator.

Color Quench

Color quench occurs with both liquid and solid scintillators.



Solid and liquid scintillators emit light in the blue region of the spectrum. Red, green and yellow colors in the counting vial absorb this light, resulting in reduced efficiency. This is illustrated in the following table:

Effect of Yellow Dye on the Counting Efficiencies of Tritiated Palmitic Acid with Liquid and Solid Scintillators

Dye	Scintillator	^{3}H Efficiency
0 µL	Liquid	45.5%
200 µL	Liquid	7.5%
0 µL	Xtalscint	39.0%
200 µL	Xtalscint	3.1%

Eliminating Color Quench

- Bleach out the color.
- Perform DPM correction with color-quenched standards for samples with cocktails.
- Use the color correct option on LS 6000 scintillation counters for samples with cocktail.

Bleaching (Cocktail)

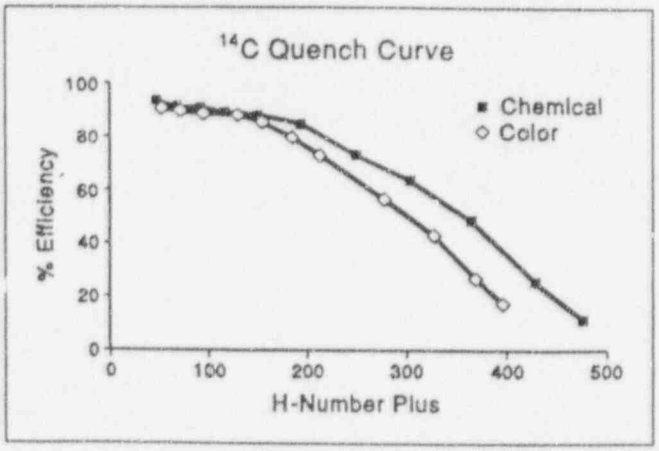
Prior to counting, you can bleach out the color with hydrogen peroxide. However, while this may reduce or eliminate one problem, it creates another. Addition of hydrogen peroxide will add oxygen and therefore cause chemical quench.

Bleaching (Xtalscint)

You can use hydrogen peroxide to reduce troublesome color quench when working with Ready Caps since there is no chemical quench with solid scintillators. A final concentration of 5% H_2O_2 is sufficient to decolorize most samples during drying.

DPM Correction With Color-Quenched Standards

Even if your counter has an external standard quench monitor, a chemical quench curve should not be used for correction of samples with strong color quench because color and chemical quench do not superimpose in the presence of heavy quench.



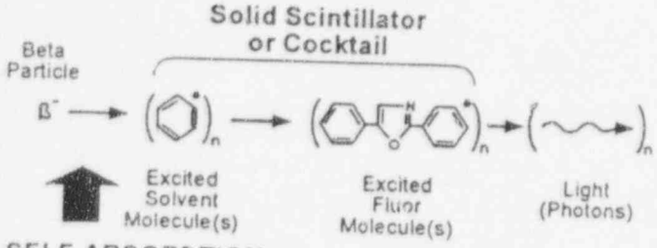
You should construct a separate quench curve for colored samples and use this whenever heavy colored samples are counted. Ideally, the coloring agent used should be the same as that in your experimental samples.

Automatic Color Correction

The 32K MCA on LS 6000 Series scintillation counters provides superior resolution for isotope and Compton spectra. This allows the counter to monitor and correct for color quench without the need for separate color and chemical quench curves. For further details, see the Advanced Technology Guide for LS 6000 Series Scintillation Counters.

Beta Particle Self-Absorption

Self-absorption quench occurs with liquid and solid scintillators. Self-absorption cannot be detected by a quench monitor.



SELF-ABSORPTION

Self-absorption quench occurs when a beta particle emitted by an isotope remains undetected because of entrapment in non-scintillating media (e.g., cell membranes, cells, precipitates). It may be particularly severe for tritium, a weak beta emitter.

Liquid Cocktail

This form of quench occurs most frequently with assays that involve filtration steps, e.g., membrane and whole cell receptor assays and cell proliferation assays. It is a common misconception that counts in particulate materials deposited on the surface of a filter are not susceptible to self-absorption quench once the filter is placed in cocktail (for further details, refer to "Pitfalls for the Unwary in Liquid Scintillation Counting" in Appendix 3). This form of quench may be reduced or eliminated only if adequate measures are taken to solubilize the material from the surface of the filter before counting (e.g., by using a specially formulated cocktail like Ready Protein+).

Solubilization techniques to minimize self-absorption quench are discussed in the Sample Preparation Chapter of this guide.

Xtalscint (Solid Scintillator)

Self-absorption is likely to be the most common form of quench when using Ready Filter, a glass fiber filter coated with Xtalscint. Stacking of material on the surface of the filter may cause severe quench, especially when tritiated compounds are used. As explained in the data sheet from Beckman entitled "Filtration assays and quench resulting from beta particle self-absorption", CS1/003 (see Appendix 2), the severity of quench resulting from self-absorption depends upon two factors:

- ❑ The amount of particulate material filtered.
- ❑ The surface area over which it is deposited.

Ready Filter is available in various formats with a range of filtration areas so that you may select one that minimizes self-absorption for your applications. The goal is to deposit your particulate sample over a large surface area to bring the radioactivity in close contact with Xtalscint. This is particularly important for tritium.

Quench Correction

All samples prepared in the laboratory are quenched to some degree. Therefore, in order to express the data in units that allow accurate comparison (that is, results that are independent of quench level), it is necessary to convert CPM (counts per minute measured in the presence of quench) to DPM (disintegration per minute = absolute activity). The relationship is the counting efficiency of the sample:

$$\text{Counting Efficiency} = \frac{\text{CPM}}{\text{DPM}} = \frac{\text{Events Observed}}{\text{Actual Disintegration in Vial}}$$

Once the CPM are obtained, the DPM calculation requires determination of counting efficiency of the sample:

$$\text{DPM} = \frac{\text{CPM}}{\text{Counting Efficiency}}$$

Counting with Constant Quench

Liquid Scintillator

If working with a counter that is not equipped with an external standardization feature for quench correction, then you may wish to simply count CPM if you know that the quench is constant in all samples.

Xtalscint

Chemical quench does not occur with Xtalscint. However, color quench may be present. Solid scintillators are designed to count CPM in situations involving constant quench. If your counter is equipped with an external quench monitor, this feature should be turned off.

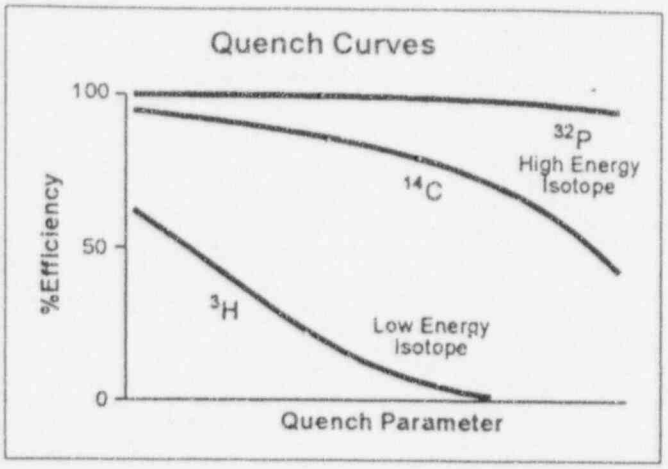
Even if your Beckman LS counter does not have the external standard feature to determine quench, you may verify that quench is constant for cocktail or Xtalscint samples by using the IC Number (Isotope Center) with LS 6000 scintillation counters. Correction for quench is needed when this number varies by more than 10% from sample to sample.

Counting with Variable Quench

Liquid Scintillator

To correct for variable quench, it is necessary to set up a "quench curve" in the scintillation system. A quench curve is the relationship between the counting efficiency and a "quench parameter".

The quench parameter is automatically measured by the scintillation system and the counting efficiency determined in regard to the known absolute activity in the quench standards. For more details see the *Advanced Technology Guide for LS 6000 Series Scintillation Counters*, available from your local Beckman office.



Xtalscint

Variable quench cannot be corrected with solid scintillator products. Fortunuately, most applications for Ready Cap and Ready Filter have constant quench, therefore, there is no need for a quench curve.

Appendix B: NRC Draft Regulatory Guide" Instruction Concerning Risks from Occupational Radiation Exposure

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

DRAFT REGULATORY GUIDE

December 1994
Division 8
Task DG-8012

Contact: A.K. Roecklein (301)415-6223

DRAFT REGULATORY GUIDE DG-8012
(Proposed Revision 1 to Regulatory Guide 8.29)

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," requires that all individuals working in or frequenting any portion of a restricted area be instructed in the health protection problems associated with exposure to radioactive materials or radiation. Section 20.1206 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that before a planned special exposure occurs the individuals involved are, among other things, to be informed of the estimated doses and associated risks.

This Revision 1 to Regulatory Guide 8.29 is being developed to describe the information that should be provided to workers by licensees about health risks from occupational exposure. This Revision 1 will conform to the revision of 10 CFR Part 20 that became effective on June 20, 1991, and was required to be implemented by licensees no later than January 1, 1994. The revision of 10 CFR Part 20 changed the occupational dose limits for adults and minors, provided for planned special exposures, established a dose limit for an embryo/fetus of an occupationally exposed declared pregnant woman, and explicitly states that Part 20 is not to be construed as limiting action that may be necessary to protect health and safety during emergencies.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing

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This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by March 15, 1995.

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review and do not represent official NRC staff positions.

Any information collection activities mentioned in this draft regulatory guide are contained as requirements in 10 CFR Part 19 or 10 CFR Part 20, which provide the regulatory bases for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

The scientific community generally accepts that exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person. These effects may be classified into three categories:

Somatic Effects: Physical effects occurring in the exposed person. These may be early effects that are observable soon after a large or acute dose (e.g., 100 rems[1] (1 Sv) or more to the whole body in a few hours); or they may be delayed effects such as cancer that may occur years after exposure to radiation.

Genetic Effects: Abnormalities that may occur in the future children of exposed individuals and in subsequent generations.

Teratogenic Effects: Effects that may be observed in children who were exposed during the fetal and embryonic stages of development.

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[1]In the International System of Units (SI), the rem is replaced by the sievert; 100 rems is equal to 1 sievert (Sv).

To avoid or limit these biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for all workers who may be occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with NRC regulations. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have whatever information on radiation risk is available to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop a healthy respect for the risks involved rather than either excessive fear or indifference.

C. REGULATORY POSITION

Strong management support is considered essential to an adequate radiation protection training program. Instruction to workers performed in compliance with 10 CFR 19.12 should be given prior to occupational exposure and periodically thereafter. If a worker is to participate in a planned special exposure, in compliance with 10 CFR 20.1206 the worker should be informed of the associated risks. In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation.

The instruction should be presented both orally and in printed form to workers and supervisors. The appendix to this guide provides information and instruction that would be adequate to demonstrate compliance with these requirements in 10 CFR Parts 19 and 20. The information should be discussed during training sessions in which each individual is given an opportunity to ask questions. Each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

This proposed revision is being issued in draft form to encourage public participation in its development. Except in those cases in which an applicant proposes acceptable alternative methods for complying with specified portions of the Commission's regulations, the methods to be described in the active guide reflecting public comments will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 19.12 and 10 CFR Part 20.

APPENDIX

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta or alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when absorbed by living tissue. A question and answer format is used. Many of the questions or subjects initially were developed by the NRC staff in consultation with workers, union representatives, and licensee representatives experienced in radiation protection training.

This Revision 1 to Regulatory Guide 8.29 updates earlier material on biological effects and risks and on typical occupational exposure. Additionally, it conforms to the revised 10 CFR Part 20, "Standards for Protection Against Radiation," which was required to be implemented by licensees no later than January 1, 1994. The information in this appendix is intended to help develop an attitude of healthy respect for the risks associated with radiation, with neither unnecessary fear nor lack of concern. Additional guidance concerning other topics ir radiation protection training is provided in other NRC regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action on the basis of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the possible risk of injury, illness, or death from occupational radiation exposure.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they might deposit energy sufficient to cause damage. Radiation can cause several different types of damage, such as very small physical displacement of molecules or a change of an atom to a different element, or ionization, which causes electrons to be removed from atoms and molecules. When the energy of these radiations is high enough, biological damage can occur: chemical bonds can be broken and cells can be damaged or killed.

The basic unit for measuring absorbed radiation is the rad (radiation absorbed dose). One rad (0.01 gray in the International System of units) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of tissue exposed to radiation. To reflect biological risk, rads must be converted to rems. This conversion accounts for the differences in the effectiveness of different types of radiation to cause damage. The rem is used to estimate biological risk.

2. What are the possible health effects of exposure to radiation?

Potential health effects from exposure to radiation include cancer such as leukemia and bone, breast, and lung cancer. Very high, acute levels of radiation exposure have been known to cause prompt (or early) effects, such as vomiting and diarrhea,[1] skin burns, cataracts, and even death. Radiation exposure has also been linked with the potential for genetic effects in future children of exposed parents. Children who were exposed to elevated levels of radiation prior to birth have shown an increased probability of mental retardation. These effects (with the exception of genetic effects) have been observed in studies of medical radiologists, uranium miners, radium workers, radiotherapy patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, the radiation effects studies with laboratory animals have provided extensive data on radiation-induced health effects, including genetic effects.

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[1]These symptoms are early indicators of what is referred to as acute radiation syndrome, which includes damage to the blood-forming organs such as bone marrow, damage to the gastrointestinal system, and at very high doses can include damage to the central nervous system.

The observations and studies mentioned above involve levels of radiation exposure or exposure rates that are generally higher than those received occupationally today. Although studies have not shown a clear cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent to assume that some effects do occur.

3. What is meant by early and continuing effects, delayed effects, and genetic effects?

EARLY AND CONTINUING EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after an exposure, within hours to a few days. They are observable after receiving a very large dose in a short period of time -- for example, 300 rems (3 Sv) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under the NRC's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells; a large number of cells within a specific organ or the whole body will have been killed. For prompt effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not necessarily cause the same effect. Our body's natural biological process is constantly repairing damaged cells and replacing dead cells; if the cell damage is not severe, our body is capable of repairing and replacing the damaged cells without any observable adverse conditions.

For example, a whole body dose of about 300 rems (3 Sv), 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death without medical treatment. These effects would not occur if the dose of 300 rems (3 Sv) were accumulated gradually over many years (Refs. 1 and 2).

It is important to distinguish between whole body and partial body exposure. A localized dose to a small area of the body would not produce the

same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to a portion of the skin and underlying tissue of the hand. An acute dose of 600 rem (6 Sv) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

Cataracts are also considered early and continuing effects. A certain level of dose to the lens of the eye is required before any observable visual impairment is observed and the impairment remains after the exposure is stopped. The threshold for cataract development is an acute dose on the order of 100 rem (1 Sv). Further, a cumulative dose of 800 rems (8 Sv) from protracted exposures over many years to the lens of the eye has also been linked to some level of visual impairment. This dose exceeds the amount that can be accumulated by the lens for normal occupational exposure (Refs. 1 and 3).

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are not the immediate, direct result of biological damage to the cells of the body but are caused indirectly when the radiation causes the cells in the body to change, thereby causing the normal function of the cell to change -- for example, turning normal healthy cells into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits for occupational doses.

GENETIC EFFECTS

Genetic effects can occur when there is radiation damage to the genetic material. These effects may show up as birth defects or other conditions in the future children of the exposed individual and succeeding generations. However, excess genetic effects clearly caused by radiation have not been observed in human populations exposed to radiation. Continuing evaluations of

the atomic bomb survivors (Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 4). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. Therefore, it is prudent to assume that radiation exposures, even at the levels allowed under the NRC's limits, do pose some risk of genetic effects. Teratogenic effects, or effects that are observable in children who were exposed during the fetal and embryonic stages of development, are discussed in Question 5.

4. *What is the difference between the effects of acute and chronic radiation exposure?*

Acute radiation doses usually refer to a large dose of radiation received in a short period of time. Chronic exposure refers to small doses received repeatedly over long time periods, for example, 20 to 100 mrem (or millirem, which is one-thousandth of a rem) (0.2 to 1 mSv) per week every week for several years. It is assumed that any radiation exposure, either acute or chronic, has a potential for causing delayed effects. However, only acute doses cause early effects; chronic doses do not cause early effects. Since NRC limits are set to prevent all early effects, concern with occupational radiation risk is primarily focused on chronic exposure to low levels of radiation over long time periods for which the delayed effects such as cancer are of concern.

The difference between acute and chronic radiation exposure can also be shown by a comparison with exposure to the sun's rays. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to repair between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer.

5. *What are the health risks from radiation exposure to the embryo/fetus?*

During certain stages of development, the embryo/fetus is much more sensitive to radiation than adults are. Studies of atomic bomb survivors

exposed to high radiation doses during pregnancy show that children born after these exposures have a higher risk of mental retardation or lower IQ scores. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in adult life; the magnitude of the risk, however, is uncertain. In recognition of this increased radiation sensitivity, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker. Guidance in conformance with the revised 10 CFR Part 20 is being developed as a proposed Revision 3 to Regulatory Guide 8.13; it has been published as Draft Regulatory Guide DG-8014, "Instruction Concerning Prenatal Radiation Exposure."

If an occupationally exposed woman declares her pregnancy to the licensee, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 500 mrem (5 mSv) for the total gestation period applies to the embryo/fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and possible loss of income. Because of these concerns, the declaration of pregnancy by a woman radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn, for example, if the woman reconsiders and feels that her benefits from receiving the occupational exposure would outweigh the increased risk to her embryo/fetus from the radiation exposure.

6. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility can be caused by radiation but not at the levels allowed under NRC's occupational limits. Sterility is an early radiation effect. There is a threshold below which these effects would not occur. Doses on the order of 10 rem (0.1 Sv) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 150 rem (1.5 Sv). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 200 rem (2 Sv) for men and about 350 rem (3.5 Sv) for women (Refs. 1 and 3).

Although high, acute doses can affect fertility, they have no direct effect on the ability to function sexually. No evidence exists that exposures within the NRC's occupational limits have any direct effect on the ability to function sexually.

7. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure," or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure." It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. The NRC requires that dose for external exposure and dose for internal exposure be added together to determine compliance with occupational limits. The sum of external and internal dose is called the Total Effective Dose Equivalent (TEDE).

Radioactive materials may enter the body through breathing, eating, or drinking, or they may be absorbed through the skin, particularly if the skin is broken. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and work-benches may be contaminated and these materials can be resuspended in air during work activities.

After entering the body, the radioactive material goes to particular organs, depending on the biochemistry of the material. For example, certain chemical forms of uranium tend to deposit in the bones, where they remain for a long time. These forms of uranium are slowly eliminated from the body, mostly by way of the kidneys. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, standards have been established for the annual limit of intake (ALI) for each radionuclide. When more than one radionuclide is involved, the intake amounts of each are reduced proportionally. NRC regulations specify the concentrations of radioactive material in the air to which a worker can be continuously exposed for the entire 2,000 working hours in a year. These concentrations are termed the

derived air concentrations (DACs).[2] These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources is the maximum allowed to the organ or to the worker's whole body.

8. How does radiation cause cancer?

When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves; no resulting damage is caused. The cells can die, much like the millions of cells that die every day in our bodies, and may be replaced through the normal biological process. Or a change can occur in the cell's reproductive structure -- the cells can mutate and subsequently be repaired with no effect, or they can form precancerous cells, which may become cancerous.

Radiobiologists have studied the relationship between radiation and cancer. These studies indicate that radiation damage to chromosomes in the cell nucleus is the main cause of cancer. Chromosome damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through reactions of chemical products produced by radiation interactions. Cells are able to repair most damage within hours; however, misrepair may occur.. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Benign changes in the cell can occur or the cell can die; these changes do not lead to cancer.

Many factors can affect susceptibility to the cancer-causing effects of radiation, such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke. However, most diseases are caused by the interaction of several factors. Other detrimental conditions such as smoking appear to increase the susceptibility.

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[2]The DAC in the revised 10 CFR Part 20, which all licensees were required to implement no later than January 1, 1994, replaced the maximum permissible concentrations (MPCs) that were formerly in 10 CFR Part 20.

9. If I receive a radiation dose, will it cause me to get cancer?

Probably not. Radiation is like most substances that cause cancer in that the effects can be seen clearly only at high doses. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 10 rad (0.1 gray) (Ref. 3). Generally, for radiation protection purposes, these estimates are made using the straight line portion of the linear quadratic model (Curve 2 in Figure 1). We have data on cancer probabilities for high doses as shown by the solid line in Figure 1. Only in the studies of radiation above occupational limits are there dependable measurements of risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. Most scientists believe that there is some risk no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect. A few believe that risk levels off so that even very small doses imply a significant risk (Curve 4). The majority of scientists today endorse the linear quadratic model (Curve 2).

For regulatory purposes, the NRC uses the straight line portion of the linear quadratic model (Curve 2), which shows the number of effects decreasing as the dose decreases. It is prudent to assume that even small doses have some chance of causing cancer. This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are man-made such as cigarette smoke, smog, and man-made radiation. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). The ALARA concept is discussed in Question 13.

10. What are the estimates of the risk of cancer from radiation exposure?

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, but we can make estimates based on extensive scientific research knowledge. We do know that the estimates of radiation effects are better known and are more certain than are those of most hazardous chemicals (Ref. 5). Being exposed to typical occupational radiation doses is taking a chance, but that chance is reasonably well understood. From

Figure 1. Some proposed models for how the effects of radiation vary with doses at low levels.

currently available data, the NRC has adopted the risk value for an occupational dose of 1 rem (0.01 Sv) as representing a risk of 4 in 10,000 of developing a fatal cancer.

Not all workers incur the same level of risk. The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 5 rems (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 5 rems (0.05 Sv) per year (Ref. 6).

According to the BEIR V report (Ref. 3), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 will die from cancer in the absence of any occupational radiation exposure. As stated earlier, there is a risk of 4 in 10,000 of a 1-rem (0.01-Sv) dose causing a fatal cancer. Another way of stating this risk of a fatal cancer is 1 in 2,500 per rem (0.01 Sv) received, or 0.0004 per rem (0.01 Sv).

To explain the significance of these estimates, we will use a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation. In this group of 10,000 workers, we could estimate that 4 would die from cancer because of that dose in addition to the 2,000 normal incidents, although the actual number could be more or less than 4. These deaths would be in addition to the natural death rate for cancer, which is 1 in 5 people. This means that a 1-rem (0.01 Sv) dose to each of 10,000 workers might increase each individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rems, we could raise the estimate to 20.4 percent. A lifetime dose of 100 rems may have increased your chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 0.3 rem (0.003 Sv) for 1992 (Ref. 6). Today, very few workers ever accumulate 100 rems (1 Sv) and the average career dose of workers at NRC-licensed facilities is 1.5 rem (0.015 Sv), which represents an increased risk of dying from cancer from 20 to about 20.06 percent.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck, will you get the ace of spades?" This question cannot be answered with a simple yes or no.

The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get the right card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who receive no occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 1 rem (0.01 Sv) is about the same as the chances of drawing an ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 10 rem (0.1 Sv) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. The numbers used here result from studies involving high doses and high dose rates.

These estimates are considered by the NRC staff to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

11. How can we compare radiation risk to other kinds of health risks?

Perhaps the most useful way to make these comparisons is to compare the average number of days of life expectancy lost per unit of exposure to each particular health risk. Estimates are calculated by looking at a large number

of persons, recording the age when death occurs from apparent causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total group observed.

Several studies have compared the projected average loss of life expectancy resulting from exposure to radiation with other health risks. The word average is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers suffer no loss.

Some representative numbers are presented in Table 1. For the NRC-regulated industries, the average measurable occupational dose in 1992 was 0.3 rem (0.003 Sv) (Ref. 6). A simple calculation based on the article by Cohen and Lee (Ref. 7) shows that 0.3 rem (0.003 Sv) per year from age 18 to 65 results in a projected estimate of life expectancy loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

Another useful comparison is to look at estimates of the average number of days of life expectancy lost from occupational exposure to radiation and to compare this number with days lost for several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include nonaccident types of occupational risks such as occupational disease and stress.

12. What are the NRC occupational dose limits?

For adults, an annual limit that does not exceed:

- 5 rems (0.05 Sv) for the Total Effective Dose Equivalent (TEDE), which is the sum of doses from external exposure to the whole body and from the equivalent internal doses from intakes of radioactive material. Doses to an organ or tissue must be multiplied by risk-weighting factors to compare the dose to a whole body exposure before they are added to the external dose.

TABLE 1
Estimated Loss of Life Expectancy from Health Risks[a]

Health Risk		Estimate of Life Expectancy Lost
Smoking 20 cigarettes a day		6 years
Overweight (by 15%)		2 years
Alcohol consumption (U.S. average)		1 year
All accidents combined		1 year
Motor vehicle accidents	207 days	
Home accidents	74 days	
Drowning	24 days	
All natural hazards (earthquake, lightning, flood, etc.)		7 days
Medical radiation		6 days
Occupational Exposure		
0.3 rem/y[b] from age 18 to 65		15 days
1 rem/y from age 18 to 65		51 days

[a]Adapted from Reference 7.
[b]From NUREG-0713, Reference 6.

TABLE 2
Estimated Loss of Life Expectancy from Industrial Accidents[a]

Industry Type	Estimates of Days of Life Expectancy Lost, Average
All industries	60
Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

[a]Adapted from Ref. 7.

- 50 rems (0.5 Sv) for the Total Organ Dose Equivalent (TODE), which is the sum of doses from external exposure to the whole body and the dose from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.

- 15 rems (0.15 Sv) for the Lens Dose Equivalent (LDE), which is the external dose to the lens of the eye.

- 50 rems (0.5 Sv) for the Shallow Dose Equivalent (SDE), which is the external dose to the sensitive portion of the skin or to any extremity.

For minors, the annual occupational dose limits are 10 percent of the dose limits for adult workers.

For the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy.

The occupational dose limit for adult workers of 5 rem (0.05 Sv) TEDE is based on consideration of potential delayed biological effects. The 5-rem (0.05 Sv) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by the NRC. The limits for individual organs are below the levels of observed early biological effects in the respective organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on consideration of the special sensitivity to radiation of the embryo/fetus. This limit is in effect only when a woman declares her pregnancy in writing to the licensee.

13. What is meant by ALARA ?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation exposure, the NRC requires that its licensees establish radiation protection programs for maintaining occupational exposures, and exposures to the public, as far below the limit as is reasonably achievable. Reasonably achievable also means

practical. What is practical depends on the purpose of the job, the state of technology, the costs for reducing the exposures, and the benefits. Although ALARA is a required integral part of each licensee's radiation protection program, it does not establish an occupational dose limit.

In practice, ALARA includes planning tasks involving radiation exposure so as to reduce exposure to individual workers, the work group, and those who, although not part of the work group, may be exposed as a result of the work group's actions. Work practices should be reviewed with the objective of preventing unnecessary exposures.

There are several ways to control radiation doses, e.g., limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose rates. The use of engineered controls is also a requirement of the ALARA concept -- from the design of facilities and equipment to the actual set-up and conduct of work activities.

The ALARA concept should also be used in determining the appropriate use of respiratory protection. To the extent practical, engineering controls such as containments and ventilation systems should be used to reduce workplace airborne radioactive materials. In evaluating whether or not to use respirators, the ALARA goal is to achieve the lowest sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure caused by longer working times. The goal is to maintain total exposure ALARA.

14. How much radiation does the average person who does not work in the nuclear industry receive?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40 and thorium) that contribute to the radiation we receive. The largest source of human radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, nonoccupational exposure. Cosmic radiation originating in space and in the sun contributes additional

exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 0.36 rem (3.6 mSv). By age 20, the average person will accumulate over 7 rems (70 mSv) of dose. By age 50, the total dose is up to 18 rems (180 mSv). After 70 years of exposure this dose is up to 25 rems (250 mSv).

TABLE 3
AVERAGE ANNUAL EFFECTIVE DOSE EQUIVALENT TO INDIVIDUALS IN THE U.S.[a]

Source		Dose Equivalent (mrems)
Natural		
	Radon	200
	Other than Radon	100
	Total	300
Nuclear Fuel Cycle		0.05
Consumer Products[b]		9
Medical		
	Diagnostic X-rays	39
	Nuclear Medicine	14
	Total	53
Total		~360 mrem/year

[a]Adapted from Table 8.1, NCRP 93 (Ref. 8).
[b]Includes tobacco, building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 8).

15. What are the typical radiation doses received by workers?

For 1992, the NRC received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 300 mrem (3 mSv) for the year. Of the total group of about a quarter of a million people, 97 percent received an annual dose of less than 1 rem (10 mSv); 99.7 percent received less than 2 rems (20 mSv); and the highest reported dose was for an individual who received between 5 and 6 rems (50 and 60 mSv).

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1992 data.

TABLE 4
Reported Occupational Doses for 1992*

Occupational Subgroup	Average Measurable Dose per Worker (millirems)
Industrial Radiography	490
Manufacturing and Distribution	260
Low-Level Waste Disposal	450
Independent Spent Fuel Storage	130
Fuel Fabrication	110
Commercial Power Reactors	310

* From Table 3.1 in NUREG-0713 (Ref. 6).

16. How do I know how much my dose (exposure) is?

The NRC requires your employer, the NRC licensee, to determine your exposure, to maintain records of your exposure, and, at least on an annual basis, to inform you of your exposure.

External exposures are monitored by using individual monitoring devices. These devices are required to be used if it appears likely that your external exposure will exceed 10 percent of your allowed annual dose. The most commonly used monitoring devices are film badges, thermoluminescent dosimeters (TLDs), electronic dosimeters, and direct reading pocket dosimeters.

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) if you are an adult, or a dose in excess of 0.05 rem (0.5 mSv) from intakes in one year if you are a minor or a declared pregnant worker. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material is in the air and the length of time during which the air was breathed.

17. What happens if a worker exceeds the annual dose limit?

The regulations do not permit any additional occupational exposure to a person who is exposed in excess of the limit during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the NRC and provide a copy to the individual. The licensee will be subject to NRC enforcement action (possibly a fine), just as you are subject to a traffic fine for exceeding the speed limit. The fines and, in some serious or repetitive cases, suspension of license are intended to encourage efforts to operate within the limits.

Radiation protection limits such as 5 rems (0.05 Sv) a year are not absolute limits that determine safe or unsafe levels of radiation exposures. Exceeding this limit does not mean that you will necessarily be harmed. It is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at the 55 mph limit, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, the revised 10 CFR Part 20 establishes a limit for normal occupational exposures of 5 rems (0.05 Sv) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's safety program has failed in some way. Investigation is warranted to determine the cause and correct the conditions leading to the exposure in excess of the limit.

Risks from higher doses that might be incurred in exceptional situations or emergencies are explained in Questions 19 and 22.

18. Is the use of extra workers a good way to reduce dose?

There is a "yes" answer to this question and a "no" answer. For a given job involving exposure to radiation, the more people who share the work, the lower the average dose to individuals. The less the dose, the less the risk. So, for you as an individual, the answer is "yes."

But how about the risk to the entire group of workers? Under assumptions used by the NRC for purposes of protection, the risk of cancer depends on the

total amount of radiation energy absorbed by human tissue, not on the number of people to whom this tissue belongs. Therefore, if 30 workers are used to do a job instead of 10, and if both groups get the same collective dose (person-rems), the total cancer risk is the same, and nothing was gained for the group by using 30 workers. From this viewpoint the answer is "no." The risk was not reduced but simply spread around among a larger number of persons.

Unfortunately, spreading the risk around often results in a larger collective dose for the job. Workers are exposed as they approach a job, while they are getting oriented to do the job, and as they withdraw from the job. The dose received during these actions is called nonproductive. If several crew changes are required, the nonproductive dose can become very large.

The use of extra workers may actually increase the total occupational dose and the resulting collective risks. The use of extra workers may not be the way to reduce the risk of radiation-induced cancer for the worker population. At best, the total risk remains the same, and it may even be increased. The best way to reduce the risk is to reduce the collective dose; that can be done only by reducing the radiation levels, the working times, or both.

19. What is meant by a "planned special exposure"?

A "planned special exposure" means an infrequent exposure to radiation, separate from, and in addition to, the doses received under the annual limits. The licensee can authorize additional dose that is equal to the annual occupational dose limits as long as the individual's total dose does not exceed five times the annual dose limits during the individual's lifetime. For example, licensees may authorize "planned special exposures" for an adult radiation worker to receive doses up to an additional 5 rems (0.05 Sv) in a year above the 5-rem (0.05 Sv) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rems (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical. Before the licensee grants approval, the licensee must ensure that the worker is informed of the purpose and circumstances for the

planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may be present. (See Regulatory Guide 8.35, "Planned Special Exposures," for further information.)

20. Why do some facilities establish administrative limits that are below the NRC limits?

There are two reasons. First, the NRC regulations state that licensees should keep exposures to radiation ALARA. By requiring specific approval for worker doses in excess of set levels, more careful risk-benefit analyses can be made as each additional increment of dose is approved for a worker. Secondly, an administrative limit that is set lower than the NRC limit provides a safety margin designed to help the licensee avoid exposures in excess of the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

NRC rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks.[3] Medical exposure to radiation is justified for reasons that are quite different, however, from those applicable to occupational exposure. A physician prescribing an x-ray should be convinced that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. Each worker must decide, however, on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

For another point of view, consider a worker who receives a dose of 2 rems (0.02 Sv) from a series of x-rays or a radioactive medicine in connection with an injury or illness. This dose and the implied risk should be justified on medical grounds. If the worker had also received 4 rems (0.04 Sv) on the job, the combined dose of 6 rems (0.06 Sv) would not incapacitate the worker.

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[3]It is likely that a significant portion of reported medical x-ray exposures are to parts of the body only. An exposure of 100 mrem (1 mSv) to the whole body is more significant than a 100-mrem (1 mSv) x-ray to the hand.

A dose of 6 rems (0.06 Sv) is not especially dangerous and is not large compared to the allowed cumulative occupational dose. Restricting the worker from additional job exposure during the remainder of the year would have no effect one way or the other on the risk from the 2 rems (0.02 Sv) already received from medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unfair to restrict the worker from employment in radiation areas for the remainder of the year.

22. How should radiation risks be considered in an emergency?

Although the use of planned special exposures allows an additional 5 rems (0.05 Sv) a year for special occasions, that allowance does not apply to emergencies. Emergencies are "unplanned" events in which actions to save lives or property may warrant additional doses for which no particular limit applies. Even though the revised 10 CFR Part 20 does not set any dose limits for lifesaving activities, workers should remember that radiation risks increase with increasing dose and that the ALARA principle applies for emergencies as well as routine activities. In addition, any doses received during emergencies have to be reported to the NRC and included on the worker's lifetime dose record. The NRC has not sanctioned any "forgivable" emergency dose that would not be counted in an individual worker's lifetime dose.

The Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 5 rems (0.05 Sv). There are some emergency situations, however, for which higher emergency limits may be justified. Justification of any such exposure must include the presence of conditions that prevent the rotation of workers or other commonly used dose reduction methods. Except as noted below, the dose resulting from such emergency exposures should be limited to 10 rems (0.1 Sv) for protecting valuable property, and to 25 rems (0.25 Sv) for lifesaving activities and the protection of large populations. In the context of this guidance, exposure of workers that is incurred for the protection of large populations may be considered justified for situations in which the collective dose avoided by

the emergency operation is significantly larger than that incurred by the workers involved.

Situations may rarely occur in which a dose in excess of 25 rems (0.25 Sv) for emergency exposure would be unavoidable in order to carry out a lifesaving operation or to avoid extensive exposure of large populations. However, persons undertaking any emergency operation in which the dose will exceed 25 rems (0.25 Sv) to the whole body should do so only on a voluntary basis and with full awareness of the risks involved, including the numerical levels of dose at which prompt effects of radiation will be incurred and numerical estimates of the risks of delayed effects.

Table 5 presents the approximate risk of premature death for a group of 1,000 workers of various ages who have all received an acute dose of 25 rems (0.25 Sv). If needed, the referenced EPA source document should be used for training regarding risks of high doses.

Even under emergency conditions, licensees and radiation workers should make every effort to evaluate the potential exposures before authorizing additional necessary doses. To the extent possible in an emergency, workers should be informed of the situation and procedures to follow to keep exposures ALARA.

TABLE 5

Risk of Premature Death
from Exposure to 25-Rem (0.25-Sv) Dose

Age at Exposure (years)	Estimated Risk of Premature Death (Deaths per 1,000 Persons exposed)
20-30	9.1
30-40	7.2
40-50	5.3
50-60	3.5

Source: EPA-400-R-92-001 (Ref. 2)

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23. Who developed the radiation risk estimates used in this guide?

Radiation risk estimates were developed by several national and international scientific organizations over the last 40 years. These organizations include the National Academy of Sciences (which has issued five reports from the Committee on the Biological Effects of Ionizing Radiations, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several recent reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombs at Hiroshima and Nagasaki. For example, UNSCEAR published revised risk estimates in 1988 (Ref. 9). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Ref. 10). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 3). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

24. How were radiation dose limits established?

The NRC radiation dose limits in 10 CFR Part 20 were established by the rulemaking procedures required for Federal agencies. Under the rulemaking procedures, the NRC staff developed a proposed rule that was then reviewed and approved by the 5-member Commission that directs the NRC. Following the Commission's approval, the proposed rule was published in the *Federal Register* for public comment. The *Federal Register* may be considered to be the government's newspaper. Publication in the *Federal Register* provided legal notice to all persons that the NRC was considering setting new radiation dose limits.

In developing the proposed dose limits, the staff considered the 1987 Presidential Guidance on occupational exposure. That guidance was developed under the lead of the EPA. The guidance was signed by the President and was intended for use by all Federal agencies. The staff also considered the recommendations of the International Commission of Radiological Protection (ICRP) and its U.S. counterpart, the National Council on Radiation Protection and Measurements (NCRP).

In addition to publication of the proposed Part 20 in the *Federal Register* in January 1986, the NRC sent copies to all NRC licensees and to many other interested parties. More than 800 sets of comments were received and considered by the staff in developing the final rule.

Note that the proposed rule presented a tentative NRC position on radiation dose limits. The final rule was developed only after consideration of comments from licensees, labor unions, public interest groups, other Federal agencies, scientific organizations, and other interested parties.

25. Several scientific reports have recommended that the NRC should use lower limits. Does the NRC plan to reduce the regulatory limits?

Since publication of the proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 11), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 10 rems (0.1 Sv) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 5 rems (0.05 Sv) in 1 year (Ref. 11). The NCRP recommended a cumulative limit, not to exceed 1 rem (0.01 Sv), times the individual's age with no more than 5 rems (0.05 Sv) in any year (Ref. 8).

The NRC does not believe that additional reductions in the dose limits are urgently required. Because of the practice of maintaining radiation exposures ALARA ("as low as is reasonably achievable"), the average radiation dose to occupationally exposed persons is well below the limits in the current Part 20 that became mandatory January 1, 1994, and the average risks to radiation workers are below those limits recommended by the ICRP and the NCRP.

For example, in 1992, only a few workers (0.3 percent) in nuclear facilities reporting to the NRC received annual doses that exceeded 2 rems

(0.02 Sv) (Ref. 6), and few are likely to exceed the 5-year limit recommended by the ICRP. The facilities included here were from six of the reporting industries that have the highest potential for occupational radiation exposures: nuclear power plants, industrial radiography, reactor fuel fabrication, low-level waste disposal, spent fuel storage, and radioisotope manufacturing. For another example, in 1992 about 97 percent of the same workers received annual doses of less than 1 rem (0.01 Sv), which provides reasonable assurance that cumulative dose limits based on age as proposed by the NCRP are being met.

The current dose limits contained in 10 CFR Part 20 are also consistent with the Federal guidance on occupational radiation exposure (described in Question 24), and any changes would be the subject of a future rulemaking.

26. What are my options if I decide the risks associated with my occupational radiation exposure are too high?

If the risks from exposure to radiation during your work are unacceptable to you, you could request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are considered acceptable when compared to other occupational risks by virtually all the scientific groups that have studied them. From an NRC regulatory basis, your employer is not obligated to guarantee you a transfer if you decide not to accept an assignment that requires exposure to radiation.

You also have the option of seeking other employment in a nonradiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, you may find different kinds of risk but you will not necessarily find significantly lower risks in another job.

You and your employer should practice the most effective work procedures so as to keep your exposure ALARA. Be aware that reducing time of exposure, maintaining distance from radiation sources, and using shielding can all lower your exposure. Plan radiation jobs carefully to increase efficiency while in the radiation area. Learn the most effective methods of using protective clothing to avoid contamination. Discuss your job with the radiation protection personnel who can suggest additional ways to reduce your exposure.

27. Where can I get additional information on radiation risk?

The following list suggests sources of useful information on radiation risk:

- Your employer - the radiation protection or health physics office where you are employed.

- Nuclear Regulatory Commission Regional Offices:

King of Prussia, Pennsylvania	(215) 337-5000
Atlanta, Georgia	(404) 331-4503
Lisle, Illinois	(708) 829-9500
Arlington, Texas	(817) 860-8100

- U.S. Nuclear Regulatory Commission Headquarters
  Radiation Protection & Health Effects Branch
  Office of Nuclear Regulatory Research
  Washington, DC 20555
  Telephone: (301) 415-6187

- Department of Health and Human Services
  Center for Devices and Radiological Health
  1390 Piccard Drive, MS HFZ-1
  Rockville, MD 20850
  Telephone: (301) 443-4690

- U.S. Environmental Protection Agency
  Office of Radiation and Indoor Air
  Criteria and Standards Division
  401 M Street NW.
  Washington, DC 20460
  Telephone: (202) 233-9290

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8. National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposure of the Population of the United States*, NCRP Report No. 93, September 1987.

9. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources, Effects and Risks of Ionizing Radiation*, Report E.88.IX.7, United Nations, New York, 1988.

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[1]Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

10. National Council or Radiation Protection and Measurements, *New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates*, Proceedings of the Twenty-third Annual Meeting of the National Council on Radiation Protection and Measurements Held on April 8-9, 1987 (1988).

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[1] Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249; or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

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Appendix C: An Overview of Regulations and Responsibilities for Users of Radioactive Materials

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The complete chapter is located on the following pages.

CHAPTER 1

An Overview of Regulations and Responsibilities for Users of Radioactive Materials

The devastating effects of high intensities of ionizing radiation on humans was illustrated vividly when the two atomic bombs were dropped on Japan to end World War II. Undoubtedly, the results of these events and the effects of radiation exposure to scientific pioneers caused the world to proceed in the peaceful applications of nuclear technology with considerable caution. Only one peacetime nuclear disaster has occurred in the world, at Russia's Chernobyl reactor site, where 31 persons were killed in 1986, and about 200 more persons probably will have their lives shortened by statistically significant amounts. However, compared with accident and fatality rates in other industries, this is an excellent record; just think of all the coal miners who have been killed during the past 30 years. But the accident at Chernobyl should not have happened, and surely would not have happened if the safety standards for the reactor's design and operation had been as stringent as those in the United States or other Western countries. Thus, the use of radioactive materials and radiation-producing equipment has been safe, although highly regulated, during the course of most of its development. An overview of current regulations concerning the use of radioactive materials in scientific investigations follows.

ATOMIC ENERGY COMMISSION

Although some regulations pertaining to radiation control existed in the United States prior to 1946, it was in that year that the Atomic Energy Act was passed. The Act created the *Atomic Energy Commission* (*AEC*), but

only the Federal Government was permitted to control and own radioactive materials. In 1954 the Act was amended to permit private organizations and individuals to own and use radioisotopes.

The AEC was given two general responsibilities:

1. Promote the peaceful use of nuclear technology.
2. Formulate and administer regulations to protect the health and safety of the general public.

Regulations concerning the use of radioactive materials were formulated with apparent conservatism for the times, and great emphasis was placed on providing training programs to persons (such as research scientists and physicians) who might utilize radioactive materials effectively in their work. It appears that among the fields of occupational safety, radiation safety led all others.

NUCLEAR REGULATORY COMMISSION

A congressional amendment and the Energy Reorganization Act was passed in 1974; this divided the responsibilities of the AEC and created two new commissions. The *Nuclear Regulatory Commission* (*NRC*) was charged with the responsibility of writing and enforcing regulations concerning the use of radioactive materials, and the *Department of Energy* (DOE) was given the other responsibilities previously held by the AEC. NRC enforces regulations by controlling the ownership and possession of radionuclides. A license is required for possession of radioactive materials, and license holders are inspected by NRC to determine if regulations are being followed by the licensee. If serious or repeated violations occur, a license may be revoked, and radioactive materials confiscated.

Other Federal agencies have responsibilities that occasionally overlap with NRC. They are the Department of Health, Education, and Welfare (HEW), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA).

ICRP AND NCRP

NRC regulations are based on reports and recommendations, primarily from two scientific bodies, the *International Commission on Radiological Protection* (*ICRP*) and, in the United States, the *National Council on Radiation Protection and Measurements* (*NCRP*). These organizations convene committees of scientists, experts in various aspects of radiation, to formulate standards and procedures, which are published as reports. Thus,

the ICRP and NCRP are advisory bodies that provide a scientific basis for regulations.

AGREEMENT STATES

Although the NRC is the federal agency responsible for adopting and enforcing rules and regulations that apply to users of radioactive materials, broad administrative responsibilities have been transferred to some state governments. An act in 1959 permitted the NRC (then the AEC) to make agreements with those states that could, and would, operate a suitable radiological health program for the radioactive material users in their states. States that have such agreements with the NRC are called *Agreement States*. Agreement states have their own state regulations and provide personnel to license and inspect users of radioactive materials. However, the NRC must approve a state's regulations and inspect its programs periodically. Effectively, an agreement state simply administers a program that is highly consistent with NRC regulations. Approximately half of the U.S. states are agreement states.

LICENSES

Licenses to use radioactive materials are issued by the NRC or by an agreement state, depending on where the radioactive materials are to be used. There are exceptions; federal agencies, such as the United States Department of Agriculture (USDA) and the Veterans Administration (VA), that have units operating within an agreement state remain under NRC control; also, nuclear power plants are licensed by NRC only.

Licenses for nonmedical uses fall into two classes: general and specific.

General Licenses

Without application, general licenses are granted to individuals and institutions, including profit-making companies. Such licenses permit the purchase and use of small quantities of certain radioisotopes that are deemed harmless to the general public. For example, many smoke alarm detectors contain a small radioactive source, and the general license permits the sale of such smoke alarms to the public.

Exempt Quantities

For small scientific experiments, demonstrations, and some clinical analytical methods, small quantities of appropriate radionuclides may be purchased under the general license. The NRC and agreement states' regula-

TABLE 1-1 Exempt Quantities of Some Radionuclides

Radionuclide	Quantity limit (μCi)
^{3}H	1000
^{14}C	100
^{32}P	10
^{125}I	1
^{90}Sr	0.1

tions provides a list of radionuclides and the maximum amount of each that may be possessed. Thus, *exempt quantities* are the amounts of a particular radionuclide that may be obtained without a specific license. The maximum amount of radioactivity listed as an exempt quantity does vary between different radionuclides as shown by a few examples in Table 1-1. The limits are consistent with the relative radiological health hazards of the radionuclides.

Specific Licenses

Specific licenses permit individuals or institutions to possess larger quantities of various radionuclides than are possible by purchasing exempt quantities. However, the license will specify which radionuclides may be obtained and the maximum quantities of each that can be possessed at any time. Thus, specific licenses are not blanket authorizations, instead they are highly individualized, and the maximum possession limits approved for specified radionuclides will depend on the licensee's needs and capability to use such materials safely and effectively.

Applications for a Specific License

Individuals may apply to either the NRC or the appropriate radiological health division of an agreement state, depending on his or her location. A typical application form is shown in Figure 1-1. Whether issued by an institution, agreement state, or the NRC, all forms are virtually identical in terms of content.

Besides the applicant's name the precise location (1–5) for the proposed use of radioactive materials is required. The specific radionuclides (6a) and maximum possession limits (6b) being requested are listed, along with their proposed use (7). If human subjects are involved additional forms are required. Because of disposal problems of animal carcasses contaminated with radioactive materials, information concerning possible animal use is needed. To determine if the licensee has access to facilities suitable for

radioactivity use, diagrams of lab facilities including fume hoods are requested (11). It is understood that radioactive materials will be used only in the facilities described. Information about radiation detection instruments (counters, survey meters) and their maintenance (10) indicate if the applicant has access to proper equipment. Training (8) is required and must be documentable. Finally, experience (9) working with radioactive materials should be listed, including formal laboratory courses and research conducted under the supervision of a licensee.

Institutional or Broad-Scope Licenses

Institutions as well as individuals may obtain Specific Licenses. Such licenses may be called *Institutional* or *Broad-Scope Licenses*, and they are useful in cases in which a company, university, or hospital has a number of individuals using radioactivity. The license would be in the name of the institution, and individuals would be listed as *Users*. The list of radionuclides and their possession limits would be sufficient for the needs of the whole institution, but each *User* would need to have the training and experience required for an individual specific license.

Effectively, a broad-scope or institutional license is an agreement between the institution and licensing agency that delineates responsibilities for user approval, safety programs, training, and disposal of radioactive wastes. The latitude given to an institution depends on the adequacy and qualifications of personnel, or, in more general terms, the institution's capability to provide an adequate radiation safety program. Just like the individual licensees, institutional licensees are inspected by their licensing agency.

Radiation Safety Officer. Institutional radiation programs generally have a *Radiation Safety Officer* (RSO) and a *Radiation Safety Committee*. Institutions may designate or hire an individual to administer the radiation program, and if the size of the program warrants it, the RSO may be a full-time employee with assistants. Generally, health physicists are selected for RSO positions. An RSO can be a valuable source of help to users in matters such as waste disposal, procurement, contamination, clean-up, and advice for unusual experiments. Occasionally, RSOs must assume police duties if violations occur.

Radiation Safety Committees. Radiation safety committees usually include several "users," the RSO, and an institutional administrator or officer. The committee may write and approve institutional rules and regulations, act on applications for prospective users, determine what action should be taken if violations occur, and advise the RSO and the administration of the institution.

Form NRH-3
(7-79)

Nebraska Department of Health

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS-Complete items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only items 1 through 7 and indicate new information or changes in the program as requested in items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: Nebraska Department of Health, Division of Radiological Health, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509. Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Regulations for the Control of Radiation and the Nebraska Radiation Control Act.

1. (a) NAME AND STREET ADDRESS OF APPLICANT (Institution, firm, hospital, person, ect.)

Telephone No: Area Code ( ) _____

STREET ADDRESS (ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED. (If different from 1 (a).)

2. DEPARTMENT TO USE RADIOACTIVE MATERIAL

Person to Contact _____

Telephone No: Area Code ( ) _____

3. This is an Application for: (Check appropriate item)

a. ☐ New license

b. ☐ Amendment to License No. _____

c. ☐ Renewal of License No. _____

4. INDIVIDUAL USERS (S). (Name and title of individual (s) who will use or directly supervise use of radioactive materials. Give training and experience in Items 8 and 9.)

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9).

6. (a) RADIOACTIVE MATERIAL. (Elements and mass number of each.)

CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM QUANTITY OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME (If sealed source (s), also state name of manufacturer, model number, number of sources and maximum activity per source.)

7. DESCRIBE PURPOSE FOR WHICH RADIOACTIVE MATERIAL WILL BE USED. (If radioactive material is for "human use," FORM NRH-5A must be completed in lieu of this item. If radioactive material is in the form of sealed sources, include the make and model number of the storage and / or device in which the source will be stored and/or used.)

FIG. 1-1 An application form for a radioactive materials license in the state of Nebraska, which is an Agreement State. Forms used by the Nuclear Regulatory Commission and other Agreement States are nearly identical.

Form NRH-3
(7-79)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection			Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience).

15. ISOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary).

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm)	USE (Monitoring, Surveying, Measuring)

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier).

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached (Circle answer) Yes No

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

CERTIFICATE

(This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH NEBRASKA DEPARTMENT OF HEALTH REGULATIONS FOR THE CONTROL OF RADIATION AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Applicant name in Item 1

Date _____ By: _____

Title of certifying official authorized to act on behalf of the applicant

User Permits. In an institution with a broad-scope license, prospective users will submit an application for a *User Permit*. Generally, the application forms are the same as those for individual licenses, and qualifications for becoming a user are the same also. However, the application may be approved by the RSO and/or the radiation safety committee. From the users perspective, a Users Permit effectively is a specific license granted by an institution.

Enforcement of Licenses

A fairly simple regulation prevents persons and institutions from possessing radioactive material without a specific license. It is illegal to transfer (sell or give) radioactive materials to another person or institution unless the recipient has a license to possess the materials. Consequently, radionuclide supply companies require information about a customer's license before they will fill an order, and license numbers must accompany orders. Regulations are violated if a licensee gives radioactive materials to another who does not hold a license that permits the possession of such materials.

License and Permit Conditions

Licenses and user permits are not granted for life, but must be renewed periodically. Renewals usually are granted unless violations indicate that an individual or institution is not performing radiation safety duties properly. Licenses have been revoked or suspended because of continued violations of approved safety practices.

Holders of individual specific licenses and user permits are inspected periodically by the licensing agency or perhaps by an institutional RSO. The purpose of inspections is to ascertain whether the users are following appropriate safety procedures. Practically speaking, the responsibility for radiation safety rests on those persons actually using the radioactive materials. This is one reason why so much emphasis is placed on the training and experience of individual users.

Training and Experience Requirements

The amount of training and experience required for approval of specific licenses or user permits is remarkably consistent. Generally, license applicants will have at least a B.S. degree in a scientific field and special training in using radiation. The required radiation training is divided into four categories (see items 8a, b, c, and d of the application form in Figure 1-1):

8a. Principles and practices of radiation protection.

8b. Radioactive measurement standardization and monitoring techniques and instruments

8c. Mathematics and calculations basic to the use and measurement of radioactivity.

8d. Biological effects of radiation.

These topics may be covered, with sufficient depth, in a formal course of about 40 hours duration. Formal courses are desirable because they are easily documented by transcripts or certificates. On-the-job training is acceptable, but it is difficult to document the content and balance of topics in such training. Self-study, and the subsequent passing of an exam to document knowledge, is another method that is gaining popularity.

Experience working with radionuclides may be gained by formal laboratory courses or performing research utilizing radioisotopes under the supervision of a licensee or permit holder. Documentation of such experience is important for first-time applicants.

Responsibilities of Licensees and Users

Laboratory rules will be discussed more fully in Chapter 16, but in general, a User must

1. Keep records showing the receipt and disposal of all radioactive materials.
2. Use adequate security methods to prevent the general public and untrained individuals from coming in contact with radioactive materials.
3. Dispose radioactive wastes by approved methods only.
4. Prevent unnecessary radiation exposure to anyone, including oneself.

CONCLUSION

The use of radioisotopic materials in biological and medical research has become essential and commonplace in about all areas of laboratory investigations. Although the regulations may appear as impediments, the possibilities of their relaxation seem remote in light of current public attitudes. Consequently, a person embarking on a scientific or medical career is well advised to seek training in the use of radioactivity. Hopefully, this chapter alerts the reader to areas of knowledge needed for licensure, and the remainder of the book provides a suitable theoretical basis for the *effective* and *safe* use of radioactive materials in research.

Additionally, some other groups exposed to radiation *in utero* have shown lower than average intelligence scores and poor performance in school (Reference 4).

The sensitivity of the brain undoubtedly reflects its structural complexity and its long developmental period (and hence long sensitive period). The most sensitive period is during about the 8th to 15th weeks of gestation followed by a substantially less sensitive period for the 2 months after the 15th week (Reference 4). There is no known effect on the child's developing brain during the first two months of pregnancy or the last three months of pregnancy (Reference 4).

No developmental effects caused by radiation have been observed in human groups at doses at or below the 5-rem (50-millisievert) occupational dose limit. Scientists are uncertain whether there are developmental effects at doses below 5 rems (50 millisieverts). It may be that the effects are present but are too mild to measure because of the normal variability from one person to the next and because the tools to measure the effects are not sensitive enough. Or, it may be that there is some threshold dose below which there are no developmental effects whatsoever.

In view of the possibility of developmental effects, even if very mild, at doses below 5 rems (50 millisieverts), scientific advisory groups consider it prudent to limit the dose to the embryo/fetus to 0.5 rem (5 millisieverts) (References 1 and 2). At doses greater than 5 rems (50 millisieverts), such as might be received during an accident or during emergency response activities, the possibility of developmental effects increases.

5. How much will the likelihood of cancer be increased?

Radiation exposure has been found to increase the likelihood of cancer in many studies of adult human and animal groups. At doses below the occupational dose limit, an increase in cancer incidence has not been proven, but is presumed to exist even if it is too small to be measured. The question here is whether the embryo/fetus is more sensitive to radiation than an adult.

While the evidence for increased sensitivity of the embryo/fetus to cancer induction from radiation exposure is inconclusive, it is prudent to assume that there is some increased sensitivity. Scientific advisory groups assume that radiation exposure before birth may be 2 or 3 times more likely to

cause cancer over a person's lifetime than the same amount of radiation received as an adult (Reference 1). If this is true, there would be 1 radiation-induced cancer death in 200 people exposed *in utero* at the occupational dose limit of 5 rems (50 millisieverts) (Reference 1). Scientific advisory groups have considered this risk to be too high and have thus recommended that the radiation dose to the embryo/fetus be limited to a maximum of 0.5 rem (5 millisieverts). At that dose, there would be 1 radiation-induced cancer death per 2000 people. This would be in addition to the 400 cancer deaths from all causes that one would normally expect in a group of 2000 people.

6. How does the risk to the embryo/fetus from occupational radiation exposure compare to other avoidable risks?

The risk to the embryo/fetus from 0.5 rem or even 5 rems of radiation exposure is relatively small compared to some other avoidable risks.

Of particular concern is excessive consumption of alcohol during pregnancy. The U.S. Public Health Service has concluded that heavy alcohol consumption during pregnancy (three drinks per day and above) is the leading known cause of mental retardation (Reference 6). Children whose mothers drank heavily during pregnancy may exhibit developmental problems such as hyperactivity, distractibility, short attention spans, language difficulties, and delayed maturation, even when their intelligence is normal.

In studies tracking the development of children born to light or moderate drinkers, researchers have also correlated their mothers' drinking patterns during pregnancy with low birth weight, decreased attention spans, delayed reaction times, and lower IQ scores at age 4 years. Youngsters whose mothers averaged three drinks per day during pregnancy were likely to have IQs averaging 5 points lower than normal.

Cigarette smoking may also harm the unborn (Reference 6). There is a direct correlation between the amount of smoking during pregnancy and the frequency of spontaneous abortion and fetal death. Children of mothers who smoke while pregnant are more likely to have impaired intellectual and physical growth. Maternal smoking has also been associated with such behavioral problems in offspring as lack of self-control, irritability,

hyperactivity, and disinterest. Long-term studies indicate that these children perform less well than matched youngsters of nonsmokers on tests of cognitive, psychomotor, language, and general academic functioning.

Alcohol and smoking are only examples of other risks in pregnancy. Many other toxic agents and drugs also present risk. In addition, many factors that cannot be controlled present risk. There is an increased risk in pregnancy with increasing maternal age. Maternal disease may be an important risk factor. Malnutrition, toxemia, and congenital rubella may be associated with birth defects. Maternal diabetes and high blood pressure have been associated with problems in the newborn. In addition, many birth defects and developmental problems occur without an obvious cause and without any obvious risk factors. For example, viruses that we may not even be aware of can cause defects, and defects can arise from spontaneous random errors in cell reproduction. But these are things that we can't do anything about.

In summary, you are advised to keep radiation exposure of your unborn child below 0.5 rem, but you should also remember that alcohol consumption, cigarette smoking, and the use of other drugs can do a great deal of harm.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure to occupational radiation at all, but your employer may not have such a position or may not be willing to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, you will receive a dose typically about 0.3 rem (3 millisieverts) from unavoidable natural background radiation (Reference 7).

8. What effect will formally declaring my pregnancy have on my job status?

Only your employer can tell you what effect a declaration of pregnancy will have on your job status. As part of your radiation safety training, your employer should tell you its policies with respect to the job status of declared pregnant women. In addition, we recommend that, before you declare

your pregnancy, you talk to your employer and ask what a declaration of pregnancy would mean specifically for you and your job status. However, if you do not declare your pregnancy, the lower exposure limit of 0.5 rem (5 millisieverts) does not apply.

It is most likely that your employer will tell you that you can continue to perform your job with no changes and still meet the NRC's limit for exposure to declared pregnant women. A large majority of licensee employees (greater than 90%) receive, in 9 months, occupational radiation doses that are below the 0.5-rem (5-millisievert) limit for a declared pregnant woman.

If the dose you currently receive is above the 0.5-rem (5-millisievert) dose allowed for a declared pregnant woman, it is quite likely that your employer can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee perform a small part of the job that accounts for much of the radiation exposure.

On the other hand, it is possible, although not common, that your employer will conclude that there is no reasonable accommodation that can be made without undue hardship that would allow you to do your job and remain within the dose limits for a declared pregnant woman. In these few instances, your employer may conclude that you can no longer be permitted to do your current job, that you must be removed from your job, and that there is no other job available for someone with your training and job skills.

If your employer concludes that you must be removed from your current job in order to comply with the lower dose limits for declared pregnant women, you may be concerned about what will happen to you and your job. The answer to that depends on your particular situation. That is why you should talk to your employer about your particular situation. In addition, telephone numbers that may be useful for obtaining information are listed in response to question 20 in this guide.

HOW TO DECLARE YOUR PREGNANCY

9. What information must I provide in my declaration of pregnancy?

You must provide your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to your employer. A sample form letter that you can use is included at the end of these questions and answers. You may use that letter or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

No. No proof is necessary.

11. Can I tell my employer orally rather than in writing that I am pregnant?

No, the declaration must be in writing. As far as the regulations are concerned, an oral declaration or statement is the same as not telling your employer that you are pregnant.

12. If I have not declared my pregnancy in writing, but my employer notices that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The choice of whether to declare your pregnancy and thereby work under the lower dose limits is your choice, not your employer's. Your employer may not remove you from a specific job because you appear pregnant.

13. If I am planning to become pregnant but am not yet pregnant, and I inform my employer of that in writing, do the lower dose limits apply?

No. The lower limits apply only if you declare that you are already pregnant.

14. What if I have a miscarriage or find out I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform your employer that you are no longer pregnant. The regulations do not require that the revocation of a declaration be in writing, but we recommend that you revoke the declaration in writing to avoid confusion. Also, your employer may insist upon a written revocation for its own protection. If you have not declared your pregnancy, there is no need to inform your employer of your new, nonpregnant status.

If you have a miscarriage and become pregnant again before you have revoked your original declaration of pregnancy, you should submit a new declaration of pregnancy because the date of conception has changed.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until (1) your employer knows you have given birth, (2) you inform your employer that you are no longer pregnant, or (3) you inform your employer that you no longer wish to be considered pregnant.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limits no longer apply.

17. What if I work under contract at the licensed facility and my employer is not the licensee?

The regulations state that you should formally declare your pregnancy to your employer in writing. You can ask your employer to give a copy of your declaration to the licensee, or you may give a copy of your written declaration directly to the licensee.

18. Can I tell my employer I am pregnant when I know I am not in order to work under the lower dose limits?

The purpose of the NRC regulations is to allow a pregnant woman to choose a heightened level of protection from radiation exposure for the embryo/fetus during her pregnancy. That purpose would not be served by intentionally declaring yourself to be a pregnant woman when you know you are not pregnant. There are no NRC regulatory requirements specifically addressing the actions your employer might take if you provide a false declaration. However, nothing in NRC regulations would prevent your employer from taking action against you for deliberately lying.

STEPS TO LOWER RADIATION DOSE

19. What steps can I take to lower my radiation dose?

Your employer should already have explained that to you as part of the instructions that licensees must give to all workers. However, you should ask your supervisor or the radiation safety officer whether any additional steps can be taken.

The general principles for maintaining exposure to radiation as low as reasonably achievable are summarized below. You should already be applying these principles to your job, but now is a good time to review them.

External Radiation Exposure: External radiation is radiation you receive from radiation sources or radioactive materials that are outside your

body. The basic principles for reducing external radiation exposure are time, distance, and shielding -- decrease your time near radiation sources, increase your distance from radiation sources, and increase the shielding between yourself and the radiation source. You should work quickly and efficiently in a radiation area so that you are not exposed to the radiation any longer than necessary. As the distance is increased from the source of radiation, the dose decreases. When possible, you should work behind shielding. The shielding will absorb some of the radiation, thus reducing the amount that reaches you.

Internal Radiation Exposure: Internal radiation is radiation you receive from radioactive materials that have gotten into your body, generally entering with the air you breathe, the food you eat, or the water you drink. Your employer will have specific procedures to minimize internal radiation exposure. Those procedures probably incorporate the following general precautions that should be taken when you are working with radioactive materials that are not encapsulated:

1. Wear lab coats or other protective clothing if there is a possibility of spills.

2. Use gloves while handling unencapsulated radioactive materials.

3. Wash hands after working with unencapsulated radioactive materials.

4. Do not eat, drink, smoke, or apply cosmetics in areas with unencapsulated radioactive material.

5. Do not pipette radioactive solutions by mouth.

These basic principles should be incorporated into the specific methods and procedures for doing your individual work. Your employer should have trained you in those specific rules and procedures.

Appendix E: Practical Aspects of Radiation Protection

Knoche, Herman W. (1991). Practical Aspects of Radiation Protection. In Radioistotopic Methods for Biological and Medical Research (PP 357-376, Chapter 16). New York: Oxford

The complete chapter is located on the following pages.

CHAPTER 16

Practical Aspects of Radiation Protection

Radiological safety procedures are designed to accomplish two broad objectives: (1) to prevent untrained persons, the general public including non-occupational co-workers, from coming in contact with sources of ionizing radiation and (2) to prevent occupational workers from receiving exposures that are unsafe or above that necessary to perform their job functions. Thus, the purposes of many procedures are to warn persons of possible hazards, to provide security for radiation sources, to contain radioactivity, and to prevent possible spread of radioactive contamination.

THE RADIATION SYMBOL AND POSTING OF AREAS

A universal symbol is used to identify sources of radiation and areas in which such sources may exist. As shown in Figure 16-1, it consists of a three-bladed figure, colored magenta, on a yellow background. The size of the symbol varies with its use, but is always a conspicuous component of warning signs and labels.

High Radiation Area

Rooms where an individual may receive a dose of 1.0 mSv (100 mrem) in 1 hr must be posted with a warning sign stating "Caution" or "Danger High Radiation Area" along with the radiation symbol. Access to such areas must be controlled by locks and keys, and visual or audible alarms may be used as a signal when persons enter the area.

FIG. 16-1 The universal symbol for radiation hazards.

Radiation Area

Areas where a person may receive a dose of 0.05 mSv (5 mrem) in 1 hr or a dose of 1.0 mSv (100 mrem) in five consecutive days must be posted with a sign stating "Caution Radiation Area."

Airborne Radioactivity Area

Areas where the concentration of airborne radioactive materials exceeds certain levels must be posted with a sign stating "Caution Airborne Radioactive Area." The levels applicable depend upon the radionuclide present and may be determined from tables that list Maximum Permissible Concentrations (MPC) of radionuclides in air. Such values are normally available in the regulations of licensing agencies, and an older version is given by Wang (1969). An abbreviated table was presented as Table 15-5.

Radioactive Materials

The most common posting for radiotracer laboratories is a warning about the presence of radioactive materials. Rooms where any radioactive material, other than natural uranium or thorium, is used or stored must be posted with a sign stating "Caution Radioactive Materials" (see Figure 16-1) unless the amounts of radioactivity are below certain levels. The amount of radioactivity requiring a sign depends on the radionuclide in question, but it is 10 times the amount given as an exempt quantity for that radionuclide. Tables provided by regulatory agencies have values for all the radionuclides, but a few values were given in Table 1-1. For ^{32}P, the exempt quantity limit is 10 μCi. Therefore, a room where 100 μCi of ^{32}P is present must be posted with a "caution radioactive materials" sign.

In many laboratories sources of several different radionuclides are present and the quantities vary from time to time. Perhaps a good policy is, if you have a specific license or a user's permit under a broad scope license, then post the areas where the materials are stored and used.

Containers of Sources

Most containers of radioactive materials must have a label attached. An example of an appropriate label is shown in Figure 16-2. Besides the usual radiation symbol and the words "Caution Radioactive Materials," there should be space to clearly indicate the quantity of radioactivity, the radionuclide, and the date. Whether labels are required depends on the radionuclide in the container. For a particular radionuclide, a label is required if the amount of radioactivity is above its "exempt quantity" level (Table 1-1) and its concentration exceeds the MPC level for a restricted area (Table 15-7). For example, a vial containing over 100 μCi of ^{14}C in a volume less than 5000 ml would require a label.

Containers in transport are packaged and labeled differently, according to the regulations of the U.S. Department of Transportation. Such labels are frequently referred to as DOT labels and one is shown in Figure 16-3.

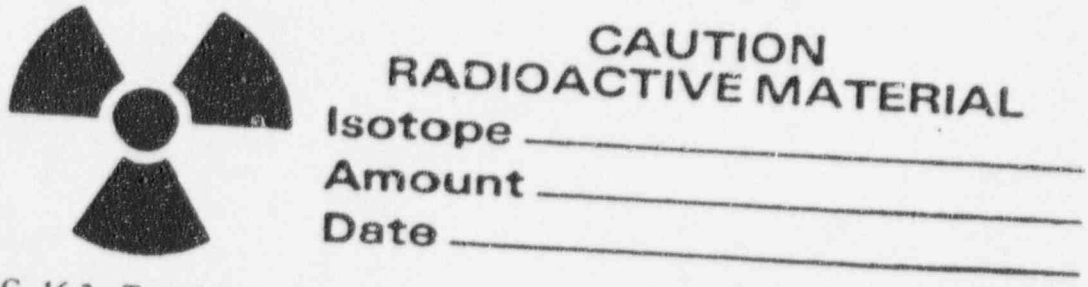


FIG. 16-2 Tape for labeling source containers.

FIG. 16-3 A "DOT" label required by the Department of Transportation for shipment of radioactive materials.

Security

To prevent untrained individuals from coming in contact with radioactive materials or accidentally operating radiation-producing equipment, laboratories or storage areas for materials should be under lock and key except when trained personnel (occupational workers) are present.

SOURCES

Frequently, sources of radioactive materials are classified as "sealed" or "open" sources. Sealed sources are those in which the radioactivity is in an impervious container and mechanically protected from crushing or destruction. The radiation emanating from such sources is used, but the actual radioactive material is not. Examples of sealed sources are the metallic capsules of ^{137}Cs that are used as external standards in liquid scintillation counters. Beta-ionization detectors used on gas chromatographs also contain a sealed source.

Leak testing of sealed sources should be conducted periodically, usually at 6-month intervals, and is performed by wiping the outside of the source with absorbent paper or cotton, and counting the wiping material with an appropriate counter.

Open sources are those from which radioactive materials may be withdrawn. Radioactive materials in glass containers, whether capped or flame-sealed, are considered to be open sources.

PERSONNEL MONITORING

A number of methods are used to aid occupational workers in keeping radiation exposures as low as reasonably achievable and in keeping records of actual exposures.

Warning Devices

Areas where exposure levels may be quite high or may change unexpectedly may be equipped with monitors that activate sound and/or light warning devices. G-M or ionization chambers are frequently used as detectors for such devices.

Survey Meters

Some survey meters have an auditory output that emits a clicking sound or howl, and may serve as a warning device. However, the primary use of survey meters is to locate small sources of radiation that represent spills or contamination.

Survey meters are inexpensive rate meters that read in units, such as cpm, μGy/hr, and mR/hr, and most have multiple range switches for selecting sensitivities appropriate for various tasks. Portable battery-operated meters, such as those shown in Figure 16-4 are popular. However, alternating current-operated meters are available and each has a long flexible cable between the meter and its probe (detector) so that the probe can be used at a considerable distance from the meter.

All types of radiation, including neutrons, may be detected with survey

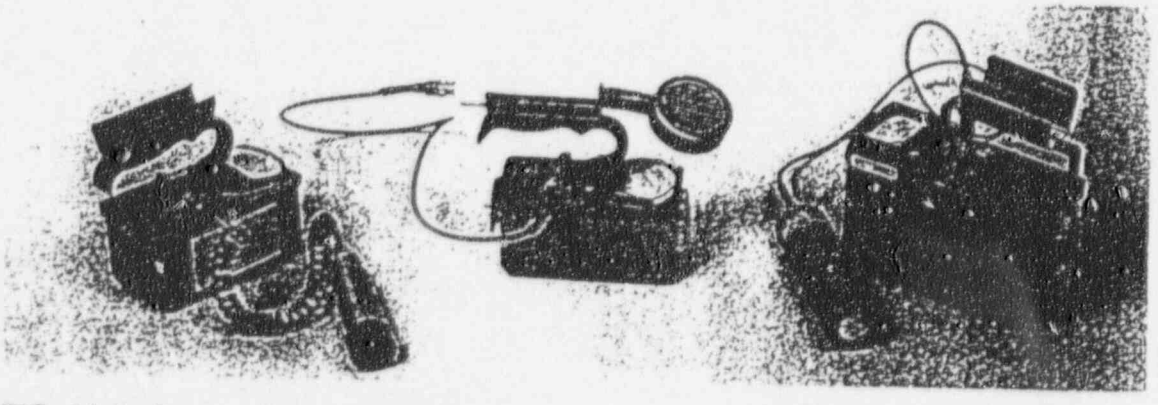


FIG. 16-4 Survey meters with different types of probes. Left to right: end-window G-M, pancake G-M, and solid scintillation probes.

meters depending on the type of detection probe employed. The most common probe for laboratory work is a rugged end-window G-M tube that has a relatively thin window so that weak β-particles and α-particles may be detected. Although detection efficiency is low, a G-M probe will detect X- and γ-rays. The so-called "pancake" probe is a G-M tube with a large diameter window and a short tube length that makes it quite sensitive in detecting low activity spots of contamination. Normally the windows of G-M tubes are protected against puncture by highly perforated covers such as plastic or wire grids. Solid scintillation crystal probes are preferred over G-M or proportional tubes when only X- and γ-rays are involved because of their greater sensistivities toward that type of radiation.

Whenever work with open sources is being performed, a survey meter with an appropriate probe should be available in the immediate vicinity, in case of an accident and to check for contamination.

Pocket Ionization Chambers

A pocket ionization chamber (or pocket dosimeter) and its charging device is shown in Figure 16-5. Such devices usually are about the size of a marking pen and are carried in a pocket by an occupational worker who might be exposed to relatively high levels of external sources of X- or γ-radiation.

The operating principle of these devices is similar to that of a Lauritsen electroscope, described in Chapter 6. At one end of the chamber is a lens with an exposure scale, perhaps with units of mR or μGy, and at the other end are contact points for charging the chamber. Translucent insulating material is used between the contact points so that light may enter, and allow a person to read the position of the quartz fiber relative to the scale.

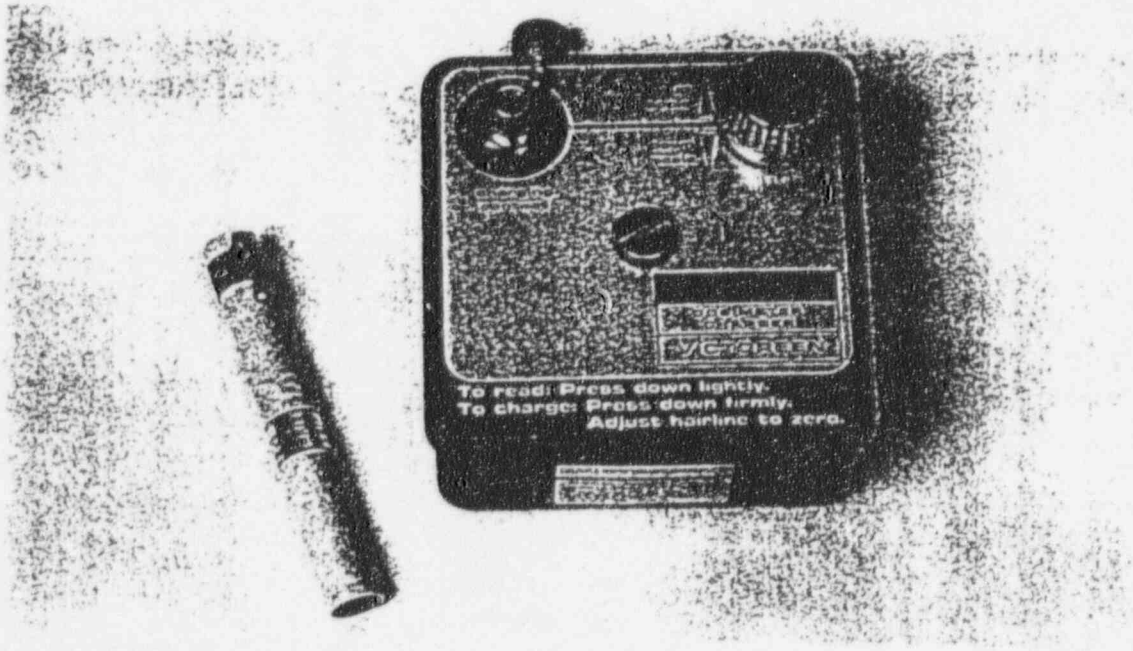


FIG. 16-5 A pocket dosimeter that operates as an electroscope, and its charger.

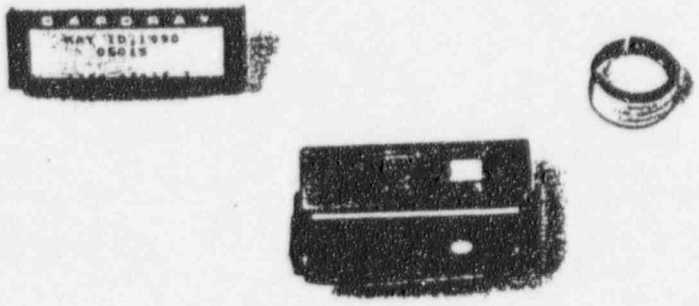


FIG. 16-6 Film badges for personnel monitoring. The "body badge" on the left is shown open in the center; note the different shielding sections. A "hand or ring badge" is shown on the right.

Beginning a work period, a person charges the dosimeter, setting the fiber to zero on the scale, and places it in his or her pocket. After completion of work the dosimeter is read, and the exposure is recorded in a log book. These pocket dosimeters are not as sensitive as some of the other types of personnel monitors. For that reason they are used primarily when the possibility of a fairly high exposure in a short period of time exists.

Film Monitors

Film badges utilize photographic emulsions as detectors. A film pack, film covered by paper to exclude light, is inserted in a plastic holder that is clipped to clothing and worn during working hours for a period of a week or a month (Figure 16-6). Film packs attached to rings are used to measure exposure to hands, while the body badges are used to estimate whole body exposures. The optical density of the developed film is related to the exposure levels. Absorption filters may be incorporated into the badge holder so that certain areas of the film are covered by different thicknesses of absorbing materials that permit estimation of the energies of the rays and determination of the type of radiation involved. These absorption filters also extend the measurable exposure range for film badges.

Generally, commercial laboratories supply, develop, read the films, and issue a monthly report to clients. The dose range most commonly used is about 30–1000 mrem (0.3–10 mSv).

Film badges are excellent monitors for X-, γ-, and high energy β-rays but are not effective for detecting low energy β-particles, α-particles, and neutrons.

Thermoluminescent Dosimeters

Thermoluminescent dosimeters are referred to as TLDs and are used in a manner similar to film badges. The energy levels of certain materials, such as LiF activated with Mg and Ti, may be raised to metastable states by the

absorption of radiation, and the molecules remain in their metastable states unless they are heated strongly. On heating, 180–25-°C, the molecules release their excess energies as photons of light, the intensity of which is measured by an M-P tube. Generally, TLDs are small packets of the solid material that are worn in a holder. At weekly or monthly intervals the packets are replaced and sent to a commercial laboratory for reading. As far as the types of radiation detected, TLDs are similar to film monitors, however, they have a greater dose detection range, about 10^{-4} to 1 Gy or 0.01 to 100 rad.

The different personnel monitoring devices discussed above serve different functions, consequently the selection of a device(s) depends on the types and levels of radiation a worker is likely to experience. Essentially, every laboratory should have a survey meter to check for contamination and some type of dosimeter, either a pocket ionization chamber, film badge, or TLD if X- or γ-rays are involved. However, the purpose of these devices is to detect and measure sources of radiation external to the worker's body.

DETECTION OF INTERNAL SOURCES OF RADIATION

Weak β-emitters and α-emitters do not constitute a serious radiological hazard unless they are taken into the body. Therefore, if such radionuclides are used, methods are needed to detect and determine body burdens when they exist.

Bioassays

Most radionuclides are excreted in urine, therefore their presence can be detected by counting urine samples. Other body fluids, such as blood and saliva, may be better for detecting certan isotopes, but these are less easily obtained. Breath samples, nose wipes, and fecal samples may also be used. Internal concentrations of ^{131}I or ^{125}I can be estimated by monitoring the thyroid gland with a sensitive external detector.

Persons working with quantities of tritium in excess of 100 mCi should monitor their urine, and thyroid monitoring should be done when working with more than 10 mCi of volatile (unbound) ^{131}I or ^{125}I.

DETECTION OF CONTAMINATION

Contamination of working areas, and possibly beyond, represents a potential hazard to the public as well as to occupational workers. Contamination may also invalidate laboratory results, therefore emphasis is placed on

methods to detect contamination so that corrective measures can be applied.

Survey Meters

Survey meters are useful for surveying working surfaces to detect possible spills, to check equipment and one's hands or clothing for contamination. Usually, the probe is held by hand and moved slowly and closely over the surfaces to be surveyed. Rate meters may have a relatively slow response time and geometric factors are not ideal for detecting a small spot of contamination, therefore considerable patience is required to adequately survey an area such as a lab bench.

Wipe Tests

If radioactive materials are present on a surface, wiping that surface with a filter paper disc or a cotton-tipped stick will remove some of the radioactivity. Assaying the wiping material will indicate if contamination is present. For example, if one is working with tritium, a 2-cm-diameter filter paper disc may be used to wipe an approximate area of 100 cm^2 in a location where contamination might be suspected. The disc is placed in a liquid scintillation vial, scintillaton fluid is added, and the sample counted for reasonably long time (10 min). Such measurements are not designed to be quantitative, but the level of activity is related to the extent of *removable* contamination. Sample counting rates less than 1.5 to 2 times the background counting rate generally are considered to be free of contamination. Of course, the types of radioactive materials that might be present govern the type(s) of counting instrument that should be used to assay wipe samples.

Occupational workers are expected to conduct wipe tests after experiments involving open sources and also at periodical intervals, weekly or monthly, to check for unsuspected contamination. Local regulations vary with respect to the frequency of wipe test surveys, but documentation of such surveys at specified intervals is required. A high frequency of surveys is considered a good practice.

GENERAL LABORATORY RULES FOR WORKERS

The rules for safe handling of radionuclides may vary among institutions, but the variation is largely a matter of format rather than intent. Therefore, the following list of rules is representative of rules a worker is likely to encounter.

Personal cleanliness and use of careful techniques are the primary

means of preventing contamination and in protecting persons against inhalation, absorption, or ingestion of radionuclides. In order to minimize contamination and prevent entrance of radionuclides into the body, the following rules should be observed in laboratories where unsealed sources are used.

1. Eating, drinking, smoking, food preparation, food storage, and application of cosmetics shall not be permitted in any laboratories where radioactive materials are used or stored.
2. Storage of food and beverages is not permitted in the same storage location (refrigerator, freezer, etc) as radioactive materials.
3. Protective gloves shall be worn when handling radionuclides.
4. Pipetting of radioactive solutions by mouth shall not be permitted no matter what activity is involved. Remote devices are available and shall be used for such applications.
5. Containers for radioactive samples shall have only one distinctive label indicating the nuclide(s), amount(s), and date(s).
6. No experiment with radionuclides should be undertaken until trial runs, complete in every detail, are made with nonradioactive materials. Such trials should be repeated until the procedure is reproducible and improvements have been incorporated as needed.
7. Any work with radionuclides susceptible to atmospheric distribution (e.g., vaporizing, aerosol producing, spillage, dusting, effervescence of solution or other releases of radioactive gas) shall be confined to suitable hood or glove box.
8. Personnel shall not be permitted to work with radionuclides if there are open cuts or abrasions on the body (e.g., fingers, hands, or arms). Extreme caution must be taken to avoid cuts or puncture wounds, especially when working with materials of high activity or high hazard.
9. Care must be exercised when using organic solvents to avoid skin contact with radioactive materials. (Solvents may make the skin more permeable and many are biohazards.) Radioactive iodine (nonbound forms) has the ability to permeate polyvinyl, latex, and rubber gloves. It permeates polyethylene gloves at a much slower rate. Therefore, when handling radio iodine, 2 pairs of gloves (preferably polyethylene) shall be worn with the outer pair changed after each handling and hands surveyed at the end of the handling.
10. Monitoring of hands, feet, and clothing is recommended when using radionuclides and will be required when large amounts of radionuclides are being used. Protective garments should be left in the laboratory when work is completed or until monitored and found free of contamination.

Contamination of laboratory facilities represent a hazard to personnel and jeopardizes experimental results. The following rules are designed to avoid laboratory contamination.

1. Contaminated equipment, or equipment that has been used and is suspected of being contaminated, shall be isolated in designated areas in the laboratory or in suitable storage spaces until it can be wipe-tested to determine the contamination level, and equipment shall be decontaminated as soon as possible. Contaminated equipment must bear the "Caution Radioactive Material" label.
2. One sink in each laboratory shall be designated for washing contaminated glassware and equipment.
3. Tools, equipment, and apparatus when used in handling radioactive material, should be placed in nonporous metal trays or pans that are lined with plastic-backed absorbent (disposable) paper. This paper should be surveyed and changed frequently.
4. Any working surface where radioactive materials are used shall be covered with plastic-backed absorbent paper (disposable) or polyethylene sheets and be appropriately labeled. This paper or polyethylene sheet should be surveyed and changed frequently.
5. Auxiliary containers, blotters, and covers shall always be used where danger of spills and contamination of personnel exist.
6. Care should be taken that equipment not immediately necessary to the operations being performed is not brought into the working area.
7. Equipment and tools shall be routinely surveyed following their use. No equipment shall be returned to stock unless it is known to be completely free of contamination inside and out.
8. Contamination shall not be allowed to remain on working surfaces unless appropriately shielded.

ACCOUNTABILITY RECORDS

A license holder or authorized user of radioactive materials must be able to account for all radioactive materials he or she has received, used, and disposed. Consequently, records must be maintained that show a complete description of the source, isotope, chemical form, quantity, specific activity, and lot number. As the material is used, each withdrawal and deposition of resulting wastes are recorded. Eventually, all material must be accounted for by disposal methods. Usually, monthly or quarterly accountability reports showing all uses, disposals, and amounts on hand are required.

RECEIPT OF RADIOACTIVE MATERIALS

When a package containing radioactive materials is received the package should be inspected visually, surveyed with a meter, and wipe tested to determine if any leakage occurred during shipment. If no contamination is detected, the package should be opened carefully, the source container wipe tested, and its contents verified and duly recorded. If leakage or apparent breakage has occurred, the supplier should be notified and the package including packing material should be disposed of properly, after a consultation with the radiation safety officer.

DISPOSAL METHODS

Acceptable methods for disposal of radioactive materials vary somewhat among radiological safety programs at different institutions, but possible methods include the following:

1. Radioactive decay
2. Transfer to persons or agencies licensed to accept such material
3. Release into the sanitary sewer system
4. Release as gases, including incineration
5. Burial

Disposal by Decay

A radionuclide that has a relatively short half-life may be disposed of easily by storing wastes until the radioactivity has decayed. As a general rule, waste materials may be disposed of by normal methods if the materials have decayed for 10 half-lives. However, it is important to have wastes segregated according to the radionuclides present and be properly labeled with the quantity of radioactivity and date when placed in storage so that decayed material can be unquestionably identified. As an added precaution the packages should be surveyed before final disposal and all radioactive labels removed or obliterated. Although a good method for disposal of ^{131}I and ^{32}P, decay is not practical for isotopes with a long half-life such as ^{3}H and ^{14}C.

Disposal by Transfer

Unused portions of sources may be transferred to other authorized users if the transfer is proper in regards to possession limits and accountability records. However, true wastes are more difficult to transfer because the

accepting agency must then dispose of the wastes. There are commercial firms that handle radioactive wastes and dispose of them, by burial primarily. Because shipment is involved, strict attention must be paid to preventing leakage of materials from containers and to follow proper labeling procedures. Effectively, liquids must be converted to solids, and this may be accomplished by using absorbents, such as sawdust and bentonite.

Disposal by Release into a Sewer System

Justification for flushing radioactive materials down a sink drain is based on the MPC levels adopted by NRC. MPC values for a few radionuclides were given in Table 15-5 and a complete list should be obtained from licensing agencies.

To an individual concerned about the environment, the fact that even low concentrations of radioactivity might be released deliberately may appear appalling. However, everything disposed of in any manner contributes to the environment. It may be modified by organisms in the environment, generally will be diluted greatly, but there are no methods certain to contain any material forever. For some radionuclides, rapid environmental dilution of a concentrated source of radioactivity is an excellent way to reduce the possibility that humans might ingest hazardous quantities of those radionuclides.

In Chapter 15 the annual absorbed dose for a person whose body water contained a concentration of tritium equal to the MPC level was calculated to be 2.02 mGy (0.202 rad). This is less than the limit for an incidental nonoccupational exposure. Nevertheless, the dose is significant and not one that should be tolerated without a significant offsetting benefit. Both ^{14}C and ^{3}H occur naturally, about 14 dpm per gram of carbon and 1 dpm per liter of water. Since vast quantities of carbon and water are in our biosphere, the current release rates of these isotopes could be increased many orders of magnitude without causing a measurable difference in the natural specific activities if adequate mixing occurs. Therefore, rapid dilution and dispersion is a logical method for disposal of ^{14}C and ^{3}H.

Because of their propensity to become diluted, soluble forms of radionuclides may be released in higher concentrations than insoluble or particulate forms. Also, higher concentrations are permitted for release in water than in air.

The point of release is an important factor in safety. An unrestricted area is one to which the public has immediate access. A restricted area is one to which the public does not have access and there is reasonable certainty that the radionuclide will be diluted to concentrations below the values given for an unrestricted area before the public can come in contact with the radionuclide. In Table 15-5 the MPC levels for tritium are listed as 1×10^{-1} and 1×10^{-3} μCi/ml for restricted and unrestricted areas, re-

spectively. For example, suppose tritium is flushed down a sink drain and into a city's sewer system at a concentration of 1×10^{-1} μCi/ml. It surely will be diluted by a factor of 33 (to 3×10^{-3} μCi/ml) before anyone could possibly come in contact with the contaminated water.

When releasing radioactivity in the sewer system it does not necessarily need to be diluted to MPC levels prior to release. Instead the amount of material that can be released depends on the water usage of the institution. Suppose in a building water is used at a rate of 2500 gal/day. In a month, 2.84×10^{8} ml of water would enter the city's sewer system and since the sewer system is a restricted area, the appropriate MPC level for tritium is 1×10^{-1} μCi/ml.

$$(1 \times 10^{-1}\ \mu\text{Ci/ml})(2.84 \times 10^{8}\ \text{ml}) = 2.84 \times 10^{7}\ \mu\text{Ci}$$

Therefore, a total of 28.4 Ci of ^{3}H could be released in a period of 1 month without the average concentration exceeding the MPC level for tritium.

Disposal as Gases

Gaseous radioactive materials are not utilized extensively in most types of biological research, but when working with gaseous products, some release is almost inevitable. The production of gaseous products or aerosols is somewhat unpredictable, therefore radioisotopic work is performed in a fume hood whenever possible. Releases into a fume hood are wastes and hence represent disposal. Safety considerations for fume hoods will be discussed later in this chapter.

If burning produces radioactive gaseous products, incineration may be a practical disposal method. Particularly for ^{14}C wastes, incineration may be feasible since the carbon may be completely oxidized (CO_2) and the volume of gases that passes through the incinerator may be sufficient to dilute the resulting $^{14}CO_2$ to appropriate MPC levels. Which MPC level for $^{14}CO_2$, restricted (5×10^{-5} μCi/ml) or unrestricted (1×10^{-6} μCi/ml), should be considered? If persons can be prevented from approaching the top of the incinerator's stack the restricted levels *may* apply. Gases move with wind currents, which generally increases gaseous dilution, but without wind currents, dilution still occurs by gaseous diffusion. Therefore, if it can be shown that diffusion will reduce the concentration of the stack's effluents to levels below that for an unrestricted area before reaching the closest unrestricted area, then restricted area levels may be used. Otherwise, unrestricted area MPC levels apply.

Example Problem 16-1. Would it be feasible to incinerate the carcasses of 10 laboratory rats, each of which had been injected with 50 μCi of a ^{14}C-labeled drug? The excreta, bedding, and other wastes would be incinerated along with the carcasses.

The incinerator available has three natural gas burners that supply a total of 1,050,000 BTU/hr and can burn 175 lb of waste in 1 hr. Three air blowers supply 500 ft^3/min of air to ensure complete combustion of carboneous wastes. Although the burners will contribute to the volume of gases that goes up the stack, we will ignore that contribution as an extra margin of safety and consider the volume of air supplied by the blowers only. The volume discharged from the stack in 1 hr would be

$$(3)(500\ ft^3/min)(60\ min/hr)(2.83 \times 10^4\ ml/ft^3) = 2.55 \times 10^9\ ml/hr$$

To avoid calculating air diffusion, we will use the unrestricted area MPC level for CO_2 at the top of the stack. The amount of ^{14}C that could be combusted in 1 hr is

$$(1 \times 10^{-6}\ \mu Ci/ml)(2.55 \times 10^9\ ml/hr) = 2.55 \times 10^3\ \mu Ci/hr$$

or

$$2.55\ mCi/hr$$

Since the total amount of radioactivity administered was only 0.5 mCi, incineration would be a good method for disposing of the carcasses without exceeding MPC levels. To help distribute the burning of the carcasses over the hour period it would be a good idea to add nonlabeled wastes such as paper and wood shavings. The burning rate (175 lb/hr) would be considered in determining the amount of unlabeled wastes to be mixed with the carcasses. Currently, the Environmental Protection Agency is proposing legislation that may reduce acceptable gaseous release rates markedly.

Disposal by Burial

From a radiological safety perspective, burial is a suitable method for waste disposal provided the geological features of the burial site are such that the buried radionuclides do not move through the soil or contaminate surface or ground water supplies. Suitable sites exist in most states, but for a license holder or user, wastes destined for burial are usually transferred to commercial firms that operate burial sites.

Recent sensitivity to the burial issue by the public and several state legislative bodies has severely, and unreasonably, curtailed burial as a means of disposal. Many states have passed laws prohibiting burial in their states and most prohibit the shipment of wastes into their states for burial purposes. As of 1990, the states of Washington, Nevada, and North Carolina are the only states that permit radioactive wastes to be shipped into their state for burial. Because of supply and demand, burial is an expensive disposal method.

Generally, wastes must be segregated according to type, must be in a solid form, and are shipped in steel drums. Regulations for shipment of wastes are determined by the U.S. Department of Transportation.

Mixed Wastes and Liquid Scintillation Samples

Mixed wastes are those that contain radioactivity plus other material classified as "hazardous" by the Environmental Protection Agency. Laboratory wastes that contain radioactivity and carcinogens or hazardous solvents generally fall in this category of wastes. Regulations concerning mixed wastes will be forthcoming, but currently there are not ratified methods for their disposal. About the only way of dealing with mixed wastes is to eliminate or reduce one of the noxious agents to innocuous levels.

Spent liquid scintillation samples may be classified as mixed wastes. However, because of MPC levels, *tritium-* and *carbon-14*-containing liquid scintillation samples may be excluded if the specific activities of their solutions are below 0.05 μCi/g, which translates to about 1×10^5 dpm/ml. Since counting samples with specific activities above this level are rare, normally ^{3}H- and ^{14}C-containing liquid scintillation vials can be disposed by methods appropriate for the type of solvents they contain; as hazardous solvent, such as toluene, or as normal refuse if their solvents are not hazardous. Consequently, liquid scintillation vial disposal problems are reduced dramatically when ^{3}H and ^{14}C are used with nonhazardous liquid scintillation solutions.

Unfortunately, similar rules do not apply to liquid scintillation samples containing ^{35}S, ^{32}P, ^{125}I, or ^{131}I. Nevertheless, all of these isotopes have short enough half-lives to permit the activity to decay away. Thus, it is feasible to store such samples for a period sufficient to reduce the radioactivity to background levels and then dispose of the solutions as dictated by the type of solvent involved.

Materials classified as biohazards, such as pathogenic bacteria and recombinant DNA, must be biologically inactivated before disposal. The common methods of inactivation include autoclaving and chemical treatment. If biohazardous materials also contain radioactivity, the wastes may be regarded as radioactive wastes only after inactivation.

LABORATORY FACILITIES

The requirements concerning laboratory construction are not stringent if moderate levels of radioactive materials are used. To the extent possible, porous construction materials should be avoided so that decontamination procedures are effective in removing radioactivity. For example, bare concrete floors are difficult to decontaminate, paint would reduce porosity, floor tile would be better, but seamless linoleum is preferred because a spill could be cleaned up more easily, and, if necessary, the floor covering could be removed and replaced. Bench tops should be of nonporous materials; stainless steel is preferred but expensive. However, large (24 × 36 × 2

in.) plastic or stainless steel trays lined with absorbent paper are recommended for working surfaces, and, if used properly, should prevent lab bench contamination. Walls should be painted with a strippable yet chemically stable paint.

Fume Hoods

A fume hood with a face velocity of at least 100 ft/min is necessary for most research laboratory facilities. The face velocity of a hood is the linear flow of air across the open face of the hood; consequently, 100 ft/min represents a flow of 100 ft^3/min for each square foot of the hood's open face or 100 $ft^3/min \cdot ft^2$. Such a flow rate is considered to be sufficient to prevent any diffusion of gases from inside the hood to the outside. Care should be taken to avoid clutter in a fume hood because objects can create eddy currents that may be directed backward.

LABORATORY ACCIDENTS

Experiments should be well planned to avoid unexpected problems but accidents do occur. In case of an accident, several immediate actions should be considered. Suppose a flask containing radioactive liquid has fallen on the floor and broken, but no injuries resulted from flying glass. What action should be taken?

1. Notify everybody in close proximity that a spill has occurred.
2. Consider your personal safety. Has your clothing been seriously contaminated? If so, remove the clothing (a good reason for requiring lab coats) and if your skin has been contaminated, wash that area lightly.
3. Prevent the radioactivity from spreading. Make an absorbent dam around the liquid and begin placing absorbent paper or towels on the liquid to soak up as much of it as possible.
4. Keep others from the area. Close the laboratory door and post a makeshift sign warning people of the accident and against entering the laboratory.
5. Call the Radiation Safety Officer or a person experienced in dealing with radioactivity for help and advice.
6. Begin decontamination procedures as soon as possible.

If injuries occur, they take first priority. For example, suppose the accident resulted in a lacerated wrist. Administer first aid to the injury, and depending on the severity of the injury, seek immediate medical attention. If you are a bystander to an accident, render aid if the person is seriously injured.

The philosophy to be considered is that serious injuries (severe lacerations, fainting, etc.) generally represent a much greater health hazard than the possible radiation dose.

DECONTAMINATION PROCEDURES

Procedures appropriate for decontamination depend on the degree of contamination and type of radionuclide involved. If large areas or quantities of radiation are involved, a person should contact his or her Radiation Safety Officer or an experienced radiological health physicist.

Laboratory Spills

For small spills or contamination, the usual method is to absorb all liquid with absorbent paper (paper towels). These materials should be placed in plastic bags (double bagging is advisable) and a label attached indicating the estimated maximum activity, the radionuclide involved, and the date. Then the area should be washed with warm soapy water. Iodine-based disinfectants or solutions are quite effective in cleaning radioactive iodine contamination. The wash water may be poured into the sink where contaminated glassware is normally washed if MPC levels are not exceeded after dilution with the building's water. After the area has dried, wipe tests or surveys with an appropriate detector should be conducted to see if contamination persists. Some areas may require several washings to reduce the contamination to an acceptable level (1.5 to 2 times the background counting rate). Of course, protective clothing such as lab coats, gloves, and probably disposable booties should be worn during the decontamination process.

Laboratory Glassware

Soap and water washing are usually sufficient to decontaminate glassware but special cleaning products are available commercially. Strong cleaning solutions $K_2Cr_2O_7$–H_2SO_4, $KMnO_4$–NaOH, 10% EDTA for metal radionuclides, and 6 *N* HCl are also appropriate for decontaminating glassware.

Hands

After completion of work and removal of gloves, a person should wash their hands with mild soap and water then monitor them with a survey meter. If contamination persists, a second or third washing may be required using a heavy lather and a soft brush. Stiff brushes or implements that abrade the skin should be avoided; instead numerous light washings are recommended.

CONCLUSION

"Results oriented" research workers may find the rules and regulations concerning the use of radioactive materials an inconvenience on some occasions, and perhaps examples can be cited where the inconvenience of a particular rule does not appear to be warranted in terms of the hazard involved. Nevertheless, it is obvious that unsafe practices are more likely to occur when individuals are given latitude in making judgments concerning the hazardousness of given operations on the spur of the moment. Therefore, rules and regulations are strictly enforced in most institutions. At this point, the reader should be able to see the logic behind all the rules and regulations, and this should aid him or her in accepting them willingly, which not only reduces personal risks but helps protect the public at large.

PROBLEMS

Some equations in Chapter 15 as well as data in Tables 15-4 and 15-5 may be used to solve some of the following problems.

1. Assume local rules permit release of radionuclides into the sanitary sewer system when their concentrations, averaged over a week period, do not exceed applicable MPC levels. In a building that has an average water usage rate of 3000 gal/da, what is the maximum amount of soluble ^{22}Na radioactivity that could be released per week?
2. Assume the same local rules described in problem 1 apply, and that during a 1-year period a total of 5.1 Ci of tritium was purchased by all of the users in the building. Would you anticipate the need for restrictions in flushing ^{3}H wastes into the sewer system? Support your conclusions with calculations.
3. A person planning to iodinate a protein with 10 μCi of ^{125}I estimated that the loss of volatile iodine would not exceed 2% during a 4-hr working period. The hood to be employed has a face velocity of 125 ft/min and an opening of 8 ft^2. If the maximum release occurred, would the average concentration in the hood exhaust during the working period exceed the MPC level for an unrestricted area?
4. To synthesize a desirable tracer, $^{3}H_2$ is to be employed for the reduction of a double bond in a biological compound. The work is to be conducted in a fume hood that has a face velocity of 125 ft/min and an opening of 10 ft^2. Calculate the maximum amount of activity that could be released in the hood during a 24-hr period without the average concentration of the hood's exhaust exceeding the MPC level for a restricted area.
5. Suppose a person transporting a solution containing 10 μCi of [^{14}C]alanine accidentally dropped and broke the container in a parking

lot. Propose a method of disposing of the resulting "liquid waste" using calculations to support your recommendations.

6. If a person somehow absorbed the amount of radioactivity in 10 ml of a ^{14}C waste solution that contained the MPC level of activity for an unrestricted area, what would be the resulting lifetime dose to that person assuming body weight to be 70 kg?

REFERENCE

Wang, Y. (1969). *Handbook of Radioactive Nuclides*. CRC Press, Boca Raton, FL.

Appendix F: Glossary of Terms

Absorbed dose	The mean energy imparted by ionizing radiation to an irradiated medium per unit mass. Units: gray, rad.
Activity	The mean number of decays per unit time of a radioactive nuclide. Units: becquerel (Bq), curie (Ci).
Background radiation	The amount of radiation to which a member of the population is exposed from natural sources, such as terrestrial radiation due to naturally occurring radionuclides in the soil, cosmic radiation originating in outer space, and naturally occurring radionuclides deposited in the human body.
Becquerel(Bq)	SI unit of activity. 1 Bq = 2.7×10^{-5} μCi
Beta particle	A charged particle emitted from the nucleus of certain unstable atomic nuclei (radioactive elements), having the charge and mass of an electron.
Dose-effect (dose-response) model.	A mathematical formulation of the way the effect (or biological response) depends on dose.
Dose equivalent (DE)	A quantity that expresses, for the purposes of radiation protection and control, an assumed equal biological effectiveness of a given absorbed dose on a common scale for all kinds of ionizing radiation. SI unit is the Sievert. A Sievert = 100 rem.
Effective dose equivalent (EDE)	Introduced by ICRP-26. A refinement of the DE (above), used to express radiation risk by weighting various body organ doses according to the probability of a harmful effect in that tissue. For example, risk from exposure to an extremity (arm) would be less than for the same exposure to bone marrow or gonads.
Gray(Gy)	SI unit of absorbed dose. Gray (SI) = 1 J/kg-100 rad
Half-life, biologic	Time required for the body to eliminate half of an administered dose of any substance by regular processes of elimination; it is approximately the same for both stable and radioactive isotopes of a particular element.
Half-life, radioactive	Time required for a radioactive substance to lose 50% of its activity by decay.
Ionizing radiation	Radiation sufficiently energetic to dislodge electrons from an atom. Ionizing radiation includes x and gamma radiation, electrons (beta radiation), alpha particle (helium nuclei), and heavier charged atomic nuclei. Neutrons ionize indirectly by colliding with atomic nuclei.

Linear energy transfer (LET)	Average amount of energy lost per unit track length. Low LET- Radiation characteristic of light charged particles such as electrons produced by x rays and gamma rays where the distance between ionizing events is large on the scale of a cellular nucleus. High LET- Radiation characteristic of heavy charged particles such as protons and alpha particles where the distance between ionizing events is small on the scale of a cellular nucleus.
Rad	A unit of absorbed dose. Replaced by the gray in SI units. A rad = 100 erg/g-0.01 Gy
Rem.(rad equivalent, man)	A unit of a dose equivalent (DE). The dose equivalent in "rem" is numerically equal to the absorbed dose in "rad" multiplied by the "quality factor", the distribution factor and any other necessary modifying factor.
Rem	A unit of dose equivalent. Replaced by the Sievert. One rem = 0.01 Sievert.
Sievert	The SI unit of radiation dose equivalent. It is equal to dose in grays times a quality factor times other modifying factors, for example, a distribution factor; 1 Sievert (Sv) equals 100 rem.
microCurie (μCi)	A unit of radioactivity, one millionth of a Curie. One μCi is 3.7×10^4 discintergrations per second (or Bq).
CPM	Counts per minute. The average number of counts the scintillation counter registers per minute. In the context of this report it equals the number of ^{14}C beta emmissions detected per minute. Divided by efficiency gives DPM (see below).
DPM	Disintegrations per minute. Is derived by dividing CPM by efficiency. In the context of this report it equals the number of ^{14}C transformations per minute.

Test Questions

1. What does ALARA mean?

2. How many μCi of ^{14}C does the PYtest capsule contain?

3. Is ^{14}C a alpha, beta or gamma emitter?

4. Name one instrument used to detect carbon 14.

5. Is Carbon 14 an external risk?

6. Which federal agency regulates radioactive materials?

7. What does dose equivalent measure?

8. What is the difference between physical and biological half life?

9. What protective apparel should be worn when working with carbon 14?

10. Who should you contact if you have a question regarding radioactivity?

Appendix G: Reporting Safety Concerns to the NRC

REPORTING SAFETY CONCERNS TO THE NRC

CONTENTS

INTRODUCTION

All individuals should feel free to communicate to the Nuclear Regulatory Commission (NRC) any safety or wrongdoing concerns. It is the policy of the NRC to encourage workers at regulated nuclear facilities to take technical safety concerns to their own management first. However, workers can bring safety concerns directly to the NRC at any time. It is the agency's responsibility to respond to those concerns in a timely manner and to protect the identity of the individual to the greatest degree possible.

This brochure provides information on how nuclear workers - such as yourself - can report safety concerns to the NRC, what degree of protection can be afforded to a worker's identity, and the NRC process for handling a worker's allegation of discrimination that may result from reprisals by licensees, their contractors, or subcontractors.

In this brochure, safety concerns encompass potential safety issues, violations of NRC requirements, nonconformances with licensee requirements, harassment and intimidation, and a work environment that discourages workers from raising safety concerns.

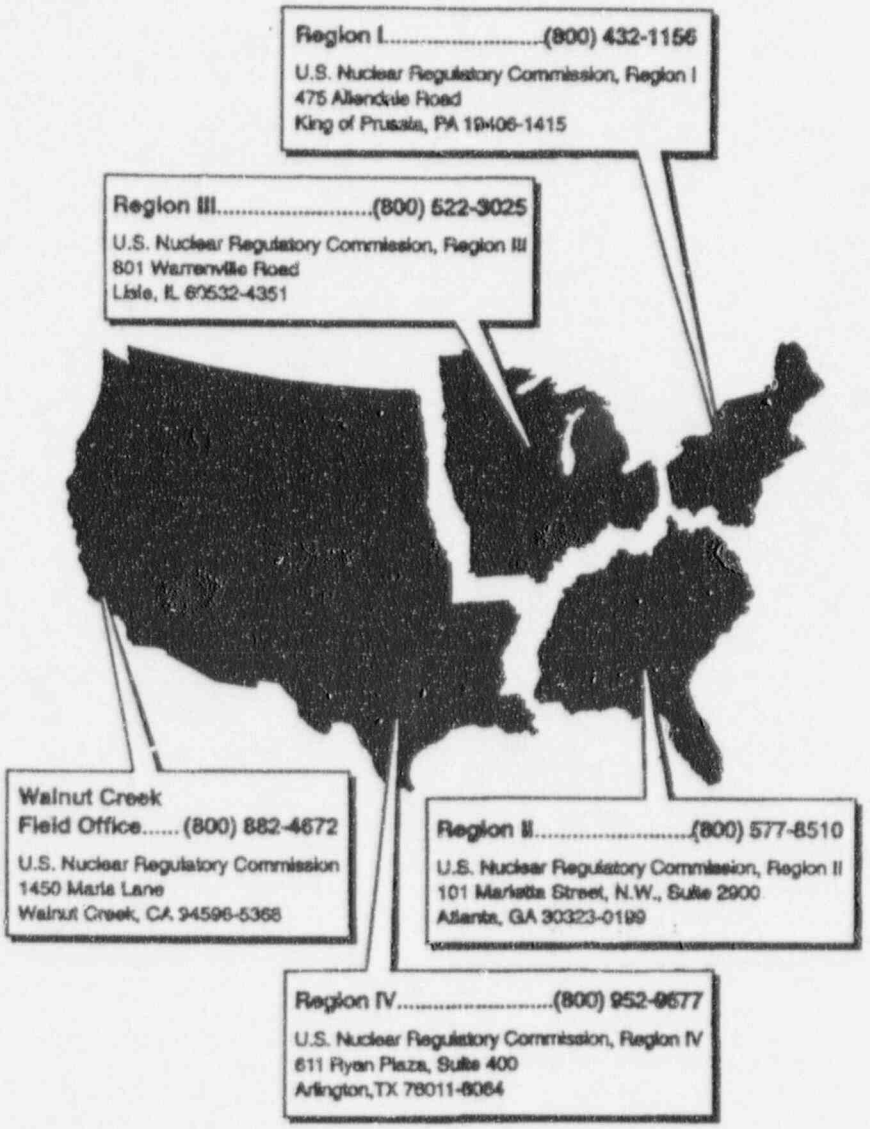
A WORKER'S ROLE IN NUCLEAR SAFETY

As a worker in the nuclear industry, you have an important role in ensuring safe operations and practices in handling nuclear materials. Protection of public health and safety begins with the Nuclear Regulatory Commission's licensing requirements for safe operation of nuclear facilities and continues with inspections to ensure that licensees comply with these requirements and their commitments. NRC considers licensee management ultimately responsible for regulatory compliance, and management relies on you, the worker, to assist them in this effort by identifying and reporting safety concerns.

NRC inspectors can observe only a small part of the day-to-day activities in nuclear facilities. Therefore, your every-day knowledge and operating experience can provide valuable insight in identifying safety concerns in the workplace to your employer and the NRC. Once nuclear facilities are licensed and operational, you become the first line of defense for preventing accidents and protecting public health and safety.

In the past, workers in NRC-regulated nuclear activities and concerned citizens have raised important safety issues and, as a result, public health and safety have benefitted. This vigilance must continue.

The NRC encourages nuclear workers to take safety concerns to their employer because licensees have primary responsibility for ensuring the safety of nuclear operations. They are in the best position to deal promptly and effectively with safety issues. Nuclear workers and concerned citizens may bring their concerns directly to the NRC at any time, but the NRC expects that employees normally will have raised their concerns with their employers either before or at the same time they come to the NRC.

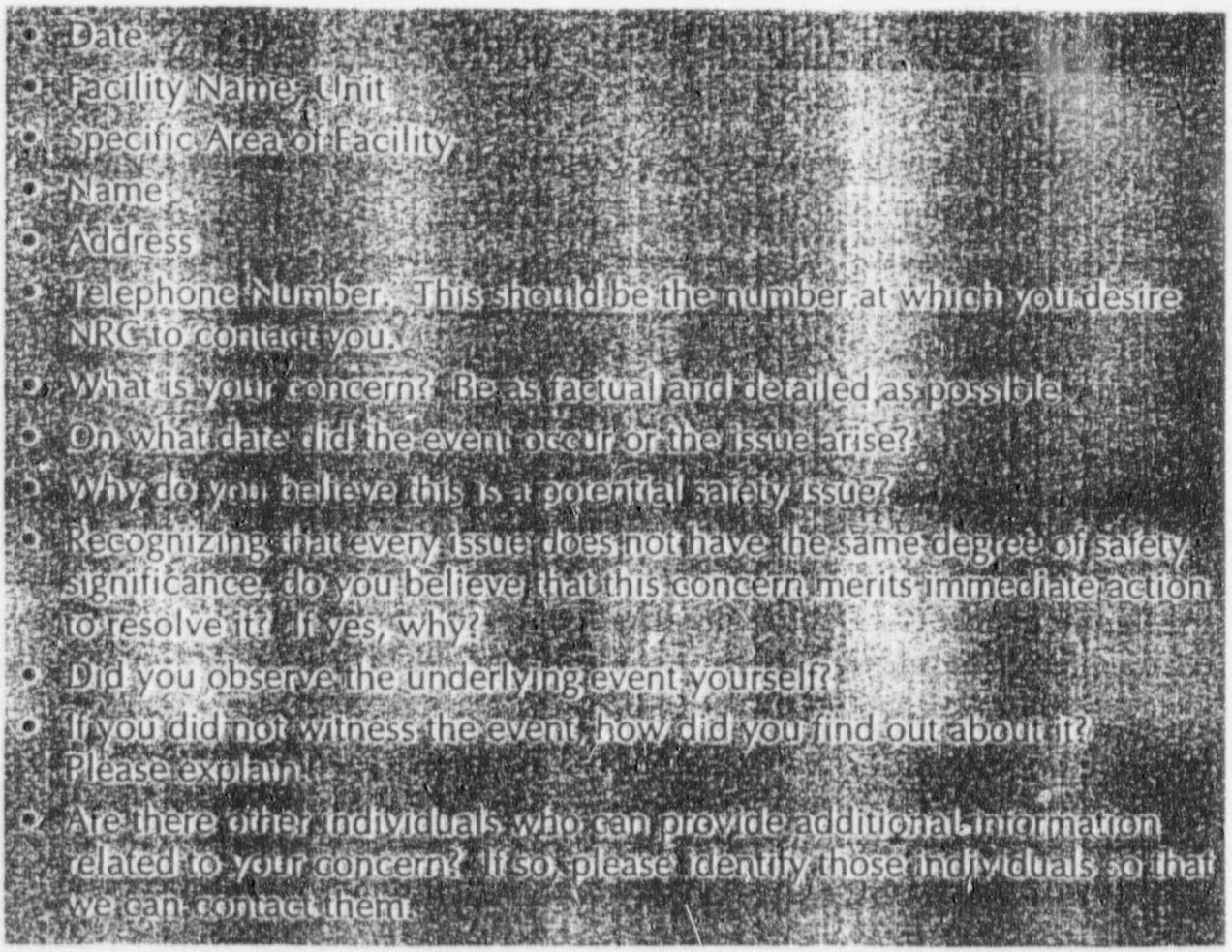


HOW TO REPORT NUCLEAR SAFETY CONCERNS TO NRC

You may contact any NRC employee, including a resident inspector, or call the NRC's toll-free Safety Hotline, 1-800-695-7403. If you call during normal business hours, you will reach the NRC Allegations Coordinator for the NRC regional office serving your State. If you call after normal business hours, your call will be directed to the NRC's headquarters Operations Center, which is staffed 24 hours a day. In addition, you may reach an NRC Allegations Coordinator through a regional office by calling the appropriate number listed on the figure to the left.

If you submit your safety concern in writing to the NRC, we recommend you clearly state in the beginning that your letter is an allegation. This helps to ensure that your letter gets prompt attention and is not placed in the public domain. It also helps protect your identity.

To assist you in reporting a safety concern, the following questions are those the NRC typically asks:



- Date
- Facility Name, Unit
- Specific Area of Facility
- Name
- Address
- Telephone Number. This should be the number at which you desire NRC to contact you.
- What is your concern? Be as factual and detailed as possible.
- On what date did the event occur or the issue arise?
- Why do you believe this is a potential safety issue?
- Recognizing that every issue does not have the same degree of safety significance, do you believe that this concern merits immediate action to resolve it? If yes, why?
- Did you observe the underlying event yourself?
- If you did not witness the event, how did you find out about it? Please explain.
- Are there other individuals who can provide additional information related to your concern? If so, please identify those individuals so that we can contact them.

- If you do not want to identify them, have you asked them to contact NRC directly? If not, why?
- Are there any records we should review that may be relevant to your concern?
- Have you discussed this with your supervisor or other licensee official? If not, why? If so, what was the response?
- If you are not satisfied with the response, explain why.
- Have you discussed this with your Employee Concerns Program representative? If not, why? If so, what was the response?
- If you are not satisfied with the response, explain why.

Although it will help NRC respond to your concerns if you can answer these questions, you do not need to have answers to all of them in order to raise a safety issue with the NRC.

ALLEGATION PROCESS

The NRC strives to review all allegations objectively to ensure the outcome is fair, sound, and timely. All allegations brought to the NRC are assigned to an employee designated as an Allegations Coordinator. The coordinator's job is to --

- Promptly contact you to confirm the details of the allegation and to confirm that the NRC has correctly interpreted and understood the information you provided. Normally, an acknowledgment letter is sent to you within 30 days of receipt of your allegation.
- Arrange for an evaluation of your concern by a group of NRC employees and managers designated as an Allegation Review Board. The Board will review the concern and make a preliminary determination of its safety significance. The Board will also determine whether the allegation will be referred to an NRC employee, the affected licensee, or another agency for further review and evaluation.
- Document NRC actions taken to resolve the allegation.
- Advise you periodically about the status of the allegation.
- Provide a final report to you upon resolution of the allegation.

The NRC's goal is to complete the review of technical concerns and provide you with a final report within 180 days. A complicated concern may take longer. If it does, you will receive a letter explaining the status of NRC's review.

CONCERNS OUTSIDE NRC'S JURISDICTION

Concerns outside the NRC's jurisdiction will be forwarded to the appropriate Federal or State agency and you will be notified of this referral action. Examples of these concerns include --

- Off-site emergency planning;
- Use of NRC-regulated materials in Agreement States;
- Control of exempt quantities of licensed material;
- Industrial or occupational safety; and
- Disposal of non-nuclear waste.

IDENTITY PROTECTION

Limitations

The NRC recognizes that some individuals will only come forward if they believe their identities will be protected from disclosure. If you are concerned about protecting your identity, representatives of the NRC will make arrangements to call you at your home or meet with you at a discreet location.

All reasonable efforts will be made by the NRC to not disclose the identity of such an individual outside the agency. Only NRC staff who have a need to know will be provided an individual's identity. This would happen, for example, when an inspector or investigator is assigned to interview the individual. Documents that contain the individual's identity will be stored in a locked cabinet within controlled access and will not be placed in NRC public document rooms.

However, the NRC may reveal your identity outside the agency under the following circumstances:

(1) You clearly state that you have no objection to being identified;

(2) Disclosure is necessary to protect the public because of an overriding safety issue identified in your allegation;

(3) Disclosure is necessary to satisfy a request from Congress or from a State or Federal agency;

(4) Disclosure is required to respond to a court order or NRC Licensing Board order;

(5) You take an action that is inconsistent with protecting your identity such as notifying the news media; or

(6) The NRC needs to pursue a wrongdoing investigation or support a hearing on an NRC enforcement action.

Furthermore, if the NRC were investigating a claim that you were a victim of discrimination because you raised a safety concern, investigating the allegation without identifying you would be extremely difficult. Therefore, when investigating claims of discrimination, the NRC will disclose your name.

Confidentiality Agreements

If you are still concerned that your identity may be disclosed, the NRC can provide formal confidentiality. However, it is not granted routinely. The NRC requires you to explicitly request confidentiality. Confidentiality affords protection of information that directly or otherwise could identify you by name and the fact that you provided the information to the NRC.

In instances where confidentiality is granted by an authorized NRC official, you and the NRC would sign a written agreement. The agreement would explain the conditions under which the NRC will protect your identity. Your identity will be divulged to other NRC employees only on a need-to-know basis.

Limitations on Confidentiality

Even if confidentiality is granted, the NRC cannot protect your identity under <u>all</u> circumstances. There are specific situations where disclosure may be necessary because --

(1) Immediate action is needed to protect public health and safety;

(2) A Federal court order has been issued;

(3) An NRC Licensing Board order has been issued during an adjudicatory proceeding;

(4) A response is required by Congress; and

(5) A response to a Federal or State agency is required to meet statutory responsibilities.

In the last case, the requesting agency must agree to provide the same protection to the confidential source that was promised by the NRC.

The sixth instance of disclosure may occur when the NRC's Office of Investigations (OI) and the Department of Justice are pursuing an investigation, or when OI is working with another law enforcement agency. It is essential that parties investigating and prosecuting wrongdoing know the identity of a confidential source to protect the source physically during the course of investigative activities.

On rare occasions, confidentiality may be revoked by the NRC, but only in the most extreme cases. This revocation may occur where the worker takes some personal action so inconsistent with the agreement that it overrides the purpose of granting confidentiality, such as discussing the matter with the news media and being publicly identified by the media. A decision to revoke confidentiality can only be made by the Commission itself, the NRC's Executive Director for Operations, or the OI Director.

LICENSEE RESPONSIBILITY

The NRC expects licensees, contractors, and their subcontractors to establish and maintain a "safety-conscious work environment" that encourages you and other employees to raise safety concerns to your management, free of any fear of reprisal for doing so. This environment is critical to a licensee's ability to safely carry out its responsibilities. In fact, often workers are hired in order to satisfy NRC requirements for identifying deficiencies or safety issues in quality assurance, radiation protection, and security activities.

Licensees must post or otherwise make available to you a copy of NRC regulations, licenses, and operating procedures that apply to work in which you are engaged. All NRC-issued Notices of Violations involving radiological working conditions and proposed imposition of civil penalties and orders are also required to be posted.

Further, licensees are required by law to post NRC Form 3 that describes your protected activities and explains how allegations of licensee violations can be reported directly to the NRC. Protected activities include but are not limited to --

- Conferring privately with NRC inspectors about any past or present condition that you believe contributed to or caused a violation of NRC regulations;
- Refusal to engage in activities that violate NRC requirements;
- Request for NRC to enforce its rules against your employer;
- Testifying, helping or taking part in an NRC, Congressional, or any Federal or State proceeding;
- Posting of radiation caution signs and labels; and
- Recording and reporting worker exposure;

Form 3 must be posted at prominent locations that permit you to view it easily on your way to or from your normal place of work. A copy of NRC Form 3 is reproduced at the end of this brochure for your reference.

HANDLING DISCRIMINATION AGAINST WORKERS

Acts of discrimination by a licensee, contractor, or subcontractor taken against a worker for bringing safety concerns to the attention of licensee management or the NRC are against the law. Specific examples of discrimination include firing, reduction in pay, poor performance appraisals, and reassignment to a lower position or job (if it can be established that these actions were taken by the licensee because a worker raised safety concerns).

You should be aware that while the NRC is the Federal agency to which you should report safety concerns of a technical nature, the Department of Labor (DOL) is the agency from which nuclear workers must seek personal remedies when discrimination has occurred for reporting a concern. The NRC's

authority is limited to taking an enforcement action against the licensee such as a fine, an order modifying an NRC license or, in criminal cases, referral to the Department of Justice for prosecution.

The NRC's Office of Investigation (OI) has the responsibility for investigating allegations of wrongdoing by NRC licensees, applicants, vendors, and contractors. The OI initiates investigations of allegations of discrimination in retaliation against a worker for having raised a safety concern. Normally, an investigator will interview you and review available documentation. Based on an evaluation, the NRC will assign a priority--"high" or "normal"--to the investigation. The NRC, like all government agencies, must prioritize its work in order to best utilize its resources and conduct its mission. All investigations assigned a high priority will be completed and a determination will be made whether discrimination actually occurred. Examples of high priority investigations include allegations of discrimination that --

- Result from providing information directly to the NRC;
- Are caused by a manager above first-line supervisor;
- Occur where a history of findings of discrimination suggests a programmatic rather than an isolated issue; and
- Appear particularly blatant or egregious.

Based on the focus of agency resources on high priority cases, about one-third of normal priority concerns are investigated to the point where a determination can be made whether discrimination occurred. An investigation generally takes about 12 to 18 months.

If the NRC concludes that discrimination occurred, the NRC will consider taking an enforcement action against the licensee. For personal remedies, such as reinstatement to your job or back pay, you must file a written complaint with the Department of Labor (DOL) within 180 days of the discrimination, clearly outlining the facts and circumstances. The DOL has authority to investigate allegations of discrimination and provide a personal remedy when retaliatory practices are found.

The entire DOL complaint process may take several years to complete. It begins with an attempt by the local DOL office to negotiate a settlement with your employer. If this fails, the local DOL office will investigate to determine if discrimination occurred and provide its conclusions to you and your employer. Usually, this phase will be completed in 30 to 90 days.

At the request of you or your employer, the conclusions of the local DOL office can be reviewed by a DOL Administrative Law Judge. The Judge will hold a hearing and issue a recommended decision that will be reviewed by the DOL Administrative Review Board. The Board's decision becomes the Secretary of Labor's final decision. Lastly, the Secretary's decision may be appealed to the U.S. Court of Appeals.

Depending on the outcome in each step of this process, you will have to await decisions concerning reinstatement to your job, payment of back wages, and compensatory damages, including repayment of legal fees. To fully preserve your rights to a personal remedy, you will need to participate in each step of the process.

The NRC is working with DOL to make the process more efficient and less costly. These initiatives include the following:

(1) Transfer of DOL investigation responsibilities from the Wage and Hour Division to the Occupational Safety and Health Administration (OSHA) that has investigators specifically experienced in investigating harassment and intimidation cases;

(2) A new rule to provide DOL with discretion to defend its findings of discrimination, thereby reducing the financial costs to allegers;

(3) Legislative changes to provide DOL adequate time to perform a more qualitative and realistic review (120 days to conduct the initial investigation, 30 days to request a hearing, 240 days to conduct a hearing and issue an Administrative Law Judge decision, 90 days for the Secretary of Labor to issue a decision); and

(4) Legislation that would permit immediate reinstatement of allegers following an initial investigation finding of discrimination.

Written complaints can be sent to the Occupational Safety and Health Administration at any of the Department of Labor's regional offices. To obtain the address of the correct regional office, you can either look it up in your local telephone directory or contact an NRC Allegations Coordinator who can also answer questions about how to file a complaint.

If you file a discrimination complaint with DOL and later find that you need NRC information, NRC's position on an issue, or NRC witnesses to pursue your complaint, you may contact the NRC by calling 1-800-368-5642 and asking for the Allegation Advisor at 415-8529.

SUMMARY

The NRC believes that all workers should feel free to raise concerns to their employers so that they can be dealt with quickly. At any time, however, employees have the option of bringing a safety concern directly to the NRC.

Workers who raise safety concerns serve a vital role in the protection of public health and safety. Retaliation against those who do so is unlawful and will not be tolerated by the NRC.

DEFINITIONS

Agency Allegation Advisor - A designated staff member who is responsible for monitoring the NRC's allegation program and providing advice and guidance to NRC management and staff on handling allegations.

Allegation - A declaration, statement, or assertion of improper or inadequate activity associated with NRC requirements.

Allegation Review Board - A group that consists of a chairman, an Allegations Coordinator, and one or more other individuals within an NRC office or region. The group determines the safety significance and action that should be taken to resolve each allegation.

Allegations Coordinator - A designated staff member who serves as the point of contact for an office or region in processing allegations.

Alleger - An individual or organization who has a potential safety concern. For example, a private citizen, a public interest group, the news media, a licensee, a current or former employee of a licensee, vendor, or a contractor, or a representative of a local, State, or Federal agency.

Confidentiality - Protection of information that directly or otherwise could identify a confidential source by name and the fact that the source provided information to the NRC.

Investigation - An activity conducted by the NRC's Office of Investigations to assist the staff, the NRC's Office of Enforcement, or the U.S. Department of Justice in resolving wrongdoing allegations.

Test Questions

1. What does ALARA mean?

2. How many μCi of ^{14}C does the PYtest capsule contain?

3. Is ^{14}C a alpha, beta or gamma emitter?

4. Name one instrument used to detect carbon 14.

5. Is Carbon 14 an external risk?

6. Which federal agency regulates radioactive materials?

7. What does dose equivalent measure?

8. What is the difference between physical and biological half life?

9. What protective apparel should be worn when working with carbon 14?

10. Who should you contact if you have a question regarding radioactivity?

Answers to Test Questions

1. ALARA is an acronym for "as low as is reasonably achievable". It means that individuals are expected to use amounts of material which are as low as is reasonably achievable even though this amount may be below the regulatory limits.

2. One

3. Beta

4. Liquid Scintillation Counter

5. No

6. Nuclear Regulatory Commission

7. Dose Equivalent is a method of measuring radiation dose which allows radiation sources to be compared regardless of the type of radiation, i.e. alpha, beta, the source of the radiation , i.e. external or internal or the organ or tissue most affected.

8. Physical Half life is the time it takes for one half of the Carbon 14 to decay. Biological half life is the time it takes for half of the isotope to leave the body.

9. Protective Clothing such as lab coats and disposable gloves.

10. The Radiation Safety Officer