Porter Medical Center, Inc.

Middlebury, Vermont 05753 • (802) 388-4701

January 24, 2005

United States Nuclear Regulatory Commission
ATTN: L.A.T
Region one
475 Allendale Road
King of Prussia, Pennsylvania 19406

03015288
44-19050-01

RECEIVED
REGION 1
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To whom it may concern:

Please find the enclosed sections of Porter Hospital's application renewal of license # **44-19050-01**. The package includes:

1. Completed NRC form 313
2. Answers to questions 5-11 on 313 detailed in sections 8.1 through 8.47.
3. Diagram of our Radiology Department.
4. "Discussion" page explaining numbered nuclear medicine rooms and adjacent radiology rooms.
5. Printout from internet contents of application sections 8.1 through 8.47.

Please note that we are not making any changes to our current license at this time. This is simply a renewal process. Since this is only a renewal, no further information has been included regarding our RSO and Authorized Users. All information regarding qualifications should already be on record with the NRC. Finally, according to chapter 7 of NUREG-1556 Vol.9, application fees are required for new licenses and some other licensing actions. I was unable to determine from 10 CFR 170.31 if any fees are required for licensing renewals. I believe we are current with our financial obligations to the NRC.

Please contact me if there are any questions, concerns, or problems. I can be easily reached directly by calling **1-802-388-8857.** Thank you for your cooperation.

Sincerely,

Steve Sweeney
(Director, Porter Radiology)
1-802-388-8857
ssweeney@portermedical.org

136312

NMSS/RGN1 MATERIALS-002

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION
(8-1999)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005

Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

SAM NUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-8931

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

030152 88
X

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [ ] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [X] C. RENEWAL OF LICENSE NUMBER 44-19050-01

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*
   Steve Sweeney
   Porter Hospital
   115 Porter Drive
   Middlebury, Vermont 05753

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   Porter Hospital
   Radiology Dept.
   115 Porter Drive
   Middlebury, Vermont 05753

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Steve Sweeney
   TELEPHONE NUMBER
   1-802-388-8857

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Pat Jannene (Vice President Patient Care)	Patricia Jannene	1/24/05

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS

APPROVED BY	DATE

CONTENTS FOR MATERIAL LICENSE RENEWAL APPLICATION

8.1: ITEM1: LICENSE ACTION TYPE

Renewal of License # 44-19050-01.

8.2: ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Steve Sweeney
Porter Hospital
Radiology Department
115 Porter Drive
Middlebury, Vermont 05753

8.3: ITEM 3: ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Porter Hospital
Radiology Department
115 Porter Drive
Middlebury, Vermont 05753

8.4: ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Steve Sweeney
1-802-388-8857

8.5: ITEM 5: RADIOACTIVE MATERIAL

BYPRODUCT MAT.	CHEM/PHY FORM	MAX.AMOUNT NEEDED
Any byproduct material Permitted by 10CFR 35.100	Any	As needed
Any byproduct material Permitted by 10CFR 35.200	Any	As needed

8.6: ITEM 5: SEALED SOURCES AND DEVICES

Not applicable

8.7 ITEM 5: RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

No response is needed.

8.8 ITEM 6: PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

10CFR 35.100 – Medical use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

10CFR 35.200- Medical use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

8.9 ITEM 7: INDIVIDUALS(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Stephen Koller, M.D. (Radiologist)

8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)

Stephen Koller, M.D. (Radiologist)
License # 44-19050-01

8.11 ITEM 7: AUTHORIZED USERS (Aus)

AUTHORIZED USERS	MATERIAL AND USE
Peter J. Holm, M.D.	35.100; 35.200
J. Lorimer Holm, M.D.	35.100; 35.200
Stanley Shapiro, M.D.	35.200 for cardiovascular clinical procedures
Stephen Koller, M.D.	35.100; 35.200
Andrea Fossati, M.D.	35.200 for cardiovascular clinical Procedures
Joseph Winget, M.D.	35.200 for cardiovascular clinical Procedures
C. Wade Cobb, M.D.	35.100; 35.200

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)

Preparation of byproduct material by the technologist for medical use is performed under the supervision of either Stephen Koller, M.D. (RSO); C. Wade Cobb, M.D.; or Peter J. Holm, M.D. All three physicians are radiologists and authorized users.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP)

Not applicable

8.14 ITEM 9: FACILITIES AND EQUIPMENT

Refer to sections 8.15 through 8.19

8.15 ITEM 9: FACILITY DIAGRAM

See attached diagram with "discussion" sheet.

8.16 ITEM 9: RADIATION MONITORING INSTRUMENTS

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.

We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10CFR 20.1501 and that meet the requirements of 10CFR 35.61

Instrument:

Victoreen survey meter
Model # 498
Serial # 258/001433

Ludlum 14c survey meter
Model # 14c/051-014
Serial # 85249

Capintec well counter
Model: Caprac
Serial# 000079

8.17 ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Porter Hospital receives only unit doses provided by "Pharmalogic", a radiopharmacy located in South Burlington.

8.18 ITEM 9: THERAPY UNIT- CALIBRATION AND USE

Not applicable

8.19 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Porter Hospital is not involved with any kind of radiopharmaceutical therapy. Not applicable.

8.20 ITEM 10: RADIATION PROTECTION PROGRAM

We have developed and will implement and maintain written procedures for the radiation protection program that meet the requirements of 10 CFR 20.1101

8.21 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

Not applicable

8.22 ITEM 10: OCCUPATIONAL DOSE

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10CFR part 20, or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG -1556, Vol 9, "Consolidated Guidance

about materials License: Program-specific guidance about medical use licensees", dated October 2002.

8.23 ITEM 10: AREA SURVEYS

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

8.24 ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

8.25 ITEM 10: SPILL PROCEDURES

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

8.26 ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Not applicable

8.27 ITEM 10: MINIMIZATION OF CONTAMINATION

Response is not required

8.28 ITEM 11: WASTE MANAGEMENT

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of subpart K to 10 CFR part 20 and 10 CFR 35.92

8.29 ITEM 12: FEES

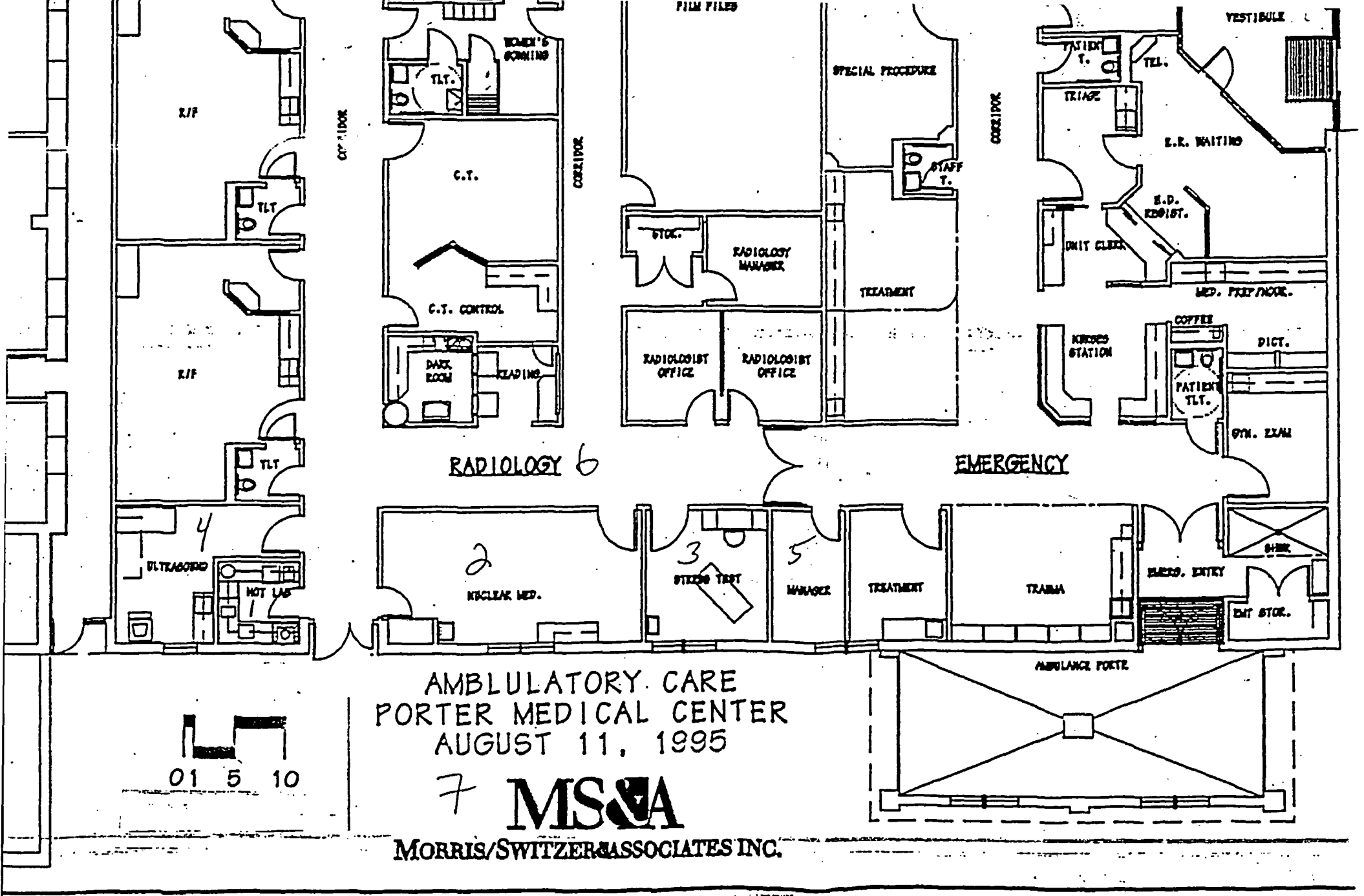
Refer to NRC form 313

8.30 ITEM 13: CERTIFICATION

Refer to NRC form 313

8.31 THROUGH 8.47

Response is not required



AMBLULATORY CARE
PORTER MEDICAL CENTER
AUGUST 11, 1995

7

MS&A

MORRIS/SWITZER&ASSOCIATES INC.

DISCUSSION

Room #

1- Room number 1 is the Hot Lab. The hot lab is used to store unit doses received from a radiopharmacy located in South Burlington. The hot lab is also used to store our tc-99m radioactive waste. The waste storage area (needles, vials, etc) is surrounded by lead bricks measuring 6"x4"x2". With lead shields in place, radiation levels are at a minimum. Usually, slightly over instrument background of 0.02mr/hr.

2- Room 2 is our imaging room. The imaging room is where all our medical imaging takes place. No radiopharmaceutical preparations are performed in this room, nor is there any storage of radioactive waste.

3- Room 3 is our stress lab. The stress lab is where Cardiolite stress testing takes place. No radiopharmaceutical preparations are performed in this room, nor is there any storage of radioactive waste.

4- Room 4 is the ultrasound room. There are no radioactive procedures performed in the ultrasound room. The room is monitored for radioactive exposure by an area monitor and is changed quarterly.

5- Room 5 is the manager/break room. It is not part of the Radiology department and lies adjacent to the cardiac stress lab.

6- Area 6 is a corridor. It is a private corridor for hospital personnel away from the general public.

7- Area 7 is the parking lot.

8.1 ITEM 1: LICENSE ACTION TYPE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
☐ A. New License	Not Applicable
☐ B. Amendment to License No.	XX-XXXXX-XX
☐ C. Renewal of License No.	XX-XXXXX-XX

Check A if the application is for a new license.

Check B for an amendment[1] to an existing license, and provide license number.

Check C for a renewal of an existing license, and provide license number.

8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.34(b); 10 CFR 35.14(b); 10 CFR 30.34(h).

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address. See Section 8.30, "Certification."

Note: NRC must be notified before control of the license is transferred or whenever bankruptcy proceedings are initiated. See Sections 1.3.3 and 1.3.4 for more details. NRC IN 97-30, "Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, discusses the potential for the security and control of licensed material to be compromised during periods of organizational instability.

[1]See Section 9, "Amendments and Renewals to a License," in this document. Licensees may request an amendment to an existing license to add authorization for other uses of byproduct material.

8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.14(b)(2).

In order to ensure compliance with 10 CFR 30.33(a)(2) and as referenced in NRC Form 313 Item 3, specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable. If byproduct material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. If applying for a license for mobile medical services as authorized pursuant to 10 CFR 35.18(b), the applicant should refer to Section 8.36 and Appendix V of this report for specific licensing guidance. NRC must be notified if the mailing address changes.

Being granted an NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed in Section 8.7 "Recordkeeping for Decommissioning and Financial Assurance," licensees must maintain permanent records on where the licensed material was used or stored while the license was in effect. These records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. NRC will contact this individual if there are questions about the application.

Notify NRC of changes of contact name or telephone number so that NRC can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment or a fee.

The individual named in Item 4 may or may not be the same individual who signs the application as the "certifying officer" on behalf of the licensee with the authority to make commitments to NRC (see Item 13 on NRC Form 313).

NRC recognizes that licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. However, NRC reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

8.5 ITEM 5: RADIOACTIVE MATERIAL

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.32; 10 CFR 32.210; 10 CFR 35.65; 10 CFR 35.100; 10 CFR 35.200; 10 CFR 35.300; 10 CFR 35.400; 10 CFR 35.500; 10 CFR 35.600; 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use (10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000).

Discussion: The applicant should indicate the byproduct material requested. The amount and type of information necessary will vary according to the type of use requested.

35.100 and 35.200 Use: For 35.100 and 35.200 use, the chemical/physical form may be "Any" unsealed byproduct material permitted by 10 CFR 35.100 or 35.200, as appropriate. For 35.100 and 35.200 use, the total amount requested may be "As Needed." The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.100	Any	As needed
Any byproduct material permitted by 10 CFR 35.200	Any	As needed

35.300 Use: For 35.300 use, the chemical/physical form may be "Any" unsealed byproduct material permitted by 10 CFR 35.300. The total amount requested must be specified. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 35.300	Any	300 millicuries

35.400, 35.500, 35.600, and 35.1000 Use: For 35.400, 35.500, 35.600, and 35.1000 use, the radionuclide, the chemical/physical form (i.e., sealed source or device identified by manufacturer and model number), the total amount in Becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), and maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
I-125 (specific radiation therapy system liquid brachytherapy source)	Liquid source (Manufacturer Name, Model #XYZ)	2 curies total
Cesium 137 (i.e., specific brachytherapy radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

For sealed sources used in devices, an applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

Calibration, Transmission, and Reference Sources: For calibration, transmission, and reference sources covered under 10 CFR 35.65, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 10 CFR 35.11 for medical use of byproduct material.

Shielding Material/Depleted Uranium: Some high activity radionuclide generators used to produce byproduct materials for 35.200 and 35.300 uses (e.g., Tc-99m generators) may include depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield the therapy sources and devices. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer's specifications for each device specified in the license request to determine: (1) if depleted uranium is used to shield the source(s) within the device; and (2) the total quantity of depleted uranium present in the device (in kilograms). The applicant should also consult the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Depleted Uranium	Metal	999 kilograms

Other Material: The applicant should make a separate entry for other items that need to be listed (e.g., more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). The following format may be used:

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material permitted by 10 CFR 31.11	Prepackaged kits	50 millicuries

Sources that are authorized by 10 CFR 35.65, "Authorization for calibration, transmission, and references sources," should *not* be listed.

Applicants should number each line entry consecutively, following the 10 CFR Part 35 material.

Blood Irradiators: If the use of a device to irradiate blood is anticipated, the applicant should review NUREG-1556, Vol. 5, "Program-Specific Guidance About Self-Shielded Irradiator Licensees."

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should be included [i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange), materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage].

Response from Applicant: The applicant should submit the information as described above.

8.6 ITEM 5: SEALED SOURCES AND DEVICES

Part 35	Applicability
100	
200	
300	
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.32(g); 10 CFR 30.33(a)(2); 10 CFR 32.210.

Criteria: In accordance with 10 CFR 30.32(g), applicants must provide the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR 35.65). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Discussion: NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of the latest version of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration" from NRC Regional Office and submit the information requested therein to NRC for review.

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR certificates without obtaining NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SSDR Registry and registration certificates, applicants may want to obtain copies of the appropriate sections of the Registry certificates and review or discuss them with the manufacturer. The SSD Registry compilation of these registration certificates may be found at <http://www.hsrd.ornl.gov/nrc/sources/index.cfm>.

Response from Applicant: If possession of sealed source(s) or device(s) is requested, the applicant shall submit the information described above.

Reference: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration," and NUREG-1556, Vol. 11, "Program-Specific Guidance About Licenses of Broad Scope."

Note: Information on SSD registration certificates is also available on the Internet at <http://www.nrc.gov/materials/miau/ssd/obtain-certs.html> or by calling NRC's Registration Assistant toll-free at (800) 368-5642, extension 415-7217.

8.7 ITEM 5: RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.34(b); 10 CFR 30.35.

Criteria: All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 10 CFR 30.35 must provide evidence of financial assurance for decommissioning.

Discussion: All licensees are required, under 10 CFR 30.35(g), to maintain records important to decommissioning in an identified location. These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. Pursuant to 10 CFR 30.35(g), licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), and must transfer records to the appropriate NRC Regional Office before the license is terminated (see 30.51(b)).

Licensees using sealed sources authorized by 10 CFR 35 generally use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, or would not contaminate work areas. The licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee's possession. However, any leakage of the sealed source in excess of the regulatory limits would warrant further NRC review of decommissioning procedures on a case-by-case basis.

Licensees authorized to possess byproduct material in excess of the limits specified in 10 CFR 30.35 must also provide evidence of financial assurance for decommissioning. The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Some medical use applicants and licensees may not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 10 CFR 30.35 or because the half-life of the unsealed byproduct material used does not exceed 120 days. Applicants requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

Applications for authorization to possess and use unsealed byproduct material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in 30.35(a) are exceeded. Acceptable methods of providing financial assurance include trust funds, escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self guarantees, external sinking funds, statements of intent, special arrangements with government entities, and standby trust funds. NUREG-1727, "NMSS Decommissioning Standard Review Plan, Appendix F," dated September 2000 contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds.

NRC will authorize sealed source possession exceeding the limits given in 10 CFR 30.35(d) without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days.

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed byproduct material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use Table 8.1 to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed byproduct material with a half-life greater than 120 days, refer to 10 CFR 30.35 and Appendix B to Part 30 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in Table 8.1 and must be used to determine the need for financial assurance for both sealed and unsealed byproduct material.

Table 8.1 Worksheet for Determining Need for Financial Assurance for Sealed Sources

Step Number	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in curies*			
2	Activity requiring financial assurance, in curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerel.

As 10 CFR 30.35 describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit a decommissioning funding plan or financial assurance, as applicable.

Response from Applicants: No response is needed from most applicants. If financial assurance is required, applicants must submit evidence as described above and as provided for in NUREG-1727.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG-1727, "NMSS Decommissioning Standard Review Plan," dated September 2000.

8.8 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(1); 10 CFR 35.100; 10 CFR 35.200; 10 CFR 35.300; 10 CFR 35.400; 10 CFR 35.500; 10 CFR 35.600; 10 CFR 35.1000.

Criteria: 10 CFR Part 35 divides byproduct material for medical use into seven types of use as follows:

10 CFR 35.100	Medical Use of Unsealed Byproduct Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
10 CFR 35.200	Medical Use of Unsealed Byproduct Material for Imaging and Localization Studies for Which a Written Directive is Not Required
10 CFR 35.300	Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required
10 CFR 35.400	Medical Use of Sources for Manual Brachytherapy
10 CFR 35.500	Medical Use of Sealed Sources for Diagnosis
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
	Medical Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
10 CFR 35.1000	Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Discussion: 35.100, 35.200, and 35.300 Use: For 35.100, 35.200, and 35.300 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100, 10 CFR 35.200) and the description of the applicable modality (e.g., any uptake dilution and excretion procedure for which a written directive is not required).

The use of unsealed byproduct material in therapy (10 CFR 35.300) involves administering a byproduct material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed byproduct material for therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

If an applicant's request is limited to I-131 under 10 CFR 35.300, the license will be limited to that radionuclide.

35.400 Use: For 35.400 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.400). If a source is to be used in a device, applicants may need to define the purpose of use by describing the manufacturer's name and model number of the device. The licensee should relate the sealed sources listed in Item 5 to the devices described in this item.

In manual brachytherapy several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer.
- Eye Plaque Implants. This is considered interstitial, not topical, treatment.
- Intracavitary Treatment of Cancer. For purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.
- Topical (Surface) Applications.

35.500 Use: For 10 CFR 35.500 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR 35 (i.e., 10 CFR 35.500) and describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

35.600 Use: For 10 CFR 35.600 use, the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35.600 (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.

35.1000 Use: Applicants must apply for authorization to use byproduct material, or radiation therefrom, in medical applications under §35.1000 when the type of use is not covered under §§ 35.100-35.600.

When applying for use under provisions of 10 CFR 35.1000, applicants should describe the purpose of use and submit the information required under Section 35.12(b) through (d), review regulatory requirements in other Subparts of 10 CFR Part 35, and use them as a guide on how to determine what should be included in an application that is required in §35.12,. It is anticipated that many of the uses of byproduct material under the provisions of §35.1000 may involve

research or product development; thus, applicants should ensure review and compliance with 10 CFR 35.6, "Provisions for the protection of human research subjects,"and 10 CFR 35.7, "FDA, other Federal, and State requirements." Use of byproduct material in a source or device after approval by U.S. Food and Drug Administration, e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption), does not relieve individuals of the responsibility to obtain a license to use the byproduct material in medicine under the provisions of 10 CFR Part 35.

If the source for the type of use sought under 35.1000 is a sealed source, Section 8.6 of this guide describes the information that must be provided at the time of application. Broad scope licensees are exempted under 35.15(a) from requirements of 35.12(d) (which relates to including certain information in an application about radiation safety aspects of medical use under 35.1000). However, broad scope licensees should make sure that the quantity needed for the proposed use is authorized on their license or apply for an increase if not. Applicants should refer to IN 99-024, "Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices" for more information on sealed sources.

Applicants for uses under 35.1000 should consult with their Regional Office to discuss the contents of their application.

Non-Medical Uses: Applicants may also describe non-medical uses (e.g., survey meter calibrations with NIST traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5.

Response from Applicant: The applicant must submit information regarding the purpose for which the licensed material will be used. The applicant should consider including the information described above, as applicable to the type of use(s) proposed.

8.9 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3); 10 CFR 33.13; 10 CFR 35.24; 10 CFR 35.50; 10 CFR 35.51; 10 CFR 35.55; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.190; 10 CFR 35.290; 10 CFR 35.390; 10 CFR 35.392; 10 CFR 35.394; 10 CFR 35.490; 10 CFR 35.491; 10 CFR 35.590; and 10 CFR 35.690.

Criteria: The RSO, AUs, AMPs, and ANPs must have adequate training and experience.

Discussion: 10 CFR 35.24 provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. Other personnel who have a role in the radiation protection program are AUs, AMPs, ANPs, and members of the RSC (if the licensee is required to establish a RSC). In 10 CFR 30.33(a)(3), NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in

such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, H, and J of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

A résumé or a curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual's training and experience for NRC purposes. Applicants should ensure that they submit the specific training information required by NRC regulations in Part 35. NRC Form 313A provides a convenient format for submitting this information.

Licensees are responsible for their radiation protection programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's management must appoint an RSO, who agrees in writing to be responsible for implementing the radiation protection program, and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions, including: identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; and verifying the implementation of corrective actions. Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H are required under 10 CFR 35.24(f) to establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. Membership of the committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer. The committee may include other members the licensee considers appropriate.

Licensees may contract for medical use services, including those involving patient services. However, the licensee should not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including training of contractor staff, is effectively implemented by the appropriate individuals.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above.

8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.2; 10 CFR 35.14; 10 CFR 35.24; 10 CFR 35.50; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.900; 10 CFR 35.2024.

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in 10 CFR 35.50 or 35.900 and allow for the following four training pathways:

- Certification as provided in 10 CFR 35.50(a) (or 35.900(a) by one of the professional boards recognized by NRC in 10 CFR 35.900);
- Didactic training (200 hours) and 1 year of work experience as described in 10 CFR 35.900;
- Didactic training (200 hours), 1 year of work experience and preceptor statement as described in 10 CFR 35.50(b);
- Identification on the license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO.

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 10 CFR 35.24, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner. NRC requires the name of the RSO on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. NRC has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy requirements of 10 CFR 35.24. Appendix I contains a model RSO Delegation of Authority. Appendix B contains NRC Form NRC 313A, which can be used to document the RSO's training and experience.

RSO Responsibilities: Some of the typical duties and responsibilities of RSOs include ensuring the following:

- Unsafe activities involving licensed materials are stopped;
- Radiation exposures are ALARA;
- Material accountability and disposal;
- Interaction with NRC;
- Timely and accurate reporting and maintenance of appropriate records;
- Annual program audits;
- Proper use and routine maintenance;
- Personnel training; and
- Investigation of incidents involving byproduct material (e.g., medical events).

Appendix I contains a detailed list of typical duties and responsibilities of the RSO.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed RSO.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

OR

- Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.

OR

- Description of the training and experience specified in 10 CFR 35.900(b).

OR

- Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

AND

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).

- The licensee must notify NRC within 30 days if an RSO permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14 and to request an amendment to change an RSO under 10 CFR 35.13.

- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities (see 10 CFR 35.50(c)) and, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.

- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.

- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subpart B or J are met. If the training and experience do not appear to meet the criteria in either Subpart B or J, NRC may request additional information from the applicant or may request the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.

- The training and experience for the RSO of a medical use broad scope license will be reviewed using the above criteria as well as criteria in 10 CFR Part 33.

8.11 ITEM 7: AUTHORIZED USERS (AUs)

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.2; 10 CFR 35.11; 10 CFR 35.14; 10 CFR 35.27; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.190; 10 CFR 35.290; 10 CFR 35.390; 10 CFR 35.392; 10 CFR 35.394; 10 CFR 35.490; 10 CFR 35.491; 10 CFR 35.590; 10 CFR 35.690; 10 CFR 35 Subpart J.

Criteria: Training and experience requirements for AUs are described in 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690, or 10 CFR 35 Subpart J.

Discussion: The responsibilities of AUs involved in medical use include the following:

- Radiation safety commensurate with use of byproduct material;
- Administration of a radiation dose or dosage and how it is prescribed;
- Direction of individuals under the AU's supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material;
- Preparation of WDs, if required.

Applicants must meet recentness of training requirements described in 10 CFR 35.59. AU applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use byproduct material for medical use under an AU's supervision in accordance with 10 CFR 35.27, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for INDs (Investigational New Drugs) and under the auspices of a Radioactive Drug Research Committee (21 CFR 361.1).

There is no NRC requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. NRC recognizes that the AU may or may not be the physician who interprets such studies. Additionally, NRC regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of byproduct material to individuals.

AU's for Non-Medical Uses: For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed AUs should include the individuals who will actually be responsible for the safe use of the byproduct material for the requested use.

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user's training and experience.

Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

Response from Applicant: Provide the following:

- Name of the proposed AU and uses requested.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.

OR

- Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.

OR

- Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.

OR

- A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;

AND

- Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).

- Licensees must notify NRC within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.

- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

Note to reviewers: Licenses will reflect any limitations on use for listed authorized users (e.g., whether administrations in excess of 33 mCi of iodine-131 are allowed and specific modalities under 10 CFR 35.600, etc.).

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)

Part 35	Applicability
100	✓
200	✓
300	✓
400	
500	
600	
1000	✓

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.2; 10 CFR 35.11; 10 CFR 35.14; 10 CFR 35.27; 10 CFR 35.55; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.980.

Criteria: Training and experience requirements for ANPs are described in 10 CFR 35.55.

Discussion: At many licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals.

Technologists, or other personnel, may prepare byproduct material for medical use under an ANP's supervision in accordance with 10 CFR 35.27, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (10 CFR 35.7). (Preparation of byproduct material for medical use may also be performed under the supervision of a physician who is an authorized user.)

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed ANP.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.

OR

- Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).

OR

- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.

AND

- Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency

  -- sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or
  -- sufficient to independently operate a nuclear pharmacy (10 CFR 35.980).

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).

- Licensees must notify NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.

- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subparts B and J are met. If the training and experience do not appear to meet the criteria in Subparts B and J, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP)

Part 35	Applicability
100	
200	
300	
400	✓
500	
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.2; 10 CFR 35.14; 10 CFR 35.51; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.433; 10 CFR 35.961.

Criteria: Training and experience requirements for AMPs are described in 10 CFR 35.51.

Discussion: At many licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 10 CFR Part 35 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the units requested.

OR

- Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b).

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested.

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested.

AND

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.

AND

- If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).

- Licensees must notify NRC within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.

- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subparts B and J are met. If the training and experience do not appear to meet the criteria in Subparts B and J, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

8.14 ITEM 9: FACILITIES AND EQUIPMENT

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.12(b)(1); 10 CFR 35.18(a).

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in 10 CFR 30.33(a)(2), 35.12(b)(1), and 35.18(a). Applications will be approved if, among other things, "the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property." Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Response from Applicant: Refer to Sections 8.15 through 8.19 for guidance.

8.15 ITEM 9: FACILITY DIAGRAM

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1003; 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1601; 10 CFR 20.1602; 10 CFR 20.1901; 10 CFR 20.1902; 10 CFR 20.2102; 10 CFR 30.33(a)(2); 10 CFR 35.12; 10 CFR 35.14; 10 CFR 35.18(a)(3); 10 CFR 35.75; 10 CFR 35.315(a); 10 CFR 35.415; 10 CFR 35.615.

Criteria: In order to issue a license, the Commission must find that facilities and equipment must be adequate to protect health and minimize danger to life or property as required under 10 CFR 30.33(a) and/or 35.18(a).

Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 35.12. The facility diagram should include the room or rooms and adjacent areas where byproduct material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For types of use permitted by 10 CFR 35.100 and 35.200, applicants should provide room numbers for areas in which byproduct materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. For types of use permitted by 10 CFR 35.300 and 35.400, applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they

cannot be released under 10 CFR 35.75. The discussion should include a description of shielding, if applicable. For types of use permitted by 10 CFR 35.500, the applicant should provide the room numbers of use.

For types of use permitted by 10 CFR 35.600, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. When preparing applications for use under 10 CFR 35.1000, applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

Licensees are required by 10 CFR 35.13 to obtain a license amendment before adding to or changing an area of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with 10 CFR 35.100 or 10 CFR 35.200.

Licensees are required by 10 CFR 35.14 to notify NRC within 30 days following changes in areas of use for 10 CFR 35.100 and 10 CFR 35.200 byproduct material.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient's room or a therapy treatment room.

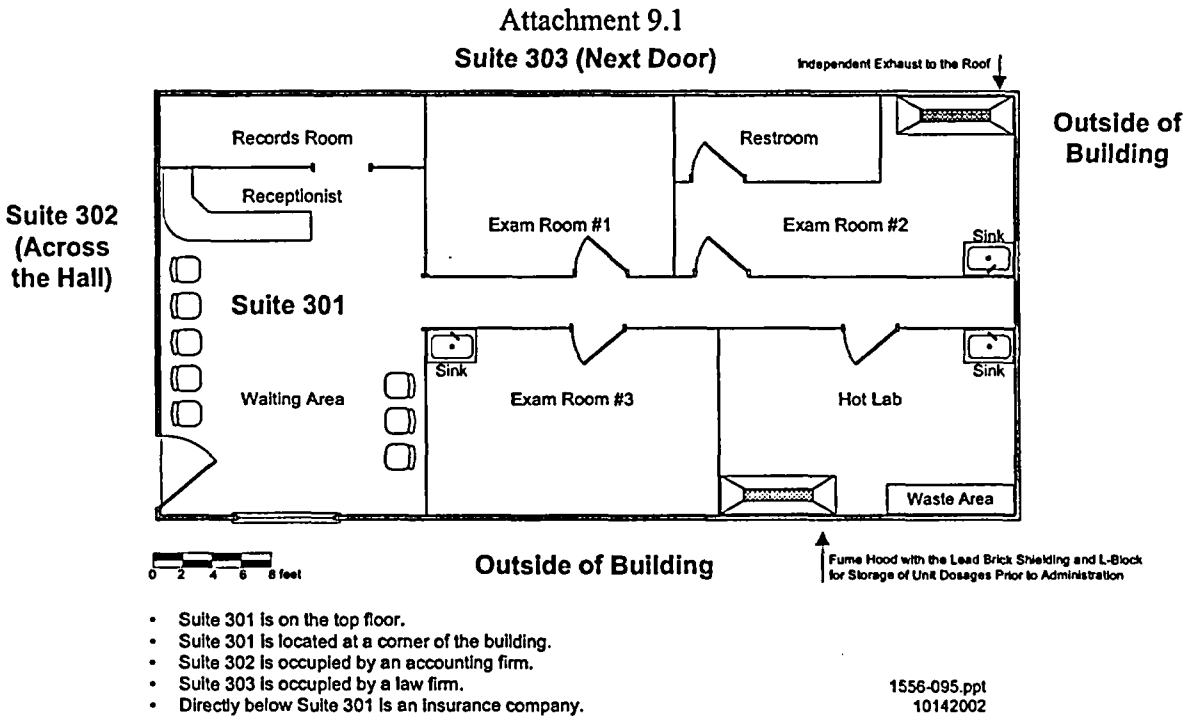


Figure 8.1: Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

- Requesting prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of 10 CFR 20.1301 will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in 10 CFR 20.1301(a). A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA (10 CFR 20.1101) must be developed (see 10 CFR 20.1301(d)).

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by NRC. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber (also called a beam catcher).

- "For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall."

- "For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall."

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

Response from Applicant: Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion";
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

References: National Council on Radiation Protection and Measurements (NCRP) Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV"; Report 102, "Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)"; and Report 40, "Protection Against Radiation from Brachytherapy Sources" may be helpful in responding to the items above. In addition, NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy" and NUREG/CR-6324, "Quality Assurance for Gamma Knives" may also be helpful in responding to the items above. However, please note that references to 10 CFR Part 35 in the NUREGs may be outdated because the rule was amended after these documents were published.

8.16 ITEM 9: RADIATION MONITORING INSTRUMENTS

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.1501; 10 CFR 20.2102; 10 CFR 20.2103(a); 10 CFR 30.3; 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.61; 10 CFR 35.2061.

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring

instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for survey instrument calibration (10 CFR 20.1501). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when byproduct material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be performed each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

Survey meter calibrations must be performed by persons, including licensed personnel, who are qualified to perform calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an NRC (or an equivalent Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Appendix K provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures to meet the requirements detailed in 10 CFR 35.61.

Response from Applicant: Provide the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."

AND/OR

- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."

AND

- A description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or

multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

AND

- A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."

Note: If calibrations will not be performed by the licensee or by a person qualified to perform survey meter calibration, the applicant should propose an alternate method of calibration for review by NRC.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.17 ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL

Part 35	Applicability
100	✓*
200	✓*
300	✓*
400	
500	
600	
1000	✓*

*If applicant will measure patient dosages or use other than unit dosages.

Regulations: 10 CFR 30.3; 10 CFR 30.33; 10 CFR 35.27; 10 CFR 35.41; 10 CFR 35.60; 10 CFR 35.63; 10 CFR 35.2060; 10 CFR 35.2063.

Criteria: In 10 CFR 35.60 and 10 CFR 35.63, NRC describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.

Discussion: As described in 10 CFR 35.63, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, (and does not split, combine, or otherwise modify unit dosages) the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

- If the licensee performs direct measurements of dosages in accordance with 10 CFR 35.63 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Currently, no NRC-regulated alpha-emitting nuclides are used in unsealed form in medicine. This document, therefore, does not provide guidance on the measurement of these radionuclides.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

Response from Applicant: If applicable, provide the following:

- A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

8.18 ITEM 9: THERAPY UNIT — CALIBRATION AND USE

Part 35	Applicability
100	
200	
300	
400	✓*
500	
600	✓*
1000	✓

* Special requirements re: brachytherapy and LDR afterloader sources and Sr-90 sources.

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.432; 10 CFR 35.630; 10 CFR 35.632; 10 CFR 35.633; 10 CFR 35.635; 10 CFR 35. 642; 10 CFR 35.643; 10 CFR 35.645; 10 CFR 35.2432; 10 CFR 35.2630; 10 CFR 35.2632; 10 CFR 35.2642; 10 CFR 35.2643; 10 CFR 35.2645.

Criteria: The above regulations contain NRC requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachtherapy sources and LDR remote afterloader sources licensees may use source activity or output determined by the manufacturer, provided that the manufacturer's measurements meet applicable requirements.

Discussion: Except for manual brachytherapy sources and low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer in accordance with 10 CFR Part 35, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber,

electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, ACR, ANSI). (Note: Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of Strontium-90 sources.) The licensee's AMP must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. The calibration procedures should address, in part:

- The method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

Full calibrations must be performed before first medical use[2], whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. Manual brachytherapy sources must be calibrated only initially, prior to use.

For sealed sources used in therapy, and in particular, for new types of use, licensees should select dosimetry equipment that will accurately measure the output or the activity of the source. Contact a Regional licensing specialist for additional assistance.

Response from Applicant: Provide the following:

- The applicant must provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.

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[2]For brachytherapy sources, "first medical use" is defined as the first use following the effective date of the revised 10 CFR Part 35, October 24, 2002.

References:

- AAPM Task Group No. 21, "A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams;"
- AAPM Task Group No. 40, "Comprehensive QA for Radiation Oncology," AAPM Report No. 54, "Stereotactic Radiosurgery;"
- AAPM Task Group No. 56, "Code of Practice for Brachytherapy Physics."

Copies of these documents and many other documents from AAPM referenced in this guide may be obtained from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from <http://www.medicalphysics.org>.

8.19 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.1801; 10 CFR 30.33(a)(2); 10 CFR 30.34; 10 CFR 35.12; 10 CFR 35.315; 10 CFR 35.415; 10 CFR 35.457; 10 CFR 35.615; 10 CFR 35.647; 10 CFR 35.657.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: The applicant should describe, in Item 9 of the application, other equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application. This description should be identified as Attachment 9.4.

The applicant must describe additional facilities and equipment for the radiopharmaceutical therapy program to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood). Also note there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium radioidide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For **teletherapy, GSR,** and **HDR facilities,** the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of 10 CFR 35.615(c) is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or

partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

10 CFR 35.615(d) requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. 10 CFR 35.615(b), in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of **PDR remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;

- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;

- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:

  - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;

  - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;

- The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation present" signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;

- The audible alarm should be sufficiently loud to be clearly heard by the facility's responsible device/patient monitoring staff at all times; and

- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees should prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

Response from Applicant: For manual brachytherapy facilities, provide a description of the emergency response equipment. For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;

- Area radiation monitoring equipment;

- Viewing and intercom systems (except for LDR units);

- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; and

- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons.

- Emergency response equipment

8.20 ITEM 10: RADIATION PROTECTION PROGRAM

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 30.33; 10 CFR 30.34(e); 10 CFR 35.24; 10 CFR 35.26; 10 CFR 35.610; 10 CFR 35.2024; 10 CFR 35.2026.

Criteria: 10 CFR 20.1101 states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. 10 CFR 30.34(e) provides that NRC may incorporate into byproduct material licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to, in part, protect health or to minimize danger to life and property. 10 CFR 35.24 describes the licensee management's authorities and responsibilities for the radiation protection program. 10 CFR 35.26 sets forth four circumstances in which the licensee may revise its radiation protection program without NRC approval. For example, no NRC approval is required when the revision does not require a license amendment.

Discussion: Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process. Tables C.1 and C.2 in Appendix C may be helpful in determining what information should be provided when requesting a license.

Response from Applicant: Respond to subsequent sections of this document regarding Item 10 of the application.

8.21 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Regulations: 10 CFR 35.12(c)(2); 10 CFR 35.610; 10 CFR 35.642; 10 CFR 643; 10 CFR 35.645.

Criteria: Before using materials under 35.600, the applicant must develop, document, submit, and implement written safety procedures for emergency response. 10 CFR 35.610 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a

remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures needed to meet 10 CFR 35.610 must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

- The names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.

A copy of these procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

Discussion: The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public should address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.

- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.

- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.

- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove

applicators or sources from the patient and tools necessary for removal of the patient from the device.

- Giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). *Note*: If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.

- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.

- Specifying who is to be notified.

- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant: Provide procedures required by 10 CFR 35.610.

References: None.

8.22 ITEM 10: OCCUPATIONAL DOSE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1003, 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1202; 10 CFR 20.1204; 10 CFR 20.1207; 10 CFR 20.1208; 10 CFR 20.1501; 10 CFR 20.1502; 10 CFR 20.2102; 10 CFR 20.2106.

Criteria: Applicants must do either of the following:

- Demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 % of the allowable limits as shown in Figure 8.2.

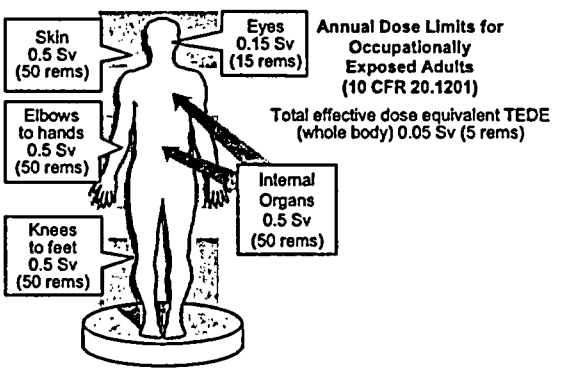

Figure 8.2 Annual Occupational Dose Limits for Adults

OR

- Monitor external and/or internal occupational radiation exposure, if required by 10 CFR Part 20.1502.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101, must include provisions for monitoring occupational dose. The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with Subpart F of 10 CFR Part 20. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

When evaluating dose from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within 10 CFR Part 20 limits.

Appendix M provides a model procedure for monitoring external occupational exposure.

If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL), and thermoluminescent dosimeters (TLDs), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv (5 rems) shallow-dose equivalent (SDE), in addition to whole-body badges. Additionally, applicants should ensure that their personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See American National Standards Institute (ANSI) N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration (10 CFR 20.1501(b)).

When personnel monitoring is needed, most licensees use either film badges or TLDs that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). Under 10 CFR 20.1501, licensees must verify that the processor is accredited by NVLAP for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 10 CFR 20.1204 and 20.1502. If internal dose assessment is necessary, the applicant shall measure the following:

- Concentrations of radioactive material in air in work areas; or
- Quantities of radionuclides in the body; or
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

The applicant should describe in its procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also should describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant should ensure that the service is licensed by an NRC (or an equivalent Agreement State) license or provide another alternative for NRC to review.

RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements," outline acceptable criteria that applicants may use in developing their bioassay programs.

Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," provides guidance for evaluation of occupational dose when some exposure is due to x-rays and dosimeters are used to measure exposure behind lead aprons and elsewhere.

Note: The definition of "shallow-dose equivalent" in 10 CFR 20.1003 was revised, effective June 4, 2002[3] to change the area for averaging dose to skin from 1 square centimeter to 10 square centimeters (see NRC Regulatory Issue Summary 2002-10, "Revision of the Skin Dose Limit in 10 CFR Part 20").

Response from Applicant: If personnel monitoring is required, provide the following:

- A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002."

OR

- A description of an alternative method for demonstrating compliance with the referenced regulations.

[3] 67 FR 16298

References:

- National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available for purchase from GPO and on the Internet at <http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm>.

- Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <http://www.ansi.org>.

- NUREG/CR-4884, "Interpretation of Bioassay Measurements;"

- RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program;" Regulatory Issue Summary 2002-06;

- "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;"

- NRC Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;"

- NRC Regulatory Issue Summary 2002-10, "Revision of the Skin Dose Limit in 10 CFR Part 20."

See the Notice of Availability on the inside front cover of this report to obtain copies of these NRC documents. Copies of Regulatory Issue Summaries are also available on the NRC's web site in the Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/>.

8.23 ITEM 10: AREA SURVEYS

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1003; 10 CFR 20.1101; 10 CFR 20.1201; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1501; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 20.2107; 10 CFR 35.70; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.604; 10 CFR 35.2070.

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 1 mSv per year (100 millirem/year) and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour from licensed operations;

- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 10 CFR 20.1201; and

- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.

- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 10 CFR 20.1101.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

There are many different kinds of surveys performed by licensees:

- Contamination:
  - Fixed;
  - Removable.
- Air Effluent;
- Water Effluent;
- Leak Test;
- Bioassays;
- Air Sample;
- Restricted Areas;
- Unrestricted Areas; and
- Personnel (during use, transfer, or disposal of licensed material).

Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate regulations. The most important types of surveys are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;

- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas;

- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;

- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and

- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Appendix R contains model procedures that represent one acceptable method of establishing survey frequencies for ambient radiation level and contamination surveys. For example, licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a written directive is required (diagnostic activities exceeding 30 μCi of I-131 and all therapy treatments); when the licensee administers radiopharamaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey of the patient's room. Licensees should perform surveys after the patient's release. Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate the public dose limits are not exceeded.

Because therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed, the following surveys shall be performed:

- Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted; and

- Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

In addition, licensees should also consider the following:

- The therapy patient's bed linens before removing them from the patient's room;

- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check);

- All trash exiting the patient's room; and

- Areas of public access in and around the patient's room.

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

8.24 ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

Part 35	Applicability
100	✓
200	✓
300	✓
400	
500	
600	
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 30.33(a)(2); 10 CFR 30.34(e); 10 CFR 35.27; 10 CFR 35.69; 10 CFR 35.70; 10 CFR 35.310.

Criteria: Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields;
- Wearing laboratory coats and gloves when handling unsealed byproduct material; and
- Monitoring hands after handling unsealed byproduct material.

Appendix T contains model procedures that provide one method for safe use of unsealed licensed material.

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

8.25 ITEM 10: SPILL PROCEDURES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓*
500	✓*
600	
1000	✓

*If source does not meet sealed source definition in 10 CFR Part 35.

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.2202; 10 CFR 20.2203; 10 CFR 30.32; 10 CFR 30.35(g); 10 CFR 30.50; 10 CFR 30.51; 10 CFR 35.27.

Criteria: Before using licensed material, the licensee must develop, document, and implement a radiation protection program that includes proper response to spills of licensed material.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Appendix N contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and NRC, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for reentering, and for decontaminating facilities (when necessary).

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

8.26 ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Part 35	Applicability
100	
200	
300	
400	
500	
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 30.32; 10 CFR 30.34; 10 CFR 35.605; 10 CFR 35.655; 10 CFR 35.2605; 10 CFR 35.2655.

Criteria: In accordance with 10 CFR 35.605 and 10 CFR 35.655, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

Discussion: Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

NRC requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 10 CFR 35.605 before responding to this item. 10 CFR 35.605 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant: No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the licensee. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the NRC to evaluate and approve such authorization (see CFR 35.605 and 10 CFR 35.655). This should include the following:

- Name of the proposed employee and types of activities requested;

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested;

AND

- Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

Note: The applicant should specify only those installation, maintenance, inspection, adjustment, and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

8.27 ITEM 10: MINIMIZATION OF CONTAMINATION

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1406; 10 CFR 35.67.

Criteria: Applicants for new licenses must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed byproduct material. As described in Item 8.25, "Spill Procedures," cleanup procedures should be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in Appendix R, Tables R.2 and R.3.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant: A response from applicants is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.

8.28 ITEM 11: WASTE MANAGEMENT

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1501; 10 CFR 20.1904; 10 CFR 20.2001-2007; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 20.2107; 10 CFR 20.2108; 10 CFR 30.33(a)(2); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 31.11; 10 CFR 35.92; 10 CFR 35.2092; 10 CFR 61.3; 10 CFR 71.5.

Criteria: Licensed materials must be disposed of in accordance with NRC requirements by:

- Transfer to an authorized recipient (10 CFR 30.41(b));
- Decay-in-storage;
- Release in effluents within the limits in 10 CFR 20.1301; or
- As authorized under 10 CFR 20.2002 through 20.2005.

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for waste disposal of licensed material. Appendix W contains model procedures that represent one way to provide for decay-in-storage and generator or other licensed material return. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

- Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with 10 CFR 20.2001(b), 10 CFR 20.2006, or in applicable regulations in 10 CFR Parts 30 or 61. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.

- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under 10 CFR 31.11 is exempt from waste disposal regulations in 10 CFR Part 20, as set forth in 10 CFR 31.11(f). Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under 10 CFR 20.1302 and 20.2003, respectively.

  - Regulations for disposal in the sanitary sewer appear in 10 CFR 20.2003. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see 10 CFR 20.2003(b)).

  - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area.

  - Liquid scintillation-counting media containing 1.85 kBq (0.05 μCi) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (10 CFR 20.2005(a)(1)).

- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with 10 CFR 20.2004. Contact the appropriate NRC Regional Office for guidance on treatment or disposal of material by incineration.

- Applicants that wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Item 8.16 (Facility Diagram):

  - A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer's specifications, annotated sketches, photographs);

  - The types, quantities, and concentrations of the waste to be compacted;

  - An analysis of the potential for airborne release of radioactive material during compaction activities;

  - The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;

  - Methods used to monitor worker breathing zones and/or exhaust systems;

  - The types and frequencies of surveys that will be performed for contamination control in the compactor area;

  - The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Nuclear pacemakers: Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases and when the licensee is not responsible for control or disposal of the pacemaker, notify the NRC and attempt to contact the hospital where the pacemaker was implanted to arrange for explantation. The licensee which implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. NRC Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," provides additional information.

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92."

8.29 ITEM 12: FEES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 170.31.

On NRC Form 313, enter the appropriate fee category from 10 CFR 170.31 and the amount of the fee enclosed with the application.

8.30 ITEM 13: CERTIFICATION

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Individuals acting in a private capacity are required to date and sign NRC Form 313. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRC Form 313. These representatives must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An application for licensing a medical facility must be signed by the applicant's or licensee's management. The individual who signs the application should be identified by title of the office held. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. Management includes the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates. NRC will return all unsigned applications for proper signature.

Note: It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).

PROGRAM-RELATED GUIDANCE -- NO RESPONSE REQUIRED FROM APPLICANTS ON NRC FORM 313

The information provided in the following sections is included because this topic is a key element of a licensee's program and the information is provided as guidance to applicants in setting up their programs to satisfy regulatory requirements.

8.31 SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 19.12; 10 CFR 35.27; 10 CFR 35.310; 10 CFR 35.410; 10 CFR 35.610; 10 CFR 35.2310.

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by 10 CFR Parts 19 and 35. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide safety instructions as required by 10 CFR 19.12. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610. 10 CFR 35.27 requires the licensee's AUs and ANPs to provide safety instruction to all personnel using byproduct material under their supervision.

Discussion: AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and if it is likely that they could receive doses over 1 mSv (100 mrem) in a year, they must receive instruction as specified by 10 CFR 19.12. For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), should be informed of the nature of the licensed material and the meaning of the radiation symbol, and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as loss of radioactive material.

In addition to safety instruction required by 10 CFR 19.12 and in accordance with 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610, the licensee must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 10 CFR 35.75. This safety instruction should be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU if the patient has a medical emergency or dies.

In accordance with 10 CFR 35.27(a), individuals working with licensed material under the supervision of an AU must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and NRC regulations and license conditions with respect to the use of byproduct material.

In accordance with 10 CFR 35.27(b), a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an ANP or an AU, as allowed by 10 CFR 35.11(b)(2), shall instruct supervised individuals in the preparation of byproduct

material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and NRC regulations. 10 CFR 35.27(c) states that a licensee that permits supervised activities, under paragraph 10 CFR 35.27(a) and (b), is responsible for the acts and omissions of the supervised individuals.

Appendix J provides a model training program that provides one way to satisfy the requirements referenced above.

Response from Applicant: No response is necessary.

8.32 PUBLIC DOSE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1003; 10 CFR 20.1101, 10 CFR 20.1301; 10 CFR 20.1302; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.2107.

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations.

- Ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from these emissions.

- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who are not radiation workers. This includes workers who live, work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored. Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using byproduct material under their supervision should have access to these keys.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

The definition of "public dose" in 10 CFR 20.1003 does not include doses received due to exposure to patients released in accordance with 10 CFR 35.75. Dose to members of the public in waiting rooms was addressed in Informational Notice (IN) 94-09.[4] The provisions of 10 CFR 20.1301(a) should not be applied to radiation received by a member of the general public from patients released under 10 CFR 35.75. If a patient is released pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02mSv (2mrem) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

10 CFR 20.1301(c) allows licensees to permit visitors to a patient who cannot be released under 10 CFR 35.75 to receive a dose greater than 0.1 rem (1 mSv) provided the dose does not exceed 0.5 rem (5 mSv) and the authorized user has determined before the visit that it is appropriate.

In assessing adequacy of facilities to control public dose, licensees should consider the design factors discussed under "Facility Diagram" in Section 8.15 and may find confirmatory surveys to be useful in assuring compliance with 10 CFR 20.1301.

The licensee must control emissions of byproduct material to air such that the individual member of the public likely to receive the highest total effective dose equivalent (TEDE) does not exceed the constraint level of 0.10 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this in accordance with 10 CFR 20.2203, and take prompt actions to ensure against recurrence.

Response from Applicant: No response required.

8.33 OPENING PACKAGES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1906; 10 CFR 20.2103.

Criteria: Licensees must ensure that packages are opened safely and that the requirements of 10 CFR 20.1906 are met. Licensees must retain records of package surveys in accordance with 10 CFR 20.2103.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 10 CFR 20.1906 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

[4]IN 94-09 - Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas Due to Presence of Patients Containing Radioactivity Following Implementation, February 1994.

Appendix P contains model procedures that represent one method for safely opening packages containing radioactive materials. Applicants are reminded that 10 CFR 20.1906(b) requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Response from Applicant: No response required.

8.34 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

Part 35	Applicability
100	
200	
300	✓
400	✓
500	
600	✓
1000	✓

Regulations: 10 CFR 35.27; 10 CFR 35.40; 10 CFR 35.41; 10 CFR 35.2040; 10 CFR 35.2041.

Criteria: 10 CFR 35.40 sets forth the requirements for WDs. 10 CFR 35.41 requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

Discussion: The procedures do not need to be submitted to NRC. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining NRC approval. Appendix S provides guidance on developing the procedures.

Response from Applicant: No response required.

8.35 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

Part 35	Applicability
100	
200	
300	✓
400	✓
500	
600	
1000	✓

Regulations: 10 CFR 35.75; 10 CFR 35.2075.

Criteria: Licensees may release from confinement patients or human research subjects (patients) who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with 10 CFR 35.75(b).

Discussion: 10 CFR 35.75 requires that the licensee provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance.

Appendix U provides guidance to the applicant on one way for determining when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (Section 1), and
- Instructions to the patient are required by 10 CFR 35.75(b) (Section 2).
- Appendix U lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

Response from Applicant: No response required.

8.36 MOBILE MEDICAL SERVICE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 35.2; 10 CFR 35.12; 10 CFR 35.18; 10 CFR 35.80; 10 CFR 35.647; 10 CFR 35.2080; 10 CFR 35.2647; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; Subpart H of 10 CFR Part 71; 10 CFR 150.20; 49 CFR Parts 171-178.

Criteria: In addition to the requirements in 10 CFR 35.80, and 35.647 as applicable, mobile medical service licensees must comply with all other applicable regulations.

Discussion: Applicants for licensure of mobile medical services should review Sections 8.1 through 8.30 of this NUREG for information to be submitted as part of their applications; many of the requirements in these sections are relevant to use of byproduct material by mobile medical service providers with details being dependent upon the scope of such programs. "Temporary job site" means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should be located on the client's property that is under the client's control.

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client's site. Companies providing transportation only will not be licensed for medical use under 10 CFR Part 35. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

The general types of services provided as mobile medical services are:

- Mobile medical services (byproduct material, trained personnel, and facility) that provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).

- Mobile medical service providers (byproduct material and trained personnel) that provide the transportation to and use of the byproduct material within the client's facility. These mobile medical service providers are also responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).

Mobile medical service licensees must ensure that the criteria in 10 CFR 35.75 are met before releasing patients treated in their facilities.

Refer to Appendix V for additional guidance on information to provide in applications.

Note: Agreement State licensees that request reciprocity for activities conducted in non-Agreement States are subject to the general license provisions described in 10 CFR 150.20. This general license authorizes persons holding a specific license from an Agreement State to conduct the same activity in non-Agreement States if the specific license issued by the Agreement State does not limit the authorized activity to specific locations or installations. NRC licensees who wish to conduct operations at temporary job sites in an Agreement State should contact that state's Radiation Control Program Office for information about state regulations, including notification requirements, and to determine if mobile medical services are allowed within the Agreement State through reciprocity. Therefore, to ensure compliance with Agreement State reciprocity requirements, an NRC licensee shall request authorization well in advance of scheduled work. In addition to the requirements specified in 10 CFR 150.20, applicants requesting a mobile medical service license should contact all states where they plan to conduct mobile medical services, to clarify requirements associated with an authorization to practice medicine within the state's jurisdiction.

Response from Applicant: No response required.

8.37 AUDIT PROGRAM

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.2102.

Criteria: Under 10 CFR 20.1101, all licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with NRC and applicable DOT regulations and the terms and conditions of the license; and
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101).

Discussion: The applicant should develop and implement procedures for the required review or audit of the radiation protection program's content and implementation. Appendix L contains model procedures that are only a suggested guide and are one way to meet this requirement. Some sections of Appendix L may not be pertinent to every licensee or to each review or audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last review or audit need not be reviewed at the next review or audit. Reviews or audits of the content and implementation of the radiation protection program must be conducted at least annually.

NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their review programs, licensees should consider performing unannounced audits of authorized and supervised users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three-step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation.
- Identify the root cause of the violation.
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Response from Applicant: No response is necessary.

References: See the Notice of Availability on the inside front cover of this report to obtain copies of: NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," and IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996. NUREG-1600 is also available on the Internet at the NRC's web site, <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1600/>.

8.38 OPERATING AND EMERGENCY PROCEDURES

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1601; 10 CFR 20.1602; 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2102; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 30.50; 10 CFR 35.12; 10 CFR 35.41; 10 CFR 35.75; 10 CFR 35.310; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.406; 10 CFR 35.410; 10 CFR 35.415; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.3045; 10 CFR 35.3047; 10 CFR 35.3067.

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document.

- Develop, implement, and maintain specific operating and emergency procedures containing the following elements:
  - Instructions for opening packages containing licensed material (see Section 8.33);
  - Using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Section 8.26);
  - Instructions for conducting area radiation level and contamination surveys (see Section 8.23);
  - Instructions for administering licensed material in accordance with the WD (see Section 8.34);
  - Steps to ensure that patient release is in accordance with 10 CFR 35.75 (see Section 8.35);
  - Instructions for calibration of survey and dosage measuring instruments (see Sections 8.16 and 8.17);
  - Periodic spot checks of therapy device units, sources, and treatment facilities (see Section 8.18);
  - Instructions for radioactive waste management (see Section 8.28);
  - Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material (see Sections 8.25, 8.44);

- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.21);

- Steps to take if a therapy patient undergoes emergency surgery or dies.

AND

The licensee should consider the following:

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);

- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

- When developing the procedures described above, the licensee is reminded that 10 CFR 20.1101(b) requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.

- When receiving and using byproduct material, the licensee is reminded that it must be licensed to possess the byproduct material and that the radioactive material must be secured (or controlled) and accounted for at all times.

Discussion: Sealed sources and unsealed byproduct material used for therapy can deliver significant doses in a short time. 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1801, and 10 CFR 20.1802 describe access control to high and very high radiation areas and the security of licensed material. Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in Section 5.3 of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.).

After its occurrence becomes known to the licensee, NRC must be notified when an incident involving licensed material occurs. Refer to the regulations (10 CFR 20.2201-20.2203, 10 CFR

30.50, 10 CFR 21.21, 10 CFR 35.3045, 10 CFR 35.3047, and 10 CFR 35.3067) for a description of when notifications are required.

Appendix N provides model procedures that are one method for responding to some types of emergencies.

Response from Applicant: No response is necessary.

Reference: Copies of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel," 1989, and NCRP Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," 1990," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically at <http://www.ncrp.com>.

8.39 MATERIAL RECEIPT AND ACCOUNTABILITY

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2201; 10 CFR 30.35(g)(2); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.67; 10 CFR 35.406.

Criteria: To maintain accountability of licensed material, licensees must do the following:

- Secure licensed material;
- Maintain records of receipt, transfer, and disposal of licensed material; and
- Conduct physical inventories at required frequencies to account for licensed material.

Discussion: Licensed materials must be tracked from "cradle to grave" to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded.

Response from Applicant: No response is necessary.

8.40 ORDERING AND RECEIVING

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 30.51.

Criteria: 10 CFR 20.1906 contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by 10 CFR 20.1801 and 10 CFR 20.1802, must be considered for all receiving areas. 10 CFR 30.51 requires licensees, in part, to maintain records showing the receipt of byproduct material.

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix O contains model procedures that are one method for ordering and receiving licensed material.

Response from Applicant: No response is necessary.

8.41 SEALED SOURCE INVENTORY

Part 35	Applicability
100	✓*
200	✓*
300	✓*
400	✓
500	✓
600	✓
1000	✓

* Sealed sources for calibration, transmission, and reference use (35.65).

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 30.51; 10 CFR 35.67; 10 CFR 35.406; 10 CFR 35.2067; 10 CFR 35.2406.

Criteria: NRC requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession.

Discussion: According to 10 CFR 35.67, the licensee must conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in 10 CFR 35.67(g). However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under 10 CFR 30.51, to indicate the current inventory of sources at the licensee's facility.

Response from Applicant: No response is necessary.

8.42 RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	
600	
1000	✓

Regulations: 10 CFR 30.51; 10 CFR 35.63; 10 CFR 35.2063; 10 CFR 35.2204; 10 CFR 35.2406.

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

Discussion: Licensees are required to make and maintain records of each dosage and administration prior to medical use. The records must include:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned);

- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);

- Date and time of dosage determination; and

- Name of the individual who determined the dosage.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements.

If molybdenum concentration is measured under 10 CFR 35.204, records of molybdenum concentration must be made under 10 CFR 35.2204 and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as kBq (μCi) of molybdenum-99 per MBq (mCi) of technetium-99m;

- Date and time of the measurement; and

- Name of the individual who made the measurement.

If the licensee uses manual brachytherapy sources, the following records of use must be kept:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage.

- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage.

- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

Response from Applicant: No response is necessary.

8.43 RECORDKEEPING

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR Part 20, Subpart L; 10 CFR 30.51; 10 CFR Part 35 Subpart L.

Criteria: Licensees must maintain records as provided in 10 CFR Part 20, Subpart L; 10 CFR 30.51; and 10 CFR Part 35 Subpart L.

Discussion: The licensee must maintain certain records to comply with NRC regulations, the conditions of the license, and commitments made in the license application and correspondence with NRC. Operating procedures should identify which individuals in the organization are responsible for maintaining which records.

A table of recordkeeping requirements appears in Appendix X.

Response from Applicant: No response is necessary.

8.44 REPORTING

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR Part 20, Subpart M; 10 CFR 21.21; 10 CFR 30.50; 10 CFR Part 35, Subpart M.

Criteria: Licensees are required to report to NRC via telephone, written report, or both in the event that the safety or security of byproduct material may be compromised. The specific events that require reporting are explained in Subpart M of Part 35, Subpart M of Part 20; and in 10 CFR CFR 21.21 and 30.50. The timing and type of report are specified within these parts.

Discussion: The NRC requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, Parts 20, 21, 30, and 35 include provisions that describe reporting requirements associated with the medical use of byproduct material.

A table of reporting requirements appears in Appendix Y.

Response from Applicant: No response is necessary.

8.45 LEAK TESTS

Part 35	Applicability
100	✓*
200	✓*
300	✓*
400	✓
500	✓
600	✓
1000	✓

*If possess sealed sources under 35.65

Regulations: 10 CFR 20.1501; 10 CFR 20.2103; 10 CFR 30.53; 10 CFR 35.67; 10 CFR 35.2067; 10 CFR 35.3067.

Criteria: NRC requires testing to determine if there is any radioactive leakage from sealed sources.

Discussion: Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with 10 CFR 35.67. Appendix Q provides model procedures that are one way to perform leak testing. 10 CFR 35.67 requires licensees to perform leak tests at six-month intervals or at other intervals approved by NRC or an Agreement State and specified in the SSDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq (0.005 μCi) of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

The leak test may be performed in-house or by a contractor who is authorized by NRC or an Agreement State to perform leak tests as a service to other licensees.

The licensee or contractor does not need to leak-test sources if:

- Sources contain only byproduct material with a half-life of less than 30 days;
- Sources contain only byproduct material as a gas;
- Sources contain 3.7 MBq (100 μCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μCi) or less of alpha-emitting material;
- Sources contain Ir-192 seeds in nylon ribbon; or
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Response from Applicant: No response is necessary.

References: See the Notice of Availability on the inside front cover of this report to obtain a copy of NUREG-1556, Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.46 SAFETY PROCEDURES FOR TREATMENTS WHEN PATIENTS ARE HOSPITALIZED

Part 35	Applicability
100	
200	
300	✓
400	✓
500	
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1501; 10 CFR 20.1801; 10 CFR 20.2103; 10 CFR 35.310; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.410; 10 CFR 35.415; 10 CFR 35.604; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.2404.

Criteria: Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public within regulatory limits.

Discussion: 10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615 require licensees to take certain safety precautions for uses of byproduct material involving radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients who cannot be released in accordance with 10 CFR 35.75. This section of the guidance does not include guidance on this subject for teletherapy or GSR outpatient treatments. The precautions described below are provided to help ensure compliance with the exposure limits in 10 CFR Part 20.

10 CFR 35.404(b) and 10 CFR 35.604(a) require licensees to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. 10 CFR 35.615(e) requires that when sources are placed within the patient's body, licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

In addition, applicants must take the following steps for patients who cannot be released under 10 CFR 35.75:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: 10 CFR 35.315(a) allows for a room shared with another radiopharmaceutical therapy patient);

- Provide a private room for patients implanted with brachytherapy sources (*Note:* 10 CFR 35.415 allows for a room shared with another brachytherapy patient);

- Visibly post a "Radioactive Materials" sign on the patient's room and note on the door or in the patient's chart where and how long visitors may stay in the patient's room (10 CFR 35.315 and 10 CFR 35.415);

- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished

from the natural background radiation level or handle them as radioactive waste (10 CFR 35.315 and 10 CFR 20.1501); and

- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615).

10 CFR 20.1501 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized in accordance with 10 CFR 35.75 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

10 CFR 20.1801 requires licensees to secure licensed material in storage from unauthorized access or removal. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material temporarily stored in the patient's room and unnecessary personnel exposures.

In order to control exposures to individuals in accordance with 10 CFR Part 20, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant: No response is necessary.

8.47 TRANSPORTATION

Part 35	Applicability
100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 71.5; 10 CFR 71.9; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; Subpart H of 10 CFR Part 71; 49 CFR Parts 171-178.

Criteria: Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with NRC and DOT regulations.

Discussion: Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421 and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met [e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv per hour (0.5 mrem per hour)].

The general license in 10 CFR 71.12, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been

issued by NRC. This general license is subject to certain conditions. 10 CFR 71.5 sets forth the requirements for transportation of licensed material. 10 CFR 71.9 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under 10 CFR Part 35 or the equivalent Agreement State regulations from the requirements in 10 CFR 71.5. This exemption applies to transport by the physician of licensed material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. 10 CFR 71.12-71.14 sets forth the Type B package requirements for transporting or delivering the package to a carrier for transport. These include registration as a user of the package and having an NRC-approved quality assurance (QA) plan. For information about these QA plans, see Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Spent Fuel Project Office by calling NRC toll-free at (800) 368-5642, extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC toll-free at (800) 368-5642, extension 415-7544.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material (see 10 CFR 30.41).
- Actually takes possession of the licensed material under its license.

Licensees should also ensure that the manufacturer (or service licensee) is authorized to possess the material at temporary job sites (e.g., the licensee's facilities).

During an inspection, NRC uses the provisions of 10 CFR 71.5 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to medical use licensees. Appendix Z lists major DOT regulations that apply to medical licensees.

Response from Applicant: No response is needed from applicants during the licensing phase. However, before making shipments of licensed materials on its own in a Type B package, a licensee must have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References:

- "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

PROGRAM-RELATED GUIDANCE

- See the Notice of Availability on the inside front cover of this report to obtain a copy of the Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979; Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986; and NUREG-1556 Vol. 18, Program-Specific Guidance About Service Provider Licenses."