8 CONTENTS OF AN APPLICATION

This section explains, item by item, the information that medical use applicants must provide on NRC Form 313 (see Appendix A) and should provide on the appropriate NRC Form 313A series of forms if electing to use this optional form (see Appendices B and D). If an application contains security-related sensitive information (see Section 5.2), the cover letter should state that the "attached documents contain security-related sensitive information." If a cover letter is not used, NRC Form 313 should include this statement. The information needed to complete Items 5 through 11 on Form 313 describes the applicant's proposed medical use Radiation Safety Program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item. Appendix AA explains additional information the applicant must provide on NRC Form 313 when requesting authorization under 10 CFR 30.32(j) for preparing PET radioactive drugs for noncommercial distribution to medical use licensees within its consortium.

Table 1 in Appendix C is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on the NRC Form 313 appear under "Response from Applicant" in this guide.

If a particular part of a section does not apply, simply note "N/A" for "not applicable." If a particular section applies, but a procedure does not have to be developed, simply note "N" for "no response required." N/A, N, or short sentence responses to Items 5 through 11 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

> As indicated on NRC Form 313 (see Appendix A), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use the appropriate NRC Form 313A series of forms (see Appendix B) to document training and experience for new AUs, medical physicists, nuclear pharmacists, and RSOs. The NRC Form 313A series of forms may also be used by experienced individuals seeking additional authorizations. Applicants may use Appendix C to assist with completion of the application.

ITEMS FOR WHICH A RESPONSE FROM MEDICAL USE APPLICANT IS REQUIRED ON NRC FORM 313

(Also see Appendix AA for items requiring a response when applying for a 10 CFR 30.32(j) authorization)

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 the license number.

Check C for a renewal of an existing license, and provide the 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 30.34(h), 10 CFR 35.14(b).

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 by 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 8.31, "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. The NRC's Information Notice (IN), 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. Sketches or street maps indicating the nearest intersection and the location of the proposed facility would be helpful but are not required. 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 8.37 and Appendix V of this report for specific licensing guidance. The NRC must be notified if the mailing address changes.

Notes:

- When responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly.
- If there is no cover letter, then Item 3 on NRC Form 313 should state "attached document contains security-related sensitive information" instead of the address if the address contains sensitive information, or in addition to the address, if the address is not sensitive but other information in the application is. Documents that give exact locations of use need to be marked "security-related information – withhold under 10 CFR 2.390."

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).

- The EPAct amended the definition of byproduct material in the Atomic Energy Act and gave NRC jurisdiction over accelerator-produced radioactive materials, discrete sources of Ra-226, and certain naturally occurring radioactive materials that are extracted or converted after extraction for use for a commercial, medical, or research activity. The definition encompasses those materials produced, extracted, or converted before, on, and after Section 651e of the EPAct was enacted. Therefore, NRC applicants and licensees who possess(ed) these materials must maintain permanent records on where the newly defined byproduct materials were used or stored prior to issuance of an NRC license, if they still possess the material once an NRC license is issued.

As discussed in Section 8.8, "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, leaking radioactive sources, or contamination from Ra-226.

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. The 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).

The 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, the 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: Byproduct material for medical use in 10 CFR Part 35 is divided 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 and material requested.

Under Section 651c of the EPAct, the NRC now has regulatory authority over accelerator-produced byproduct material as well as discrete sources of Ra-226. Although sealed Ra-226 sources (e.g., Ra-226 needles) were once used for manual brachytherapy and are no longer believed to be used for medical uses, the medical use of discrete sources of Ra-226 is included in this guidance because its use for this purpose is not prohibited. The guidance also distinguishes between discrete sources of Ra-226 and sealed sources of Ra-226 because not all discrete sources are sealed sources.

The medical uses of the other new byproduct materials are essentially the same as the uses of the previously defined byproduct materials. However, some of the radionuclides now included in the expanded definition of byproduct material have significantly shorter half-lives and higher energy levels (e.g., PET radionuclides) that may result in delivery of the unsealed material by direct transfer tube from the accelerator production facility to the 35.100 and 35.200 medical use areas. This may result in higher potential radiation doses to workers and the public if additional handling and shielding precautions are not implemented, and licensees should consider this in evaluating their equipment, facilities, and programs.

35.100 and 35.200 Use: For 10 CFR 35.100 and 35.200 medical uses, the chemical/physical form may be "Any" unsealed byproduct material permitted by 10 CFR 35.100 or 35.200, as appropriate. For 10 CFR 35.100 and 35.200 medical uses, 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[1]

35.300 Use: For 10 CFR 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

[1] Applicants that have their own cyclotrons and produce PET radionuclides that they use to produce PET radioactive drugs for their own use under the appropriate provisions of 10 CFR Part 35 may have different shielding or special equipment requirements than most medical use applicants who receive unit doses, multi-dosage vials, or generators from drug manufacturers or commercial nuclear pharmacies that are packaged in self-shielding radiation transport shields. Information needed for the different shielding or special equipment requirements can be found in Section 9.

35.400, 35.500, 35.600, and 35.1000 Use: For 10 CFR 35.400, 35.500, 35.600, and 35.1000 use, the radionuclide, the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number), the total amount in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), and the maximum number of sources or activity possessed at any one time must be specified. Sealed sources of Ra-226 may be used for 10 CFR 35.400, 35.500, and 35.1000 uses. Unsealed Ra-226 can only be used for medical use under 35.1000. 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, 35.1000 use)	Liquid source (Manufacturer Name, Model #DEF)	2 curies total
Ra-226	Sealed source or device (Manufacturer Name, Model #HIJ)	Not to exceed 50 millicuries per source and 250 millicuries total
Cesium 137 (i.e., specific brachytherapy radionuclide, 35.400 use)	Sealed source or device (Manufacturer Name, Model #MNO)	2 curies total
Pd-103 (i.e., specific manual brachytherapy source, 35.400 use)	Sealed source or device (Manufacturer Name, Model #QRS)	Not to exceed 0.5 millicuries per source and 3 curies total
Gadolinium 153 (i.e., specific diagnostic sealed-source radionuclide, 35.500 use)	Sealed source or device (Manufacturer Name, Model #TUV)	Not to exceed 500 millicuries per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed-source radionuclide, 35.600 use)	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, 35.600 use)	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, 35.600 use)	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 Registry (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 all calibration, transmission, and reference sources, including those with Ra-226, 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 the medical use of byproduct material.

Shielding Material/Depleted Uranium: Some high-activity radionuclide generators used to produce byproduct materials for 10 CFR 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. This includes identifying depleted uranium used as shielding in linear accelerators because, even though NRC does not regulate the accelerator, it does regulate the depleted uranium in the accelerator. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in 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 required items (e.g., Ra-226 not previously described, 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
Ra-226	unsealed	1 millicurie

Sources that are authorized by 10 CFR 35.65, "Authorization for calibration, transmission, and reference 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, Volume 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses."

Production of Radionuclides by Accelerators: If the applicant will use an accelerator to produce radionuclides, a separate license application will be needed for the production of the radionuclides. The applicant should review NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator."

Production of PET Radioactive Drugs for Noncommercial Distribution to Medical Use Licensees Within a Consortium: If the applicant will use PET radionuclides to produce PET radioactive drugs for its own medical use and noncommercial distribution to other members of its consortium, the applicant, to satisfy 10 CFR 30.33(a)(1), should identify the PET radionuclides, the proposed use of the material, and the maximum activity. The applicant should also review Appendix AA.

The following format may be used for unsealed PET radionuclides used to produce PET radioactive drugs for noncommercial transfer to other members within the consortium.

Byproduct Material	Chemical/Physical Form	Maximum Amount
PET Radionuclides for noncommercial distribution	Any	____ curies

When applying for this authorization, the applicant should also consider applying for authorization to take back potentially contaminated transport shields from other consortium members. Each consortium member should dispose of unused dosages and used syringes and vials at its own facility.

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. Certain information about quantities of radioactive materials is no longer released to the public and needs to be marked "security-related information – withhold under 10 CFR 2.390." Therefore, when responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly. Applicants requesting authorization for the medical use of a discrete source of Ra-226 (which includes a sealed source of Ra-226) or other NARM sources or devices containing NARM sources that do not have the information described above (e.g., manufacturer and model number from an SSDR certificate), or the information required in 10 CFR 30.32(g)(3), should consult the appropriate NRC Regional Office to discuss the contents of their application.

8.6 ITEM 5: SEALED SOURCES AND DEVICES (including Ra-226 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, and certain NARM sources for which this information is not available). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC, an Agreement State or a non-Agreement State, or certain sources when information required in 10 CFR 30.32(g)(3) is provided.

Under the EPAct, the NRC was given regulatory authority over additional byproduct material including accelerator-produced radionuclides and discrete sources of Ra-226. See 10 CFR 30.4 for a complete definition of byproduct material.

Applicants and licensees should determine whether they possess, or will possess, sealed sources or devices containing this new byproduct material for uses under 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, or 10 CFR 35.1000, as well as check, calibration, transmission, and references sources that are not included in 10 CFR 35.65.

Applicants will need to request authorization for possession of these sealed source(s) or device(s). It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither the NRC, an Agreement State, nor a non-Agreement State, may have performed a safety evaluation of the sealed source or device and it may not have an Sealed Source and Device Registry (SSDR) certificate. Information that must be submitted for all sources is described in 10 CFR 30.32(g).

Discussion: The 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. Some non-Agreement States may also have performed similar safety evaluations for sealed sources and devices containing NARM, and these safety evaluations may be documented in SSDR certificates.

Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify whether 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, Volume 3, Revision 1, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and

Registration," from an NRC Regional Office and submit the information requested therein to NRC for review.

If the sealed source or device that has not been reviewed contains NARM material and was produced before the effective date of the rule, November 30, 2007, the information required by 10 CFR 32.210 may not be available. If this is the case, the applicant must provide the information required in 10 CFR 30.32(g)(3).

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. Licensees providing information in accordance with the provisions of 10 CFR 30.32(g) may not make changes to the sealed sources, device, or source-device combination that would alter the description provided to NRC 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 certificates, applicants may want to review or discuss them with the manufacturer.

Response from Applicant: If the possession of a 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, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," and NUREG-1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope."

Note: To obtain copies of the SSDR certificate, applicants should contact the manufacturer/distributor of the device or the appropriate NRC Regional Office (see Figure 2.1 for addresses and telephone numbers).

8.7 ITEM 5: DISCRETE SOURCE OF Ra-226 (OTHER THAN SEALED SOURCES)

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

Regulation: 10 CFR 30.33(a)(2)

Criteria: Licensees will be authorized to possess and use discrete sources of Ra-226 specifically authorized by the NRC or an Agreement State.

Response from Applicant: If possession of a discrete source of Ra-226 is requested, provide a complete description of the discrete source, including manufacturer, model number, activity, and intended use. Applicants who do not have this information for a discrete source of Ra-226 should consult with the appropriate NRC Regional Office to discuss the content of their application.

8.8 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), leaking sealed sources, and Ra-226 contamination. 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 nonlicensed 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)).

The EPAct amended the definition of byproduct material in the Atomic Energy Act and gave NRC jurisdiction over accelerator-produced radioactive materials, discrete sources of Ra-226, and certain naturally occurring radioactive materials that are extracted or converted after extraction for use for a commercial, medical, or research activity. The expanded definition encompasses those materials produced, extracted, or converted before, on, and after Section 651(e) of the EPAct was enacted. Therefore, NRC applicants and licensees who possess(ed) these materials must maintain permanent records on where the newly defined byproduct materials were used or stored prior to issuance of an NRC license and any other information relevant to spills and leaking sealed sources that is important for decommissioning, if they still possess the material once an NRC license is issued.

Licensees using sealed sources authorized by 10 CFR Part 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 from Ra-226 sources or other sealed sources 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 10 CFR 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. Appendix A to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," dated September 2003, contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds.

The 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 a 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 Ra-226 and 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 10 CFR 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 Applicant: 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-1757, Volume 3. If applicants have questions about financial assurance requirements associated with discrete sources of Ra-226, they should consult with the appropriate NRC Regional Office to discuss the contents of their application.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG-1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," dated September 2003.

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

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

Regulations: 10 CFR 30.32(j), 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: In 10 CFR Part 35, byproduct material for medical use is divided into seven types of use as follows:

10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required
10 CFR 35.300	Use of unsealed byproduct material for which a written directive is required
10 CFR 35.400	Use of sources for manual brachytherapy

10 CFR 35.500	Use of sealed sources for diagnosis
10 CFR 35.600	Use of a sealed source(s) in a device for therapy-teletherapy unit
	Use of a sealed source(s) in a device for therapy-remote afterloader unit
	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

Under 10 CFR 30.32(j), medical use licensees within a consortium are authorized to produce PET radioactive drugs for noncommercial distribution to medical use licensees within the consortium. Appendix AA provides additional information on this 10 CFR Part 30 use.

Discussion:

10 CFR 35.100, 35.200, and 35.300 Use: For 10 CFR 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) 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: The applicant should define the purpose of use by stating that the applicable section of 10 CFR Part 35 is 10 CFR 35.400. If a source is to be used in a device, applicants may need to define the purpose of use by including the manufacturer's name and model number of the device. The licensee should relate the sealed sources, including sealed sources of Ra-226, 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 that the applicable section of 10 CFR 35 is 10 CFR 35.500 and including the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources, including sealed sources of Ra-226, listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to the 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 including the manufacturer's name(s) and model number(s) of the device(s) 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 authorization is being requested for an additional source 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 10 CFR 35.1000 when the type of use is not covered under 10 CFR 35.100-35.600. This includes the medical use of unsealed Ra-226 or of Ra-226 sealed sources for uses other than those described by 10 CFR 35.400 or 35.500.

When applying for use under the 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 Section 35.12. It is anticipated that many of the uses of byproduct material under the provisions of Section 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 the U.S. Food and Drug Administration (FDA) (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 10 CFR 35.1000 is a sealed source, including sealed sources of Ra-226, 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 the need to put into an application certain information about the radiation safety aspects of medical use under Section 35.1000). However, broad-scope licensees should ensure 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 Section 35.1000 should consult with the appropriate NRC Regional Office to discuss the contents of their application.

Nonmedical Uses: Applicants may also describe nonmedical uses (e.g., survey meter calibrations with NIST-traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5. This would include the nonmedical use of discrete sources of Ra-226.

Authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium for medical use is another nonmedical use. Applicants intending to produce PET radioactive drugs under this provision should include this use under this section, list the applicable radioactive materials under Item 5, and review Appendix AA for additional information.

Radionuclide Production by an Accelerator: Production of radionuclides for both medical and nonmedical uses is beyond the scope of this guidance and a medical use license. See NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator."

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.

When responding to this section, follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly.

8.10 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS AND THEIR TRAINING AND EXPERIENCE

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

Regulations: 10 CFR 30.33(a)(3), 10 CFR 30.34(j), 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 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

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

Discussion: "Authorized user (AU)" is not defined for nonmedical use, but for purposes of this discussion, the term AU will be used to also mean individuals who are authorized for such nonmedical uses. The requirements in 10 CFR 35.24 describe 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 Radiation Safety Committee (RSC) (if the licensee is required to establish an RSC). In 10 CFR 30.33(a)(3), the 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, and H of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs; AUs for nonmedical uses must meet the criteria in 10 CFR 30.33(a)(3).

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 10 CFR Part 35. The NRC Form 313A series of forms provides a convenient format for submitting the information required in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For nonmedical use AUs, the information provided should focus on educational training and radiation safety training and experience specific to the radionuclides and uses requested.

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 an RSC to oversee all uses of byproduct material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. 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 the training of contractor staff, is effectively implemented by the appropriate individuals.

Training for an experienced RSO, teletherapy or medical physicist, AU or nuclear pharmacist; recentness of training. Under 10 CFR 35.57(a)(1) and (a)(2), experienced individuals, who may be candidates to serve as RSO, AMP, or ANP, are not required to meet the requirements of Sections 35.50, 35.51, or 35.55, respectively (are "grandfathered"), under certain conditions (e.g., the individual is named on an NRC or Agreement State license). Under 10 CFR 35.57(b)(1) and (b)(2), AUs are also not required to meet the requirements in Subparts D-H of 10 CFR Part 35 under certain conditions (e.g., if they are named on an NRC or Agreement State license). The individuals must have been named on a license or permit before the applicable date in Section 35.57.

Subsequent to the EPAct, RSOs, medical physicists, nuclear pharmacists, physicians, podiatrists, and dentists that only used accelerator-produced radioactive material, discrete sources of Ra-226, or both, are also grandfathered, under NRC regulations in 10 CFR 35.57(a)(3) and (b)(3), for medical uses or the practice of nuclear pharmacy when using materials for the same uses performed before or under NRC's waiver issued August 31, 2005. The requirements in 10 CFR 35.59 (that the training and experience specified in 10 CFR 35, Subparts B, D, E, F, G, and H, must have been obtained within 7 years preceding the date of application or the individual must have related continuing education and experience) do not apply to those individuals "grandfathered" under the regulations implementing the EPAct. Also, 10 CFR 35.57 provides that nuclear pharmacists, medical physicists, physicians, dentists, and podiatrists that meet the criteria in 10 CFR 35.57(a)(3) and (b)(3) qualify as ANPs, AMPs, and AUs for those materials and uses performed before or under NRC's waiver of August 31, 2005.

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

8.11 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 35.2024.

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

- Certification as provided in 10 CFR 35.50(a) by a specialty board whose certification process has been recognized by the NRC or an Agreement State, plus a written attestation signed by a preceptor RSO as provided in 35.50(d) and training as specified in 35.50(e); or
- Completion of classroom and laboratory training (200 hours) and 1 year of full-time radiation safety experience as described in 10 CFR 35.50(b)(1) plus a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e); or

- Certification as provided in 10 CFR 35.50(c)(1) as a medical physicist under 35.51(a), plus a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e); or
- Identification as provided in 10 CFR 35.50(c)(2) on the licensee's 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, with a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e).

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 10 CFR 35.24(b).

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. The 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. The NRC has authorized individuals who 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 the requirements of 10 CFR 35.24. Appendix I contains a model RSO Delegation of Authority. Appendix B contains NRC Form NRC 313A (RSO), "Medical Use Training and Experience and Preceptor Attestation [35.50]," 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 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 pathways to meeting requirements for training and experience.

In implementing the EPAct, the NRC "grandfathered" RSOs that performed as RSOs for medical uses of only accelerator-produced radioactive material, discrete sources of Ra-226, or both. These individuals do not have to meet the requirements in either 10 CFR 35.59 or 10 CFR 35.50; however, the applicant must document that the individual meets the criteria in 10 CFR 35.57 (a)(3).

Response from Applicant: Provide the following:

- Name of the proposed RSO.

AND

For an individual previously identified as an RSO on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee on which the individual was named as the RSO.

For an individual qualifying under 10 CFR 35.57 (a)(3):

(***Note:*** This is only for a new medical use license requesting use of only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for the same uses authorized under NRC's waiver of August 31, 2005.)

- Documentation that this individual functioned as an RSO for only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, before or during the effective period of NRC's waiver of August 7, 2005;

AND

- Documentation that the individual performed as the RSO for the same medical uses requested.

For an individual qualifying under 10 CFR 35.50(a):

- Copy of certification by a specialty board whose certification process has been recognized[2] by the NRC or an Agreement State under 10 CFR 35.50(a);

AND

[2] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

- Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

AND

- Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience specified for certification, as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

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

For an individual qualifying under 10 CFR 35.50(b):

- 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 the applicant seeks approval of an individual to serve as RSO;

AND

- Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

AND

- Written attestation, signed by a preceptor RSO, that the individual has successfully completed the training and experience in 10 CFR 35.50(b), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

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

For an individual qualifying under 10 CFR 35.50(c)(1):

- Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized[3] by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 35.50(c)(1) demonstrating that the proposed RSO

[3] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

is qualified by experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

AND

- Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

AND

- Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 35.50(c)(1), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

AND

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

For an individual qualifying under 10 CFR 35.50(c)(2):

- Copy of the licensee's license indicating that the individual is an AU, AMP, or ANP identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO;

AND

- Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO;

AND

- Written attestation, signed by a preceptor RSO, that the individual satisfactorily completed the requirements in 35.50(c)(2), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO;

AND

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

Notes:

- NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.50.
- The licensee must notify the NRC within 30 days if, under 10 CFR 35.14, an RSO permanently discontinues his or her duties under the license or has a name change; licensees must also request an amendment to change an RSO under 10 CFR 35.13.
- An AU for medical uses, 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)(2)) and, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the 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.

8.12 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 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

Criteria: Training and experience requirements for AUs for medical uses 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 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, or 10 CFR 35.690.

Discussion: Although NRC does not define "AU" for nonmedical uses, for purposes of this discussion the term AU will be used to also mean individuals authorized for such nonmedical uses.

AU for Medical Uses: 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 written directives (WD), if required.

Applicants must meet recentness of training requirements described in 10 CFR 35.59. The 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 training pathways.

Section 35.57 of 10 CFR Part 35 provides that experienced AUs who are named on a license or permit are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in Section 35.57 (check the regulations to determine this date). For example, a physician who was authorized to use sodium iodine-131 for imaging and localization, involving greater than 30 microcuries (a quantity for which a written directive is required under 10 CFR 35.40), would continue to be authorized for this use.

In implementing the EPAct, the NRC "grandfathered" physicians, podiatrists, and dentists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical use, for the same uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements in 10 CFR 35.59, 35.190, 35.290, 35.390, 35.396, or 35.490. However, the applicant must document that the individual meets the criteria in 10 CFR 35.57(b)(3). This Section also states that physicians, dentists, and podiatrists who met certain criteria will qualify as AUs for those materials and uses performed before NRC's waiver was terminated for them.

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 the conduct of certain types of clinical research after the submission of applications for Investigational New Drugs (IND) 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. The 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 for Nonmedical 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. This includes the individuals responsible for the production of PET radioactive drugs for noncommercial transfer to other medical users within a consortium (see Appendix AA).

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 nonmedical 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:

AU for Medical Uses: Provide the following:

- Name of the proposed AU and uses requested;

AND

- Medical, podiatry, or dental license number and issuing entity;

AND

For an individual previously identified as an AU on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested;

AND

- For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c)). A preceptor attestation may also be required. (For example, a preceptor attestation is needed to meet the requirements of 10 CFR 35.396 and 35.690.)

For an individual qualifying under 10 CFR 35.57(b)(3):

- Documentation that the physician, dentist, or podiatrist used only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005;

AND

- Documentation that the physician, dentist, or podiatrist used these materials for the same medical uses requested;

AND

- For an AU requesting a medical use for which he or she is not currently authorized on a license or permit, a description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested. A preceptor attestation may also

be required. (For example, training, experience, and attestations are needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c).)

For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:

- A copy of the certification(s) by a specialty board(s) whose certification process has been recognized[4] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested;

AND

- For a physician with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought;

AND

- For a physician with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating that the proposed AU is also qualified for imaging and localization medical uses;

AND

- For a physician with a board certification recognized under 10 CFR 35.490 or 10 CFR 35.690 for medical uses described in 10 CFR 35.396, a description of the training and supervised work experience and a copy of the attestation required in 10 CFR 35.396(d) to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive;

AND

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;

AND

- A written attestation, signed by a preceptor physician AU, that the training and experience specified for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. For individuals seeking authorization under 10 CFR 35.390, 10 CFR 35.396, and 10 CFR 35.690, the attestation must also include successful completion of the clinical case work in 10 CFR 35.390(b)(1)(ii)(G), or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, as appropriate;

AND

[4] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

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

For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:

- 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(s) requested;

AND

- For an individual seeking authorization under 10 CFR Part 35, Subpart H, a description of the training specified in 10 CFR 35.690(c), demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought;

AND

- A written attestation, signed by a preceptor physician AU, that the above training and experience have 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, a description of recent related continuing education and experience as required by 10 CFR 35.59.

Notes:

- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"; or NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"; or NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]" may be used as appropriate to document training and experience for those individuals qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H.
- Licensees must notify the 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.
- Descriptions of training and experience will be reviewed using the criteria listed above. The 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, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

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

AU for Nonmedical Uses: Provide the following:

- Name of the proposed nonmedical use AU,
- Description of types, quantities, and proposed nonmedical uses for which the individual is responsible, and
- Description of individual's educational and radiation safety training and experience with the types of materials and uses requested. This may include:
  - A copy of the NRC or Agreement State License listing the individual as an AU for the same types, quantities, and uses requested.
  - A permit issued by a Master Materials License licensee or broad-scope licensee or broad-scope permittee identifying the individual as an AU for the types, quantities, and uses requested.

Note: Authorized nonmedical 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.

8.13 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 32.72(b)(2), 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.

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 of radiopharmaceuticals under the provisions of 10 CFR 35.100(b), 35.200(b), or 35.300(b). This may include the production of PET radioactive drugs under the provisions of 10 CFR 30.32(j).

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 AU.)

Applicants are reminded that the recentness of training requirements described in 10 CFR 35.59 also apply to training and experience requirements in 10 CFR Part 35, Subpart B. 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 training pathways for meeting requirements for training and experience.

In implementing the EPAct, the NRC "grandfathered" nuclear pharmacists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, in the practice of nuclear pharmacy for the uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.55. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(3). Section 35.57 also provides that nuclear pharmacists who met certain criteria will qualify as ANPs for those materials and uses performed before or under NRC's waiver of August 31, 2005.

Response from Applicant: Provide the following:

- Name of the proposed ANP;

AND

- Pharmacist's license number and issuing entity;

AND

For an individual previously identified as an ANP on an NRC or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

OR

For an individual qualifying under 10 CFR 35.57(a)(3):

- Documentation that the nuclear pharmacist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, in the practice of pharmacy before or during the effective period of NRC's waiver of August 31, 2005;

AND

- Documentation that the nuclear pharmacist used these materials for the same uses as requested.

OR

For an individual qualifying under 10 CFR 35.55(a):

- Copy of the certification of the specialty board whose certification process has been recognized[5] under 10 CFR 35.55(a);

AND

[5] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

- Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.

AND

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

OR

For an individual qualifying under 10 CFR 35.55(b):

- Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience;

AND

- Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP 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 (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55.
- Under 10 CFR 35.14, licensees must notify the NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

8.14 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.

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

Discussion: While the AMP may not administer the dose, at licensed medical facilities conducting radiation therapy

treatments, an AMP is directly involved with the calculation and other tasks associated with the 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 training pathways for meeting requirements for training and experience.

In implementing the EPAct, the NRC "grandfathered" medical physicists using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical uses performed before or under the NRC waiver of August 31, 2005. These individuals do not have to meet the requirements of 10 CFR 35.59 or 10 CFR 35.51. The applicant must, however, document that the individual meets the criteria in 10 CFR 35.57(a)(3). Section 35.57 also provides that medical physicists who met certain criteria will qualify as AMPs for those materials and uses performed before or under NRC's waiver of August 31, 2005. ***Note:*** Although there may be a number of medical physicists working with manual brachytherapy sources during the waiver, the NRC only requires AMPs for the medical use of strontium-90 eye applicators, teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units. Because none of these devices are known to contain only NARM material, the NRC expects few, if any, medical physicists to meet the criteria in 10 CFR 35.57 of an AMP.

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

For an individual previously identified as an AMP on an NRC or Agreement State license or permit:

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.

OR

For an individual qualifying under 10 CFR 35.57(a)(3):

- Documentation that the medical physicist used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses before or during the effective period of NRC's waiver of August 31, 2005;

AND

- Documentation that the medical physicist used these materials for the same medical uses as requested.

OR

For an individual qualifying under 10 CFR 35.51(a):

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[6] under 10 CFR 35.51(a);

AND

- Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system;

AND

- Written attestation, signed by a preceptor AMP, that the required training and experience required for certification, as well as the required training in 10 CFR 35.51(c) for the types of uses specified, have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;

AND

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

OR

For an individual qualifying under 10 CFR 35.51 (b):

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested;

AND

- Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the licensee seeks approval of an individual as AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system;

AND

- Written attestation, signed by a preceptor AMP, that the training and experience required in 10 CFR 35.51(b)(1), as well as the training in 10 CFR 35.51(c) for the types of use specified, have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;

AND

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[6] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

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

Notes:

- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.51.
- Under 10 CFR 35.14, licensees must notify NRC within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change.
- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

8.15 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, types of radioactive emissions, quantity and form of radioactive materials possessed, production of PET radioactive drugs under 30.32(j) authorization). 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 8.16 through 8.20 for guidance.

8.16 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 NRC 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).

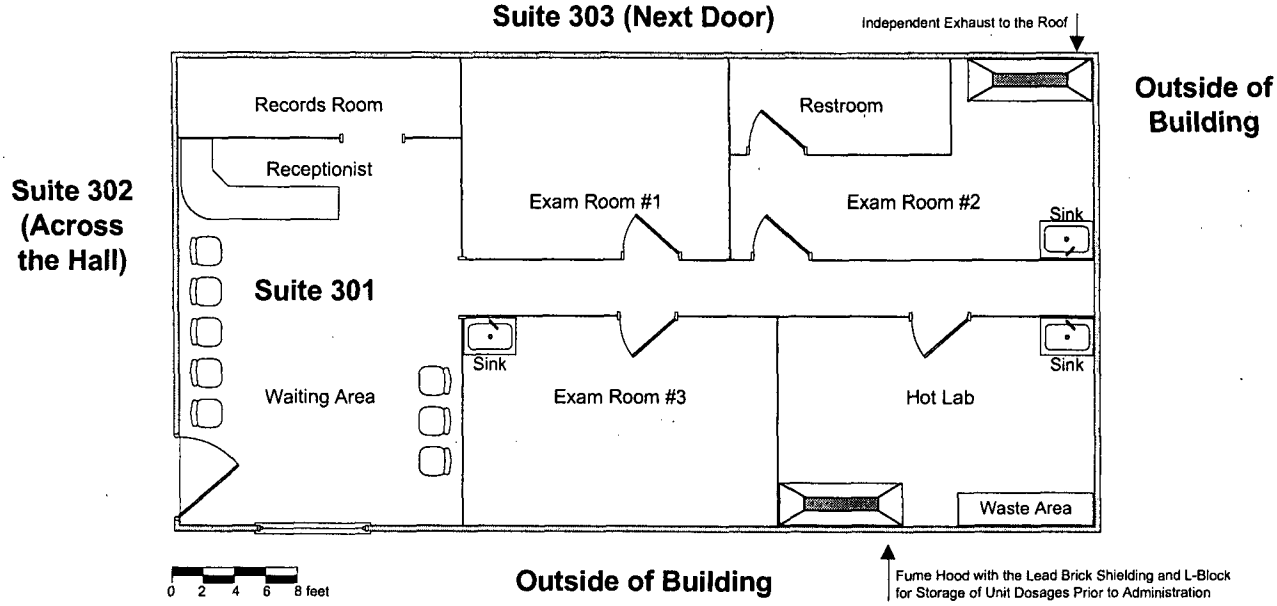
Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The facility diagram should include the room or rooms and adjacent areas where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "security-related information – withhold under 10 CFR 2.390." (See Section 5.2.)

If the applicant receives PET radionuclides from either an offsite or onsite PET radionuclide production facility by direct transfer tube to a PET radioactive drug production area, the facility diagram should include the direct transfer tube as well as a diagram of the PET radioactive production area.

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"). (See Figure 8.1 for a sample attachment to 9.1.) If the applicant has a radionuclide delivery line from a PET radionuclide/radioactive drug production area in the 10 CFR 35.100 or 35.200 medical use area, a description of the room, location, and delivery line should be provided. A discussion of the shielding associated with the delivery line, including shielding calculations, should also be provided.

Attachment 9.1
SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

*For the purposes of this NUREG, the facility diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8.1 Facility Diagram for Nuclear Medicine Suite

Most applicants requesting the use of PET radioactive drugs will designate an area or room as a "quiet room" where patients wait after the PET radioactive drug is administered. This room should be included in the facility diagram. The location and design of the "quiet room" should be considered when implementing the ALARA requirements in 10 CFR 20.1101. The applicable public dose limits are discussed in Section 8.33 of this document.

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, and production of PET radioactive drugs, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. Applicants should also describe the equipment used in the PET radioactive drug production area (e.g., hot cells, remote manipulation devices in the hot

cells, equipment and/or method used to physically transfer PET radionuclides during the chemical synthesis, "real-time" effluent (stack) monitoring equipment). 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.

All limited specific medical use 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. This includes additions and relocations of areas where PET radionuclides are produced or additions and locations of a radionuclide/radioactive drug delivery line from the PET radionuclide production area to a 10 CFR 35.100 or a 35.200 medical use area. However, other changes and additions to the 10 CFR 35.100 and 35.200 medical use areas do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes. The broad-scope medical use licensee does not have to notify NRC of changes that do not require a license amendment.

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.

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.

  Note: 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.

- 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 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: All medical use applicants, including broad-scope medical use applicants, are required to provide facility diagrams. The applicant should follow the guidance in Section 5.2 to determine if the response includes security-related sensitive information and needs to be marked accordingly. Provide the following on the facility diagrams:

- Drawings should be to scale, and the scale used should be indicated;
- Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored; location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility, or production area of PET radioactive drugs under 10 CFR 30.32(j), as provided above under the heading "Discussion"; and areas where higher energy gamma-emitting radionuclides (e.g., PET radionuclides) are used, including a "quiet room";
- 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, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and
- Shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and 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; shielding for PET radionuclide direct transfer tubes; PET radioactive drug production areas).

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, it should be noted that references to 10 CFR Part 35 in the NUREGs may be outdated because the rule was amended after these documents were published.

8.17 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 30.33(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.

For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters,
- Portable or stationary dose rate or exposure rate meters,
- Area Monitors,
- Single or multichannel analyzers,
- Liquid Scintillation Counters (LSC),
- Gamma counters,

- Proportional counters,
- Solid state detectors, and
- Hand and foot contamination monitors.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed-source diagnostic procedures, unless the diagnostic study involves localization of radioactive seeds, since it is not expected that a survey will be performed each time such a diagnostic study 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. For localization studies using sealed sources, survey meters are needed to verify source integrity and assist in source accountability.

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 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 calibrations, 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, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.18 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 30.34(j), 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, the NRC describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages. Section 10 CFR 30.34(j) contains requirements for possession, calibration, and check of instruments used to measure dosages of PET radioactive drugs noncommercially transferred to other members of the consortium.

Discussion: If the licensee produces PET radioactive drugs for noncommercial distribution to other consortium members under 10 CFR 30.32(j), the licensee is required by 10 CFR 30.34(j) to possess and calibrate all instruments used for measuring dosages (see Appendix AA).

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, or a PET radioactive drug producer authorized under 10 CFR 30.32(j) (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.

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 for the type and energy of radiation emitted 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.

The inherent technical difficulties in measuring alpha-emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured and quantified in relation to the alpha particle emissions, most alpha measuring instruments (e.g., gas proportional counters and liquid scintillation counters) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. To avoid these difficulties, the best method is to use unit dosages and the manufacturer's or commercial nuclear pharmacy's dose label for measurement of the dosage and decay-correct the dosage to the time of administration. These difficulties can also be avoided when not using unit dosages by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation.

Response from Applicant: If applicable.

For the administration of gamma- and beta-emitting unsealed byproduct materials, 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."

For the administration of the alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, provide the following:

- A statement that: "Dosages will be determined relying on the provider's dose label for measurement of the radioactivity and combination of volumetric measurement and mathematical calculation."

OR

- A description of the equipment used to measure the dosages. Identify the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument for the alpha-emitters measured, and provide a description of the procedures to be followed when measuring the dosage.

8.19 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 brachytherapy sources and low dose-rate (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 LDR 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[7], 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 licensing specialist at an NRC Regional Office 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.

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.

8.20 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.

[7] 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.

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 PET radionuclide and radiopharmaceutical therapy programs 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 (e.g., private room with private bath). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., 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 iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For **PET radionuclide use** and **PET radioactive drug production areas**, the applicant should focus on the need for (1) additional shielding, (2) hot cells containing remote handling devices, (3) other remote handling devices that may be needed when handling and storing the higher energy emissions of these materials, and (4) special delivery systems if the applicant prepares its own PET radionuclides or has them delivered by a direct transfer tube or system from a PET radionuclide producer. Applicants synthesizing PET radioactive drugs should also focus on volatility issues and releases.

For **teletherapy**, **GSR**, and **high dose-rate (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.

Section 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 communications 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. Section 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 on-off control for the source(s) is reset at the console.

Due to the unique characteristics of **pulsed dose-rate (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 the appropriate internal error condition(s) exists.
  - 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.
  - 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: Follow the guidance in Section 5.2 to determine if the response to this section includes security-related sensitive information and needs to be marked accordingly.

For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, describe the additional facilities and equipment for these uses.

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) is in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
- Emergency response equipment.

8.21 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: The regulations in 10 CFR 20.1101 state 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 10 CFR Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material.

Under 10 CFR 30.34(e), the NRC may incorporate into byproduct materials licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life and property. Licensee management's authorities and responsibilities for the Radiation Protection Program are described in 10 CFR 35.24, while 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. If the licensee has authority for the production of PET radioactive drugs under 10 CFR 30.32(j), the radiation production program must include radiation safety issues associated with this nonmedical use.

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

8.22 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

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

Regulations: 10 CFR 30.34(j), 10 CFR 35.12(c)(2), 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645.

Criteria: When applying for authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium, the applicant must develop, document, and implement certain procedures. See Appendix AA for discussion and response from applicant.

Before using materials under 10 CFR 35.600, the applicant must develop, document, submit, and implement written safety procedures for emergency response. Section 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 the 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, specifying 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.
- Radiation safety priorities, such as 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. See Appendix AA for responses required by 10 CFR 30.32(j).

8.23 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.

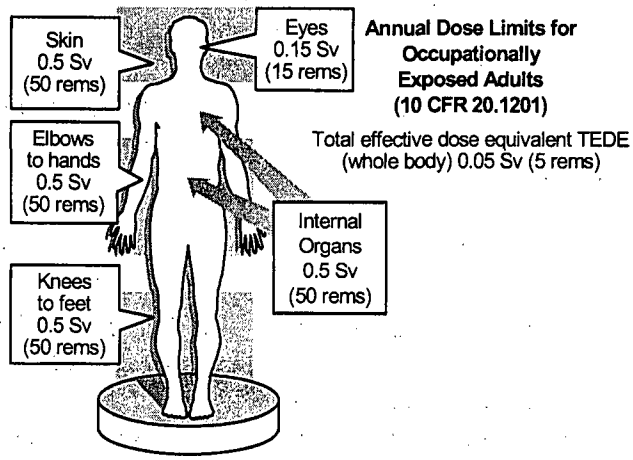


Figure 8.2 Annual Occupational Dose Limits for Adults

TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE) = DEEP DOSE FROM EXTERNAL EXPOSURE + DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES

OR

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

Discussion: The NRC was given regulatory authority over accelerator-produced radioactive materials and discrete sources of Ra-226 by the EPAct. For individuals working with or near NRC-regulated materials, 10 CFR Part 20 has always included the radiation exposure from radiation sources NRC did not regulate (e.g., x-rays, radiation from NARM materials). With the new definition of byproduct material, workers that previously were not subject to the requirements in 10 CFR Part 20 because they did not use NRC-regulated materials will now be subject to these requirements if they work with or near accelerator-produced radioactive materials or Ra-226. Applicants should review the use of all NRC-regulated materials (including

the new accelerator-produced and discrete Ra-226 byproduct materials) when determining, for NRC requirements, who is an occupationally exposed individual.

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, and individuals producing PET radioactive drugs under a 10 CFR 30.32(j) authorization) 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 an 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 doses 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 (OSL) dosimeters, 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 in such a way 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. Also, it is recommended that ANPs, AUs, radiopharmacy technologists, and individuals producing PET radioactive drugs under 10 CFR 30.32(j) wear a

pocket/audible dosimeter in addition to their personal dosimeter(s) when they are working with high-energy gamma-emitting radionuclides such as positron-emitting radionuclides.

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 bioassays (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 NRC (or an equivalent Agreement State) for that service or provide an alternative for NRC to review.

Acceptable criteria that applicants may use in developing their bioassay programs are outlined in RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," and NUREG/CR-4884, "Interpretation of Bioassay Measurements." ***Note:*** These documents predate the EPAct and may not address the criteria for accelerator-produced radionuclides or for discrete sources of Ra-226.

Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," provides guidance for evaluating 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[8], 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 1 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, Volume 9, Revision 1, 'Consolidated

[8] 67 FR 16298

Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' "

OR

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

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/Standards/scopes/programs.htm.
- ANSI N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," 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."
- "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 the 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/.

8.24 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. Licensed material

now also includes accelerator-produced radionuclides and discrete sources of Ra-226. 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;
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal; and
- 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 instruments 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, or
  - 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;
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier); and
- Surveys (by licensees authorized under 10 CFR 30.32(j) for noncommercial distribution of PET radioactive drugs) of PET packages being sent to other members of the consortium.

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 medical use ambient radiation levels and contamination surveys. Appendix R contains some of the information an applicant requesting authorization under 10 CFR 30.32(j) must include in its procedures to meet survey requirements.

For example, medical use 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 radiopharmaceuticals 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 that public dose limits are not exceeded. Licensees should survey areas near direct transport tubes used to transfer PET radionuclides or radiopharmaceuticals to administration areas from onsite or offsite PET radionuclide production facilities.

Because therapy sealed sources (including applicators, catheters, and therapy sources used for diagnostic purposes) 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.
- 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 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."

8.25 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. Unsealed licensed material now also includes unsealed quantities of accelerator-produced radionuclides and Ra-226, and may also include large activities of PET radionuclides used to produce PET radioactive drugs.

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 of. 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.

The Radiation Protection Program must cover the uses of accelerator-produced radioactive materials and Ra-226, which are now included in the definition of byproduct material as a result of the EPAct.

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.

When producing PET radioactive drugs, protective measures may include remote manipulation of material in shielded hot cells and the use of remote handling tools in other production tasks.

Appendix T contains model procedures that provide one method for the safe use of unsealed licensed material. This Appendix addresses some elements needed for the production of PET radioactive drugs.

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."

8.26 ITEM 10: SPILL/CONTAMINATION 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. Licensed material now also includes accelerator-produced radionuclides and Ra-226.

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, and containment of spills and other releases, as well as appropriate methods for reentering and decontaminating facilities (when necessary).

The provisions for responding to spills and other contamination events must cover any unique properties of accelerator-produced radionuclides or discrete sources of Ra-226 that the applicant possesses. These radioactive materials are now included in the definition of byproduct material as a result of the EPAct. When producing PET radioactive drugs, the procedures should also address spills or loss of control of curie quantities of material.

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."

8.27 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).

The 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. Section 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, as described in a certificate or letter from the manufacturer of the device, that document the employee's training in the requested function(s).

8.28 ITEM 10: MINIMIZATION OF CONTAMINATION

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

Regulations: 10 CFR 20.1406 and 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 8.26, "Spill/Contamination 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.

The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226 under the new definition of byproduct material resulting from the EPAct. There may be sources and devices containing this newly defined byproduct material that do not have SSDR certificates. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.

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 the applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facility and equipment, facility diagram, Radiation Protection Program, and waste management.

8.29 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. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct. 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. ***Note:*** Some short half-life radionuclide products (e.g., Tc-99m/Mo-99 generator columns and some yttrium-90 (Y-90) microspheres) contain long half-life contaminants that may preclude disposal by decay-in-storage.
- 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 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. If PET radioactive drugs are produced, the program should include methods of measuring, monitoring, and controlling effluent releases at all stages of production.
  - 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 their 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, and methods of handling uncompacted waste and examining containers for defects.

- "Empty" transport shield return: Applicants requesting authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use members in the consortium should request authorization to receive contaminated transport shields returned from consortium members. Individual consortium members are responsible for handling unused dosages, empty vials, and syringes under their own waste management program. (See Appendix AA.)

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 that implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. The NRC Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," provides additional information.

Response from Applicant:

- Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration.
- See Appendix AA when requesting authorization to receive contaminated transport shields from consortium members.
- For other treatment or disposal of waste, 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 of 10 CFR 35.92."

8.30 ITEM 12: FEES

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

Regulation: 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.

Note: There is no fee category associated with the authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs for noncommercial distribution to medical use consortium members.

8.31 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 Section 3, "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. The 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 it 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.

8.32 ITEM 8: 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 instructions as required by 10 CFR Parts 19 and 35. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct. 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. Under 10 CFR 35.27 the licensee's AUs and ANPs are required to provide safety instruction to all personnel using byproduct material under their supervision.

Discussion: The AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. If an applicant produces PET radioactive drugs under 10 CFR 30.32(j), or prepares them under 10 CFR 35.100(b), 35.200(b), or 35.300(b), the employees making them or preparing them for noncommercial transfer to other consortium members are also likely to receive doses in excess of 1 mSv (100 mrem) in a year. 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, including the newly defined byproduct material, should receive safety instructions 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 instructions 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) may assist in controlling abnormal events, such as loss of radioactive material.

In addition to safety instructions 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 instructions 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 (which includes the newly defined byproduct material) under the supervision of an AU must receive instructions 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, including the newly defined 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. Under 10 CFR 35.27(c), a licensee that permits supervised activities, under paragraphs 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. Appendix J does not address special considerations applicable to the production of PET radioactive drugs. Therefore, licensees producing and transferring these drugs must include in their training programs additional elements needed to satisfy the requirements.

Response from Applicant: No response is necessary.

8.33 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 1 hour from licensed operations. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct.
- Ensure that 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 1 year from these emissions.
- Control and maintain constant surveillance of licensed material, including the newly defined byproduct material, that is not in storage and secure stored licensed material to prevent unauthorized access, removal, or use.

Discussion: "Member of the public" is defined in 10 CFR 20.1003 as "any individual except when that individual is receiving an occupational dose." 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, including the newly defined byproduct 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 defined in 10 CFR 20.1003 as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." 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, including the newly defined byproduct 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.[9] 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., visitors in a waiting room or individuals near a PET "quiet room") from a patient to 0.02 mSv (2 mrem) in any one hour. Patient waiting rooms and "quiet rooms" need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

The regulations in 10 CFR 20.1301(c) allow 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 AU has determined before the visit that it is appropriate.

In assessing the adequacy of facilities to control public dose, licensees should consider the design factors discussed under "Facility Diagram" in Section 8.16 and may find confirmatory surveys to be useful in assuring compliance with 10 CFR 20.1301.

The licensee must control emissions to air of all byproduct material, including the newly defined byproduct material, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level in 10 CFR 20.2101 of 0.10 mSv (10 mrem) per year

[9] 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 of Revised 10 CFR Part 20," dated February 1994.

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.

8.34 OPENING PACKAGES

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

Regulations: 10 CFR 20.1906 and 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.

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, including those containing the newly defined byproduct material, 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. If authorized under 10 CFR 30.32(j) for the production and noncommercial transfer of PET radioactive drugs, the package opening procedures should be followed when receiving "empty" radiation transport shields back from consortium members.

Response from Applicant: No response required.

8.35 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: The requirements for written directives (WDs) are set forth in 10 CFR 35.40. Under 10 CFR 35.41, medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by AUs. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct.

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.

8.36 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 to their parent or guardian) in accordance with 10 CFR 35.75(b). Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct.

Discussion: Under 10 CFR 35.75, the licensee is required to 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.

8.37 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 10 CFR 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 8.31 of this NUREG for information to be submitted as part of their applications; many of the requirements in these sections are relevant to the use of byproduct material, including the newly defined 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 the 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. Mobile PET medical service licensees must consider a "quiet room" as an area of use if the patients in the "quiet room" cannot be released under the provisions of 10 CFR 35.75.

A 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 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. An NRC licensee who wishes 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, whether the AU meets the requirements to be an AU in that State, and 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, including training and experience requirements for AUs, as well as requirements associated with an authorization to practice medicine within the State's jurisdiction.

Response from Applicant: No response required.

8.38 AUDIT PROGRAM

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

Regulations: 10 CFR 20.1101 and 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. Appendix L also addresses some aspects of the Radiation Safety Program audit items associated with the production of PET radioactive drugs and other nonmedical uses authorized on the license. Licensees engaged in these activities may need to supplement the audit items in Appendix L to address any additional regulatory requirements for nonmedical uses. Reviews or audits of the content and implementation of the Radiation Protection Program must be conducted at least annually.

The 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.

The 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: NRC's Enforcement Policy, "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. The NRC's Enforcement Policy is also available on the Internet at the NRC's Web site, http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1600.

8.39 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. The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226 under the new definition of byproduct material resulting from the EPAct.

The licensee must develop, implement, and maintain specific operating and emergency procedures containing the following elements:

- Instructions for opening packages containing licensed material (see Section 8.34);

- Instructions for 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 8.27). ***Note:*** There may be sources and devices containing the newly defined byproduct material that do not have SSDR certificates. If these legacy sources or devices have manufacturers' recommendations or instructions, they should be followed. If not, contact the appropriate NRC Regional Office for licensing guidance. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.
- Instructions for conducting area radiation level and contamination surveys (see Section 8.24);
- Instructions for administering licensed material in accordance with the WD (see Section 8.35);
- Steps to ensure that patient release is in accordance with 10 CFR 35.75 (see Section 8.36);
- Instructions for calibration of survey and dosage measuring instruments (see Sections 8.17 and 8.18);
- Periodic spot checks of therapy device units, sources, and treatment facilities (see Section 8.19);
- Instructions for radioactive waste management (see Section 8.29);
- 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 8.26, 8.45);
- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.22); and
- Steps to take if a therapy patient undergoes emergency surgery or dies.

The licensee should consider the following:

- Making operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);
- Maintaining a current copy of the procedures at each location of use (or, if this is not practicable, posting 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 (which includes the newly defined 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. The same may be true for high-activity PET radionuclides used to produce PET radioactive drugs, if not shielded. Access control to high- and very-high-radiation areas and the security of licensed material are described in 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1801, and 10 CFR 20.1802. Unauthorized access to licensed material, including the newly defined byproduct 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, including the newly defined byproduct 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. When an operation or autopsy is to be performed, there should be an increased awareness of 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 sources, medical events, interlock failures, stuck sources).

After its occurrence becomes known to the licensee, the NRC must be notified when an incident involving licensed material, including the newly defined byproduct 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. Applicants requesting authorization for licensed activities not addressed by the model procedures in Appendix N should develop operational and emergency procedures to address these other activities.

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.

8.40 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.

Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct.

Discussion: Licensed materials must be tracked from "cradle to grave," from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal in order to ensure accountability; to identify that licensed material is missing and document the last confirmed possession of the material when it is lost, stolen, or misplaced; and to ensure that possession limits listed on the license are not exceeded.

Response from Applicant: No response is necessary.

8.41 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 30.32(j), 10 CFR 30.51.

Criteria: The requirements for receiving packages containing licensed material are found in 10 CFR 20.1906. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct. Additionally, the security of licensed material, required by 10 CFR 20.1801 and 10 CFR 20.1802, must be considered for all receiving areas. Under 10 CFR 30.51, licensees are required, in part, to maintain records showing the receipt of byproduct material.

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

When ordering PET radioactive drugs produced under the provisions of 10 CFR 30.32(j), the medical use licensee must be a member of the consortium. ***Note:*** Authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs for noncommercial transfer to medical use licensee members in the consortium restricts the transfer of these drugs only to members of the consortium. Licensees with this authorization must ensure that the drugs produced under this provision are transferred only to consortium members. The definition of a consortium is found in 10 CFR 30.4. Members of the consortium are authorized to receive these PET radioactive drugs by provisions in 10 CFR 35.100(a), 35.200(a), and 35.300(a).

Appendix O contains model procedures that are one method for ordering and receiving licensed material. Applicants that request authorization to produce PET radioactive drugs for noncommercial transfer to other medical use consortium members may have to supplement the procedures in Appendix O by developing procedures for filling orders for these drugs from other consortium members to meet regulatory requirements.

Response from Applicant: No response is necessary.

8.42 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: The 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, under 10 CFR 30.51, the licensee must maintain records of GSR source receipt, transfer, and disposal to indicate the current inventory of sources at the licensee's facility.

Response from Applicant: No response is necessary.

8.43 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 35.204, 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 or an NRC or Agreement State medical use licensee authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to consortium members.

See Appendix AA for requirements to measure dosages for applicants applying for authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for consortium members.

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 strontium-82 (SR-82) and strontium-85 (Sr-85) concentrations are measured under 10 CFR 35.204, records of Sr-82 and Sr-85 concentrations must be made under 10 CFR 35.2204 and must include for each measured elution of rubidium-82 (Rb-82):

- Ratio of the measurements expressed in KBq (μCi) of Sr-82 per MBq (mCi) of Rb-82 Chloride and KBq (μCi) of Sr-85 per MBq (mci) of Rb-82,
- 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.

8.44 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.

8.45 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 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, 10 CFR 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.

8.46 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: The 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. The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226 under the new definition of byproduct material resulting from the EPAct. There may be sources and devices containing this newly defined byproduct material that do not have SSDR certificates. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.

Appendix Q provides model procedures that are one way to perform leak testing for sealed sources, including Ra-226 sealed sources. Under 10 CFR 35.67, licensees are required 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, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," dated November 2000.

8.47 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: Under 10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615, licensees are required 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. Byproduct material now includes accelerator-produced radioactive material and discrete sources of Ra-226, as a result of the EPAct. This section of the guidance does not include guidance on safety procedures 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.

Under 10 CFR 35.404(b) and 10 CFR 35.604(a), licensees are required 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. When sources are placed within the patient's body, 10 CFR 35.615(e) requires that 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 indicating 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).

Licensees are required to perform adequate surveys to evaluate the extent of radiation levels (10 CFR 20.1501). 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).

Licensees are required to secure licensed material in storage from unauthorized access or removal (10 CFR 20.1801). 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.

8.48 TRANSPORTATION

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

Regulations: 10 CFR 20.1101, 10 CFR 30.32(j), 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, 10 CFR 71, Subpart H; 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 the use of Type A packages. Licensed material now includes accelerator-produced radioactive material and discrete sources of Ra-226 as currently included in the new definition of byproduct material resulting from the EPAct. Applicants requesting authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to consortium members should also review Appendix AA for requirements for providing information about the shielded radiation transport packages.

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. The requirements for transportation of licensed material are set forth in 10 CFR 71.5. The regulations in 10 CFR 71.9 exempt from the requirements in 10 CFR 71.5 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. 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. The Type B package requirements for transporting or delivering the package to a carrier for transport are set forth in 10 CFR 71.12-71.14. These include registration as a user of the package and 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 Division of Spent Fuel Storage and Transportation by calling NRC toll-free at (800) 368-5642, extension 492-3300. 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), and
- 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, the 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.
- 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, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses."

9 AMENDMENTS AND RENEWALS TO A LICENSE

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

Regulations: 10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.13.

The NRC now has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226, under the new definition of byproduct material resulting from the EPAct. Licensees may need license amendments for such purposes as to authorize use of these materials, to revise their Radiation Safety Programs to meet new requirements, or to provide new facility diagrams. The NRC issued a waiver on August 31, 2005, that permitted licensees to continue to use the newly defined byproduct material until the waiver was terminated on August 8, 2009. Licensees in Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana who possess and use accelerator-produced radioactive material or discrete sources of Ra-226, or both, may continue to use these materials for medical use or prepare PET radioactive drugs for noncommercial distribution to other consortium members until the date of NRC's final licensing determination, provided the licensee submits an amendment application within 6 months after November 30, 2007. Other licensees should check with the appropriate NRC Regional Office to determine when they have to submit their license amendments.

Licensees are responsible for applying for amendments to licenses and for keeping them up-to-date. Furthermore, to continue a license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date (10 CFR 2.109, 10 CFR 30.36(a)).

Under 10 CFR 35.13, a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of byproduct material for a type of use permitted by 10 CFR Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU for medical uses, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) (information required to document training and experience may be provided on the appropriate NRC Form 313A series of forms for change or addition of AU for medical uses, AMP, ANP, or RSO);
- Changing the RSO;
- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than, currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license. This includes additions and relocations of areas where PET radionuclides are produced or additions or relocations of a radionuclide delivery line from the PET radionuclide production area to a 10 CFR 35.100 or 10 CFR 35.200 medical use area. However, other

changes and additions to the 10 CFR 35.100 and 10 CFR 35.200 medical use area do not require a license amendment and can be made, provided NRC is notified as required by 10 CFR 35.14 within 30 days following the changes, and

- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the materials licensing staff at the appropriate NRC Regional Office.

For both renewal and amendment requests, applicants should do the following:

- Use the most recent guidance in preparing an amendment or renewal request,
- Submit in duplicate either an NRC Form 313 or a letter requesting an amendment or renewal, and
- Provide the license number.

10 APPLICATIONS FOR EXEMPTIONS

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

Regulations: 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11, 10 CFR 35.15, 10 CFR 35.19.

Criteria: Licensees may request exemptions to regulations. The licensee must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.

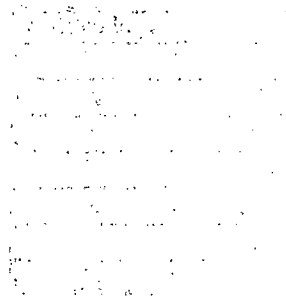
Discussion: Various sections of NRC's regulations address requests for exemptions (e.g., 10 CFR 19.31, 10 CFR 20.2301, 10 CFR 30.11(a)). These regulations state that NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests should be accompanied by descriptions of the following:

- Exemption and justification of why it is needed.
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested.
- Alternative methods for complying with the regulation and why compliance with the existing regulations is not feasible.

Until the NRC has granted an exemption in writing, it expects strict compliance with all applicable regulations.

Type A broad-scope licensees are granted certain exemptions as described in 10 CFR 35.15.



11 TERMINATION OF ACTIVITIES

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

Regulations: 10 CFR 20.1401, 10 CFR 20.1402, 10 CFR 20.1403, 10 CFR 20.1404, 10 CFR 20.1405, 10 CFR 20.1406, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.51(f).

Criteria: Pursuant to the regulations described above, the licensee must do the following:

- Notify NRC, in writing, within 60 days of:
  - the expiration of its license;
  - a decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
  - a decision to permanently cease licensed activities in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements (see Note);
  - no principal activities having been conducted at the entire site under the license for a period of 24 months; and
  - no principal activities having been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements (see Note).

  Note: Residual radioactivity includes that from accelerator-produced radionuclides and discrete sources of Ra-226, which are now included in the definition of byproduct material as a result of the EPAct.

- Submit a decommissioning plan, if required by 10 CFR 30.36(g);
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j); and
- Submit, to the appropriate NRC Regional Office, a completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, the licensee must send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: Useful guidance and other aids related to decommissioning are:

- NUREG-1757, Volume 2, "Consolidated NMSS Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," dated September 2003.
- NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, containing the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- Appendix B of NUREG/BR-0241 containing a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1727 contains a list of superseded guidance; however, due to ongoing revisions, applicants are encouraged to consult with NRC staff regarding updates of decommissioning guidance.
- NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission.
- An acceptable computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is DandD, Version 2.1.0, (McFadden and others, 2001).
- NUREG-1757, Volume 2, includes a table (Table H.1) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NUREG-1757, Volume 2, also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

Response from Applicant: The applicant is not required to submit a response to NRC during the initial application. The licensee's obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions as summarized in the "Criteria."

References:

- NRC Form 314, "Certificate of Disposition of Materials," is available at http://www.nrc.gov/reading-rm/doc-collections/forms/.
- McFadden, K., D.A. Brosseau, W.A. Beyeler, and C.D. Updegraff, "Residual Radioactive Contamination from Decommissioning - User's Manual DandD, Version 2.1," NUREG/CR-5512, Volume 2, U.S. Nuclear Regulatory Commission, Washington, DC, April 2001.