APPENDICES X-Z

RECORDKEEPING AND REPORTING REQUIREMENTS AND DOT RULES FOR SHIPPING

APPENDIX X

Recordkeeping Requirements

Recordkeeping Requirements

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the recordkeeping requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Results of surveys and calibrations	20.1501; 20.1906(b)	20.2103(a)	3 years
Results of surveys to determine dose from external sources		20.2103(b)(1)	duration of license
Results of measurements and calculations used to determine individual intakes		20.2103(b)(2)	duration of license
Results of air samplings, surveys, and bioassays	20.1703(c)(1); 20.1703(c)(2)	20.2103(b)(3)	duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		20.2103(b)(4)	duration of license
Determination of prior occupational dose		20.2104	duration of license
Planned special exposure	20.1206	20.2105	duration of license
Individual monitoring results	20.1502	20.2106	duration of license
Dose to individual members of the public	20.1301	20.2107	duration of license
Waste disposal	20.2002; 20.2003; 20.2004; 20.2005	20.2108	duration of license
Records of receipt of byproduct material		30.51(a)(1)	duration of possession and 3 years after transfer
Records of transfer of byproduct material		30.51(a)(2)	3 years after transfer
Records of disposal of byproduct material		30.51(a)(3)	duration of license

Table X.1 Typical Records and Retention Times (continued)

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Authority and responsibilities of Radiation Protection Program	35.24(a)	35.2024	5 years
Radiation Protection Program changes	35.26(a)	35.2026	5 years
Written directives	35.40	35.2040	3 years
Procedures for administrations requiring a written directive	35.41(a)	35.2041	duration of license
Calibrations of instruments used to measure activity of unsealed byproduct material	35.60	35.2060	3 years
Radiation survey instrument calibrations	35.61	35.2061	3 years
Dosages of unsealed byproduct material for medical use	35.63	35.2063	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	35.67(b)	35.2067	3 years
Surveys for ambient radiation exposure rate	35.70	35.2070	3 years
Release of individuals containing unsealed byproduct material or implants containing byproduct material	35.75	35.2075	3 years
Mobile medical services	35.80(a)(1)	35.2080	3 years
Decay-in-storage	35.92	35.2092	3 years
Molybdenum-99 or strontium-82 or strontium-85 concentrations	35.204(b)	35.2204	3 years
Safety instruction	35.310; 35.410; 35.610	35.2310	3 years
Surveys after source implant and removal	35.404; 35.604	35.2404	3 years
Brachytherapy source accountability	35.406	35.2406	3 years
Calibration measurements of brachytherapy sources	35.432	35.2432	3 years
Decay of strontium-90 sources for ophthalmic treatments	35.433	35.2433	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.604	35.2605	3 years

Table X.1 Typical Records and Retention Times (continued)

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Safety procedures	35.610(a)(4); 35.610(d)(2)	35.2610	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.630	35.2630	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	35.632; 35.633; 35.635	35.2632	3 years
Periodic spot-checks of teletherapy units	35.642	35.2642	3 years
Periodic spot-checks of remote afterloader units	35.643	35.6243	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	35.645	35.6245	3 years
Additional technical requirements for mobile remote afterloader units	35.647	35.6247	3 years
Surveys of therapeutic treatment units	35.652	35.2652	duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

APPENDIX Y

Reporting Requirements

Reporting Requirements

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the reporting requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Reports to individual workers	none	annually	10 CFR 19.13(b)
Reports to former individual workers	none	upon request	10 CFR 19.13(c)
Notification of special circumstances to individuals	none	30 days	10 CFR 19.13(d)
Reports to worker terminating employment	none	upon request	10 CFR 19.13(e)
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i), 10 CFR 20.2203 (a)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii), 10 CFR 20.2203 (a)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i), 10 CFR 20.2203 (a)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii), 10 CFR 20.2203(a)
Doses in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(3)
Planned special exposures	none	30 days	10 CFR 20.2204
Report to individuals of exceeding dose limits	none	30 days	10 CFR 20.2205
Report of individual monitoring	none	annually	10 CFR 20.2206

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)
Licensee permits individual to work as AU, ANP, or AMP	none	30 days	10 CFR 35.14(a)
AU, ANP, or AMP discontinues performance of duties under license or has a name change	none	30 days	10 CFR 35.14(b)(1)
Licensee's mailing address changes	none	30 days	10 CFR 35.14(b)(2)
Licensee's name changes without constituting a transfer of control	none	30 days	10 CFR 35.14(b)(3)
Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license if the change or addition did not involve movement of a PET radionuclide production facility or transfer line from a PET radionuclide production facility	none	30 days	10 CFR 35.14(b)(4)
Medical event	1 day	15 days	10 CFR 35.3045
Dose to embryo or nursing child	1 day	15 days	10 CFR 35.3047
Leaking source	none	5 days	10 CFR 35.3067

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550, except as noted.

APPENDIX Z

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Licensed Material

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the requirements for transportation of licensed material also apply to transportation of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Licensed material must be transported in accordance with the Department of Transportation (DOT) regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:

- Table of Hazardous Materials and Special Provisions, 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers, 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking, 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for nonbulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in nonbulk packaging;
- Package Labeling, 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles, 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, "RADIOACTIVE" placard;
- Emergency Response Information, 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training, 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging, 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415,

49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and

- Carriage by Public Highway, 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials," or at the DOT Web site http://www.dot.gov.

APPENDIX AA

Production and Noncommercial Distribution by the Medical Facility of PET Radioactive Drugs to Consortium Members under Authorization of 10 CFR 30.32(j)

PURPOSE OF APPENDIX

The purpose of this Appendix is to provide guidance to the medical use applicant, in a "consortium" as defined in 10 CFR 30.4, that is requesting authority under 10 CFR 30.32(j) for the production and noncommercial distribution of PET radioactive drugs to other medical use licensees within the consortium. The information required by the regulations and addressed in this Appendix is specific to this authorization and supplements information required for other uses of byproduct material provided in the applicant's medical use byproduct materials license application.

Section 10 CFR 30.4 states: "Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility."

The regulatory requirements for what an application from educational institutions, Federal facilities, and medical facilities must include for authorization to produce PET radioactive drugs for noncommercial distribution to licensees in a consortium are found in 10 CFR 30.32(j). Regulatory requirements for licensees with this specific authorization are found in 10 CFR 30.34(j). The noncommercial distribution of PET radioactive drugs can be requested as an additional authorization on a licensee's current byproduct material possession license (e.g., educational institution or Federal facility broad-scope or limited specific license). The information associated with the Radiation Safety Program specifically needed for producing PET radioactive drugs can be found in this volume and the current version of NUREG-1556, Volume 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." To avoid duplication, sections in this Appendix refer the applicant to the appropriate sections in this volume or Volume 13.

It should be noted that, as stated in 10 CFR 30.34(j)(1), the authorization under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial distribution to medical use licensees in a consortium does not relieve the applicant or licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

CONSORTIUM CRITERIA

This Appendix addresses only the authorization in 10 CFR 30.32(j) for medical facilities to noncommercially transfer (distribute) PET radioactive drugs to medical use licensees in the medical facility's consortium. Therefore, the staff must have sufficient information to make the necessary determination that the licensee is a member of a consortium that meets the definition in 10 CFR 30.4, and that the applicant will distribute the PET radioactive drugs only to medical use licensees in its consortium. To assist the staff in making this determination, the applicant should describe this consortium. This description should focus on the regulatory requirements. This includes a description of the geographical area in which the members are located. Even if the names of the individual members of the consortium are provided, the applicant should

provide documentation of the terms of the association demonstrating the joint ownership or sharing of the operation and maintenance cost of the PET radionuclide production facility. This documentation may include, but may not be limited to, copies of signed agreements or contracts indicating roles and responsibilities of all of the individuals/entities involved.

The applicant for authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs is required to be a consortium member but is not required to be the consortium member that has the PET radionuclide production facility. The applicant is required by 10 CFR 30.32(j)(1) to either request authorization for the production of PET radionuclides, if the applicant has the PET radionuclide production facility and does not have a license for it, or provide evidence of an existing license issued under 10 CFR Part 30 or the Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

Response from the Applicant:

- Identify the medical use members of the consortium or provide a description of the criteria for consortium membership.
- Describe the geographical area in which the members are located.
- Provide documentation of the terms of the association, demonstrating the joint ownership or sharing of the operation and the maintenance cost of the PET radionuclide production facility.
- Request authorization for the production of PET radionuclides, if the applicant has the PET radionuclide production facility but does not have a license for it.
- Provide evidence of an existing license issued under 10 CFR Part 30 or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

QUALIFICATION TO PRODUCE PET RADIOACTIVE DRUGS

Section 10 CFR 30.32(j)(2) requires that the applicant be qualified to produce PET radioactive drugs for medical use by providing evidence that meets one of the following criteria:

- Registered with the FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
- Registered or licensed with a State agency as a drug manufacturer;
- Licensed as a pharmacy by a State Board of Pharmacy;
- Operating as a nuclear pharmacy within a Federal medical institution; or
- A PET drug production facility registered with a State agency.

Response from the Applicant: Follow the guidance in Section 5.2 of this document to determine if the response includes security-related sensitive information and needs to be marked accordingly.

- Provide documentation of registration with the U.S. Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
- Provide a copy of a State agency registration or license as a drug manufacturer; or
- Provide a copy of the State Board of Pharmacy pharmacy license; or
- Provide evidence of operation as a nuclear pharmacy within a Federal medical institution; or
- Provide a copy of a State agency registration as a PET drug production facility.

RADIOACTIVE MATERIALS AND USES

10 CFR 30.32(j)(4) requires the applicant to identify the PET radioactive drugs authorized under 10 CFR 30.32(j) for production and noncommercial distribution and requires the applicant to submit information on the radionuclide in the PET radioactive drug, including its chemical and physical form. Because applicants are only authorized for the noncommercial distribution of these PET radioactive drugs, the applicant should request authorization to receive potentially contaminated "empty" radiation transport shields back from consortium members. It is the responsibility of the other medical use consortium licensees under 10 CFR 20.2001 to properly dispose of licensed materials such as unused dosages and residual radioactivity remaining in syringes and vials that were received from the licensee authorized to produce and transfer PET radioactive drugs to consortium members.

Response from the Applicant:

- Identify the radionuclide, including the chemical and physical form, for each PET radioactive drug produced under this authorization.
- Request authorization to receive potentially contaminated "empty" radiation transport shields back from consortium members.

INDIVIDUALS RESPONSIBLE FOR RADIOACTIVE SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Individuals responsible for the Radiation Safety Program for the production of PET radioactive drugs and their transfer are the applicant's (or licensee's) Radiation Safety Officer (RSO) and the authorized individual(s) responsible during the processing of the PET radionuclides into PET radioactive drugs. The applicant's RSO and authorized individuals must be qualified to use the material as required by 10 CFR 30.33(a)(3). If these individuals are already identified on an NRC or Agreement State license or permit issued by an NRC or Agreement State licensee for similar materials and uses, they may already be qualified to use the quantities, materials, and uses by experience with radiation safety practices similar to those associated with the process of

producing PET radioactive drugs. In order to demonstrate that these individuals are qualified by their training and experience to use these materials for the purpose requested, as required by 10 CFR 30.33(a)(3), the applicant should describe the additional training and experience these individuals have for quantities, materials, and radiation safety considerations that differ substantially from the authorization(s) on current licenses or permits. If the applicant is producing the PET radioactive drugs in a pharmacy, the applicant, under 10 CFR 30.32(j)(3), must have an Authorized Nuclear Pharmacist (ANP). The applicant should refer to Section 8.13 of this document for guidance on the minimum training and experience requirements for an ANP. The applicant may chose to use NRC Form 313A (ANP) to document the individual's training and experience. See Appendix B for a copy of this form and Appendix D for instructions in completing it.

A licensee that produces PET radioactive drugs under a 10 CFR 30.32(j) authorization in a pharmacy is permitted under 10 CFR 30.34(j)(3) to allow an individual that meets the board certification requirements in 10 CFR 35.55(a), is listed on a license as an ANP, or is recognized in an appropriate licensee or master materials licensee permit as an ANP, to begin work as an ANP, provided NRC is notified within 30 days of the individual beginning work and specified information is provided to the NRC.

Response from the Applicant:

- Identify the individuals responsible for the Radiation Safety Program and describe their training and experience using similar quantities, materials, and uses of radioactive materials.
- Describe the RSO's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- Describe the authorized individual's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- If producing the PET radioactive drugs in a pharmacy, identify at least one individual who meets the requirements of an ANP and document that his/her training and experience meet the requirements in 10 CFR 35.55 for a new ANP or in 10 CFR 35.57 for an experienced ANP. The NRC Form 313A (ANP) may be used to document this information for a new ANP.

TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Individuals working with licensed material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. In addition, those individuals who, in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must be instructed according to 10 CFR 19.12. A commitment to provide this training for individuals working in or frequenting restricted areas should already be included as part of the medical use possession license application.

Additionally, to meet the requirements in 49 CFR 172.704, applicants must commit to providing training for individuals that will be involved in the preparation and transport of hazardous materials packages. The training must include:

- General awareness and familiarization training designed to provide familiarity with DOT requirements and to enable the employee to recognize and identify hazardous materials;
- Function-specific training concerning the DOT requirements that are specifically applicable to the functions the employee performs (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling); and
- Safety training concerning emergency response information, measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed in the workplace, and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The hazardous materials training must be provided initially, and every 3 years thereafter. Records of training must be maintained. ***Note:*** When the licensee uses a common carrier to transport radioactive materials packages, the common carrier, not the licensee, is responsible for ensuring its employees have DOT-required HAZMAT training (49 CFR 172.702).

If the PET radioactive drugs will be produced under the supervision of an ANP or the applicant's qualified medical use AU, the supervised individuals who will prepare PET radioactive drugs under 10 CFR 30.32(j)(3)(ii) must be instructed in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material, and are required to follow the instructions of the supervising AU or ANP regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the relevant regulations in 10 CFR Part 35, and license conditions.

Response from the Applicant:

For personnel involved in the preparation and transport of hazardous materials, the applicant should submit the following statement:

"We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.704."

For supervised individuals preparing radioactive drugs, the applicant does not need to provide a response. Supervision will be reviewed during inspection.

FACILITIES AND EQUIPMENT

Applicants should have already provided information under Section 9 of this document regarding the facilities and equipment used for the medical use facility. As part of this information, to demonstrate that the facilities and equipment are adequate to protect the public health and safety, as required by 10 CFR 30.33(a)(2), the applicant must provide a description of the facilities and

equipment used for the production of PET radioactive drugs and the noncommercial distribution to consortium members. Therefore, applicants should describe the equipment and/or method used to physically transfer (e.g., transfer lines) PET radiochemicals to the chemical synthesis equipment for radioactive drug production and then to the dispensing area. The description should include shielding used for the transfer of radioactive materials and the shielding equipment (e.g., hot cells) and remote handling equipment used for chemical synthesis and/or preparing the PET radioactive drugs for noncommercial transfer. Due to the short half-lives of positron-emitting radionuclides, PET radioactive drug production facilities generally produce high amounts of activity (curies), which could lead to fairly high activities (millicuries) of effluents released in the air if the proper engineering controls are not used. Examples of some engineering controls that should be used would include exhaust filtration (e.g., HEPA and carbon filters) and/or containment for decay of effluents. It is also recommended that a continuous "real-time" effluent (stack) monitor be installed at the facility. Appendix R of the current version of NUREG-1556, Volume 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," provides more information on effluent monitoring. Note that the majority of the radioactive effluents at a PET radioactive drug production facility are produced during the chemical synthesis process of the PET radioactive drug.

Response from the Applicant: As part of the description of facilities and equipment for the PET radioactive drug production and noncommercial transfer areas and the facilities diagram for this area, include the following:

- Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of produced PET radioactive drugs and the location(s) for radioactive waste storage;
- Sufficient detail in the diagram to indicate locations of shielding and/or shielding equipment (e.g., hot cells for positron-emitting radionuclides), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety, such as remote handling equipment and area monitors;
- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the production, use, or storage of radioactive drugs; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

RADIATION SAFETY PROGRAM

To receive authorization under 10 CFR 30.32(j) for the PET radioactive drug production and noncommercial transfer operations, applicants must provide sufficient information to demonstrate that they meet the criteria in 10 CFR 30.33(a)(2) for these activities. Applicants

should refer to the Radiation Safety Program described in Sections 8.21 through 8.28 and 8.32 through 8.48 of this document.

Dosage Measurement System

Section 10 CFR 30.34(j)(2)(ii) requires a licensee to possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and have procedures for use of the instrumentation. Under 10 CFR 30.34(j)(2)(ii), licensees are also required to measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. Also the licensee must perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; make adjustments when necessary; and check each instrument for constancy and proper operation at the beginning of each day of use. Generally, PET radionuclides can be measured using direct measurement only and do not require calculations to be performed, which is often required for beta-emitting radionuclides.

In addition to checking all systems each day of use for constancy to ensure continued proper operation of the system, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers). Licensees should assay patient dosages in the same type of vial or syringe and geometry as used to determine the correct dose calibrator settings. The use of vials or syringes other than those used for geometry dependence may result in measurement errors. Also, the applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Response from the Applicant:

- Describe instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium.
- Describe the types of systems (measurement or combination of measurement and calculation) intended for the measurement of PET radioactive drugs.
- For each dose measurement system used to measure the amount of radioactivity in PET radioactive drugs, state: "We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 30.34(j)(2)(ii)."

Radioactive Drug Labeling for Distribution

Section 30.34(j)(2)(i) of 10 CFR Part 30 requires the licensee for the noncommercial transfer of PET radioactive drugs to label each transport radiation shield to include the radiation symbol and include the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The term "transport radiation shield" refers

to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. In order to demonstrate that the shielding is appropriate for the safe handling and storage of radioactive drugs as required to comply with 10 CFR 30.32(j)(4), the transport radiation shield should be constructed of material appropriate for the isotope to be transferred for noncommercial distribution. The "transport radiation shield" does not refer to the outer suitcase, packaging, or other carrying device used as the transportation packaging for DOT purposes, even though the transportation packaging may provide some radiation shielding.

The licensee must also label each syringe, vial, or other container (e.g., generator) used to hold PET radioactive drugs for noncommercial transfer to consortium members. The label must include the words "CAUTION, RADIOACTIVE MATERIAL" OR "DANGER, RADIOACTIVE MATERIAL." The label must also include an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

Response from the Applicant:

- Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the transport radiation shield or the container used to hold the radioactive drug).
- Confirm that the required labels will be affixed to all transport radiation shields and each container used to hold the radioactive drugs.

Radioactive Drug Shielding for Noncommercial Transfer

Under 10 CFR 30.32(j)(4), the applicant must provide information to demonstrate that shielding provided for each radioactive drug to be noncommercially distributed is appropriate for safe handling and storage by the consortium members. The applicant must provide appropriate transport radiation shields for the primary container of each PET radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to distribute. Typically, transport radiation shields used to carry radioactive drugs include two-piece, shielded syringe and vial containers (or "pigs"). Facilities have used lead and tungsten shields for gamma/photon-emitting materials. The applicant should select appropriate shielding materials and dimensions to ensure not only that occupational doses are ALARA, but also that the transport radiation shield can be easily handled.

Response from the Applicant: For each PET radioactive drug to be noncommercially distributed,

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe),
- Describe the type and thickness of the "transport radiation shield" provided for each type of container, and
- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.

Note: With respect to the transport radiation shield, it is not acceptable to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the "transport radiation shield."

Transportation

For the transportation of PET radioactive drugs to consortium members, the required transportation information should be consistent with the information provided for the production and distribution of accelerator-produced radionuclides.

The types and quantities of PET radionuclides in PET radioactive drugs shipped by noncommercial transfer to other medical use licensees in the consortium will usually meet the criteria for shipment in a "Type A" package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For applicants who transport their own packages, the packages must be secured to prevent shifting (e.g., blocked and braced), and shipping papers must be used and located properly in the driver's compartment (49 CFR 173.448 and 49 CFR 177.817).

Packaging used for the noncommercial transfer of PET radioactive drugs should be similar to those used by commercial radiopharmacies. These packages will normally meet the criteria for "Type A" quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in 49 CFR 173.465. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and for maintaining a certificate of testing (49 CFR 173.415). Shippers are not required to personally test the packages but must ensure that the testing was performed before use and maintain a record of the testing.

An outline of DOT and NRC requirements is included in Appendix Z.

Response from Applicant: No response is required. The licensee's program for the transportation of radioactive materials will be reviewed during inspection.

WASTE MANAGEMENT

Radioactive waste generated as part of the production of PET radioactive drugs for noncommercial distribution to consortium members must be disposed of in accordance with regulatory requirements and license conditions. In order to comply with the regulations in 10 CFR Part 20 and 10 CFR 30.51, appropriate records of waste disposal must be maintained. Section 8.29 (Item 11: Waste Management) of this document provides guidance on the information required for handling waste.

Return Waste

It is the responsibility of the other medical use consortium licensees to dispose of unused dosages, empty syringes, and vials received from the licensee authorized to produce and transfer PET radioactive drugs to its consortium members. Under 10 CFR 20.2001, these consortium members can only send radioactive waste to individuals authorized to receive it, and the licensee authorized to produce and transfer PET radioactive drugs to consortium members will not be authorized to receive returned, used or unused, radioactive drugs from consortium members. Therefore, only "empty" radiation transport shield packages can be returned to the production facility.

APPENDIX BB

January 2003 Summary of Public Comments on the August 1998 and March 2002 Drafts and NRC Responses

Summary of Public Comments on the August 1998 and March 2002 Drafts and NRC Responses

The initial draft of NUREG-1556, Volume 9, was published for public comment in August 1998. A revised draft was published in March 2002. Appendix Z of the March 2002 draft included a summary of comments on the 1998 draft and NRC responses. The NRC held two public workshops, on April 25 and April 30, 2002, to receive stakeholder comments on the March 2002 draft. The NRC also received written public comments during a 60-day comment period (April 5 to June 4, 2002). A summary and analysis of the set of comments for the August 1998 draft, as well as the set of comments for the March 2002 draft, were published as a separate document, Appendix BB to NUREG-1556, Volume 9 (January 2003), and this document is available on NRC's Web site http://www.nrc.gov in the Electronic Reading Room. Interested parties may also check NRC's Web site on the Medical Use of Byproduct Material http://www.nrc.gov/miau/med-use-toolkit.html.

APPENDIX CC

List of Documents Considered in the Development of this NUREG

List of Documents Considered in the Development of this NUREG

This report incorporates and updates the guidance previously found in the Regulatory Guides (RG), Policy and Guidance Directives (P&GD), and Information Notices (IN) listed in the table below. When this report is issued in final form, the documents in the table will be considered superseded and should not be used. Other references were also used in this report and are listed in "References."

Some sections of the guidance include references to other documents that may be useful to the applicant. Appendix CC provides a complete list of documents referenced in the guidance. While specific availability information is included for some reference documents, the documents also may be accessed at the NRC Public Document Room, which is located at NRC Headquarters in Rockville, Maryland, or the NRC Electronic Reading Room at www.nrc.gov. See the Notice of Availability on the inside front cover of this report for more information.

Document Identification	Title	Date
RG 10.8, Revision 2	Guide for the Preparation of Applications for Medical Use Programs.	8/87
Appendix X to RG 10.8, Revision 2	Guidance on Complying With New Part 20 Requirements.	6/92
Draft RG DG-0009	Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.	3/97
Draft RG FC 414-4	Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs.	12/85
P&GD FC 87-2	Standard Review Plan (SRP) for License Applications for the Medical Use of Byproduct Material.	12/87
Supplement 1 to P&GD FC 86-4; Revision 1	Mobile Remote Afterloading Brachytherapy Licensing Module.	5/97
P&GD FC 86-4, Revision 1	Information Required for Licensing Remote Afterloading Devices.	9/93
Addendum to Revision 1 to P&GD FC 86-4	Information Required for Licensing Remote Afterloading Devices – Increased Source Possession Limits.	7/95
P&GD 3-15	Standard Review Plan for Review of Quality Management Programs.	6/95
RG 8.39	Release of Patients Administered Radioactive Materials.	4/97
RG 8.33	Quality Management Program.	10/91
P&GD 3-17 (previously 16)	Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants.	
RG 8.23	Radiation Safety Surveys at Medical Institutions, Revision 1.	1/81

The additional references listed below were used.

References

Title 10, Code of Federal Regulations

1. Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.

2. Part 19 – Notices, Instructions, and Reports to Workers; Inspections and Investigations.

3. Part 20 – Standards for Protection Against Radiation.

4. Part 21 – Reporting of Defects and Noncompliance.

5. Part 30 – Rules of General Applicability to Domestic Licensing of Byproduct Material.

6. Part 31 – General Domestic Licenses for Byproduct Material.

7. Part 32 – Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.

8. Part 33 – Specific Domestic Licenses of Broad Scope for Byproduct Material.

9. Part 35 – Medical Use of Byproduct Material.

10. Part 40 – Domestic Licensing of Source Material.

11. Part 70 – Domestic Licensing of Special Nuclear Material.

12. Part 71 – Packaging and Transportation of Radioactive Material.

13. Part 150 – Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.

14. Part 170 – Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended.

15. Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

Title 49, Code of Federal Regulations

1. Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements.

2. Part 173 – Shippers – General Requirements for Shipments and Packaging.

3. Part 177 – Carriage by Public Highway.
4. Part 178 – Specifications for Packaging.

NRC Regulatory Guides (RG)

1. RG 1.86 – Termination of Operating Licenses for Nuclear Reactors, June 1974.
2. RG 3.66 – Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72, June 1990.
3. RG 7.10 – Revision 1 – Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, June 1986. (Superseded by NUREG 1556, Volume 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Radiography Licenses," August 1998.)
4. RG 8.4 – Direct-Reading and Indirect-Reading Pocket Dosimeters, February 1973.
5. RG 8.7 – Instructions for Recording and Reporting Occupational Radiation Exposure Data, Revision 1, June 1992.
6. RG 8.9 – Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program, Revision 1, June 1993.
7. RG 8.10 – Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable, Revision 1-R, September 1975.
8. RG 8.13 (Final) – Instruction Concerning Prenatal Radiation Exposure, June 1999.
9. RG 8.18 – Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable, Revision 1, October 1982. (Superseded by NUREG 1736, "Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation," October 2001.)
10. RG 8.21 – Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.
11. RG 8.25 – Air Sampling in the Workplace, Revision 1, June 1992.
12. RG 8.29 – Instruction Concerning Risks from Occupational Radiation Exposure, Revision 1, February 1996.
13. RG 8.34 – Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, July 1992.
14. RG 8.36 – Radiation Dose to the Embryo/Fetus, July 1992.

15. RG 10.2 – Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope, Revision 1, December 1976. (Superseded by NUREG 1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," December 1999.)

16. RG 10.5 (Draft) – Applications for Type A Licenses of Broad Scope, October 1994.

17. RG 10.8 – Revision (Draft NUREG-1569 - never published), Program-Specific Guidance for Medical Use Licensees, 1997.

18. RG FC 412-4 (Draft) – Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985.

19. RG FC 413-4 (Draft) – Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985.

NRC Information Notices (IN) and Regulatory Issue Summaries (RIS)

1. IN 89-25, Revision 1 – Unauthorized Transfer of Ownership or Control of Licensed Activities.

2. IN 94-09 – Release of Patients with Residual Radioactivity.

3. IN 94-70 – Issues Associated with Use of Strontium-89 and Other Beta-Emitting Radiopharmaceuticals.

4. IN 96-28 – Suggested Guidance Relating to Development and Implementation of Corrective Action.

5. IN 97-30 – Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises.

6. IN 99-24 – Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices.

7. IN 99-33 – Management of Wastes Contaminated with Radioactive Materials.

8. RIS 2002-06 – Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays, April 2002.

9. RIS 2002-10 – Revision of the Skin Dose Limit in 10 CFR Part 20, July 2002.

10. RIS 2005-31 – Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material.

NRC Fuel Cycle (FC) and Policy and Guidance Directives (P&GD)

1. FC 412-4 (Draft) – Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985. (Superseded by NUREG 1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," November 2000.)

2. FC 413-4 (Draft) – Guide for the Preparation of Applications of Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985. (Superseded by NUREG 1556, Volume 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses," November 2000.)

3. P&GD 1-23 – Guidance for Multi-Site Licenses, April 1996. (Superseded by NUREG 1556, Volume 20, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Administrative Licensing Procedures," December 2000.)

4. P&GD FC 90-2, Revision 1 – Standard Review Plan for Evaluating Compliance with Decommissioning Requirements, April 1991. (Superseded by NUREG 1757, Volume 3, "Consolidated NMSS Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," September 2003.

5. P&GD 8-11 – NMSS Procedures for Reviewing Declarations of Bankruptcy, August 1996. (Superseded by NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," November 2000.)

NRC NUREGs

1. NUREG-0267, Revision 1 – Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, October 1982.

2. NUREG-1134 – Radiation Protection Training for Personnel Employed in Medical Facilities, May 1985.

3. NUREG-1400 – Air Sampling in the Workplace, September, 1993.

4. NUREG-1492 – Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, February 1997.

5. NUREG-1539 – Methodology and Findings of the NRC's Materials Licensing Process Redesign, April 1996.

6. NUREG-1541 (Draft) – Process and Design for Consolidating and Updating Materials Licensing Guidance, April 1996.

7. NUREG-1556, Volume 3, Rev. 1 – Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration, April 2004.

8. NUREG-1556, Volume 11 – Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope.

9. NUREG-1556, Volume 15 – Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses, November, 2000.

10. NUREG-1556, Volume 18 – Consolidated Guidance About Materials Licenses: Program- Specific Guidance About Service Provider Licenses, November 2000.

11. NUREG-1556, Volume 20 – Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures, December 2000.

12. NUREG-1556, Volume 21 – Consolidated Guidance About Materials Licenses: Program- Specific Guidance About Possession Licenses for Production of Radioactive Sources using an Accelerator.

13. NUREG-1600 – General Statement of Policy and Procedures for NRC Enforcement Actions, June 1995, and Compilation of NRC Enforcement Policy as of September 10, 1997.

14. NUREG/CR-4444 – Radiation Safety Issues Related to Radiolabeled Antibodies, 1991.

15. NUREG/CR-4884 – Interpretation of Bioassay Measurement, July 1987.

16. NUREG-CR-5631, PNL-7445, Rev. 2 – Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses, 1996.

17. NUREG-CR-6276 – Quality Management in Remote Afterloading Brachytherapy, October 1994.

18. NUREG/CR-6323 – Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices: A Preliminary Application, September 1995.

19. NUREG/CR-6324 – Quality Assurance for Gamma Knives, September 1995.

20. NUREG-1736 – Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation, 2001.

21. NUREG 1757 – Consolidated NMSS Decommissioning Guidance, September 2003.

National Council on Radiation Protection and Measurements (NCRP) Publications

(Available from NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095, or ordered electronically from http://www.ncrp.com)

1. NCRP Report No. 30 – Safe Handling of Radioactive Materials, 1964.

2. NCRP Report No. 37 – Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970.

3. NCRP Report No. 40 – Protection Against Radiation from Brachytherapy Sources, 1972.

4. NCRP Report No. 49 – Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV, 1976.

5. NCRP Report No. 57 – Instrumentation and Monitoring Methods for Radiation Protection, 1978.

6. NCRP Report No. 58 – A Handbook of Radioactivity Measurement Procedures, Second Edition, 1985.

7. NCRP Report No. 69 – Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, 1981.

8. NCRP Report No. 71 – Operational Radiation Safety – Training, 1983.

9. NCRP Report No. 87 – Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, February 1987.

10. NCRP Report No. 88 - Radiation Alarms and Access Control Systems, 1986.

11. NCRP Report No. 102 – Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use), 1989.

12. NCRP Report No. 105 – Radiation Protection for Medical and Allied Health Personnel, 1989.

13. NCRP Report No. 107 – Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, 1990.

14. NCRP Report No. 111 – Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities, 1991.

15. NCRP Report No. 112 – Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination, 1991.

16. NCRP Commentary No. 11 – Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, February 1995.

International Commission on Radiological Protection (ICRP) Publications
(Published by Elsevier Science: www.elsevierhealth.com/journals/icrp.)

1. ICRP Report No. 26 – Recommendations of the International Commission on Radiological Protection, 1977.

2. ICRP Report No. 30 – Limits for Intakes of Radionuclides by Workers, 1978.

3. ICRP Report No. 35 – General Principles of Monitoring for Radiation Protection of Workers, 1982.

4. ICRP Publication No. 53 – Radiation Dose to Patients from Radiopharmaceuticals, 1987.

5. ICRP Publication 54 – Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation, 1987.

ANSI Standards (Available from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036 or ordered electronically from http://www.ansi.org)

1. ANSI N13.4-1971 (R1983) – Specification of Portable X- or Gamma-Radiation Survey Instruments.

2. ANSI N13.5-1972 (R1989) – Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma-Radiation.

3. ANSI N13.6-1966 (R1999) – Practice for Occupational Radiation Exposure Records Systems.

4. ANSI N14.5-1987 – Leakage Tests on Packages for Shipment of Radioactive Materials.

5. ANSI N42.12-1994 – Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides.

6. ANSI N42.13-1986 (R1993) – Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.

7. ANSI N42.15-1990 – Performance Verification of Liquid Scintillation Counting Systems.

8. ANSI N42.17A-1989 – Performance Specifications for Health Physics Instrumentation-Portable Instrumentation for Use in Normal Environmental Conditions.

9. ANSI N322 – Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters.

10. ANSI N323A-1997 – Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.

11. ANSI N449.1-1978 (R1984) – Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment.

American Association of Physicists in Medicine (AAPM) Reports (Available from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from http://www.medicalphysics.org. Readers may wish to contact AAPM to determine if more recent documents or reports on these topics have been issued by AAPM. Such documents should be reviewed by applicants for compliance with 10 CFR Part 35 prior to use.)

1. AAPM Task Group No. 21 – A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams, 1984.

2. AAPM Report No. 41 – Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41), 1993.

3. AAPM Report No. 46 – Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40), 1994.

4. AAPM Report No. 51 – Dosimetry of Interstitial Brachytherapy Sources, (Radiation Therapy Committee Task Group No. 43), 1995.

5. AAPM Report No. 54 – Stereotactic Radiosurgery, (Radiation Therapy Committee Task Group No. 42), 1995.

6. AAPM Report No. 59 – Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56), 1997.

7. AAPM Report No. 61 – High Dose Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59), 1998.

8. AAPM Report No. 67 – Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams, Medical Physics 26(9), pp. 1847-1870, (Radiation Therapy Committee Task Group No. 51) September, 1999.

Other Technical Publications

1. International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, 1968.

2. U.S. Department of Health, Education, and Welfare, "Radiological Health Handbook," 1970.

3. R. C. T. Buchanan and J. M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.

4. International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.

5. IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971.

6. A. P. Jacobson, P. A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.

7. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10-6 a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.

8. Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.

9. Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.

10. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable over Ten Years Post Intake," *Radiation Protection Dosimetry*, Volume 11, No. 1, 1985.

11. "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987.

12. J. R. Johnson and D. W. Dunford, "GENMOD – A Program for Internal Dosimetry Calculations," AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987.

13. K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, 1988.

14. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal*, Volume 55, No. 6, 1988.

15. A. S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990.

16. R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990.

17. M. G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991.

18. P. Early, D. B. Sodee, "Principles and Practice of Nuclear Medicine," 2nd ed., 1995.

19. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," *Pediatric Nuclear Medicine*, 1995.

20. "Intravascular Brachytherapy – Guidance for Data to be Submitted to the Food and Drug Administration In Support of Investigational Device Exemption (IDE) Applications," Draft Version 1.3, 1996.

21. R. O. Dunkelberger, II, "Which Probe Should I Use," *Baltimore-Washington Health Physics Society Newsletter.*

APPENDIX DD

Summary of Comments Received on Draft Revision 2 of NUREG-1556, Volume 9

Summary of Comments Received on Draft Revision 2 of NUREG-1556, Volume 9

Note: The page number references associated with each comment under the location heading refers to the page numbers in the July 2007 NUREG-1556 Draft Report for Comment version of Volume 9, Revision 2, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Comments were requested on the specific changes in this NUREG related to the expanded definition of byproduct material, the NARM Rule, and revision of the NRC Form 313A series of forms. Therefore, generally, only comments related to these topics were considered. Comments that were raised related to other issues will be evaluated during any future revision of this NUREG.

Table DD.1 Comments from the State of Wisconsin, Dated August 29, 2007

Location	Subject	Comment
Section 8.5 (Page 8-10, Other Material-table)	Ra-226, unsealed	Delete "Ra-226, unsealed, 1 millicurie" as this would not be included under the new definition of byproduct material. It is also improbable that a medical licensee would request to use unsealed Ra-226.
NRC Staff Response: Unsealed radium-226 is included in the new definition of byproduct material. The NRC now has regulatory authority over discrete sources of Ra-226. The term discrete sources includes both sealed and unsealed material and this point is included in several places in this and other sections of the guidance. The NRC recognizes that it is improbable that medical licensees would use unsealed Ra-226 but it is included in the guidance because the use of discrete sources of Ra-226 for medical use is not prohibited by the regulations.		
Location	**Subject**	**Comment**
Section 8.9 (Page 8-18, 35.1000 Use)	Ra-226, unsealed	Delete "unsealed Ra-226 or" as this would not be included under the new definition of byproduct material. It is also improbable that a medical licensee would request to use unsealed Ra-226 for medical use as Ra-226 is a known bone-seeker.
NRC Staff Response: See the previous response.		

Location	Subject	Comment
Section 8.10 (Page 8-21)	grandfathered individuals and new 10 CFR 35.57 criteria	The last sentence in this item needs clarification. It states that authorized users (generic, i.e. all types) that meet the criteria in 10 CFR 35.57 qualify under NRC's waiver of August 31, 2005 and can be "grandfathered" in as authorized users. What does this mean to the licensee or reviewer? It would be more straight-forward to state that authorized users of "accelerator-produced radioactive material, discrete sources of Ra-226, or both" (per page 8-23 for the RSO) can be "grandfathered" and then explain any limiting conditions, for example, what is the effective period of NRC's waiver of August 7, 2005?
NRC Staff Response: The NRC staff agrees that without references to specific paragraphs under the revised 10 CFR 35.57, the guidance in this section is confusing. References to specific 10 CFR 35.57 paragraphs are added for clarity. These paragraphs include all conditions for grandfathering. The intent of the last sentence is to remind applicants and license reviewers that nuclear pharmacists, medical physicists, physicians, podiatrists, and dentists that used the newly defined byproduct material before November 30, 2007, and under NRC's waiver of August 31, 2005, are considered ANPs, AMPs, and AUs for the uses performed, before or under the waiver.		
Location	**Subject**	**Comment**
Section 8.11 (Page 8-23)	10 CFR 35.57(a)(3)	This section and its Response from Applicant section references 35.57(a)(3). There is no (a)(3) in the current 10 CFR 35 regulation.
NRC Staff Response: The reference to 35.57(a)(3) is correct. Paragraph (a)(3) was added to 10 CFR 35.57 as part of the amendment to NRC's regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the EPAct of 2005. See 72 FR 55864, Oct. 1, 2007, for the final rule.		
Location	**Subject**	**Comment**
Section 8.12 (Pages 8-27 and 8-28)	10 CFR 35.57(b)(3).	This section and its Response from Applicant section reference 35.57(b)(3). There is no (b)(3) in the current 10 CFR 35 regulation.
NRC Staff Response: The reference to 35.57(b)(3) is correct; paragraph (b)(3) was added to 10 CFR 35.57 as part of the amendment to NRC's regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the EPAct of 2005.		

Location	Subject	Comment
Section 8.13 (Page 8-32)	10 CFR 35.57(a)(3)	This Section and its Response from Applicant section reference 35.57(a)(3). There is no (a)(3) in the current 10 CFR 35 regulation.
NRC Staff Response: As indicated in a response to a prior comment, the reference to 35.57(a)(3) is correct; paragraph (a)(3) was added to 10 CFR 35.57 as part of the amendment to NRC's regulations to include jurisdiction over discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the EPAct of 2005.		
Location	**Subject**	**Comment**
Section 8.14 (Pages 8-34 and 8-35)	10 CFR 35.57(a)(3)	This section and its Response from Applicant section references 35.57(a)(3). There is no (a)(3) in the current 10 CFR 35 regulation.
NRC Staff Response: See previous response.		
Location	**Subject**	**Comment**
Section 8.25 (Page 8-58)	Ra-226, unsealed	Delete "and Ra-226." Unsealed Ra-226 would not be considered byproduct material under the new definition. It is improbable that unsealed Ra-226 would be used under a medical license.
NRC Staff Response: As discussed earlier, unsealed Ra-226 is included in the new definition of byproduct material. The term discrete sources includes both sealed and unsealed material. The NRC recognizes that it is improbable that medical licensees would use unsealed Ra-226 but it is included because its medical use is not prohibited by the regulations.		
Location	**Subject**	**Comment**
Appendix AA (Page AA-4 and AA-5)	Department of Transportation (DOT) Security training	There is no mention of DOT Security training as required in (4).
NRC Staff Response: This comment is not related to the NARM regulations or the revision of NRC Form 313A, and is therefore beyond the scope of this revision. The comment will be evaluated during any future revision of this NUREG.		

Table DD.2 Comments from Darrell R. Fisher, Dated August 30, 2007

Location	Subject	Comment
Entire Volume	General Comment	This is a 458-page document. Some of the document seems to be excessively wordy and repetitive. Any effort to provide a shorter, briefer guidance document would probably be appreciated by prospective and current licensees.
NRC Staff Response: This comment is not related to the NARM regulations or the revision of NRC Form 313A, and is therefore beyond the scope of this revision. The comment will be evaluated during any future revision of this NUREG. Note, however, that this guidance document contains information that is repeated in different sections because it is used by a diverse body of medical users that may focus only on sections applicable to them and miss common information if it only appeared once.		
Location	**Subject**	**Comment**
Entire document	General Comment	Also throughout, this reviewer noted several inconsistent uses of "mCi" and "mci" for millicuries.
NRC Staff Response: The corrections were made.		
Location	**Subject**	**Comment**
Overview (Page 1-7)	alpha particle quality factor	Add text as underlined: The quality factor <u>used in 10 CFR 20</u> for alpha particles is 10. This will show the reader that the value 10 was taken from 10 CFR 20. Clarification is needed because the RBE for alpha emitters is determined experimentally and may vary widely for given circumstances. Quality factor is an upper limit on the RBE, chosen by committee, and the quality factor recommended by ICRP is 20. Therefore, it would be helpful for the reader to know why the NRC uses a value of 10 for the quality factor in this document, and where it was obtained.
NRC Staff Response: The clarification was made.		

Location	Subject	Comment
Section 8.14 (Page 8-34 Authorized Medical Physicist (AMP))	AMP	The text states that "an AMP is directly involved with the calculation and administration of the radiation dose." Instead, the text should read: "an AMP is directly involved with radiation therapy treatment planning." The AMP would not normally be involved in administration of therapy radiation to a patient.
NRC Staff Response: The statement in the guidance is a general statement of the AMP's role in the use of byproduct material in high-dose remote-afterloader, teletherapy, and gamma stereotactic radiosurgery units for medical uses. The AMP's role is not restricted only to direct involvement in radiation therapy treatment planning, but includes other medical physics tasks during the administration and after the completion of the procedure. The text was revised to clarify that the AMP may not administer the dose but is directly involved with medical physics tasks associated with the administration of the radiation dose.		
Location	**Subject**	**Comment**
Section 8.17 (Page 8-42)	survey instruments	The text states that "Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, unless the procedure involves localization of radioactive seeds, since it is not expected that a survey will be performed each time such a procedure is performed." However, the text fails to mention the importance of having a survey meter on hand during and after a brachytherapy seed implant to look for seeds that may have been misplaced, that may have fallen to the floor, or that may remain in equipment after the procedure. Furthermore, these seeds are used for therapeutics, not diagnostic procedures as the text incorrectly suggests.
NRC Staff Response: The paragraph only addresses sealed source diagnostic procedures. The text correctly indicates that some radioactive seeds that would normally be considered for therapeutic brachytherapy use are now being used for diagnostic purposes to mark the tissue and tissue boundaries for surgical removal. The word "procedure" has been replaced with the phrase "diagnostic study" to correct any ambiguity, as warranted. Also, the first paragraph in the discussion in this section addresses the need for survey instruments for traditional brachytherapy seed use.		

Location	Subject	Comment
Section 8.18 (Page 8-43, Dose Calibrator)	dosages vs. activity	Throughout this section, the text implies that a dose calibrator measures dosages. More correctly, the dose calibrator measures activity or radioactivity, not dosages. The text describes "instruments (e.g., dose calibrators) used to measure patient dosages." Instead, it would be more correct to state that the dose calibrators are used "to measure the radioactivity present in a syringe, tube, vial, or capsule." Further, the text states that "As described in 10 CFR 35.63, dosage measurement is required for licensees who prepare patient dosages." More correctly, this sentence should read "...measurement is required for licensees who prepare radiopharmaceuticals for administration to patients.
NRC Staff Response: No change was made in response to this comment. The use of the term "dosage" in this section conforms with NRC's use of the term in 10 CFR Part 35; e.g., in the 10 CFR 35.2 definition of prescribed dosage and in 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use." The dose calibrator is used to measure the activity of the patient dosage. While the dose calibrator may be used to measure activity in syringes, tubes, vials, capsules, or any other container, the intent of this section is to describe the requirements for use of the dose calibrator and other equipment to measure activities of unsealed byproduct material that will be administered for medical use; i.e., for patient and human research subject dosages.		

Location	Subject	Comment
Section 8.20 (Page 8-47)	typo	Correct spelling should be as follows (underlined): "When patients are treated with I-131 sodium iodide, sources of contamination include . . ."
NRC Staff Response: The correction was made.		

Location	Subject	Comment
Section 8.39 (Page 8-78)	beta radiation vs gamma and brehmssthralung	The statement is given that: "The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation." I question the accuracy of this statement. The beta dose from tissue surfaces is only a small part of the total from within the body. Most of the beta radiation is locally absorbed, except for small amounts present on tissue surfaces. The major dose to man is still gamma from brehmsstralung, even during an operation or an autopsy. The skin dose to hands is negligible. I have experience doing this kind of work with the assistance from radiation monitoring specialists.
NRC Staff Response: The sentence was revised to clarify that the intent of the statement is not to diminish the importance of the exposure due to gamma radiation and bremsstralung but to heighten awareness of potential beta exposure.		

Location	Subject	Comment
Section 8.40 (Page 8-79)	accountability and security	The statement is given that: "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; identify when licensed material could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded." However, there seems to be a thought disconnect between proper tracking "from cradle to grave" and inadvertent losses of material by theft. Further, it will NOT BE POSSIBLE, in advance, to anticipate how licensed material would be lost, stolen, or misplaced if the licensee is doing everything possible to prevent loss and theft. There could be almost an unlimited number of ways that theft or loss could happen and times when it could happen. Further, there seems to be a disconnect between the concept of theft or loss and the concept of possession-limit tracking. I recommend that you separate the distinctly different concepts of tracking possession limits and safeguarding against theft or loss.
NRC Staff Response: The statement was not intended to mean the licensee can predict when loss or theft of licensed material will happen, but rather that licensees should identify when licensed material is missing and document its last confirmed possession of the licensed material. The purpose of this sentence is to reinforce that a licensee is accountable for the material it possesses from receipt to transfer/disposal. The sentence has been revised to clarify this intent.		

Table DD.3 Comments from the Washington University in St. Louis, Dated August 31, 2007

Location	Subject	Comment
Section 8.5 (Page 8-11), Section 8.6 (Page 8-12), and Section 8.7 (Page 8-13)	10 CFR 30.32(g)	The NRC's guidance is inconsistent in this draft on how a licensee should add a Ra-226 or NARM sealed source or device to its NRC license when that source or device does not have an SSDR certificate. The information NRC requests in 10 CFR 30.32(g)(1) and (2) may not be readily available to the applicants if they purchased the source from someone else. If NRC asks for this information under 10 CFR 30.32(g)(3) from every applicant possessing the sealed source, then it appears that NRC will be receiving multiple requests to do a safety evaluation for the same sealed source model. We **recommend** that NRC work directly with the sealed source manufacturers to begin conducting safety evaluations and issuing SSDR certificates. Guidance for applicants who only possess these sealed sources should be to provide NRC with the manufacturer name, source model number, and general physical description; e.g., Ge-68 rod source 1/4" diameter & 8" long.

NRC Staff Response: The NRC staff does not agree that the guidance in this draft is inconsistent. The guidance clarifies that if the applicant has a NARM or Ra-226 sealed source, device, or source and device combination that is not in the SSDR, the applicant must either submit all the information required in 10 CFR 30.32(g)(2), if the information is available, or if not, provide the information required in 10 CFR 30.32(g)(3). The information required under 10 CFR 30.32(g)(1) and (2) applies to all sealed sources, devices, and sealed source-device combinations. As part of the NARM rule, a new paragraph (3) was added to 10 CFR 30.32(g) that allows for the licensing of sealed sources and devices containing NARM that were manufactured before the effective date of the rule and for which all of the information required in 10 CFR 30.32(g)(1) and (2) is not available. Without this provision, an applicant who wanted to use the NARM source or device that was not registered in the SS&D Registry would have been required to submit all of the safety information identified in 10 CFR 32.210(c), because this information had not been submitted already by the manufacturer or distributor as part of registering the source or device. When all the information required by 10 CFR 32.210(c) is not available, 10 CFR 30.32(g)(3) delineates additional information that will be required to license a NARM source or device.

The NRC will be working with sealed source and device manufacturers to include NARM and Ra-226 sealed sources in the SSDR. The NRC recognizes that a number of "legacy" sources containing these materials were produced by manufacturers that are no longer in business or stopped making the devices some time ago. These are the sources for which NRC expects to receive information under the provisions of 10 CFR 30.32(g)(3).

Location	Subject	Comment
Section 8.42 (Page 8-80)	National Source Tracking regulations	"Sealed Source Inventory" section was not updated in this draft guidance, but we **recommend** that NRC update this section in Rev. 2 to reflect the guidance needed by medical use licensees to meet the new National Source Tracking regulations (71 FR 65686, November 8, 2006).
NRC Staff Response: This comment is not related to the NARM regulations or the revision of NRC Form 313A, and is therefore beyond the scope of this revision. The comment will be evaluated during any future revision of this NUREG. Note, however, that NRC postponed the implementation date of the National Source Tracking regulations from the effective date stated in the Federal Register referenced in the comment.		
Location	**Subject**	**Comment**
Section 8.5 (Page 8-7)	Activation products	How will NRC deal with very short-lived radioactive materials (e.g., half-life less than 2 minutes) that may be activated to activities exceeding the requested limits? Should the license application state that possession limits apply to incidentally activated radioactive materials with half-lives greater than or equal to 2 minutes? This is a repeat question from WU comment letter for Volume 21, dated July 3, 2007.
NRC Staff Response: This comment pertains to radionuclide production and not medical use. As indicated in NUREG-1556, Volume 21, the possession limits in question will be addressed on the radionuclide production license. The radionuclides possessed on the medical use license will be those used for medical use and will not include the short half-life incidentally activated radioactive materials produced during the production of the radionuclides by the accelerator.		

Location	Subject	Comment
Section 8.5 (Page 8-7)	Identifying incidental contaminants in radioactive drugs	What guidance does NRC give license applicants for 10 CFR 32.72 distribution of radionuclides that may contain other radionuclide contaminants? Should not guidance on how to describe these potential contaminants be included in this document? Examples of these types of radiopharmaceuticals that are widely used include: Sm-153 Quadramet which can include Eu-154 and Eu-155 Tl-201 Thallous Chloride which can include Tl-200, Tl-202 and Pb-203 In-111 Indium Chloride which can include In-114m and Zn-65 This is a repeat question from WU comment letter for Volume 13, Rev. 1, dated August 1, 2007.
NRC Staff Response: Guidance for applicants seeking a license for distribution of radionuclides under the provisions of 10 CFR 32.72 is not within the scope of this medical use guidance document. This is not an issue for medical use licenses because most radionuclides used for medical uses described in 10 CFR 35.100, 35.200, or 35.300, such as those mentioned in the comment, are requested and listed as "any byproduct material" permitted by 10 CFR 35.100, 35.200, or 35.300, respectively. In other cases, when NRC has to list individual radionuclides, the NRC authorizes the possession and use of the main radionuclide and assumes that the contaminants are part of the main radionuclide's characteristics. For example, the NRC recognizes that certain long-lived radionuclides are present in small amounts in the Mo-99/Tc-99m generators and list only Molybdenum-99 (Mo-99) and Tc-99m. Also, Tc-99m is listed although small amounts of Mo-99m may also be present. In generator elutions, a minimum activity of contaminant is permitted and must be tested for.		

Location	Subject	Comment
Sections 8.10 (Page 8-21), Section 8.11 (Page 8-23), Section 8.12 (Page 8-27), Section 8.13 (Page 8-32), and Section 8.14 (Page 8-34)	10 CFR 35.57 Grandfathering of individuals and preceptor statements	As NRC is preparing to "grandfather" individuals who have used accelerator-produced radionuclides to be an ANP (or an AU, AMP or RSO), there is an opportunity to bring the training and experience criteria for ANPs (AUs, AMPs and RSOs) more in line with the preceptor definition. We agree that a preceptor statement from a current ANP is appropriate for those individuals seeking to become an ANP by the alternative pathway. WU strongly **recommends** that the NRC Staff and, in particular, the Nuclear Regulatory Commissioners reconsider the need for an ANP preceptor statement for those individuals who are board-certified by an NRC-recognized specialty board. Each of the specialty boards recognized by the NRC have proven to the NRC that their board-eligible candidates meet the training and experience requirements for the type(s) of medical use for which they are recognized. In order to sit for a board exam, an individual requires the recommendation of a sponsor who verifies the individual has met all of the requirements to become board-certified. While this sponsor may not be an ANP, the sponsor is responsible to the board for recommending only individuals who meet the board's, and therefore the NRC's, requirements. Successful completion of the board exam by the individual gives further verification of the individual's training and experience. WU believes the current regulations imposing the additional requirement of an ANP preceptor statement is an unnecessary redundancy that has greatly complicated the process of approving an individual as an ANP, and has led to the trivialization of long-established radiopharmacy board-certification. This is a repeat recommendation made in WU comment letter for Volume 13, Rev. 1, dated August 1, 2007.
NRC Staff Response: Any revisions to the training and experience requirements would require a revision to NRC's current regulations. Therefore, this comment is beyond the scope of this guidance document revision.		

Location	Subject	Comment
Section 8.10 (Page 8-21), Section 8.11 (Page 8-23), Section 8.12 (Page 8-27), Section 8.13 (Page 8-32), and Section 8.14 (Page 8-34)	10 CFR 35.57 Grandfathering of individuals	We appreciate that NRC has taken care to ensure the continuing access of PET imaging techniques by allowing the "grandfathering" of individuals who have used accelerator-produced radionuclides to become ANPs (or AUs, AMPs or RSOs). We believe that NRC also "grandfathering" individuals who have received board-certification prior to NRC's recognition of a specialty board would be in line with the grandfathering for medical use of the new byproduct materials. In certain cases, such as those individuals who have been board certified by the American Board of Health Physics (ABHP) prior to January 1, 2005, and never named as RSO on a NRC or Agreement State license, an individual could not currently be named as an RSO based on their board-certification even though the ABHP made no changes in its certification process to receive NRC-recognition. WU also strongly **recommends** that NRC allow grandfathering of all individuals who were board-certified prior to NRC-recognition for any specialty boards which receive NRC-recognition prior to the required implementation date, August 9, 2009, for the new byproduct definition. This is a repeat recommendation made in WU comment letter for Volume 13, Rev. 1, dated August 1, 2007.
NRC Staff Response: No change was made to the guidance in response to this comment. The comment is beyond the scope of this guidance document revision and would require rulemaking. No changes were made to the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H in the NARM rule. The guidance accurately reflects the rule text changes to 10 CFR 35.57 which address "grandfathering" of individuals that only used NARM and discrete sources of Ra-226 before or under NRC's waiver of August 31, 2005.		

Location	Subject	Comment
General Comment	NRC Form 313A series	As stated in this draft guidance, NRC is committed to risk-informed, performance-based regulation, guidance, inspection and enforcement. We believe the latest revision of NRC 313A forms documenting training and experience, plus the preceptor statement, indicate that NRC is moving towards prescriptive "requirements" in the name of "guidance" which has the effect of impeding individuals from being approved as an RSO, an authorized user, an authorized nuclear, pharmacists, or an authorized medical physicist.
NRC Staff Response: The NRC staff does not agree with this comment. NRC is committed to risk-informed performance-based activities. The NRC Form 313A series of forms provide applicants with a means of documenting the training and experience requirements in the regulations. The forms do not require any information that is not required in the regulations, and the preceptor forms include only attestations required by the regulations. Also, the latest revision does not ask for any new information that was not a part of the previous form.		
Location	**Subject**	**Comment**
General Comment	Regulation by guidance	We also see further indication of NRC's tendency to "regulate via guidance" as it appears in the recent NRC guidance on licensing the Leksell Gamma Knife® Perfexion™ (guidance document not dated, but medical generic communications sent notice of availability on August 8, 2007). This new gamma knife guidance states that this new device must be licensed under 35.1000 rather than 35.600, but does not justify why the existing 35.600 regulations do not adequately cover the radiation safety considerations for the new gamma knife device. We agree that specific training for a new gamma knife device that has expanded treatment capabilities is required, but we do not agree this change in device capability warrants a change in the type of medical use. By telling licensees to consider the use of this new gamma knife device as 35.1000, NRC will be imposing unnecessary training and experience documentation of individuals who are currently approved for another gamma knife, and vice versa.
NRC Staff Response: This comment is beyond the scope of this guidance document revision. Guidance for the 10 CFR 35.1000 uses is posted on the NRC public Web site and updated when necessary to address comments from stakeholders.		

Location	Subject	Comment
General Comment	NRC 313A series of Forms and 10 CFR 35.1000 guidance on Leksell Gamma Knife® Perfexion	We ask that NRC evaluate the current NRC 313A forms, and the current guidance on licensing the Leksell Gamma Knife® Perfexion™, with regard to NRC's policy promoting risk-informed, performance-based regulation, guidance, inspection and enforcement. We note that NRC did not ask for public comment on these documents, nor has NRC taken full advantage of the expert review that NRC's Advisory Committee on the Medical Use of Isotopes could provide NRC if given the time to really partner with the NRC Staff in developing these documents. We are concerned that NRC is moving away from these valuable review processes. As medical use of PET and other accelerator-produced radionuclides come under NRC authority, the problems we are experiencing with training and experience documentation, and with NRC issuing minimally reviewed prescriptive guidance, will be compounded.
NRC Staff Response: This comment is beyond the scope of this guidance document revision. However, note that the Advisory Committee on the Medical Use of Isotopes discussed and provided comments on the NRC 313A series of forms and the guidance for completing the forms. Guidance for the 10 CFR 35.1000 Leksell Gamma Knife® Perfexion™ is posted on the NRC public Web site and is updated when necessary to address comments from stakeholders.		

Location	Subject	Comment
Section 3 (Page 3-1)	Management	Definition of "Management" should be similar to that found in Volume 11 (Broad Scope). We suggest it should be the same for all NUREG 1556 volumes, and thus be modified to read: "'Management' refers to the processes for conduct and control of a Radiation Safety Program and to the individuals who are responsible for those processes and have *authority to provide necessary resources* to ensure safety and to achieve regulatory compliance."
NRC Staff Response: No change was made in response to this comment. The definition of "management" used in NUREG 1556, Volume 9, as indicated in Section 3 of this document, is the same as the definition of "management" found in 10 CFR 35.2, "Definitions."		

Location	Subject	Comment
Section 8.5 (Page 8-8)	Typo	The word, cyclotron, is misspelled in the footnote.
NRC Staff Response: The correction was made.		
Location	**Subject**	**Comment**
Section 8.16 (Page 8-40)	Updating references	We suggest that the references should be updated: replace NCRP Report 49 with NCRP Report 147; replace NCRP Report 102 with NCRP Report 151; and add NCRP Report 144 "Radiation Protection for Particle Accelerator Facilities" to the list.
NRC Staff Response: This comment is beyond the scope of this revision and will be addressed during a subsequent revision of the guidance.		
Location	**Subject**	**Comment**
Appendix B	NRC Form 313A series	Will this appendix have the current NRC 313A forms in the final version, or will you just point to the NRC website for the current forms?
NRC Staff Response: The current NRC Form 313A series of forms will be included in the hard copy of NUREG 1556, Vol, 9, Revision 2. In the electronic version of Volume 9, Revision 2, the NRC Form 313As will be hyperlinked to the forms on the NRC Web site within the medical use license toolkit. The most current version of the forms will always be on NRC's public Web site so that they are available to applicants if they are revised before subsequent revisions are made to the NUREG.		
Location	**Subject**	**Comment**
Appendix AA	Medical licensees noncommercial distribution to PET radioactive drugs to other medical use licensees in its consortium	This appendix appears to be the same kind of guidance as in NUREG 1556 Volume 21 draft Appendix P, but is not word for word the same. Will these two appendices be made identical in the final publications of these two NUREG 1556 volumes?
NRC Staff Response: Although the basic information in both is the same, the two appendices will not be identical because Appendix AA of NUREG-1556, Volume 9, Revision 2, will refer the medical use applicant primarily to the Radiation Safety Program requirements in this volume. While NUREG-1556, Volume 21, Appendix Q, can be used by medical use facilities, as well as the nonmedical use facilities at educational institutions and Federal facilities, it refers the applicant to the radiation safety requirements in other volumes.		

Location	Subject	Comment
NARM Rule	Review of implementation	In reviewing the draft of Volume 21 and updates for Volumes 13 and 9 of the NUREG 1556 guidance documents, we noted that only NRC Staff plus one former state regulator were involved in the drafting of these documents. We appreciate that the NRC Staff have been under a tight time schedule to provide these much needed guidance documents in advance of the final rule being published. We have also faced this time pressure in being allowed only 30 days to review and comment on these guidance documents. Because of the limited involvement by people who have safely produced and worked with cyclotron-produced radioactive materials for many years, we hope that the NRC Staff accepts the recommendations made by this community. In the May 14, 2007, NRC memo announcing that the Commission had approved implementation of the final rule, they made this recommendation: "The staff should conduct a review of the effectiveness of this rulemaking after it has gained some experience with implementing the new regulations. This review should occur no sooner than 18 months after the effective date of the rule and include recommendations for studies or rule changes that may be needed to more effectively implement the EPAct." We support and suggest that the NRC more fully include the newly regulated community in this effort.
NRC Staff Response: This comment is beyond the scope of this guidance document revision. The staff will review the effectiveness of the rulemaking through licensing, inspection, and stakeholder interactions. The NRC will work with the Agreement States during this review process.		

Table DD.4 Comments from the Department of Environmental Quality, State of Michigan, Dated September 7, 2007

Location	Subject	Comment
Section 8-16 (Page 8-37) and Section 8-33 (Page 8-71)	"quiet rooms"	Patients administered F-18 fluorodeoxyglucose (FDG) are typically kept in a "quiet room" for an hour because the diagnostic procedure requires the patient to remain still to make sure the FDG uptake in normal muscles is as low as possible. The location of quiet rooms and adjacent areas should be specifically mentioned in the text.
NRC Staff Response: The NRC staff is identifying the "quiet room" in this guidance as a potential area of radiation exposure that the applicant should include in the facility diagram and consider under its ALARA program. The text references "quiet rooms" and adjacent areas. Text has also been added to address the appropriate public dose criteria for areas in and around a "quiet room."		
Location	**Subject**	**Comment**
Section 8.23 (Page 8-55)	Web link	Replace the link to NIST, http:// ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm with http://ts.nist.gov/Standards/scopes/programs.htm .
NRC Staff Response: The link was revised.		
Location	**Subject**	**Comment**
Section 8.37 (Page 8-74) and Appendix V (Page V-1)	"quiet room" shielding	Some mobile positron emission tomography (PET) services inject the patient in the van but have the patient wait in a quiet room in each facility. A shielding evaluation for these quiet rooms needs to be performed to determine if additional shielding is required to meet public dose limits for adjacent occupants.
NRC Staff Response: The reference to a "quiet room" was added to the discussion on public dose limits in Section 8.33. Section 8.37 was revised to indicate when PET mobile service licensees must consider the "quiet room" an area of use based upon the patient release criteria in 10 CFR 35.75. The applicant should refer to Sections 8.1 through 8.31 regarding information that must be provided. These sections provide guidance regarding the "quiet room," including the need to identify this area on the facility diagram, the need to identify its location, the need to consider the design of the "quiet room" under the applicant's ALARA program, and the need to review Section 8.33 to determine the appropriate public dose limits for adjacent occupants to determine if additional shielding is needed. Appendix V was revised to add a discussion of whether the "quiet room" is an area of use under the license.		

Location	Subject	Comment
Appendix CC (Pages CC-6, 7, 8)		The commenter noted that there are NCRP, ICRP, and ANSI documents that have been revised and replaced with more recent documents.
NRC Staff Response: The reference to ANSI 13.1 was revised. Revision of other documents is beyond the scope of this revision and will be addressed during subsequent revisions of the document, as may be warranted.		
Location	**Subject**	**Comment**
Entire document	typos	The commenter noted a number of "typos" throughout the document.
NRC Staff Response: The typos have been corrected.		

Table DD.5 NRC Staff Identified Comments

Location	Subject	Comment
Section 8.5 (Page 8-11)	10 CFR 30.32(g) Guidance	The following sentence contained an error. "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, or the information required in 10 CFR 30.32(g)(3) (e.g., manufacturer and model number from an SSDR certificate) should consult with the appropriate NRC Regional Office to discuss the contents of their application."
NRC Staff Response: This error has been corrected. The words in the parentheses "manufacturer and model number from an SSDR certificate" should have come after the words "information described above." Applicants would only use the provisions of 10 CFR 30.32(g)(3) if the NARM source or device is not in the SSDR or the applicant does not have enough information to determine if there is an SSDR certificate. Further, while applicants may contact the Regional Office at any time, they do not have to contact the Regional Office if they can use any of the provisions in 10 CFR 30.32(g).		

Location	Subject	Comment
Section 8.6 (Page 8-12)	SSDR	The following sentence created confusion regarding sources, devices, or source-device combinations not in the SSDR: "Applicants must provide the manufacturer's name and model number for each requested sealed source and device so that NRC can verify that they have been evaluated in an SSDR certificate or specifically approved on a license."
NRC Staff Response: The sentence was revised to change "that" they have been evaluated in an SSDR certificate to"whether" they have been evaluated in an SSDR certificate.		
Location	**Subject**	**Comment**
Appendix B (Pages B-18, 22, and 29)	AU Preceptor Attestations	Stakeholders mistakenly assumed that the attestation required in the preceptor attestation refers to the physician's general clinical competency in areas not under NRC regulation.
NRC Staff Response: The NRC staff revised NRC Forms 313A (AUD), 313A (AUS), and 313A (AUT) in Appendix B by adding a note that checking the attestation boxes did not mean that the preceptor was attesting to the individual's "general clinical competency." This clarification was also added to Appendix D under the discussion of the preceptor attestations.		
Location	**Subject**	**Comment**
Appendix D (Pages D-7 and D-10)	Information on supervising individual for specific training	The language clarifying when the applicant had to provide information on the supervising individual providing the specific training required under 10 CFR 35.50(e) and 35.51(c), was not consistent.
NRC Staff Response: The guidance was revised for consistency.		

Location	Subject	Comment
Section 8.10 (Page 8-21), Section 8.11 (Page 8-23), Section 8.12 (Pages 8-27 and 8-28), Section 8.13 (Page 8-32), Section 8.14 (Pages 8-34 and 8-35), Appendix C (Pages C-9, C-12, C-14, and C-16), Appendix D (Page D-1), and Appendix E (Pages E-10, E-11, and E-12)	Experienced individuals using only accelerator-produced or discrete sources on radium-226 before the EPAct of 2005 and termination of NRC's Waiver of August 30, 2005	The guidance regarding individuals eligible to be recognized as an RSO, AU, AMP, or ANP because they only used accelerator produced materials or discreet sources of Radium-226 before the EPAct or termination of NRC's waiver of August 30, 2005, does not include the period before the NRC waiver.
NRC Staff Response: All the references have been changed to reflect that individuals using these materials before and during the waiver are included.		
Location	**Subject**	**Comment**
Appendix U (Page U-22)	Footnotes	The last digit in the numbers under "Thyrodial Component, Effective Half-Life" should reference numbers for footnotes 1 and 2 respectively.
NRC Staff Response: The correction was made.		
Location	**Subject**	**Comment**
Appendix H	NRC Form 314	The OMB date has expired
NRC Staff Response: The old form was replaced with the new form, including the new OMB expiration date.		