NUREG-1556
Volume 9, Rev. 3

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

Draft Report for Comment

Office of Nuclear Material Safety and Safeguards

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Federal Rulemaking Website: Go to http://www.regulations.gov and search for documents filed under Docket ID NRC-2016-0122. Address questions about NRC dockets to Carol Gallagher at 301-415-3463 or by e-mail at Carol.Gallagher@nrc.gov.

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ABSTRACT

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for the medical use of byproduct material. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License," and the NRC Form 313A series for authorized users (AU), authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), and Radiation Safety Officers (RSO). This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

The document contains appendices that include (i) copies of necessary forms; (ii) a sample license application for different types of medical uses of byproduct materials; and (iii) examples of the types of supporting documents, such as procedures, that may need to be prepared by applicants. Guidance in this document represents one means acceptable to NRC staff of complying with NRC regulations and is not intended to be the only means of satisfying requirements for a license.

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FOREWORD

The U.S. Nuclear Regulatory Commission's (NRC's) NUREG–1556 technical report series provides a comprehensive source of reference information about various aspects of materials licensing and materials program implementation. These reports, where applicable, describe a risk-informed, performance-based approach to licensing consistent with the current regulations. The reports are intended for use by applicants, licensees, license reviewers, and other NRC personnel. The NUREG–1556 series currently includes the following volumes:

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses
2	Program-Specific Guidance About Industrial Radiography Licenses
3	Applications for Sealed Source and Device Evaluation and Registration
4	Program-Specific Guidance About Fixed Gauge Licenses
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers
8	Program-Specific Guidance About Exempt Distribution Licenses
9	Program-Specific Guidance About Medical Use Licenses
10	Program-Specific Guidance About Master Materials Licenses
11	Program-Specific Guidance About Licenses of Broad Scope
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
18	Program-Specific Guidance About Service Provider Licenses
19	Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters" and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)
20	Guidance About Administrative Licensing Procedures
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator

The current document, NUREG–1556, Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," is intended for use by applicants, licensees, and other NRC staff. This revision provides a general update to the previous information contained in NUREG–1556, Volume 9, Revision 2, January 2008. See Appendix AA of this NUREG for a list of documents considered in the development of this NUREG–1556 report.

This report takes a risk-informed, performance-based approach to licensing the use of byproduct material for medical uses. A team composed of staff from NRC Headquarters, NRC regional offices, and Agreement States prepared this document, drawing on their collective experience in radiation safety in general and as specifically applied to medical uses of byproduct material.

The Medical Uses Licensee Toolkit, which contains the following items, serves as another source of guidance for the implementation of Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR Part 35:

- questions and answers on the implementation of 10 CFR Part 35
- specialty board certifications recognized by NRC
- Inspection Procedures for inspections of medical use licensees
- other guidance for emerging technology (10 CFR 35.1000) [e.g., Yttrium-90 Microsphere Brachytherapy, Leksell Gamma Knife Perfexion]
- list server subscription for automatic e-mail notifications of medical-related generic communications, *Federal Register* Notices, and NRC newsletters
- forms (e.g., Training and Experience for authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers; License Applications; Disposition of Materials)

NUREG–1556, Volume 9, Revision 3, is not a substitute for NRC or Agreement State regulations. The approaches and methods described in this report are provided for information only. Methods and solutions different from those described in this report may be acceptable, if they include a basis for the staff to make the determinations needed to issue or renew a license.

Daniel Collins, Director
Division of Material Safety, State, Tribal, and Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

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The working group would like to thank the staff in the regional offices of the U.S. Nuclear Regulatory Commission, the Advisory Committee on the Medical Uses of Isotopes, and all of the States who provided comments and technical information that assisted in the development of this report.

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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
AEA	Atomic Energy Act
ACMUI	Advisory Committee on the Medical Use of Isotopes
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	authorized medical physicist
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
AU	authorized user
AUD	Authorized User Diagnostic
AUS	Authorized User Sealed Source
AUT	Authorized User Therapy
bkg	background
Bq	becquerel
CEDE	committed effective dose equivalent
CFR	*Code of Federal Regulations*
Ci	curie
cc	cubic centimeter
cm	centimeter
cm^2	square centimeter
Co-57	cobalt-57
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DDE	deep-dose equivalent
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
FDA	U.S. Food and Drug Administration
GBq	gigabecquerel
GM	Geiger-Mueller
GSR	gamma stereotactic radiosurgery
HDR	high-dose rate
h	hour
I-125	iodine-125
I-131	iodine-131
ICRP	International Commission on Radiological Protection
IN	Information Notice
Ir-192	iridium-192
kBq	kilobecquerel
L/C	License Condition
LDR	low-dose rate
MBq	megabecquerels
MDR	medium-dose rate
mGy	milliGray
MML	Master Materials License
mCi	millicurie
mg	milligram
Mo-99	molybdenum-99
mR	milliroentgen

1	mrad	millirad
2	mrem	millirem
3	mSv	millisievert
4	NaI	sodium iodide
5	NARM	Naturally Occurring and Accelerator-Produced Material
6	NCRP	National Council on Radiation Protection and Measurements
7	NIST	National Institute of Standards and Technology
8	NMSS	Office of Nuclear Material Safety and Safeguards
9	NRC	U.S. Nuclear Regulatory Commission
10	NSTS	National Source Tracking System
11	NSTTR	National Source Tracking Transaction Report
12	NVLAP	National Voluntary Laboratory Accreditation Program
13	OMB	Office of Management and Budget
14	PET	Positron Emission Tomography
15	P-32	phosphorus-32
16	PDR	pulsed dose-rate
17	PII	Personally Identifiable Information
18	Q	quality factor
19	QA	quality assurance
20	R	roentgen
21	Ra-226	radium-226
22	Rb-82	rubidium-82
23	RG	Regulatory Guide
24	RIS	Regulatory Issue Summary
25	RSC	Radiation Safety Committee
26	RSO	Radiation Safety Officer
27	SDE	shallow-dose equivalent
28	SLN	sentinel lymph node
29	Sr-82	strontium-82
30	Sr-85	strontium-85
31	Sr-90	strontium-90
32	SSD	sealed source and device
33	std	standard
34	Sv	Sievert
35	Tc-99m	technetium-99m
36	TEDE	total effective dose equivalent
37	TI	Transport Index
38	TLD	thermoluminescent dosimeters
39	U-235	uranium-235
40	UN	United Nations
41	U.S.C.	United States Code
42	WD	written directive
43	Y-90	yttrium-90
44	yr	year
45	µCi	microcurie
46	µGy	microGray
47	%	percent

1 OVERVIEW

1.1 Purpose of Report

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

This report provides guidance to an applicant applying for medical use of byproduct material and also provides the U.S. Nuclear Regulatory Commission (NRC) staff with the criteria for evaluating such applications. This document uses the terms "byproduct material," "licensed material," and "radioactive material" interchangeably.

Chapter 8, "Contents of an Application," of this report identifies the information needed to complete the following application forms: NRC Form 313, "Application for Materials License" (see Appendix B of this NUREG), for medical use of byproduct material. Additionally, this report provides instructions and examples for completing the following supplemental NRC Form 313A series forms found in Appendix E:

- NRC Form 313A (RSO), "Radiation Safety Officer Medical Use Training and Experience Preceptor Attestation [10 CFR 35.50]"
- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]"
- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]"
- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 10 CFR 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]"
- NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 10 CFR 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"
- NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 10 CFR 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]"

This report outlines NRC criteria for evaluating a medical use license application and provides guidance for the following types of medical uses of byproduct material:

- use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive (WD) is not required under Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 35.40, "Written Directives" (see Subpart D, 10 CFR 35.100-190)
- use of unsealed byproduct material for imaging and localization studies for which a written directive (WD) is not required under 10 CFR 35.40 (see Subpart D, 10 CFR 35.200-290)
- use of unsealed byproduct material for which a WD is required under 10 CFR 35.40 (see Subpart E, 10 CFR 35.300-396)

- use of sources for manual brachytherapy (see Subpart F, 10 CFR 35.400-491)
- use of sealed sources for diagnosis (see Subpart G, 10 CFR 35.500-590)
- use of a sealed source in a photon-emitting remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (see Subpart H, 10 CFR 35.600-690)
- other medical uses of byproduct material or radiation from byproduct material not specifically covered by 10 CFR Part 35, "Medical Use of Byproduct Material," Subparts 35.100 through 35.600 (see 10 CFR 35.1000, Subpart K)

To assist applicants, this report includes gray text boxes at the beginning of each section to indicate the type of use to which the guidance pertains. These boxes are intended to guide the applicant through the sections of the guidance that are relevant to the applicant's particular type of use of byproduct material. A bullet indicates that applicants for that type of use should review the guidance section. Table 1-1 summarizes the material in the text boxes.

Table 1-1. Sections of NUREG–1556, Volume 9, Revision 3, That Applicants for a Particular Type of Use Should Review

NUREG–1556-Volume 9, Rev. 3 Section:		Type of Part 35 Use						
		100	200	300	400	500	600	1000
8.1	License Action Type	●	●	●	●	●	●	●
8.2	Name and Mailing Address of Applicant	●	●	●	●	●	●	●
8.3	Address(es) Where Licensed Material Will Be Used or Possessed	●	●	●	●	●	●	●
8.4	Person to Be Contacted about This Application	●	●	●	●	●	●	●
8.5.1	Byproduct Material and Depleted Uranium	●	●	●	●	●	●	●
8.5.2	Financial Assurance and Recordkeeping for Decommissioning	●	●	●	●	●	●	●
8.6	Purpose(s) for which Licensed Material Will Be Used	●	●	●	●	●	●	●
8.7	Individual(s) Responsible for Radiation Safety Program and their Training and Experience	●	●	●	●	●	●	●
8.7.1	Radiation Safety Officer (RSO)	●	●	●	●	●	●	●
8.7.2	Authorized Users (AUs)	●	●	●	●	●	●	●
8.7.3	Authorized Nuclear Pharmacist (ANP)	●	●	●				●
8.7.4	Authorized Medical Physicist (AMP)				●		●	●
8.8	Training for Individuals Working In or Frequenting Restricted Areas	●	●	●	●	●	●	●
8.9	Facilities and Equipment	●	●	●	●	●	●	●
8.9.1	Facility Diagram	●	●	●	●	●	●	●
8.9.2	Radiation Monitoring Instruments	●	●	●	●	●	●	●
8.9.3	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material	●	●	●				●
8.9.4	Therapy Unit - Calibration and Use				●		●	●
8.9.5	Other Equipment and Facilities	●	●	●	●	●	●	●
8.10	Radiation Protection Program	●	●	●	●	●	●	●

Table 1-1. Sections of NUREG–1556, Volume 9, Revision 3, That Applicants for a Particular Type of Use Should Review								
NUREG–1556-Volume 9, Rev. 3 Section:		Type of Part 35 Use						
		100	200	300	400	500	600	1000
8.10.1	Audit Program	●	●	●	●	●	●	●
8.10.2	Occupational Dose	●	●	●	●	●	●	●
8.10.3	Public Dose	●	●	●	●	●	●	●
8.10.4	Operating and Emergency Procedures	●	●	●	●	●	●	●
8.10.5	Spill/Contamination Procedures	●	●	●	●	●	●	●
8.10.6	Emergency Procedures for Therapy Devices Containing Sealed Sources						●	●
8.10.7	Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						●	●
8.10.8	Ordering and Receiving	●	●	●	●	●	●	●
8.10.9	Opening Packages	●	●	●	●	●	●	●
8.10.10	Material Receipt and Accountability	●	●	●	●	●	●	●
8.10.11	Leak Tests	●	●	●	●	●	●	●
8.10.12	Sealed Source Inventory	●	●	●	●	●	●	●
8.10.13	Area Surveys	●	●	●	●	●	●	●
8.10.14	Procedures for Administrations When a Written Directive Is Required			●	●		●	●
8.10.15	Safe Use of Unsealed Licensed Material	●	●	●				●
8.10.16	Safety Procedures for Treatments When Patients Are Hospitalized			●	●		●	●
8.10.17	Mobile Medical Service	●	●	●	●	●	●	●
8.10.18	Release of Patients or Human Research Subjects			●	●			●
8.10.19	Minimization of Contamination	●	●	●	●	●	●	●
8.10.20	Records of Dosages and Use of Brachytherapy Source	●	●	●	●			●
8.10.21	Recordkeeping	●	●	●	●	●	●	●
8.10.22	Reporting	●	●	●	●	●	●	●
8.10.23	Transportation	●	●	●	●	●	●	●
8.10.24	Security Program for Category 1 and Category 2 Materials				●		●	●
8.11	Waste Management	●	●	●	●	●	●	●
8.12	License Fees	●	●	●	●	●	●	●
8.13	Certification	●	●	●	●	●	●	●

Applicants should also be aware that 10 CFR Part 35 contains general information, administrative requirements, and technical requirements that are pertinent to some or all of the types of use listed above. See 10 CFR 35.1 through 35.92.

This report is intended to consolidate, into one document, guidance that relates to satisfying regulations other than 10 CFR Part 35 that apply to medical use licensees, including the following:

- provisions of 10 CFR Part 20, "Standards for Protection Against Radiation," that relate to radiation safety

- provisions of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," that relate to licensing (e.g., 10 CFR 30.33, "General requirements for issuance of specific licenses")

This report does not address certain aspects of licensing and radiation safety for the medical use of byproduct materials. In particular, applicants and licensees should consider the following:

- NUREG–1556, Volume 15, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"

- 10 CFR Part 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations"

- 10 CFR Part 21, "Reporting of Defects and Noncompliance"

Other regulatory requirements potentially applicable to medical use licensees listed in Chapter 4, "Applicable Regulations" Section 1.2.2, "Specific License of Broad Scope," provides a general discussion on specific licenses of broad scope. NUREG–1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," provides additional licensing guidance on medical use programs of broad scope.

This report does not address the commercial aspects of manufacturing, distribution, and service of sources containing byproduct material in devices. Licensees should review NUREG–1556, Volume 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," and NUREG–1556, Volume 18, "Program-Specific Guidance About Service Provider Licenses."

This report does not address the accelerator production of radionuclides by the medical use licensee for either commercial or noncommercial distribution of radionuclides. Licensees should review NUREG–1556, Volume 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses," and NUREG–1556, Volume 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," for additional guidance. "Consortium," as used here and in 10 CFR Part 30, is defined as an association of medical use licensees and a Positron Emission Tomography (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 distribution among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution, a Federal facility, or a medical facility.

Specific guidance for applicants requesting authorization to produce radioactive material using an accelerator is included in NUREG–1556, Volume 21, "Consolidated Guidance About

Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator," and is not within the scope of this guidance for medical use licensees. Note that this guidance should be used for the activities that take place after the radiochemical is produced, which would include the radiochemistry or compounding of the radiochemical into a radiopharmaceutical by an ANP or qualified AU for the applicant's medical use.

As a guidance document intended to assist a wide variety of applicants, this report contains a considerable amount of information about how licensees may choose to implement programs to meet NRC regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the regulations in 10 CFR. This report provides specific guidance on what information should be submitted in an application to satisfy NRC requirements. Except for procedures required by Subpart H, "Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units," of 10 CFR Part 35, written procedures do not need to be submitted as part of the license application.

Guidance and model procedures provided in this NUREG that are not required to be submitted are for illustrative purposes to guide licensees in developing programs. Use of the word "should" implies "may" and is not intended to mean "must" or "shall;" the procedures provided in this guidance are intended to serve only as examples.

Chapters 1 through 7 of this document provide background information. Chapter 8 describes, item by item, the information that should be provided in Items 1 through 11 of NRC Form 313, in completing a license application.

The format within this document for each item of technical information is as follows:

- Regulations—references the regulations applicable to the item.
- Criteria—outlines the criteria used to evaluate the applicant's response.
- Discussion—provides additional information about the topic.
- Response from Applicant—provides suggested response or responses, offers the option of an alternative reply, or indicates that no response is needed on that topic during the licensing process.

Notes and references are self-explanatory and may not be found for each item on NRC Form 313.

Some sections of the guidance include references to other documents or resources that may be useful to the applicant. Appendix AA of this NUREG provides a complete list of documents that were used to prepare or are referenced in this guidance. If reference or resource documents or resources include information conflicting with current regulations, the regulations in 10 CFR apply. For example, some references or resources may include alternate limits for occupational and public dose; however, licensees should note that the limits in 10 CFR Part 20 are applicable. Many of the documents may be accessed online at the NRC Library or using the links provided in Appendix AA of this NUREG. See the Notice of Availability on the inside front cover of this report for more information.

NRC Form 313 does not have sufficient space to provide full responses to Items 5 through 11, as indicated on the form. Applicants should address those items on separate sheets of paper and submit them along with the completed NRC Form 313. For the convenience and streamlined handling of medical use applications, Appendix C of this NUREG may be used to provide supporting information. Additionally, Appendix D of this NUREG describes how to fill out the NRC Form 313A series of forms.

Other appendices to this report provide the following supplementary information:

- Appendix A provides a copy of the NRC's Safety Culture Policy Statement.
- Appendix F provides a checklist for withholding proprietary information.
- Appendices G through W provide model procedures.
- Appendices X, Y, and Z provide recordkeeping, reporting, and transportation requirements, respectively.
- Appendix AA provides a list of references and resources.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in 10 CFR Part 20. To describe units of radiation exposure or dose, rem and its International System of Units equivalent, sievert (Sv) (1 rem = 0.01 Sv), are used. This is because 10 CFR Part 20 sets dose limits in terms of rem (Sv), rather than rad or roentgen. When the radioactive material emits beta and gamma rays, 1 roentgen is assumed to equal 1 rad, which is assumed to equal 1 rem. For alpha and neutron-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from absorbed dose (rad) from alpha particles and neutrons requires the use of an appropriate quality factor (Q) value. These Q values are used to convert absorbed dose (rad) to dose equivalent (rem); Tables 1004(b)(1) and (2) in 10 CFR 20.1004, "Units of radiation dose," address the Q values for alpha and neutrons.

1.2 Types of Licenses

Specific Medical Use License

The NRC defines "medical use" as "the intentional internal or external administration of byproduct material, or the radiation from byproduct material, to patients or human research subjects under the supervision of an authorized user" (10 CFR 35.2, "Definitions"). An "authorized user" is defined as "a physician, dentist, or podiatrist" who meets the training and experience requirements specified in the board certification pathway in the applicable sections of 10 CFR Part 35 or who is identified as an AU (i) on an NRC or Agreement State license, (ii) on a permit issued by an NRC master materials licensee or an NRC master materials broad scope permittee that is authorized to permit the medical use of byproduct material, or (iii) on a permit issued by an NRC or Agreement State broad scope licensee authorized to permit the medical use of byproduct material (10 CFR 35.2).

The NRC issues two types of specific licenses for the medical use of byproduct material in medical practices and facilities:

- the specific license of limited scope (see Section 1.2.1)
- the specific license of broad scope (see Section 1.2.2)

Medical use includes research involving human subjects, which may occur under either limited scope or broad scope specific licenses (see Section 1.2.3).

Although the NRC usually issues a single byproduct materials license to cover an entire radionuclide program, the NRC may issue separate licenses to individual licensees for different medical uses. The NRC does not usually issue separate licenses to different departments in a medical facility or to individuals employed by a medical facility or with whom the medical facility has contracted. Only the facility's management may sign the license application.

General Laboratory License

The NRC also issues a general license, pursuant to 10 CFR 31.11, under which a physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital may use byproduct material for certain *in vitro* clinical or laboratory testing. Such testing does not involve internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals (see Section 1.2.4).

Overview

Applicants should study this report, related guidance, and all applicable regulations carefully before completing NRC Form 313 and the NRC Form 313A series of forms. The NRC expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to NRC Form 313. When necessary, the NRC may ask the applicant for additional information in order to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- statements, representations, and procedures contained in the application and in correspondence with the NRC, when incorporated into a license by reference
- terms and conditions of the license
- NRC regulations

In 10 CFR 30.9, "Completeness and Accuracy of Information," the NRC requires that the information in the application be complete and accurate in all material aspects. This includes preceptor attestations for training and experience for authorized individuals, as described in IN-2007-38, "Ensuring Complete and Accurate Information in the Documentation of Training and Experience for Individuals Seeking Approval as Medical Authorized Users," December 14, 2007.

Information is considered material if it has the ability to change or affect an agency decision on issuing the license.

1.2.1 Specific License of Limited Scope

The NRC issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one

medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license, because 10 CFR 30.33(a)(2) refers to the applicant's facilities. Since a physicians' group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are specifically listed in the license.

Byproduct material may be administered to patients on an inpatient (i.e., hospitalized) or outpatient basis. For patients to whom byproduct material is administered and who are not releasable under 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms; therefore, procedures requiring hospitalization of the patient under 10 CFR 35.75 cannot be performed.

A specific license of limited scope may also be issued to an entity requesting authorization to perform mobile medical services (10 CFR 35.80, "Provision of a Mobile Medical Service;" 10 CFR 35.647 "Additional Technical Requirements for Mobile Remote Afterloader Units"). A medical institution or a private or group practice may apply for authorization to use byproduct material in a mobile medical service.

1.2.2 Specific License of Broad Scope

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal, and medical procedures may request a specific license of broad scope in accordance with 10 CFR Part 33. No medical use of byproduct material, including research involving human subjects, may be conducted without an authorization in a license from the NRC or an Agreement State, as provided in 10 CFR Part 35. The criteria for the various types of broad scope licenses are found in 10 CFR 33.13 through 10 CFR 33.17. Generally, the NRC issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of byproduct material for medical use under Part 35, as well as other uses) to institutions that (i) have experience successfully operating under a specific license of limited scope and (ii) are engaged in medical research and routine diagnostic and therapeutic uses of byproduct material. NUREG–1556, Volume 11, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," offers additional guidance to applicants for a specific license of broad scope.

1.2.3 Research Involving Human Subjects

In 10 CFR 35.2, the definition of "medical use" includes the administration of byproduct material or radiation therefrom to human research subjects. Furthermore, 10 CFR 35.6, "Provisions for the protection of human research subjects," addresses the protection of the rights of human subjects involved in research by medical use licensees. For these licensees, prior NRC approval is not necessary if the research is conducted, funded, supported, or regulated by another Federal Agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an Institutional Review Board, in accordance with the meaning of those terms under the Federal Policy. In accordance with 10 CFR 35.6(a), research involving human subjects shall be conducted only with byproduct materials listed in the license for the uses authorized in the license. IN 2000-19, "Implementation of Human Research

Protocols Involving U.S. Nuclear Regulatory Commission Regulated Materials," December 5, 2000, reminds licensees that 10 CFR 35.6 is not a blanket authority to conduct research involving human subjects, and compliance with all regulatory requirements and license conditions is necessary.

1.2.4 General *In Vitro* License

In 10 CFR 31.11, "General license for use of byproduct material for certain *in vitro* clinical or laboratory testing," NRC establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain byproduct material for *in vitro* clinical or laboratory tests not involving "medical use" (i.e., not involving administration to humans). 10 CFR 31.11 explains the requirements for using the materials listed. If the general license alone meets the applicant's needs, only NRC Form 483, "Registration Certificate – *In Vitro* Testing With Byproduct Material Under General License," needs to be filed. Medical use licensees authorized under 10 CFR Part 35 do not need to file the form.

The NRC limits possession to a total of 200 microcuries (µCi) [7.4 megabecquerels (MBq)] of photon-emitting materials listed in 10 CFR 31.11 at any one time, at any one location of storage or use. The use of materials listed in 10 CFR 31.11 within the inventory limits of that section is subject only to the requirements of that section and not the requirements of 10 CFR Parts 19, 20, and 21, except as set forth in 10 CFR 31.11.

An applicant needing more than 200 µCi [7.4 MBq] of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on NRC Form 313. This type of applicant generally requests an increased limit of 3 millicuries [111 MBq]. If requesting an increased inventory limit, the applicant will be subject to the requirements of 10 CFR Parts 19, 20, and 21, including the requirements for waste disposal.

1.3 Other Requirements

1.3.1 The "As-Low-As-Reasonably-Achievable (ALARA) Concept

In 10 CFR 20.1101, "Radiation protection programs," regulations state that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities…" and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are…ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

References and Resources: Applicants should consider the ALARA philosophy detailed in the following reports when developing plans to work with licensed radioactive materials. The following documents and resources contain information, methods, and references useful to

those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities:

- Regulatory Guide (RG) 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA," September 1975.

- RG 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," February 1996.

- RG 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be ALARA," April 2011.

- NUREG–1736, "Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation," contains information directly related to radiation protection standards in 10 CFR Part 20.

- National Council on Radiation Protection and Measurements (NCRP) Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," December 31, 1990.

- NCRP Report No. 127, "Operational Radiation Safety Program," 1998.

WRITTEN DIRECTIVE PROCEDURES

In 10 CFR 35.41, "Procedures for administrations requiring a written directive," certain medical use licensees are required to develop, implement, and maintain written procedures to provide high confidence that before each administration requiring a WD, the patient's identity is verified, and the administration is in accordance with the WD. This regulation also specifies what an applicant must, at a minimum, address in these procedures. Appendix S of this NUREG provides further information on developing these procedures.

1.3.2 Office of Management and Budget (OMB) Clearances

The information collection requirements in 10 CFR Parts 30 and 35, NRC Form 313, and the NRC Form 313A series of forms have been approved under the OMB Clearance Numbers 3150-0017, 3150-0010, and 3150-0120, respectively.

2 AGREEMENT STATES

2.1 Jurisdiction Determination

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

Certain States, called Agreement States (see Figure 2-1), have entered into agreements with the U.S. Nuclear Regulatory Commission (NRC) that give them the authority to license and inspect byproduct, source, and special nuclear materials, in quantities not sufficient to form a critical mass, which are used or possessed within their borders. Any applicant, other than a Federal entity, who wishes to possess or use licensed material in one of these Agreement States should contact the responsible officials in that State for guidance on preparing an application. These applications should be filed with State officials, not with the NRC. In areas under exclusive Federal jurisdiction within an Agreement State, the NRC continues to be the regulatory authority.

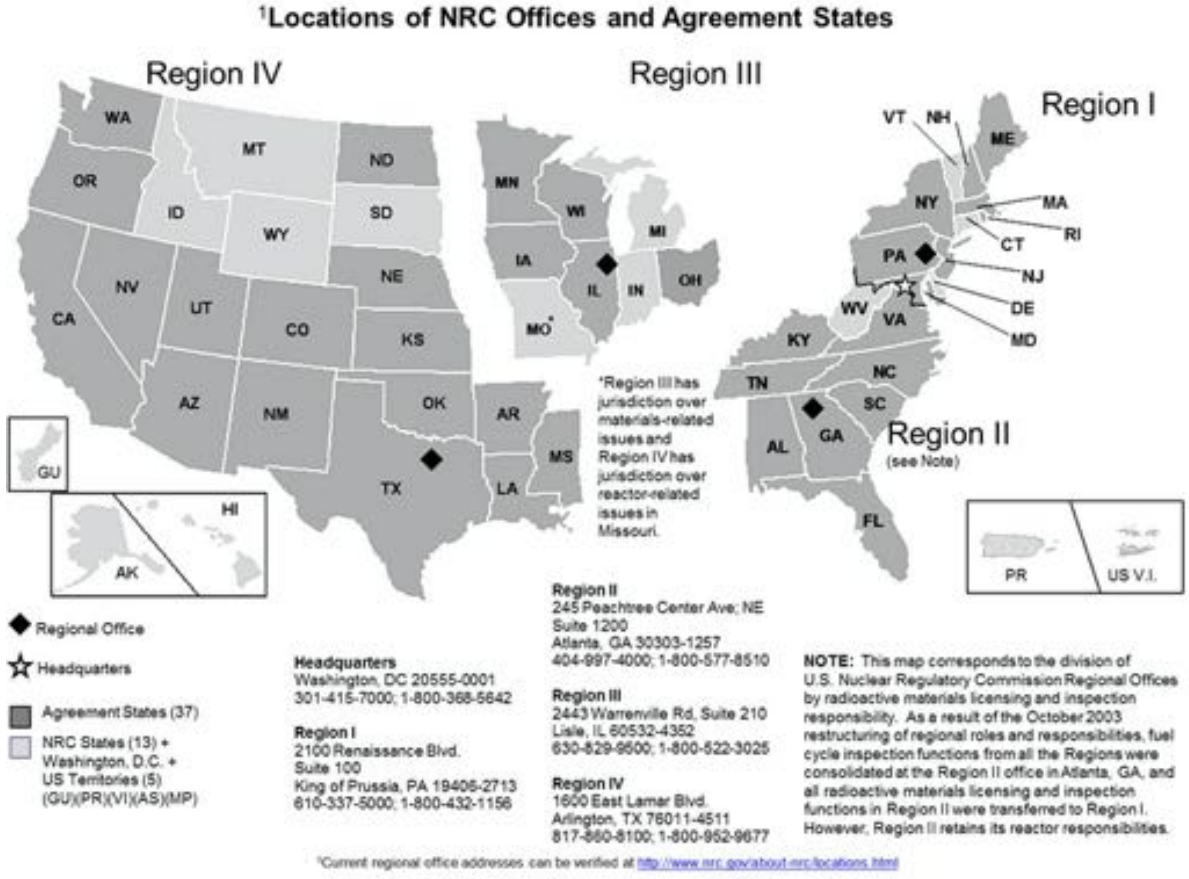


Figure 2-1. U.S. Map: Locations of NRC Offices and Agreement States

In the special situation of work at federally controlled sites in Agreement States, it is necessary to ascertain the jurisdictional status of the area to determine whether the NRC or the Agreement

State has regulatory authority. These areas can also include Tribal lands of federally recognized Indian tribes.[2]

The NRC has regulatory authority over land determined to be "exclusive Federal jurisdiction," while the Agreement State has jurisdiction over nonexclusive Federal jurisdiction land. Applicants are responsible for determining, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. Additional guidance on determining jurisdictional status is found in the Office of Nuclear Material Safety and Safeguards (NMSS) procedures in the State Agreement series, SA-500, "Jurisdiction Determination."

Table 2-1 provides a quick way to evaluate whether the NRC or an Agreement State has regulatory authority.

Table 2-1. Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that the U.S. Department of Energy and, under most circumstances, its prime contractors are exempt from licensing, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.12, "Persons using byproduct material under certain U.S. Department of Energy and U.S. Nuclear Regulatory Commission contracts")	NRC
Non-Federal entity in non-Agreement State, District of Columbia, U.S. territory or possession, or in offshore Federal waters	NRC
Federally recognized Indian Tribe or Tribal member on Indian Tribal land	NRC
Non-Federal entity on federally recognized Indian Tribal land	NRC[3]
Federally recognized Indian Tribe or Tribal member outside of Indian Tribal land in Agreement State.	Agreement State
Non-Federal entity in Agreement State	Agreement State[4]

[2]For the purposes of this guidance, an "Indian tribe" is defined as an Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994. A list of federally recognized tribes is available at http://www.bia.gov.

[3]The NRC can exercise jurisdiction as the regulatory authority on tribal land of a federally recognized Indian Tribe. Section 274b. agreements do not give States the authority to regulate nuclear material in these areas. However, there may be States that exercise regulatory authority over these areas based on treaties or agreements with specific tribes. Companies owned or operated by federally recognized Indian Tribe members or non-Indians that wish to possess or use licensed material on Tribal lands should contact the appropriate NRC regional office to determine the jurisdictional status of the Tribal lands and identify the appropriate regulatory agency for licensing and reciprocity.

[4]Section 274m. of the Atomic Energy Act (AEA) withholds to the NRC regulatory authority over radioactive materials covered under the Section 274b. agreements when the activity can affect the Commission's authority to protect the common defense and security, to protect restricted data, or guard against the loss or diversion of special nuclear material. (This is an uncommon situation that NRC usually evaluates on a case-by-case basis.) Individuals or companies wishing to possess or use licensed material should contact the licensee to determine the jurisdictional status for specific AEA radioactive materials they intend to possess or use.

Table 2-1. Who Regulates the Activity?	
Applicant and Proposed Location of Work	**Regulatory Agency**
Non-Federal entity in Agreement State at federally controlled site **not** subject to exclusive Federal jurisdiction	Agreement State[4]
Non-Federal entity in Agreement State at federally controlled site subject to exclusive Federal jurisdiction	NRC
Non-Federal entity in Agreement State using radioactive materials (except industrial radiography) directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	NRC
Non-Federal entity in Agreement State using radioactive materials **not** directly connected with 10 CFR Part 50 or 52 reactor operations or needed during the construction and preoperational phases of a reactor.	Agreement State[4]

Reference: A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) is available on the NMSS Directory of Agreement State and Non-Agreement State Directors and State Liaison Officers. A request for the list can also be made to an NRC regional office.

2.2 Reciprocal Recognition of Specific Licenses

Performing licensed activities in other jurisdictions is possible through reciprocal recognition of specific licenses (i.e., reciprocity). Agreement States have reciprocity provisions that permit NRC licensees to perform licensed activities under circumstances when an Agreement State is the regulatory authority (See Section 2.1). NRC licensees and Agreement State licensees are subject to the regulations of the regulatory authority, as indicated in Section 2.1. To ensure compliance with an Agreement State's reciprocity requirements, licensees are advised to request authorization from the appropriate Agreement State radiation control program office well in advance of the scheduled use of licensed material.

Agreement State licensees that wish to conduct licensed activities in areas under NRC jurisdiction must either obtain a specific NRC license or file for reciprocity with the appropriate NRC regional office for the Agreement State that issued their license. Failure to file for reciprocity or obtain a specific NRC license before working in areas under NRC jurisdiction can result in NRC enforcement action, which may include civil penalties. The reciprocity filing must be renewed annually.

Specific guidance regarding NRC licensees filing for reciprocity in Agreements States and Agreement State licensees filing for reciprocity with the NRC or another Agreement State are provided in NUREG–1556, Volume 19, "Consolidated Guidance About Materials Licenses: Guidance for Agreement State Licensees About NRC Form 241 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and 'Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity).'"

3 MANAGEMENT RESPONSIBILITY

The U.S. Nuclear Regulatory Commission (NRC) recognizes that effective radiation safety program management is vital for achieving safe, secure, and compliant operations. Consistent compliance with NRC regulations provides reasonable assurance that licensed activities will be conducted safely and that effective management will result in increased safety, security, and compliance. See Title 10 of the *Code of Federal Regulations* (10 CFR) 35.24, "Authority and responsibilities for the radiation protection program."

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

"Management," as used in this volume, refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

3.1 Commitments and Responsibilities

To ensure adequate management involvement in accordance with 10 CFR 35.12(a), "Application for license, amendment, or renewal," and 35.24(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted application. If it is not clear whether the application was signed by someone duly authorized to act for and on behalf of the applicant or licensee, NRC license reviewers may ask for additional assurances that the individual who signed the application is duly authorized to act for and on behalf of the applicant or licensee. The signature on an application acknowledges the licensee's commitments and responsibility for the following:

- Radiation safety, security, and control of radioactive materials and compliance with regulations.
- Completeness and accuracy of the radiation safety records and all information provided to the NRC (10 CFR 30.9, "Completeness and accuracy of information").
- Knowledge about the contents of the license application.
- Compliance with current NRC and U.S. Department of Transportation regulations, the licensee's operating, emergency, and security procedures, and NRC license commitments.
- Commitment to provide adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards and that compliance with regulations is maintained.
- Selection and assignment of a qualified individual to serve as the radiation safety officer (RSO), who agrees, in writing, to be responsible for implementing the radiation protection program. The RSO shall have independent authority to stop unsafe operations and will be given sufficient time to fulfill radiation safety duties and responsibilities.
- Commitment to ensure that radiation workers have adequate training.

- Prevention of discrimination against employees engaged in protected activities (10 CFR 30.7, "Employee protection").

- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in 10 CFR 30.7, "Employee protection," and 10 CFR 30.10, "Deliberate misconduct."

- Commitment to obtain NRC's prior written consent before transferring control of the license (see Section 9.2.1, "Transfer of Control," of this NUREG.)

- Notification of the appropriate NRC regional administrator in writing, immediately following the filing of petition for voluntary or involuntary bankruptcy (10 CFR 30.34(h)), as discussed further in Section 9.2.2, "Notification of Bankruptcy Proceedings," of this NUREG.

- Approval of qualified individual(s) to serve as authorized medical physicists, authorized nuclear pharmacist, and authorized users for licensed activities.

For information on inspection, investigation, enforcement, and other compliance programs, see a description of the NRC's Enforcement process at NRC Enforcement Policy and the NRC's Inspection Procedures found on the Medical Uses Licensee Toolkit.

3.2 Safety Culture

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority.

"Nuclear safety culture" is defined in the NRC's Safety Culture Policy Statement (76 FR 34773; June 14, 2011) as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to Table 3-1 for the traits of a positive safety culture from NRC's Safety Culture Policy Statement.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance, to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety

culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The NRC, as the regulatory agency with an independent oversight role, reviews the performance of individuals and organizations to determine compliance with requirements and commitments through its existing inspection and assessment processes. However, the NRC's Safety Culture Policy Statement and traits are not incorporated into the regulations. Many of the safety culture traits may be inherent to an organization's existing radiation safety practices and programs. For instance, time-outs before a therapeutic procedure may provide an opportunity for the medical team to double-check treatment parameters and the WD to reduce the likelihood of a medical event. The use of time-outs may correspond with the safety culture trait "Work Processes" (the process of planning and controlling work activities is implemented so that safety is maintained) (Table 3-1). However, licensees should be aware that this is just an example and should consider reviewing their radiation safety programs in order to develop and implement a safety culture commensurate with the nature and complexity of their organizations and functions.

Refer to Appendix A of this NUREG for the NRC's Safety Culture Policy Statement. More information on NRC activities relating to safety culture can be found on the NRC Safety Culture Web site.

Table 3-1. Traits of a Positive Safety Culture

Leadership Safety Values and Actions	**Problem Identification and Resolution**	**Personal Accountability**
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.

Table 3-1. Traits of a Positive Safety Culture		
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

4 APPLICABLE REGULATIONS

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable regulations, to read and understand the requirements of each of these regulations, and to comply with each applicable regulation. The following parts of Title 10 of the *Code of Federal Regulations* (CFR) contain regulations applicable to licensing medical use of byproduct material. materials. Some of these parts are specific to one type of license, while others are general and will apply to many, if not all, licensees.

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

The current versions of the following parts can be found online in the U.S. Nuclear Regulatory Commission (NRC) library using the links provided:

- 10 CFR Part 2 "Agency Rules of Practice and Procedure"
- 10 CFR Part 19 "Notices, Instructions, and Reports to Workers: Inspection and Investigations"
- 10 CFR Part 20 "Standards for Protection Against Radiation"
- 10 CFR Part 21 "Reporting of Defects and Noncompliance"
- 10 CFR Part 30 "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 CFR Part 31 "General Domestic Licenses for Byproduct Material"
- 10 CFR Part 32 "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 CFR Part 33 "Specific Domestic Licenses of Broad Scope for Byproduct Material"
- 10 CFR Part 35 "Medical Use of Byproduct Material"
- 10 CFR Part 37 "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
- 10 CFR Part 40 "Domestic Licensing of Source Material"
- 10 CFR Part 71 "Packaging and Transportation of Radioactive Material"
- 10 CFR Part 150 "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 10 CFR Part 170 "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"

- 10 CFR 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"

Copies of these documents may be obtained by calling the Government Printing Office Customer Contact Center toll-free at (866) 512-1800, or in Washington, DC; calling (202) 512-1800; or online at the U.S. Government Bookstore.

NRC regulations can also be accessed on the NRC Regulations Web site. Regulations are periodically amended, and the NRC (as well as all other Federal agencies) is required to publish notice of such amendments in the *Federal Register*.

5 HOW TO FILE

5.1 Application Preparation

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

Applicants for a materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete U.S. Nuclear Regulatory Commission (NRC) Form 313 (Appendix B of this NUREG), Items 1 through 4, 12, and 13 on the form itself.
- Complete NRC Form 313, Items 5 through 11, on supplementary pages, or use Appendix C of this NUREG.
- Complete the appropriate NRC Form 313A series (Appendix E of this NUREG) of forms to document training and experience.
- Provide sufficient detail for the NRC to determine that equipment, facilities, training, experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property.
- For each separate sheet other than the NRC Forms 313 and 313A series (Appendix B and Appendix E of this NUREG) or Appendix C of this NUREG submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers.
- Avoid submitting proprietary information and personally identifiable information.
- If submitted, proprietary information and other sensitive information (e.g., personal privacy and security related) should be clearly identified in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 2.390, "Public inspections, exemptions, and requests for withholding." (See Chapter 6, "Identifying and Protecting Sensitive Information.")

5.2 Where to File

Applicants wishing to possess or use licensed material in any State, U.S. territory, or U.S. possession subject to NRC jurisdiction must file an application with the NRC regional office for the locale in which the material will be possessed or used. Figure 2-1 identifies the NRC's four regional offices and their respective areas for licensing purposes and the Agreement States. Section 8.10.17, "Mobile Medical Service," and Appendix V of this NUREG provide further information on filing procedures for applicants who wish to perform mobile medical services. Note that all materials license applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in the Region II geographical area should send their applications to Region I.

In general, applicants wishing to possess or use licensed material in Agreement States must file an application with the Agreement State and not with the NRC. However, if work will be conducted at federally controlled sites, or federally recognized Indian Tribal lands, in Agreement

States, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See Chapter 2, "Agreement States," for additional information.

5.3 Paper Applications

Paper applications received by the NRC are scanned through an optical character reader and converted to an electronic format. To ensure a smooth transfer to an electronic format, applicants should do the following:

- Submit all documents, typed, on 8½ × 11-inch or legal-sized paper that will feed easily into a document scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, or Futura (the text of this document is in the Arial font).
- Use 11-point or larger font.
- Avoid stylized characters, such as script or italics.
- Ensure that the print is clear and sharp.
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

Applications must be signed by the applicant's or licensee's management, as required by 10 CFR 35.12(a). (See Section 8.13, "Certification.")

5.4 Electronic Applications

Applications may be submitted in electronic form via the NRC's Electronic Information Exchange or CD-ROM. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's e-submittal Web site. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of non-public information.

6 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

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

All licensing applications, except for portions containing sensitive information, will be made available for review in the U.S. Nuclear Regulatory Commission's (NRC's) Public Document Room and electronically at the NRC Library.

The applicant or licensee should identify, mark, and protect sensitive information against unauthorized disclosure to the public. License applications that contain sensitive information should be marked, as indicated below, in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 2.390 before the information is submitted to the NRC. Key examples are as follows:

- Proprietary Information and Trade Secrets: If it is necessary to submit proprietary information or trade secrets, follow the procedure in 10 CFR 2.390(b). Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Appendix F includes a checklist for requests for withholding information from public disclosure.

- Personally Identifiable Information: Personally identifiable information (PII) about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of PII are social security number, home address, home telephone number, date of birth, and radiation dose information. If PII is submitted, a cover letter should clearly state that the attached documents contain PII, and the top of every page of a document that contains PII should be clearly marked as follows: "Privacy Act Information—Withhold Under 10 CFR 2.390." For further information, see Regulatory Issue Summary (RIS) 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission," dated March 9, 2007, and Information Notice 2013-22, "Recent Licensing Submittals Containing Personally Identifiable Information," dated November 15, 2013, which can be found on the NRC's Generic Communications Web page.

- Security-Related Sensitive Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid the release of information that terrorists could use to plan or execute an attack against facilities or citizens in the U.S. As a result, certain types of information are no longer routinely released and are treated as sensitive unclassified information. For example, certain information about the quantities and locations of radioactive material at licensed facilities, and associated security measures, are no longer released to the public. Therefore, a cover letter should clearly state that the attached documents contain security-related sensitive information and the top of every page of a document that contains such information should be clearly marked: "Security Related Information—Withhold Under 10 CFR 2.390." For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see 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," December 22, 2005. Additional information on procedures and any updates are available in the NRC Library on the Witholding of Sensitive Information page.

The regulations list various forms of information that can be protected from public disclosure. These include:

- trade secrets and commercial or financial information
- interagency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with NRC
- certain records or information compiled for law enforcement purposes
- geological and geophysical information and data, including maps, or information concerning wells
- personnel, medical, and other information, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

In 10 CFR 2.390, NRC specifies the procedures and requirements for persons to submit sensitive information to NRC so that it may be properly protected from disclosure.

Except for personal privacy information, which is not subject to the affidavit requirement, if NRC determines that the application or affidavit is deficient (i.e., does not contain the required information as outlined in 10 CFR 2.390), the applicant will be notified that additional information is needed and that the review will continue when the required information is received.

If the request is denied, in whole or in part, NRC will give the applicant the option of withdrawing the information or application, as permitted in 10 CFR 2.390. If the applicant decides not to withdraw the information or application, NRC will notify the applicant in writing that the request for withholding has been denied and that NRC will disregard any references concerning the proprietary status of the information.

Any part of a license application or information provided by a licensee or applicant that the NRC determines should be withheld from public disclosure will be handled in accordance with Management Directive 12.6, "NRC Sensitive Unclassified Information Security Program," and the licensee or applicant will be notified in writing that NRC plans to honor the request.

Anyone submitting a request to withhold information from public disclosure should thoroughly review 10 CFR 2.390 and be familiar with its requirements and limitations.

Withholding from public inspection will not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, NRC may send copies of this information to NRC consultants working in that area. NRC will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, the licensee or applicant should promptly notify the NRC. The licensee or applicant also should understand that NRC may have cause to review this determination in the future; for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if NRC makes a determination adverse to the above, the licensee or applicant will be notified in advance of any public disclosure. Anyone submitting commercial or financial information they believe to be privileged, confidential, or a trade secret must remember that the NRC's policy is to achieve an effective balance between legitimate concerns for the protection of competitive positions and the right of the public to be fully apprised of the basis for, and the effects of, licensing or rulemaking actions. It is within NRC's discretion to withhold such information from public disclosure.

7 APPLICATION AND LICENSE FEES

Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 170.31, "Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses," to determine the amount of the fee. The U.S. Nuclear Regulatory Commission (NRC) will not issue a license until the fee is received. Consult 10 CFR 170.11, "Exemptions," for information on exemptions from these fees. Once the technical review of an application has begun, no fees will be refunded. Application fees will be charged regardless of the NRC's disposition of an application or the withdrawal of an application.

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

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16, "Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC." Consult 10 CFR 171.11 for information on exemptions from annual fees and 10 CFR 171.16(c) on reduced annual fees for licensees that qualify as "small entities." Note that in order to pay reduced fees, a licensee that qualifies as a "small entity" must provide proper certification of this status to the NRC each year, along with its annual fee payment.

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 by calling the Office of the Chief Financial Officer at NRC Headquarters in Rockville, Maryland, 301-415-7554. Information about fees may also be obtained by calling NRC's toll-free number, 800-368-5642, extension 415-7554. The e-mail address is Fees.Resource@nrc.gov.

8 CONTENTS OF AN APPLICATION

This chapter explains, item by item, the information that medical use applicants must provide on U.S. Nuclear Regulatory Commission (NRC) Form 313 and should provide on the appropriate NRC Form 313A series of forms, if electing to use these optional forms. See Appendix D of this NUREG for details on how to complete the NRC Form 313A series of forms.

All items in the application should be completed in enough detail for the NRC to determine whether the proposed equipment, facilities, training and experience, and the radiation safety program satisfy regulatory requirements and are adequate to protect public health and safety and minimize danger to life and property. Consideration should be given when developing the application to the concepts of keeping exposure as low as is reasonably achievable (ALARA), minimizing contamination, and maintaining control of radioactive materials.

Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 20.1101(b) states: "The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Regulatory Guide (RG) 8.10, Revision 2, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," discusses the ALARA concept and philosophy. The application should document ALARA considerations, including establishing administrative action levels and monitoring programs.

10 CFR 20.1406, "Minimization of contamination," requires applicants for licenses to describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste. As with ALARA considerations, applicants should address these concerns for all aspects of their programs.

The application should include information on how the licensee will implement the security requirements in 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material not in storage."

If an application contains security-related sensitive information, the cover letter should state that the "attached documents contain security-related sensitive information." See Chapter 6, "Identifying and Protecting Sensitive Information," for more instructions on marking sensitive documents submitted to the NRC. If a cover letter is not used, NRC Form 313 should include this statement. The information needed to complete Items 5 through 11 on Form 313 describes the applicant's proposed medical use radiation safety program. To assist the applicant in submitting complete information on these items, the applicable regulations are referenced in the discussion of each item.

Tables C–1 and C–2 in Appendix C of this NUREG are provided to help applicants submit information required to complete Items 5 through 11 of NRC Form 313. Lengthy responses and supplemental information should be appended as attachments.

Table C–3 in Appendix C of this NUREG is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures. Suggested responses for each block on the NRC Form 313 appear under "Response from Applicant" in this guide.

All information submitted to the NRC during the licensing process may be incorporated as part of the license and will be subject to review during inspection.

Applicants must submit NRC Form 313 to apply for a license. Applicants may use the appropriate NRC Form 313A series of forms to document training and experience for new authorized users (AU), authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), and radiation safety officers (RSO). Applicants may use Tables C–1 and 2 in Appendix C of this NUREG to assist with completion of the application.

8.1 Item 1: License Action Type

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

Item 1 of NRC Form 313 states the following:

This is an application for (check appropriate item):

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

Check box A for a new license request. Note that a prelicensing visit may be conducted prior to issuance of the license. Also, note that an initial security inspection may be conducted in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program," before issuance of the license.

Check box B for an amendment to an existing license, and provide the license number.

Check box C for a renewal of an existing license, and provide the license number. See Chapter 9, "License Amendments and Renewals," of this report.

8.2 Item 2: Name and Mailing Address of Applicant

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

Regulations: 10 CFR 35.12

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

Notify the NRC of changes in mailing address. These changes do not require a fee.

See Section 8.13, "Certification" for proper signature of NRC forms.

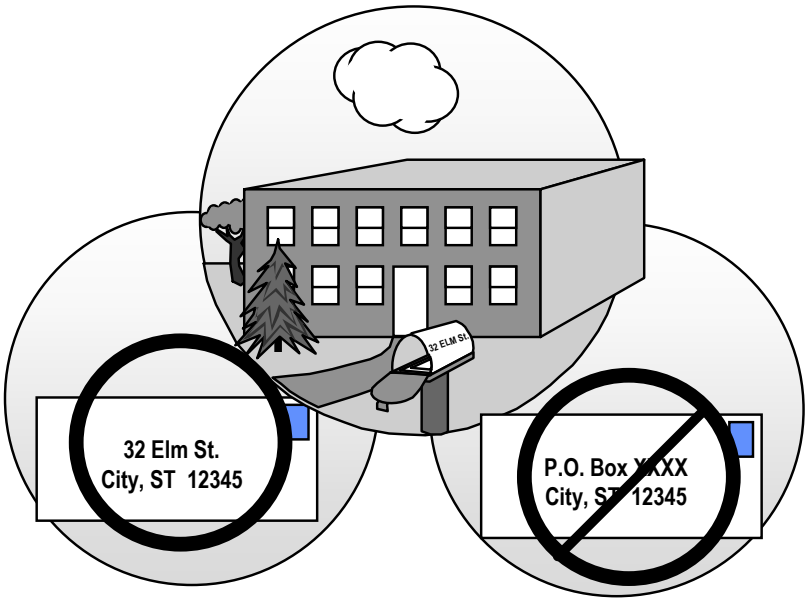
***Note**:* The NRC must be notified and the transfer approved before control of the license is transferred (see Section 9.2.1, "Transfer of Control"). The NRC must also be notified when bankruptcy proceedings have been initiated (see Section 9.2.2, "Notification of Bankruptcy Proceedings"). Guidance on information to be supplied to the NRC is available in NUREG–1556, Volume 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," and Regulatory Issue Summary (RIS) 2014-08, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses," May 27, 2014.

8.3 Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

Regulations: 10 CFR 30.33(a)(2), 10 CFR 30.34(c), 10 CFR 35.12

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

Specify the street address, city, and State or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility at which licensed material will be used or stored. The descriptive address should be sufficient to allow an NRC inspector to find the facility location. A post office box address is not acceptable. See Figure 8-1 below.



An acceptable location of use or possession specifies street address, city, State, and zip code and does not include a post office box number.

Figure 8-1. Location of Use

If byproduct material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. If applying for a license for mobile medical services, as authorized pursuant to 10 CFR 35.18(b), the applicant should refer

to Section 8.10.17 "Mobile Medical Service," and Appendix V of this NUREG for specific licensing guidance. For additional addresses where licensed material will be used or possessed, an amendment must be approved.

A license amendment is required before receiving, using, or storing licensed material at an address or location not already listed on the license.

> An NRC license does not relieve a licensee from complying with other applicable Federal, State, or local regulations (e.g., local zoning requirements).

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should mark these documents as "Security-Related Information—Withhold Under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," for more details.

Note: As discussed in Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning," licensees must maintain permanent records describing where licensed material was used or stored while the license was in effect. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material is (or was) used or stored and any records of leaking radioactive sources, spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or other unusual occurrences involving the possible spread of contamination in or around the licensee's facilities.

8.4 Item 4: Person To Be Contacted About This Application

Identify the individual who can answer questions about the application, and include a telephone number where the individual may be contacted. Also include business cell phone numbers and e-mail addresses.

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

Note: Contact information provided should not contain Personally Identifiable Information (PII) (e.g., home telephone number, personal cellular telephone number, or home email address). For additional information on PII, see Chapter 6, "Identifying and Protecting Sensitive Information."

This individual, usually the RSO, will serve as the point of contact during the review of the application. If this individual is not a full-time employee of the licensed entity, his or her position and relationship to the licensee should be specified. The NRC should be notified if the person assigned to this function changes or if his or her telephone number, cell phone number, or e-mail address changes. Notification of a contact change is only provided for informational purposes and would not be considered an application for license amendment, unless the notification involves a change in the contact person who is also the RSO.

> As indicated on NRC Form 313 (see Appendix B of this NUREG), Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C of this NUREG for this purpose and should note that using the suggested wording of responses and committing to use the model procedures in this report will facilitate the NRC's review.

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

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

8.5 Item 5: Radioactive Material

8.5.1 Byproduct Material and Depleted Uranium

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

Regulations: 10 CFR 20.2207, 10 CFR 30.32, 10 CFR 31.11, 10 CFR 32.210, 10 CFR 35.65, 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, 10 CFR 35.1000, 10 CFR Part 37, 10 CFR 40.4

Criteria: Byproduct material for medical use in 10 CFR Part 35 is divided into seven types of use: 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. Depleted uranium is used in shielding and collimation in medical devices. Licensees must also protect aggregated Category 1 and Category 2 quantities of radioactive material, as defined in 10 CFR 37.5, from theft, diversion, and sabotage.

Discussion: The applicant should indicate the byproduct material requested. Specifically, NRC Form 313 requests element and mass number, chemical and/or physical form, and the maximum amount that will be possessed at any one time. The applicant should refer to Table C–1 of Appendix C of this NUREG for an acceptable format for describing the radioactive material. The amount and type of information necessary will vary according to the type of use and material requested.

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

35.300 Use: The chemical/physical form may be "Any" unsealed byproduct material permitted by 10 CFR 35.300. The total amount requested must be specified. Table C–1 of Appendix C of this NUREG provides examples, if only one radionuclide is used.

35.400, 35.500, 35.600 Use: The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in becquerels (Bq), microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use in order to minimize the need for license amendments if they change model or vendor.

For therapy devices, the applicant must consider the shipped, installed, and medical use limitations on activity. Limitations are described in the Sealed Source and Device (SSD) registration certificates and U.S. Food and Drug Administration (FDA) 510k certificates.

Gamma stereotactic radiosurgery (GSR) and teletherapy sources are usually at or above Category 1 quantities, and co-located high dose-rate (HDR) brachytherapy sources are usually at or above Category 2 quantities. The applicant should also review NUREG–2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,'" January 2015 and NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material," May 2014, for additional guidance implementing 10 CFR Part 37 requirements for these therapy devices. Applicant information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly. See Chapter 6, "Identifying and Protecting Sensitive Information." Category 1 and Category 2 sources regulated by the NRC and Agreement States must be tracked in the National Source Tracking System (NSTS).

For 35.1000 Use: The radionuclide, the chemical/physical form, and the total amount must be specified. Applicants should refer to the Medical Uses Licensee Toolkit and consult with the appropriate NRC Regional Office to discuss the contents of the application.

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

Shielding Material/Depleted Uranium: Some high-activity radionuclide generators used to produce byproduct materials for 10 CFR 35.200 and 35.300 uses [e.g., technetium-99m (Tc-99m) generators] may include depleted uranium [i.e., uranium depleted in uranium-235 (U-235), as defined in 10 CFR 40.4] as shielding material. If a generator has depleted uranium shielding, an applicant should request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield or collimate the therapy sources and devices. This includes identifying depleted uranium used as shielding in linear accelerators because, even though the NRC does not regulate the accelerator, it does regulate the depleted uranium in the accelerator. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in U-235) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer's specifications for each device specified in the license request to determine (i) if depleted uranium is used to shield the source(s) within the device and (ii) the total quantity of depleted uranium present in the device in kilograms. The applicant should also consult the manufacturer's specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers in kilograms.

***Note**:* Most depleted uranium used for shielding or beam collimation in therapy devices is covered under a general license, in accordance with 10 CFR 40.25. Applicants or licensees may either request to include the depleted uranium on the specific medical license or, as applicable, submit NRC Form 244, "Registration Certificate – Use of Depleted Uranium Under General License," to register the material.

Sealed Sources and Devices: In accordance with 10 CFR 30.32(g), applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR 35.65, and certain Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) sources for which this information is not available). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the NRC or an Agreement State or when information required in 10 CFR 30.32(g)(3) is provided.

Applicants will need to request authorization for possession of these sealed source(s) or device(s). The NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSD registration certificate issued to the manufacturer (or distributor). Prior to 2005, some non-Agreement States may also have performed similar safety evaluations for sealed sources and devices containing NARM, and these safety evaluations may be documented in SSD registration certificates. If the sealed source or device contains NARM material and was produced before the effective date of the rule, November 30, 2007, it may not have a SSD registration certificate and the information required by 10 CFR 32.210 may not be available. If this is the case, the applicant must provide the information required in 10 CFR 30.32(g)(3). For example, if a discrete source of radium-226 (Ra-226) is requested, provide a complete description of the discrete source, including manufacturer, model number, activity, and intended use. If the source is not registered, include construction and testing of the sealed source, as described in 10 CFR 32.210(c).

Sources that are authorized by 10 CFR 35.65, "Authorization for calibration, transmission, and reference sources," should *not* be listed. However, calibration, transmission, and reference sources that do not meet the criteria or exceed the quantity in 10 CFR 35.65 should be specifically described.

Consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSD designations registered with the NRC or an Agreement State. Licensees may not use any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSD registration certificates without obtaining the NRC's prior permission in a license amendment. Licensees providing information in accordance with the provisions of 10 CFR 30.32(g) may not make changes to the sealed sources, device, or source-device combination that would alter the description or specifications provided to the NRC without obtaining the NRC's prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SSD registration certificates, applicants may want to review or discuss them with the manufacturer. The licensee or applicant should contact the manufacturer and distributor of the device for a copy of the SSD registration certificate. If the manufacturer and distributor is no longer in service, the licensee or applicant should contact the NRC or the issuing Agreement State for further guidance. In addition, the International Commission on Radiation Units and Measurements, "Certification of Standardized Radioactive Sources," Report No. 12, 1968, contains useful information for standardizing activity measured in sources.

Other Material: The applicant should make a separate entry for other required items (e.g., unsealed Ra-226 not previously described; more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11; radiation survey meter calibration source; dosimetry system constancy check source; material for *in vitro*, animal, or human research studies).

Sources that are authorized by 10 CFR 35.65 should *not* be listed.

Blood Irradiators: If the use of a device to irradiate blood is anticipated, the applicant should review NUREG–1556, Volume 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," and submit information as applicable. The applicant should also review NUREG–2155, "Implementation Guidance for 10 CFR Part 37, 'Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material,'" January 2015 and NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material," May 2014, for additional guidance implementing 10 CFR Part 37 requirements for blood irradiators. Applicant information on manufacturers, model numbers, and possession limits is sensitive and should be marked accordingly. See Chapter 6, "Identifying and Protecting Sensitive Information." Category 1 and Category 2 sources regulated by the NRC and Agreement States must be tracked in the NSTS.

> The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated "Category 1 quantity of radioactive material" or "Category 2 quantity of radioactive material." These terms are defined in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37. See Section 8.10.24, "Security Program for Category 1 and Category 2 Radioactive Material," of this NUREG for more information on the applicability and requirements of 10 CFR Part 37.

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

Production of PET Radioactive Drugs for Noncommercial Distribution to Medical Use Licensees Within a Consortium: If the applicant will produce Positron Emission Tomography (PET) radioactive drugs for its own medical use and noncommercial distribution to other members of its consortium, the applicant should review NUREG–1556, Volume 13, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," and NUREG–1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator."

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

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

Response from Applicant: The applicant should submit the information as described above. When responding to this section, follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response includes security-related sensitive information and needs to be marked accordingly.

8.5.2 Financial Assurance and Recordkeeping for Decommissioning

Regulations: 10 CFR 30.34(b), 10 CFR 30.35, 10 CFR 30.51

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

Criteria: Licensees authorized to possess licensed material with half-lives greater than 120 days and in excess of the limits specified in 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," must provide evidence of financial assurance for decommissioning.

Licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where devices are used or stored, as well as records related to leaking sources. Pursuant to 10 CFR 30.35(g), licensees must transfer records important to decommissioning to new licensees before licensed activities are transferred or assigned, according to 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, each licensee shall forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office.

Decommissioning records described above are not required for temporary jobsite locations.

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

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

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

determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

Applications for authorization to possess and use unsealed byproduct material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in 10 CFR 30.35(a) are exceeded. Acceptable methods of providing financial assurance may be found in NUREG–1757, Volume 3, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness."

The NRC will authorize sealed source possession exceeding the limits given in 10 CFR 30.35(d) without requiring decommissioning financial assurance, for the purpose of a normal sealed source exchange, on a case-by-case basis. For example, the licensee may temporarily exceed the limits in 10 CFR 30.35(d) requiring decommissioning financial assurance during source exchange for GSR.

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed byproduct material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider Ra-226 and licensed material in sealed sources to evaluate the need for financial assurance. Use Table 8-1 to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed byproduct material with a half-life greater than 120 days, refer to 10 CFR 30.35 and Appendix B to 10 CFR Part 30 for possession limits requiring financial assurance. The sum-of-the-fractions procedure is also depicted in Table 8-1 and must be used to determine the need for financial assurance for both sealed and unsealed byproduct material.

Table 8-1. Worksheet for Determining Need for Financial Assurance for Sealed Sources

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

*This table uses only conventional units. The conversion to the International System of units is: 1 curie = 37 gigabecquerels.

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

Response from Applicant: No response is needed from most applicants. If financial assurance is required, applicants must submit evidence of financial assurance following the guidance of NUREG–1757, Volume 3 "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness," February 2012. If applicants have questions about financial assurance requirements associated with discrete sources of Ra-226, they should consult with the appropriate NRC Regional Office to discuss the contents of their application.

8.6 Item 6: Purpose(s) for Which Licensed Material Will Be Used

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

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

Criteria: Byproduct material for medical use in 10 CFR Part 35 is divided into seven types of use: 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000. The applicant should refer to Table C–1 of Appendix C of this NUREG for an acceptable method for describing purpose of use.

Discussion: 10 CFR 30.33(a)(1) limits the purpose of use authorized by the Atomic Energy Act of 1954, as Amended. Details for each purpose of use are listed below.

10 CFR 35.100, 35.200, and 35.300 Use: The applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (e.g., 10 CFR 35.100) and the description of the applicable modality (e.g., any uptake, dilution, and excretion study).

For licensees conducting sentinel lymph node (SLN) biopsy, SLN tissue may be transferred to a nonlicensed facility for pathology analysis as long as the tissue does not contain more than 100 µCi [3.7 megabecquerels (MBq)] of Tc-99m, which is based on the exemption criteria in 10 CFR 30.18, "Exempt Quantities." See RIS 2008-31, "Licensing Requirements for Sentinel Lymph Node Biopsy," December 1, 2008, for additional information.

If an applicant's request is limited to one radionuclide under 10 CFR 35.300, the license will be limited to that radionuclide. In addition, the radionuclide and purpose may be limited, if the AU's training or experience is limited.

35.400 Use: The applicant should define the purpose of use by stating that the applicable section is 10 CFR 35.400, and the use is manual brachytherapy.

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

- interstitial treatment of cancer
- eye plaque implants (considered interstitial, not topical, treatment)
- intracavitary treatment of cancer (for purposes of the NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use)
- topical (surface) applications [e.g., strontium-90 (Sr-90) eye applicators]

35.500 Use: The applicant should define the purpose of use by stating that the applicable use is 10 CFR 35.500 and, if applicable, confirm that the sources requested in Item 5 and the associated devices are compatible.

35.600 Use: The applicant should define the purpose of use by stating the applicable section of 10 CFR 35.600 (e.g., teletherapy, remote afterloading, GSR) and include the manufacturer's

name(s) and model number(s) of the device(s) containing a sealed source(s) [e.g., for use in a (Manufacturer's Name and Unit Type, Model) radiation therapy unit for the treatment of humans]. An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible and conform to the SSD registry designations registered with the NRC or an Agreement State. If applicable, the applicant should specify that authorization is being requested for an additional source to be stored in its shipping container, incident to source replacement.

Shielding Material/Depleted Uranium Use: If applicable, the applicant should state that depleted uranium is used as shielding or collimation for a medical device.

35.1000 Use: The applicant must apply for authorization to use byproduct material, or radiation therefrom, in medical applications under 10 CFR 35.1000 when the type of use is not covered under 10 CFR 35.100-35.600. Applicants should refer to the Medical Uses Licensee Toolkit and consult with the appropriate NRC Regional Office to discuss the contents of the application.

Non-medical Uses: Applicants may also describe nonmedical uses [e.g., radiation survey meter calibrations with National Institute of Standards and Technology (NIST)-traceable brachytherapy sources] and reference the applicable radioactive material provided in response to Item 5.

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

When responding to this section, follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response includes security-related sensitive information and needs to be marked accordingly.

8.7 Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

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

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.51, 10 CFR 35.55, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690.

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

Discussion: The requirements in 10 CFR 35.24, "Authority and responsibilities of the radiation protection program," describe the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. Other personnel who have a role in the radiation protection program are AUs, AMPs, ANPs, and members of the Radiation Safety Committee (RSC), if the licensee is required to establish an RSC. The AU, AMP, ANP, and RSO are defined in 10 CFR 35.2, "Definitions." The term AU will be used to also mean individuals who are authorized for nonmedical uses. In 10 CFR 30.33(a)(3), the NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F,

G, and H of 10 CFR Part 35 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs; AUs for nonmedical uses must meet the criteria in 10 CFR 30.33(a)(3).

Applicants should ensure that they submit the specific training information required by NRC regulations in 10 CFR Part 35, Subparts B, D, E, F, G, and H. The NRC Form 313A series of forms provides a convenient format for submitting this information. A résumé or a curriculum vitae is not generally appropriate, because such documents usually contain PII (See Chapter 6, "Identifying and Protecting Sensitive Information"), and the document usually does not supply all the information needed to evaluate an individual's training and experience for NRC purposes. In addition, 10 CFR 35.57 describes "grandfathering" of RSOs, AMPs, AUs and ANPs and 10 CFR 35.59, "Recentness of training," requires that the training and experience specified in 10 CFR 35, Subparts B, D, E, F, G, and H, must have been obtained within 7 years preceding the date of application, or the individual must have related continuing education and experience. For nonmedical use AUs, the information provided should focus on educational training and radiation safety training and experience specific to the radionuclides and uses requested.

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

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

Licensees that are authorized for two or more different types of uses of byproduct material under 10 CFR Part 35 Subparts E, F, and H, or two or more types of units under Subpart H are required under 10 CFR 35.24(f) to establish an RSC to oversee all uses of byproduct material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

Response from Applicant: Refer to Sections 8.7.1 – 8.7.4 for each type of individual responsible for the radiation protection program.

8.7.1 Radiation Safety Officer (RSO)

100	✓
200	✓
300	✓
400	✓
500	✓
600	✓
1000	✓

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.13, 10 CFR 35.14, 10 CFR 35.24, 10 CFR 35.50, 10 CFR 35.57, 10 CFR 35.59.

Criteria: The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 10 CFR 35.24(e). The RSO must have adequate training and experience. The training and experience requirements for the RSO are described in 10 CFR 35.50, "Training for Radiation Safety Officer," and allow for the following training pathways:

- certification as provided in 10 CFR 35.50(a) by a specialty board whose certification process has been recognized by the NRC or an Agreement State, plus a written attestation signed by a preceptor RSO as provided in 35.50(d) and training as specified in 35.50(e)

- completion of classroom and laboratory training (200 hours) and 1 year of full-time radiation safety experience as described in 10 CFR 35.50(b)(1) plus a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e)

- certification as provided in 10 CFR 35.50(c)(1) as a medical physicist under 35.51(a), plus a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e)

- identification as provided in 10 CFR 35.50(c)(2) on the licensee's license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of byproduct material use for which the individual has RSO responsibilities, with a written attestation signed by a preceptor RSO as provided in 10 CFR 35.50(d) and training as specified in 35.50(e)

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. The RSO should have independent authority to stop operations that he or she considers unsafe. In accordance with 10 CFR 35.24, "Authority and responsibilities of the radiation protection program," the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in 10 CFR 35.24 to ensure that radioactive materials are used in a safe manner.

Typical RSO duties are described in the list below and in Appendix I of this NUREG. The NRC requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix I of this NUREG also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO. NRC Form 313A (RSO), "Radiation Safety Officer" can be found on the Medical Uses Licensee Toolkit. Instructions for completing the form can be found in Appendix D of this NUREG.

Usually, the RSO is a full-time employee of the licensed facility. The NRC has authorized individuals who are not employed full-time by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be onsite periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 10 CFR 35.24.

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

- stopping unsafe activities involving licensed materials
- ensuring radiation exposures are ALARA
- conducting material accountability and disposal
- interacting with the NRC
- providing timely and accurate reporting and maintenance of appropriate records
- conducting annual program audits
- ensuring proper use and routine maintenance
- ensuring personnel are trained
- conducting investigations of incidents involving byproduct material (e.g., medical events)
- for licensees possessing an aggregated Category 1 or Category 2 quantity of radioactive material, participating in the development and implementation of a security program for radioactive material in accordance with 10 CFR Part 37. A "Category 1 quantity of radioactive material" and a "Category 2 quantity of radioactive material" are defined terms in 10 CFR 37.5, and the radionuclides referenced in these 10 CFR 37.5 definitions are listed in Appendix A to 10 CFR Part 37

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

Response from Applicant: Provide the following:

- name of the proposed RSO

AND

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

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

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

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

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

AND

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

For an individual qualifying under 10 CFR 35.50(a)

- copy of certification by a specialty board whose certification process has been recognized[1] by the NRC or an Agreement State under 10 CFR 35.50(a)

AND

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

AND

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

[1]Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit.

AND

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

For an individual qualifying under 10 CFR 35.50(b)

- description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO

AND

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

AND

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

AND

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

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

- copy of the certification(s) as a medical physicist by a board whose certification process has been recognized by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO

AND

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

AND

- written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 35.50(c)(1), as well as the required training and experience in radiation safety, regulatory issues, and emergency procedures for the

types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO

AND

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

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

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

AND

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

AND

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

AND

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

AND

- If the RSO is an outside consultant or contractor, address the following in the application or amendment:

  — Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of onsite time (hours per week).

  — Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

— Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.

— Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his or her presence.

***Notes**:*

- NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.50.

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

- An AU for medical uses, AMP, or ANP may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities [see 10 CFR 35.50(c)(2)] and, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.

- Descriptions of training and experience will be reviewed using the criteria listed above. The NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35, Subpart B, are met. If the training and experience do not appear to meet the criteria in Subpart B, the NRC may request additional information from the applicant or may request the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.

- The training and experience for the RSO of a medical use broad scope license will be reviewed using the above criteria as well as criteria in 10 CFR Part 33 "Specific Domestic Licenses of Broad Scope for Byproduct Material."

8.7.2 Authorized Users (AUs)

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

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.27, 10 CFR 35.57, 10 CFR 35.59, 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, 10 CFR 35.690

Criteria: Training and experience requirements for AUs for medical uses are described in 10 CFR 35.190, 10 CFR 35.290, 10 CFR 35.390, 10 CFR 35.392, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, 10 CFR 35.590, or 10 CFR 35.690

Discussion: 10 CFR 35.2 defines AU for medical use. Although the NRC does not define "AU" for nonmedical uses, for purposes of this discussion the term AU will also be used to mean individuals authorized for the nonmedical uses described below.

AU for Medical Uses: The responsibilities of AUs involved in medical use include the following:

- radiation safety commensurate with use of byproduct material
- administration of a radiation dose or dosage and how it is prescribed
- direction of individuals under the AU's supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material
- preparation of written directive (WD), if required

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

Regulations in 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist," provide that experienced AUs who are named on a license or permit are not required to comply with the training requirements in Subparts D through H to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in 10 CFR 35.57 (check the regulations to determine this date). For example, a physician who was authorized to use sodium iodine-131 (I-131) for imaging and localization, involving greater than 30 µCi (a quantity for which a WD is required under 10 CFR 35.40), would continue to be authorized for this use.

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

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

NRC Forms 313A (AUD, AUT, and AUS) can be found on the Medical Uses Licensees Toolkit. Instructions for completing the form can be found in Appendix D of this NUREG. Information in 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," regarding training and experience for emerging technologies (e.g., microspheres) can also be found at the Medical Use Licensee Toolkit.

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

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user's training and experience. Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

Response from Applicant:

AU for Medical Uses: Provide the following:

- name of the proposed AU and uses requested

AND

- state or territory where licensed

AND

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

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

AND

- For an AU requesting a medical use not currently authorized on a license or permit, a description of the additional training and experience is needed to demonstrate the AU is also qualified for the new medical uses requested [e.g., training and experience needed to meet the requirements in 10 CFR 35.290(b), 35.396, 35.390(b)(1)(ii)(G) or 35.690(c)]. A preceptor attestation may also be required. (For example, a preceptor attestation is needed to meet the requirements of 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," and 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.")

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

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

AND

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

AND

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

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

- A copy of the certification(s) by a specialty board(s) whose certification process has been recognized[2] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested.

AND

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

AND

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

AND

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

AND

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

AND

- A written attestation, signed by a preceptor physician AU, that the training and experience specified for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved. For individuals seeking authorization under

[2]Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit.

10 CFR 35.390, 10 CFR 35.396, and 10 CFR 35.690, the attestation must also include successful completion of the clinical case work in 10 CFR 35.390(b)(1)(ii)(G), or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, as appropriate.

AND

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

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

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

AND

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

AND

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

AND

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

For an individual qualifying under Subpart K

- Training and experience as described for the emerging technology on the Medical Uses Licensee Toolkit.

***Notes**:*

- NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590];" or NRC Form 313A (AUT), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396];" or NRC Form 313A (AUS), "Authorized User Training and Experience and Preceptor Attestation (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]" may be used as appropriate to document training and experience for those individuals qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H.

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

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

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

AU for Nonmedical Uses: **Provide the following**:

- name of the proposed nonmedical use AU

- description of types, quantities, and proposed nonmedical uses for which the individual is responsible

- description of individual's educational and radiation safety training and experience with the types of materials and uses requested; this may include

  — a copy of the NRC or Agreement State license listing the individual as an AU for the same types, quantities, and uses requested

  — a permit issued by an MML licensee or broad scope licensee or broad scope permittee identifying the individual as an AU for the types, quantities, and uses requested

- detailed radiation training and experience applicable to the use requested

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

8.7.3 Authorized Nuclear Pharmacist (ANP)

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

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

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

Discussion: At many licensed medical facilities, an ANP is directly involved with the preparation of radiopharmaceuticals under the provisions of 10 CFR 35.100(b), 35.200(b), or 35.300(b).

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

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

Response from Applicant: Provide the following:

- name of the proposed ANP

AND

- state or territory where licensed

AND

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

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

OR

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

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

AND

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

OR

For an individual qualifying under 10 CFR 35.55(a)

- copy of the certification of the specialty board whose certification process has been recognized[3] under 10 CFR 35.55(a);

AND

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

AND

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

OR

For an individual qualifying under 10 CFR 35.55(b)

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

AND

- written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved

AND

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

***Notes**:*

- NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" may be used to document training and experience for those individuals qualifying under 10 CFR 35.55.

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

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

[3]Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit.

applicant or may request the assistance of the ACMUI in evaluating such training and experience.

8.7.4 Authorized Medical Physicist (AMP)

Regulations: 10 CFR 30.33(a)(3), 10 CFR 35.2, 10 CFR 35.14, 10 CFR 35.51, 10 CFR 35.57, 10 CFR 35.59

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

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

Discussion: While the AMP may not administer the dose, at licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and other tasks associated with the administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

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

Response from Applicant: Provide the following:

- name of the proposed AMP

AND

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

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

OR

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

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

AND

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

OR

For an individual qualifying under 10 CFR 35.51(a)

- copy of the certification(s) of the specialty board(s) whose certification process has been recognized[4] under 10 CFR 35.51(a)

AND

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

AND

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

AND

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

OR

For an individual qualifying under 10 CFR 35.51 (b)

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

AND

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

AND

- written attestation, signed by a preceptor AMP, that the training and experience required in 10 CFR 35.51(b)(1), as well as the training in 10 CFR 35.51(c) for the types of use

[4]Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit.

specified, have been satisfactorily completed, and that a level of competency sufficient to function independently as an AMP has been achieved

AND

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

OR

For an individual qualifying under Subpart K

- training and experience as described for the emerging technology on the Medical Uses Licensee Toolkit

***Notes**:*

- NRC Form 313A (AMP), "Authorized Medical Physicist Training and Experience and Preceptor Attestation [10 CFR 35.51]," may be used to document training and experience for those individuals qualifying under 10 CFR 35.51.

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

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

8.8 Item 8: Training for Individuals Working in or Frequenting Restricted Areas

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

Regulations: 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610, 10 CFR 37.43

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

Any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material (as defined in 10 CFR 37.5) must implement a training program for those individuals implementing the security program.

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

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

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

In accordance with 10 CFR 35.27(b), a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an ANP or an AU, as allowed by 10 CFR 35.11(b)(2), shall instruct supervised individuals in the preparation of byproduct material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and NRC regulations. Under 10 CFR 35.27(c), a licensee that permits supervised activities, under paragraphs 10 CFR 35.27(a) and (b), is responsible for the acts and omissions of the supervised individuals.

Appendix J of this NUREG provides a model training program that provides one way to satisfy the requirements referenced above. In addition, the Medical Uses Licensee Toolkit provides guidance for training suggested for emerging technologies [e.g., yttrium-90 (Y-90) microsphere brachytherapy], regulated under 10 CFR 35.1000.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must implement a training program in accordance with 10 CFR 37.43, "General security program requirements," and specifically, must comply with 10 CFR 37.43(c), "Training," to ensure that those individuals who may have a responsibility to implement portions of the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. Additionally, in accordance with 10 CFR 37.43(c)(3), refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: No response is necessary.

8.9 Item 9: Facilities and Equipment

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.12(b)(1), 10 CFR 35.18(a), 10 CFR Part 37, 10 CFR 37.5, 10 CFR 37.49, 10 CFR 37.53.

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

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

If licensee possesses aggregated Category 1 and Category 2 quantities of radioactive material, as defined by 10 CFR 37.5, facilities and equipment must be adequate to protect health and minimize danger to life or property and provide enhanced physical protection of the aggregated Category 1 and Category 2 quantities of radioactive material.

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

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- implement the physical protection requirements in 10 CFR Part 37 for material in use and storage, at both permanent and temporary jobsites; and
- in accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices, and immediately detect any unauthorized removal of Category 1 quantities of radioactive material from the security zone. (Monitoring and detection systems may include, among other methods, monitored video surveillance systems and electronic devices for intrusion detection alarms.)
- for mobile devices containing Category 1 or Category 2 quantities of radioactive material, have two independent physical controls to secure the material from unauthorized removal when the device is not under direct control and constant surveillance in accordance with 10 CFR 37.53. "Mobile device" is defined in 10 CFR 37.5

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: Refer to Sections 8.9.2 through 8.9.5 for guidance.

8.9.1 Facility Diagram

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

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.13, 10 CFR 35.14, 10 CFR 35.18(a)(3), 10 CFR 35.75, 10 CFR 35.315(a), 10 CFR 35.415, 10 CFR 35.615

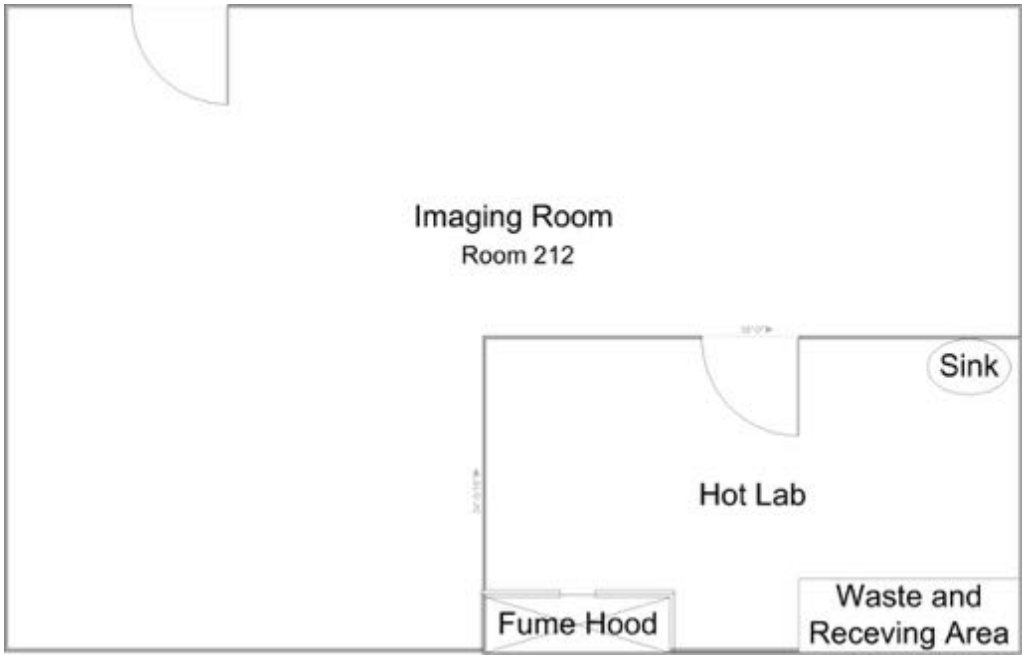
Criteria: In order to issue a license, the NRC must find that facilities and equipment are adequate to protect health and minimize danger to life or property as required under 10 CFR 30.33(a)(2) and/or 35.18(a)(3). In accordance with 10 CFR 20.1101, the licensee must design facilities to achieve occupational doses and doses to members of the public ALARA.

Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The facility diagram should include the room or rooms where byproduct material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property. Due to the low energy of radionuclides used in nuclear medicine departments for diagnostic studies, a description of adjacent areas is unnecessary. However, if PET radionuclides are used, a description of the specialized PET facilities should be provided. The description should include facility diagrams, the shielding installed, specialized handling equipment, and survey results to ensure that the regulatory limits in 10 CFR 20.1201, "Occupational dose limits for adults," and 10 CFR 20.1301, "Dose limits for individual members of the public," are met. For therapy facilities, the applicant should demonstrate that the limits specified in 10 CFR 20.1301(a) will not be exceeded and how access will be controlled in accordance with 10 CFR 20.1601 and 10 CFR 20.1602. If the facility descriptions or calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.

Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information."

For types of use permitted by 10 CFR 35.100 and 35.200, applicants should provide room numbers for areas in which byproduct materials are used or prepared for use (i.e., "hot labs"). (See Figure 8-2.)

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



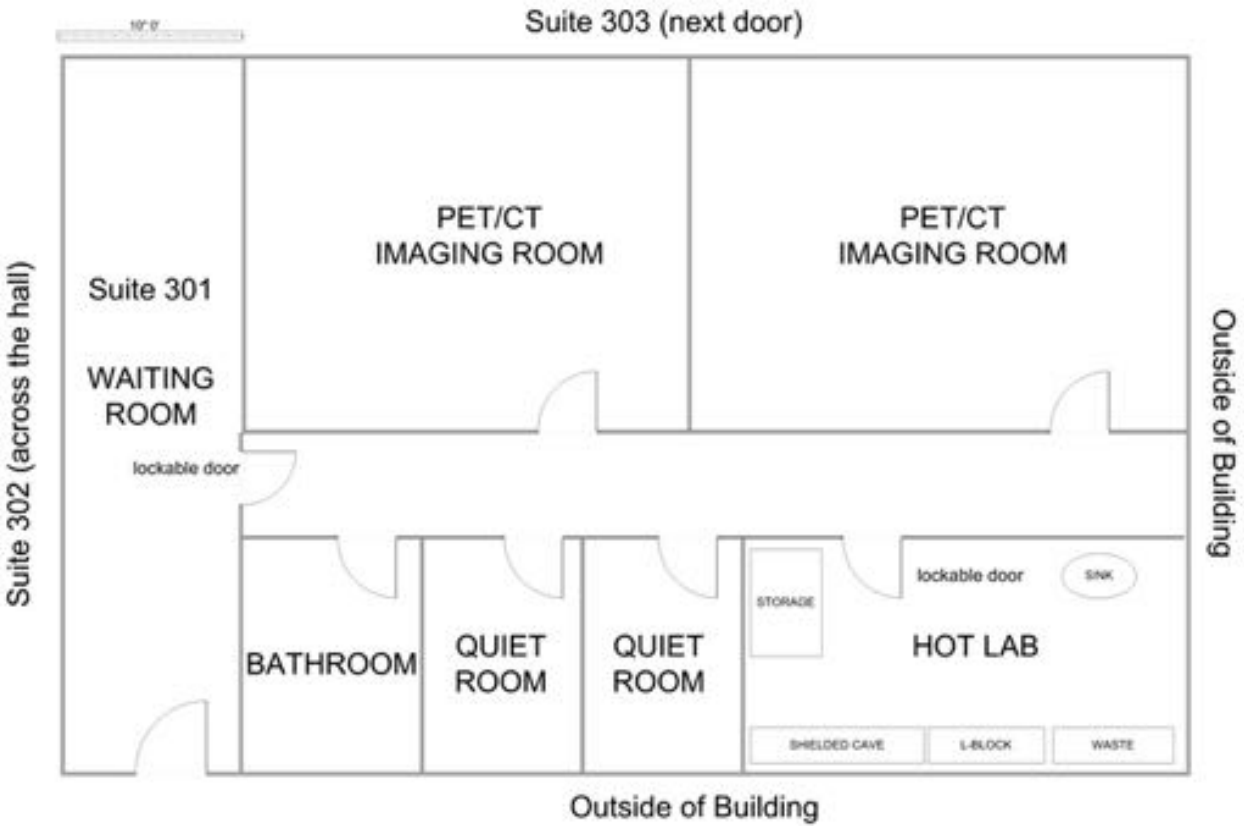
SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

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

Figure 8-2. Facility Diagram for Nuclear Medicine Suite

If the applicant uses PET radionuclides under 10 CFR 35.100 or 35.200, the applicant should provide a description of the imaging rooms, quiet rooms, hot cells (if applicable), and location of the PET delivery line (if applicable). A discussion of the shielding associated with the PET facility, including shielding calculations, should also be provided. (See Figure 8-3). AAPM Task Group 108, "PET and PET/CT Shielding Requirements," provides guidance on how to design a PET facility and perform associated shielding calculations. The document also provides guidance on appropriate safety equipment to use.

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



Suite 301 is on the top floor in the corner of the building
Suite 302 is occupied by an oncology practice
Suite 303 is occupied by obstetrics and gynecology practice
Directly below Suite 301 is a dental practice
As noted in AAPM Task Group Report 108, 0.65 centimeters (cm) of lead or 7 cm of poured concrete in doors, walls, ceiling, and floors of hot lab, quiet rooms, and imaging rooms is sufficient to meet the regulatory requirements in 10 CFR 20.1301.
Assumed work load is 40 patients per week.

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

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

Figure 8-3. Facility Diagram for PET Suite

For types of use permitted by 10 CFR 35.300 and 35.400, applicants should provide the locations where sources are stored (e.g., fume hood or shielded cave). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. Since this radionuclide is volatile in either liquid or capsule form, applicants should consider establishing appropriate radiological controls. In addition, in accordance with 10 CFR 35.315(a) and 10 CFR 35.415, the applicant should describe the rooms where patients will be housed, if they cannot be released under 10 CFR 35.75. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

The discussion should include a description of shielding to ensure that the dose rates in adjacent areas are in accordance with the regulations. Regulatory requirements, the principle of ALARA, and access control should be considered when determining the location of the therapy patient's room.

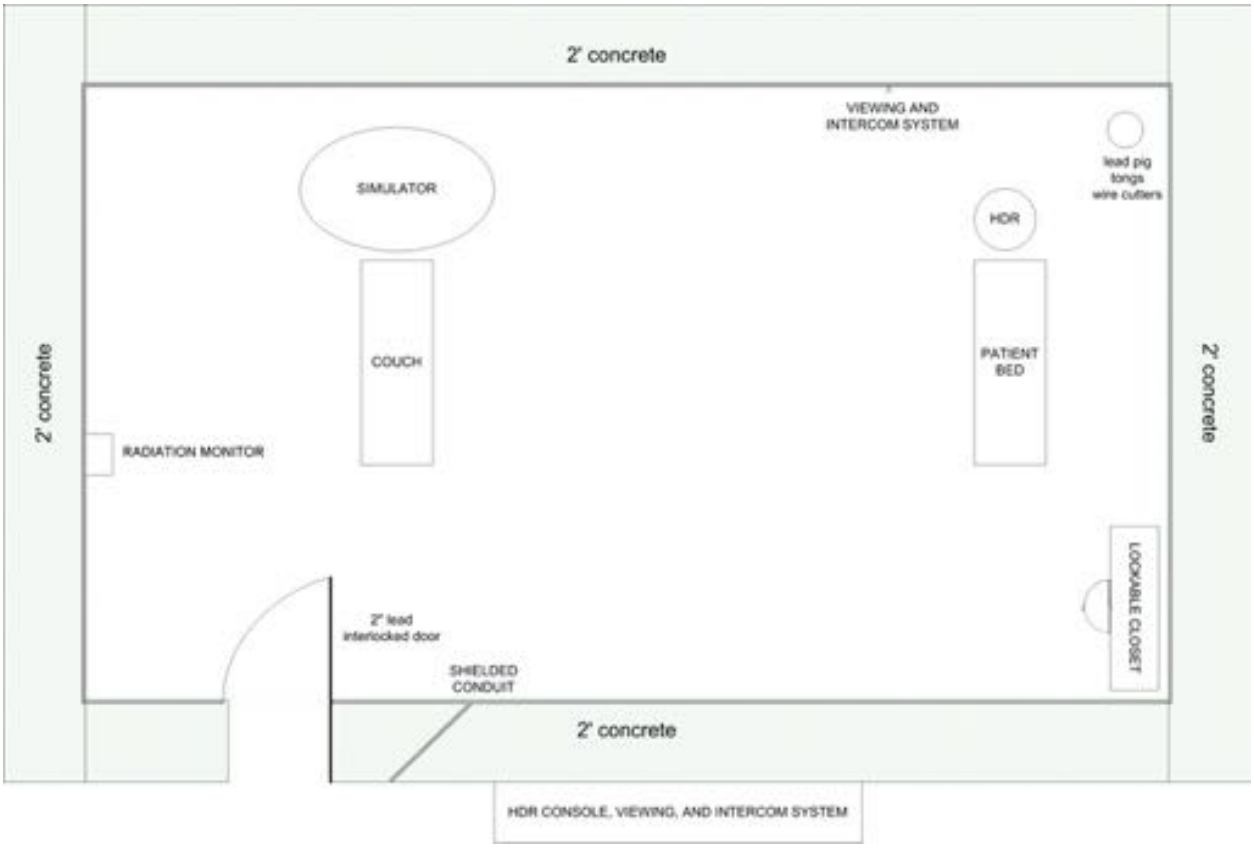
If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original information provided. A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

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

For types of use permitted by 10 CFR 35.500, the applicant should provide the room numbers of use.

For types of use permitted by 10 CFR 35.600 and as required by 10 CFR 35.615, the applicant should provide a diagram and the shielding calculations for the facility. (See Figure 8-4).

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*



Iridium-192 (Ir-192) gamma constant from NCRP Report No. 49: 4.8 roentgen-$cm^2h^{-1}mCi^{-1}$
Ir-192 Tenth Value Layer from NCRP Report No. 49: 2 cm lead, 14.7 cm poured concrete
2 ft of concrete assumes 20 min beam on-time per hour (h) and 1 ft minimum distance from each wall; 10 ft from the door; maximum loading 12 Ci

SECURITY-RELATED INFORMATION – WITHHOLD UNDER 10 CFR 2.390*

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

Figure 8-4. Facility Diagram for HDR Suite

When preparing applications for use under 10 CFR 35.1000, applicants should review the guidance on the Medical Uses Licensee Toolkit to determine the type of information appropriate to evaluate the adequacy of the facilities.

All limited specific medical use licensees are required by 10 CFR 35.13, "License amendments," to obtain a license amendment before adding to or changing an area of use identified in the application or on the license. However, changes and additions to the 10 CFR 35.100 and 35.200 medical use areas located in the same address of use do not require a license amendment and can be made, provided the NRC is notified as required by 10 CFR 35.14 within 30 days following the changes. The broad scope medical use licensee does not have to notify NRC of changes that do not require a license amendment.

Response from Applicant: All medical use applicants, including broad scope medical use applicants, are required to provide facility diagrams. The applicant should follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response includes security-related sensitive information and needs to be marked accordingly. Provide the following:

- Facility diagrams. Drawings should be to scale, or the scale used should be indicated.
- Location, room numbers, and principal use of each room, including patient treatment rooms, or area where byproduct material is prepared, used, or stored.
- Shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
- For radiopharmaceutical and sealed source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003.
- For teletherapy facilities, applicants should provide the directions of primary beam use for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.
- For 10 CFR 35.1000 (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the Medical Uses Licensee Toolkit.

References and Resources:

- National Council on Radiation Protection and Measurements (NCRP) Report No. 40, "Protection against Radiation from Brachytherapy Sources," 1972.
- 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.
- 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.
- NCRP Report No. 151 "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," 2005.
- AAPM Task Group 108, "PET and PET/CT Shielding Requirements," 2006.

8.9.2 Radiation Monitoring Instruments

Regulations: 10 CFR 20.1101, 10 CFR 20.1501, 10 CFR 30.33(a)(2), 10 CFR 35.61

Criteria: All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection, including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

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

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

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

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- area monitors
- single or multichannel analyzers
- liquid scintillation counters
- gamma counters
- proportional counters
- solid state detectors
- hand- and foot-contamination monitors

It is not necessary for a licensee to possess a radiation survey meter solely for sealed source use under 10 CFR 35.500, but a radiation survey meter should be available on short notice in the event of an accident or emergency involving the sealed source.

Radiation survey meter calibrations must be performed by persons, including licensed personnel, who are qualified to perform calibrations. One method a licensee may use to determine if the service vendor is qualified to perform these activities is to determine that it has an NRC (or an equivalent Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration. Regardless of whether an applicant is authorized to calibrate radiation survey meters or contracts an authorized vendor to perform calibrations, the licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made in accordance with 10 CFR 20.2103(a).

Appendix K of this NUREG provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures if the licensee requests to perform in-house calibration of their own radiation survey meters to meet the requirements detailed in 10 CFR 35.61, "Calibration of survey instruments."

Response from Applicant: Provide the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

AND/OR

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

AND

- A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

Note: A licensee reserves the right to upgrade survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

8.9.3 Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.60, 10 CFR 35.63

Part 35	Applicability
100	✓*
200	✓*
300	✓*
400	
500	
600	
1000	✓*
*If applicant will measure patient dosages or use other than unit dosages	

Criteria: In 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material," and 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use," the NRC describes requirements for the use, possession, calibration, and check of instruments (e.g., dose[5] calibrators) used to measure patient dosages.

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

If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35," or a PET radioactive drug producer authorized under 10 CFR 30.32(j) (and does not split, combine, or otherwise modify unit dosages), the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

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

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards [e.g., American National Standards Institute (ANSI)] or the manufacturer's

[5]NRC introduced the term, "dosage," in the 2002 revision of 10 CFR Part 35 with the new definition of prescribed dosage in an effort to replace the previous term, "dose," which also refers to the amount of energy absorbed per unit mass. However, NRC understands "dose" continues to be used by many medical professionals to refer to the *activity* of unsealed byproduct material, hence the name dose calibrator.

instructions. The measurement equipment may be a well-type ionization chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately for the type and energy of radiation emitted and is both accurate and reliable.

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

The inherent technical difficulties in measuring alpha-emitting radionuclides are even greater than those of measuring beta emissions. In the absence of an additional photon, gamma, or beta particle emission that can be measured with traditional instrumentation used in nuclear medicine (e.g., ion chambers) and quantified in relation to the alpha particle emissions, most alpha measuring instruments (e.g., gas proportional counters and liquid scintillation counters) will require preparation and measurement of an aliquot of the unsealed byproduct material. Measurement of aliquots introduces additional uncertainties associated with removing precise and reproducible volumes from homogeneous samples. For example, NRC issued Information Notice (IN) 2016-03, "Revision to the National Institute of Standards and Technology Standard for Radium-223 and Impact on Dose Calibration for the Medical Use of Radium-223 Dichloride," October 23, 2015, to notify licensees of a correction in measuring radium-223, which is primarily an alpha-emitter. To avoid these difficulties, the best method is to use unit dosages and the manufacturer's or commercial nuclear pharmacy's dose label for measurement of the dosage and decay-correct the dosage to the time of administration. These difficulties can also be avoided when not using unit dosages by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation.

Licensees who use rubidium-82 (Rb-82)/strontium-82 (Sr-82) generators should refer to the following for further guidance on the measurement of dosages:

- RIS 2013-12, "Notice of Issuance of Enforcement Guidance Memorandum—Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages," August 23, 2013

- Enforcement Guidance Memorandum – Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages

Response from Applicant, if Applicable:

For the administration of alpha-, gamma- and beta-emitting unsealed byproduct materials, provide the following:

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

AND

A description of the equipment used to measure the dosages.

***Note**:* For alpha-emitters where gamma or beta emissions are not measureable, licensees should identify the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

8.9.4 Therapy Unit – Calibration and Use

Regulations: 10 CFR 30.33(a)(2), 10 CFR 35.12(c)(2), 10 CFR 35.432, 10 CFR 35.433, 10 CFR 35.630, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.652.

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

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

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

Discussion: Except for manual brachytherapy sources and LDR remote afterloader sources, where the source output or activity is determined by the manufacturer, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. In accordance with 10 CFR 35.432, if the manual brachytherapy source output or activity is not determined by the manufacturer, the licensee must perform a calibration prior to medical use. Dosimetry systems and sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 10 CFR 35.630, "Dosimetry equipment." The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, American College of Radiology, ANSI). Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of Sr-90 sources. In accordance with 10 CFR 35.433, the licensee's AMP must calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments.

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy, in accordance with written procedures established by the AMP (10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645). These procedures must be submitted in accordance with 10 CFR 35.12(c)(2). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. See Appendix H of this NUREG for model procedures for performing spot-checks of remote afterloader devices.

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

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

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

In accordance with 10 CFR 35.652, licensees must perform surveys around therapy devices to ensure that the maximum radiation levels and the average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the SSD registry.

Response from Applicant: Provide the following:

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

References and Resources:

- AAPM Task Group No. 21, "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams," 1984.
- AAPM Report No. 46, "Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40)," 1994.
- AAPM Report No. 54, "Stereotactic Radiosurgery," 1995.
- AAPM Report No. 59, "Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56)," 1997.
- AAPM Report No. 61, "High Dose Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59)," 1998.

- 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.

- AAPM Report No. 68, "Permanent Prostate Seed Implant Brachytherapy, (AAPM Task Group No. 64)," October 1999.

- AAPM Report No. 84, "Update of AAPM Task Group No. 43 Report: A Revised AAPM Protocol for Brachytherapy Dose Calculations," March 2004.

- Erratum: "Supplement to the 2004 update of the AAPM Task Group No.43 Report," December 2004.

- AAPM Report No. 84S, "Supplement to the 2004 Update of the AAPM Task Group No. 43 Report," June 2007.

- 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.

8.9.5 Other Equipment and Facilities

Regulations: 10 CFR 20.1101, 10 CFR 20.1901, 10 CFR 20.1902, 10 CFR 30.33(a)(2), 10 CFR 35.12, 10 CFR 35.415, 10 CFR 35.615

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

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

Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. The applicant should describe, in Item 9 of the application, any other proposed equipment and facilities available for safe use and storage of byproduct material listed in Item 5 of this application. In accordance with 10 CFR 20.1901 and 10 CFR 20.1902, the applicant should ensure that the facilities include the appropriate caution signs and postings. For uses authorized by 10 CFR 35.400, 35.600, and 35.1000, as applicable, applicants are required to provide a description of emergency response equipment. In addition, the items below describe other necessary radiation safety equipment.

For PET radionuclide use: The applicant should focus on remote handling devices and storage containers that may be needed when handling and storing the higher energy emissions of these materials.

For radiopharmaceutical therapy: The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations described in Section 8.9.1 (e.g., private room with private bath). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood). Also note there are hazards associated with volatile iodine in capsule form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For manual brachytherapy: The applicant should describe emergency response equipment in accordance with 10 CFR 35.415.

For teletherapy, GSR, and HDR facilities: The applicant should focus on facilities and equipment required by 10 CFR 35.615:

- Appropriate radiation monitors to be used by any individual entering the treatment room to ensure that radiation levels have returned to ambient levels. One method of meeting this requirement is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.

- A system for continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again.

- A system for communication with the patient in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

- An electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the on-off control for the source(s) is reset at the console.

For pulsed dose-rate (PDR) remote afterloaders: The applicant should focus on the alarm system because of the unique characteristics and the lack of constant surveillance of their operation. A more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

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

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

- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
  - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position.

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

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

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

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

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

For LDR remote afterloaders: The applicant should describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

For LDR and PDR remote afterloaders: The applicant may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

Response from Applicant: Follow the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," to determine if the response to this section includes security-related sensitive information and needs to be marked accordingly.

For PET radionuclide use and radiopharmaceutical therapy programs describe the additional equipment for these uses.

For manual brachytherapy facilities, provide a description of the emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

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

- area radiation monitoring equipment
- viewing and intercom systems (except for LDR units)
- steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
- methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons
- emergency response equipment

Reference:

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

8.10 Item 10: Radiation Safety Program

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

Regulations: 10 CFR 20.1101, 10 CFR 30.32, 10 CFR 30.34(e), 10 CFR 35.24, 10 CFR 35.26

Criteria: Applicants must develop, document, and implement a radiation safety program commensurate with the scope of the licensed activity, in accordance with 10 CFR 20.1101, and submit portions of that program, when required, to assist in NRC's review of the application, in accordance with 10 CFR 30.32. The program must be sufficient to ensure compliance with the provisions of 10 CFR Part 20 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. Under 10 CFR 30.34(e), the NRC may incorporate into byproduct materials licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life and property. Licensee management's authorities and responsibilities for the radiation safety program are described in 10 CFR 35.24, while 10 CFR 35.26 sets forth four circumstances in which the licensee may revise its radiation protection program without NRC approval:

- The revision does not require a license amendment under 10 CFR 35.13.
- The revision is in compliance with the regulations and the license.
- The revision has been reviewed and approved by the RSO and licensee management.
- The affected individuals are instructed on the revised program before the changes are implemented.

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

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

Reference:

- NCRP Report No. 127, "Operational Radiation Safety Program," 1998
- International Commission on Radiological Protection (ICRP) Report No. 75, "General Principles for the Radiation Protection of Workers," 1997

8.10.1 Audit Program

Regulations: 10 CFR 20.1101, 10 CFR 37.33, 10 CFR 37.55

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

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

- The radiation protection program complies with NRC and applicable U.S. Department of Transportation (DOT) regulations and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101).

Licensees that are subject to the requirements in 10 CFR Part 37 must annually review their access authorization program and security program.

Discussion: Appendix L of this NUREG contains a suggested annual audit program that is specific to medical licensees and is acceptable to the NRC. Since all areas indicated in Appendix L may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist. Reviews or audits of the content and implementation of the radiation protection program must be conducted at least annually.

The NRC encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff, and spot-checking required records. As part of the review or audit programs, licensees should consider including unannounced audits of authorized and supervised users to observe whether radiation safety procedures are being followed.

It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner. Information Notice (IN) 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject. The NRC routinely reviews licensee's records to verify whether appropriate corrective actions were implemented in a timely manner to address recurrence. It is in the best interest of the licensee to identify potential violations of regulatory requirements and take necessary steps to correct them. The NRC can opt to exercise discretion and may elect not to cite the licensee for these violations if prompt and effective corrective actions are implemented. The NRC's Enforcement Policy and Enforcement Manual provide additional information. For examples of the NRC's use of discretion in issuing a notice of violation, refer to the most recent version of NRC's enforcement documents.

With regard to audit records, 10 CFR 20.2102 requires, in part, that licensees maintain records of "audits and other reviews of program content and implementation" for 3 years after the record is made. The NRC has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow up.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- in accordance with 10 CFR 37.33, review its access authorization programs at least annually to confirm compliance with the requirements of Subpart B of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified; and

- in accordance with 10 CFR 37.55, review its security program at least annually to confirm compliance with the requirements of Subpart C of 10 CFR Part 37 and ensure that comprehensive actions are taken to correct any noncompliance that is identified.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant**:** No response is necessary.

Reference:

- NCRP Report No. 162, "Self Assessment of Radiation-Safety Programs," 2009

8.10.2 Occupational Dose

Regulations: 10 CFR 19.13, 10 CFR 20.1003, 10 CFR 20.1201, 10 CFR 20.1202, 10 CFR 20.1203, 10 CFR 20.1204, 10 CFR 20.1207, 10 CFR 20.1208, 10 CFR 20.1501, 10 CFR 20.1502, 10 CFR 20.1703, 10 CFR 20.2104, 10 CFR 20.2106, 10 CFR 20 Appendix B

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

Criteria: Licensees must evaluate the potential occupational exposure of all workers and monitor occupational exposure.

The use of individual monitoring devices for external dose is required, pursuant to 10 CFR 20.1502(a), for:

- adults who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately)
  - — 5 mSv [0.5 rem] deep-dose equivalent
  - — 15 mSv [1.5 rems] lens (of the eye) dose equivalent

- 50 mSv [5 rems] shallow-dose equivalent to the skin of the whole body
- 50 mSv [5 rems] shallow-dose equivalent to the skin of any extremity

- minors who are likely to receive an annual dose from sources external to the body in excess of any of the following (each evaluated separately)

  - 1.0 mSv [0.1 rem] deep-dose equivalent
  - 1.5 mSv [0.15 rem] lens (of the eye) dose equivalent
  - 5 mSv [0.5 rem] shallow-dose equivalent to the skin
  - 5 mSv [0.5 rem] shallow-dose equivalent to any extremity

- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 1.0 mSv [0.1 rem] deep-dose equivalent

- individuals entering a high or very high radiation area

Internal exposure monitoring is required, pursuant to 10 CFR 20.1502(b), for the following:

- adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation

- minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 1.0 mSv [0.1 rem] and declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv [0.1 rem]

The licensee must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person, in accordance with 10 CFR 20.1201(f).

Discussion: Applicants should review the use of all NRC-regulated materials and State-regulated activities (e.g., x-ray and accelerator operation) when determining, for NRC requirements, who is an occupationally exposed individual. The definitions in 10 CFR 20.1003 define occupational dose, a minor, a declared pregnant woman, and the embryo/fetus of a declared pregnant woman.

The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with Subpart F of 10 CFR Part 20. If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any applicable limit (See Figure 8-5 for annual dose limits), monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant females as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that an adult individual's dose is not likely to exceed 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. However, the evaluation should be documented. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the

facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. The licensees must also consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure and must have a program in place to sum those exposures in accordance with 10 CFR 20.1202.

Total effective dose equivalent (TEDE) equals the effective dose equivalent (for external exposures) plus the committed effective dose equivalent (for internal exposures).

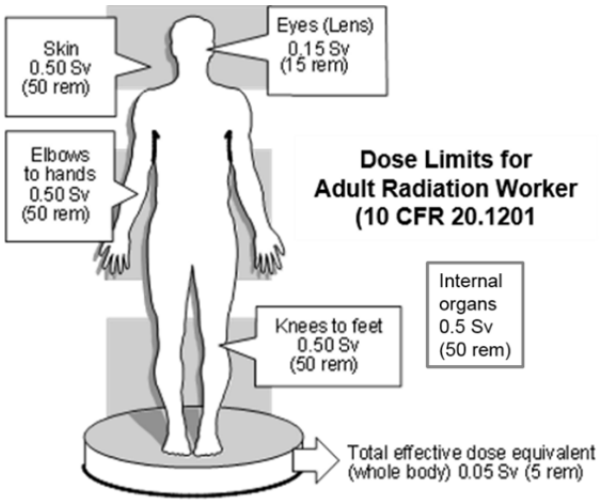


Figure 8-5. Annual Occupational Dose Limits for Adults

Licensees should use NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," to record individual dose. If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "N/A" for "not applicable" in the blocks on NRC Form 4, "Cumulative Occupational Dose History," and NRC Form 5, "Occupational Dose Record for a Monitoring Period," to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "not detectable."

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring and reporting of the results of monitoring performed, regardless of the actual dose received, is required. Licensees must provide individual radiation exposure data to each worker as required by 10 CFR 19.13.

Licensees should also perform prospective evaluations of the doses that may be received by occupationally exposed minors and declared pregnant women. As with individual adult workers, licensees must supply and require the use of individual monitoring devices to monitor external

exposures and monitor the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in 10 CFR 20.1502.

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

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

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

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

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 10 CFR 20.1502(a), licensees must use dosimeters supplied by a National Voluntary Laboratory Accreditation Program (NVLAP) -approved processor. Most licensees use either film badges or TLDs. The exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP approved processor for its recommendations for exchange frequency and proper use of the dosimeter. The NIST maintains a directory of laboratories that are NVLAP-approved.

RG 8.4, "Methods for Measuring Effective Dose Equivalent from External Exposure," June 18, 2015, provides guidance for evaluating occupational dose when some exposure is due to x-rays, and dosimeters are used to measure exposure behind lead aprons and elsewhere.

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

- concentrations of radioactive material in air in work areas
- quantities of radionuclides in the body
- quantities of radionuclides excreted from the body
- combinations of these measurements

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

Acceptable criteria that applicants may use in developing their bioassay programs are outlined in RG 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," July 1993.

For guidance about methodologies for determination of internal occupational dose and summation of occupational dose, refer to Table 8-2.

Table 8-2. Guidance on Personnel Monitoring and Bioassay

Regulatory Guide 8.7, Revision 2	Instructions for Recording and Reporting Occupational Radiation Exposure Data
Regulatory Guide 8.9, Revision 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program
Regulatory Guide 8.20, Revision 2	Applications of Bioassay for Radioiodine
Regulatory Guide 8.25, Revision 1	Air Sampling in the Workplace
Regulatory Guide 8.34	Monitoring Criteria and Methods to Calculate Occupational Radiation Doses
Regulatory Guide 8.36	Radiation Dose to the Embryo/Fetus
ANSI N13.30-2011	Performance Criteria for Radiobioassay
Information Notice 2000-10	Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits

Response from Applicant: Provide one of the following statements:

"We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."

OR

"We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program–Occupational Dose' in NUREG–1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"

OR, IN LIEU OF THESE STATEMENTS,

Provide a description of an alternative method for demonstrating compliance with the referenced regulations.

References and Resources:

- 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

- ANSI N322-1997, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters."

- NUREG/CR–4884, "Interpretation of Bioassay Measurements," July 1987.

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

- NCRP Report No. 124, "Sources and Magnitude of Occupational and Public Exposures from Nuclear Medicine," March 1996.

- ICRP Report No. 26, "Recommendations of the International Commission on Radiological Protection," 1977.

- ICRP Publication No. 54, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation," 1987.

- ICRP Publication No. 60, "1990 Recommendations of the International Commission on Radiological Protection," 1991.

- ICRP Publication No. 78, "Individual Monitoring for Internal Exposure of Workers," 1997.

- RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," July 1993.

- RG 8.4, "Methods for Measuring Effective Dose Equivalent from External Exposure," June 18, 2015.

8.10.3 Public Dose

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

Regulations: 10 CFR 20.1101(d), 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1801, 10 CFR 20.1802

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv [100 mrem] in a year, and the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour from licensed operations [10 CFR 20.1301(a)(1) and (2)].

- Ensure that air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv [10 mrem] [total effective dose equivalent (TEDE)] in a year from these emissions [10 CFR 20.1101(d)].

- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material to prevent unauthorized access, removal, or use (10 CFR 20.1801 and 20.1802).

Discussion: Public dose is defined in 10 CFR 20.1003 as "the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is when he or she receives the dose.

10 CFR 20.1302 describes how compliance may be achieved for public dose limits. Public dose is controlled, in part, by ensuring that licensed material is secure (e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using byproduct material under their supervision should have access to these keys.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD), are often used to show compliance.

The definition of "public dose" in 10 CFR 20.1003 does not include doses received due to exposure to patients released in accordance with 10 CFR 35.75. Dose to members of the public in waiting rooms was addressed in Informational Notice (IN) 94-09, "Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas Due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20," February 1994. The provisions of 10 CFR 20.1301(a) should not be applied to radiation

received by a member of the general public from patients released under 10 CFR 35.75. If a patient is released pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitors in a waiting room or individuals near a PET "quiet room") from a patient to 0.02 mSv [2 mrem] in any one hour. Patient waiting rooms and "quiet rooms" need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

The regulations in 10 CFR 20.1301(c) allow licensees to permit visitors to a patient who cannot be released under 10 CFR 35.75 to receive a dose greater than 0.1 rem [1 mSv], provided the dose does not exceed 0.5 rem [5 mSv], and the AU has determined before the visit that it is appropriate. RIS 2005-24, "Control of Radiation Dose to Visitors of Hospital Patients," November 23, 2005, discusses some of the measures that may be used to maintain control and minimize doses to visitors. RIS 2006-18, "Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients," August 31, 2006, describes dose limits for members of the public that are designated as caregivers. Caregiver dose limits may be established on a case-by-case basis by the licensee. The justification for incurring the exposure is that it is beneficial, or possibly essential, to the wellbeing of the patient, and may, therefore, be considered an extension of the patient's medical treatment.

In assessing the adequacy of facilities to control public dose, licensees should consider the design factors discussed under "Facility Diagram" in Section 8.9.1 and may find confirmatory surveys to be useful in assuring compliance with 10 CFR 20.1301.

The licensee must control emissions to air of all byproduct material such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level in 10 CFR 20.1101(d), "Radiation Protection Programs," of 0.10 mSv/year (yr) [10 mrem/yr] from those emissions. If exceeded, the licensee must report this as described in Section 8.10.22 and Appendix Y of this NUREG and take prompt actions to ensure against recurrence.

Response from Applicant: No response required.

8.10.4 Operating and Emergency Procedures

Regulations: 10 CFR 19.11(a)(3), 10 CFR 20.1101,10 CFR 20.1601, 10 CFR 20.1602, 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906, , 10 CFR 20.2201-2203, 10 CFR 21.21, 10 CFR 35.12, 10 CFR 35.41, 10 CFR 35.75, 10 CFR 35.310, 10 CFR 35.315, 10 CFR 35.404, 10 CFR 35.406, 10 CFR 35.410, 10 CFR 35.415, 10 CFR 35.610, 10 CFR 35.615, 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 35.3067, 10 CFR Part 37, 10 CFR 37.21(a), 10 CFR 37.45, 10 CFR 37.49

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

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document. The regulatory requirements are listed above for ease of reference by the applicant. In addition, these procedures must be posted in accordance with 10 CFR 19.11(a)(3).

The licensee must develop, implement, and maintain specific operating and emergency procedures sufficient to ensure compliance with 10 CFR 20.1101(a) and applicable sections in 10 CFR Part 35. Operating and emergency procedures must encompass the scope of the program, which may include the following elements:

- Instructions for opening packages containing licensed material (see Section 8.10.9, "Opening Packages").

- Instructions for using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Section 8.10.7, "Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources"). There may be sources and devices containing NARM that do not have SSD registration certificates. If these legacy sources or devices have manufacturers' recommendations or instructions, they should be followed. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.

- Instructions for conducting area radiation level and contamination surveys (see Section 8.10.13, "Area Surveys").

- Instructions for administering licensed material in accordance with the WD (see Section 8.10.14, "Procedures for Administrations when a Written Directive Is Required").

- Steps to ensure that patient release is in accordance with 10 CFR 35.75 (see Section 8.10.18, "Release of Patients or Human Research Subjects").

- Instructions for calibration of survey and dosage measuring instruments (see Sections 8.9.2, "Radiation Monitoring Instruments," and 8.9.3, "Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material.").

- Periodic spot-checks of therapy device units, sources, and treatment facilities (see Section 8.9.4, "Therapy Unit – Calibration and Use").

- Instructions for radioactive waste management (see Section 8.11, "Waste Management").

- Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material (see Sections 8.10.5, "Spill/Contamination Procedures," and 8.10.22, "Reporting").

- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.10.6, "Emergency Procedures for Therapy Devices Containing Sealed Sources").

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

The licensee should:

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

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

- Use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA, in accordance with 10 CFR 20.1101(b).

- Secure or control byproduct material at all times.

Additionally, licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material, listed in Appendix A to 10 CFR Part 37, must also establish, implement, and maintain its access authorization program; coordinate, to the extent practicable, with local law enforcement authorities, for responding to threats to the licensee's facility; and be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones.

Discussion: Sealed sources and unsealed byproduct material used for therapy can deliver significant doses in a short time. The same may be true for high-activity PET radiopharmaceuticals, if not shielded. Access control to high- and very-high-radiation areas and the security of licensed material are described in 10 CFR 20.1601, "Control of access to high radiation areas;" 10 CFR 20.1602, "Control of access to very high radiation areas;" 10 CFR 20.1801, "Security of stored material;" and 10 CFR 20.1802, "Control of Material Not in Storage." Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. When an operation or autopsy is to be performed, there should be an increased awareness of the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006.

Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking sources, medical events, interlock failures, stuck sources). After its occurrence becomes known to the licensee, the NRC must be notified when an incident involving licensed material occurs. Refer to the regulations (10 CFR 20.2201-20.2203, 10 CFR 30.50, 10 CFR 21.21, 10 CFR 35.3045, 10 CFR 35.3047, and 10 CFR 35.3067) for a description of when notifications are required.

Appendix N of this NUREG provides model procedures that are one method for responding to some types of emergencies. Applicants requesting authorization for licensed activities not addressed by the model procedures in Appendix N of this NUREG should develop operational and emergency procedures to address these other activities.

In accordance with 10 CFR Part 37, any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things,

- In accordance with 10 CFR 37.21(a), establish, implement, and maintain its access authorization program in accordance with the requirements of 10 CFR Part 37, Subpart B.
- In accordance with 10 CFR 37.45, coordinate with their local law enforcement agency (LLEA) for responding to threats to a licensee's facility.
- In accordance with 10 CFR 37.49, be able to monitor, detect without delay, assess, and respond to any unauthorized entries into security zones, including those surrounding mobile devices.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not to be submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: No response is necessary.

8.10.5 Spill/Contamination Procedures

Regulations: 10 CFR 20.1101

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

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

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

Response from Applicant: Provide the following statement:

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

Reference:

- NCRP Report No. 65, "Management of Persons Accidentally Contaminated with Radionuclides," 1980

8.10.6 Emergency Procedures for Therapy Devices Containing Sealed Sources

Regulations: 10 CFR 35.12(c)(2), 10 CFR 35.610, 10 CFR 35.615

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

Criteria: Before using materials under 10 CFR 35.600, "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit," the applicant must develop, document, implement, and submit written emergency procedures in accordance with 10 CFR 35.12(c)(2). Regulations in 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a GSR unit. The procedures needed to meet 10 CFR 35.610 must include

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally

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

Regulations in 10 CFR 35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require the physical presence of certain individuals for therapy units to ensure that safety precautions are appropriately implemented. The following documents provide useful information regarding physical presence requirements:

- IN 2012-08, "High Dose-Rate Remote Afterloader (HDR) Physical Presence Requirements," April 10, 2012
- RIS 2005-23, "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments," October 7, 2005

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

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

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

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

- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.

- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

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

- Specifying who is to be notified.

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

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

8.10.7 Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Regulations: 10 CFR 20.1101, 10 CFR 30.32, 10 CFR 35.605, 10 CFR 35.655

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

Criteria: Applicants requesting authorization to install, maintain, adjust, repair, and inspect their own therapy devices containing sealed sources must develop, document, submit, and implement those procedures in accordance with 10 CFR 20.1101 and 10 CFR 30.32. In accordance with 10 CFR 35.605, "Installation, maintenance, adjustment, and repair," and 10 CFR 35.655, "Five-year inspection for teletherapy and gamma stereotactic radiosurgery units," licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSD registry. In addition, 10 CFR 35.655 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

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

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

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

- name of the proposed employee and types of activities requested

AND

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

AND

- copy of the manufacturer's training certification and an outline of the training received

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

8.10.8 Ordering and Receiving

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

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.1906

Criteria: The requirements for receiving packages containing licensed material are found in 10 CFR 20.1906, "Procedures for receiving and opening packages." Additionally, the security of licensed material, required by 10 CFR 20.1801 and 10 CFR 20.1802, must be considered for all receiving areas.

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

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

Response from Applicant: No response is necessary.

8.10.9 Opening Packages

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

Regulations: 10 CFR 20.1906

Criteria: Licensees must ensure that packages are opened safely and that the requirements of 10 CFR 20.1906 are met.

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

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

Response from Applicant: No response required.

8.10.10 Material Receipt and Accountability

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

Regulations: 10 CFR 20.1801, 10 CFR 20.1802, 10 CFR 20.2108,10 CFR 20.2201, 10 CFR 20.2207, 10 CFR 30.41, 10 CFR 30.51, 10 CFR 35.67, 10 CFR 35.406, 10 CFR 37.49, 10 CFR 37.71, 10 CFR 37.75, 10 CFR 37.77.

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

- Secure licensed material. (10 CFR 20.1801 and 10 CFR 20.1802)
- Maintain records of receipt, transfer, and disposal of licensed material. (10 CFR 30.51, 10 CFR 30.41, and 10 CFR 20.2108)
- Conduct physical inventories at required frequencies to account for licensed material. Ensure that material received does not exceed license possession limits.
- Update transactions in the National Source Tracking System (NSTS), including an annual inventory reconciliation. [10 CFR 20.2207]
- Conduct physical inventories at semi-annual intervals (not to exceed 6 months) to account for all sealed sources containing byproduct material. (10 CFR 35.67)
- Maintain accountability for brachytherapy sources in storage or use. (10 CFR 35.406)
- Before transferring aggregated Category 1 or Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37, use NRC's license verification system to verify that the recipient licensee is authorized to possess the radioactive material.
- Preplan, coordinate, and provide advance notification of shipment of Category 1 quantities of radioactive material and coordinate shipment of Category 2 quantities of radioactive material listed in Appendix A to 10 CFR Part 37. (10 CFR 37.75 and 10 CFR 37.77)

Discussion: Licensed materials must be tracked from "cradle to grave," from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal in order to ensure accountability; to identify that licensed material is missing and document the last confirmed possession of the material when it is lost, stolen (10 CFR 20.2201), or misplaced; and to ensure that possession limits listed on the license are not exceeded.

For aggregated Category 1 and Category 2 quantities of radioactive material, licensees must, in accordance with 10 CFR 37.49(a)(1), continuously monitor and detect, without delay, all unauthorized entries into security zones. Additionally, for Category 1 quantities of radioactive material, 10 CFR 37.49(a)(3)(i) requires immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. For Category 2 quantities of radioactive material, 10 CFR 37.49(a)(3)(ii) requires weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

Licensees are required under 10 CFR 20.1801 and 20.1802 to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in Table X–1 in Appendix X of this NUREG. Typically, these records contain the following types of information:

- radionuclide and the activity (in units of becquerels or curies) of byproduct material in each sealed source
- manufacturer's or distributor's name, model number, and serial number (if appropriate) of each device containing byproduct material
- location of each sealed source and device
- for inventories, the date of the inventory, and name and signature of the individual conducting the inventory
- for materials transferred or disposed of, the date of the transfer or disposal, the name and license number of the recipient, and a description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's or distributor's name and model number, serial number)

Category 1 and Category 2 sealed sources listed in Appendix E to 10 CFR Part 20 (i.e., nationally tracked sources) must be tracked in the National Source Tracking System (NSTS) in accordance with 10 CFR 20.2207. The regulations in 10 CFR 20.2207 require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks Category 1 and Category 2 nationally tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.

There are additional security requirements for shipment and transfer of a Category 1 and Category 2 quantity of radioactive material listed in Appendix A to 10 CFR Part 37. Prior to transferring Category 1 or Category 2 quantities of radioactive material, licensees must use NRC's license verification system (or contact the licensing authority) to verify that the recipient licensee is authorized to possess the radioactive material. Licensees that ship Category 1 or Category 2 quantities of radioactive material must preplan and coordinate such shipments in accordance with 10 CFR 37.75. Shipments of Category 1 quantities are also subject to the 10 CFR 37.77 advance notification requirements. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant:

- If applicable, provide the following statement: "We will comply with the National Source Tracking System (NSTS) reporting requirement as described in 10 CFR 20.2207."

8.10.11 Leak Tests

Regulations: 10 CFR 20.1501, 10 CFR 35.67

Part 35	Applicability
100	✓*
200	✓*
300	✓*
400	✓
500	✓
600	✓
1000	✓
*If possess sealed sources under 10 CFR 35.65	

Criteria: The NRC requires testing to determine if there is any radioactive leakage from sealed sources. The NRC finds testing to be acceptable if it is conducted by an organization licensed by the NRC or an Agreement State or if it is conducted in accordance with procedures submitted by the applicant and approved by the NRC or an Agreement State. Leak test records shall be retained for 3 years after they are made or until the source in storage is removed.

Discussion: Licensees must perform leak testing of sealed sources possessed under 10 CFR Part 35 (e.g., calibration, transmission, reference, or brachytherapy sources), in accordance with 10 CFR 35.67, "Requirements for possession of sealed sources and brachytherapy sources." In addition, licensees must perform leak testing of all other sealed sources possessed under 10 CFR Part 30 (e.g., survey instrument calibration sources), in accordance with 10 CFR 20.1501.

The NRC has regulatory authority over sealed sources and devices containing accelerator-produced radioactive material and discrete sources of Ra-226, in accordance with the Energy Policy Act of 2005. There may be sources and devices containing this NARM byproduct material that do not have SSD registration certificates. These devices and sources are, however, subject to the standard leak test provisions included in materials licenses.

Appendix Q of this NUREG provides model procedures that are one way to perform leak testing for sealed sources. Under 10 CFR 35.67, licensees are required to perform leak tests at 6-month intervals or at other intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate and before first use, unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 185 Bq [0.005 µCi] of radioactivity on the sample. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. The leak test may be performed in-house or by a contractor who is authorized by the NRC or an Agreement State to perform leak tests as a service to other licensees.

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

- Sources contain only byproduct material with a half-life of less than 30 days.
- Sources contain only byproduct material as a gas.
- Sources contain 3.7 MBq [100 µCi] or less of beta-emitting or gamma-emitting material, or 0.37 MBq [10 µCi] or less of alpha-emitting material.

- Sources contain iridium-192 seeds in nylon ribbon.

- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Response from Applicant: No response is necessary, if leak testing is performed in-house. If a contractor is used to perform leak testing, the licensee should state the following:

"Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

8.10.12 Sealed Source Inventory

Regulations: 10 CFR 30.51, 10 CFR 35.67, 10 CFR 35.406

Criteria: The NRC requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession. The licensee must maintain the inventory records for 3 years.

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

*Sealed sources for calibration, transmission, and reference use (10 CFR 35.65)

Discussion: According to 10 CFR 35.67, 10 CFR 35.406, and per license condition, if applicable (e.g., instrument calibration source), the licensee must conduct a semi-annual physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in 10 CFR 35.67(g). However, under 10 CFR 30.51, the licensee must maintain records of GSR source receipt, transfer, and disposal to indicate the current inventory of sources at the licensee's facility.

Response from Applicant: No response is necessary.

8.10.13 Area Surveys

Regulations: 10 CFR 20.1003, 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1501, 10 CFR 35.70, 10 CFR 35.315, 10 CFR 35.404, 10 CFR 35.604

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

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

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 1 mSv/yr [100 mrem/yr] and that the dose in any unrestricted area will not exceed 0.02 mSv [2 mrem] in any one hour from licensed operations, in accordance with 10 CFR 20.1301.

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

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

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

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for area surveys. Surveys, as defined in 10 CFR 20.1003, are evaluations of radiological conditions and potential hazards. These evaluations, as required by 10 CFR 20.1501, may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

There are many different kinds of surveys performed by licensees:

- contamination
  - fixed
  - removable

- personnel (during use, transfer, or disposal of licensed material)
- air effluent
- water effluent
- leak test
- bioassays
- air sample
- external radiation exposure levels
- restricted areas
- unrestricted areas

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

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

- measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas (Refer to RG 8.25, "Air Sampling in the Workplace," June 1992, and NUREG–1400, "Air Sampling in the Workplace," September 1993, for further guidance on air sampling.)

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

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

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

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Appendix R of this NUREG contains model procedures that represent one acceptable method of establishing survey frequencies for medical use, ambient radiation levels, and contamination surveys.

For example, in accordance with 10 CFR 35.70, medical use licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a WD is required (diagnostic activities exceeding 1.1 MBq (30 µCi) of I-131 and all therapy treatments); when the licensee administers radiopharmaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey of the patient's room. Licensees should perform surveys after the patient's release, in accordance with 10 CFR 35.315. Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate that public dose limits are not exceeded.

As therapy sealed sources (including applicators, catheters, and therapy sources used for diagnostic purposes) may become dislodged during implantation or after surgery, and inadvertently lost or removed, the licensee must perform surveys in accordance with 10 CFR 35.404:

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

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

In addition, the licensee should also consider the following:

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

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

- all trash exiting the patient's room or surgical recovery room

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

In accordance with 10 CFR 35.604, the licensee must survey patients and the remote afterloader unit to confirm that the source has been removed from the patient and returned to the safe shielded position.

Response from Applicant: Provide the following statement:

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

References and Resources:

- NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," 1978.
- RG 8.25, "Air Sampling in the Workplace," June 1992.
- NUREG–1400, "Air Sampling in the Workplace," September 1993.

8.10.14 Procedures for Administrations When a Written Directive Is Required

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

Regulations: 10 CFR 35.40, 10 CFR 35.41, 10 CFR 35.457, 10 CFR 35.657

Criteria: The requirements for WDs are set forth in 10 CFR 35.40, "Written directives." Under 10 CFR 35.41, "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by AUs.

Discussion: A medical use licensee preparing WDs must develop, implement, and maintain written procedures to provide high confidence that, among other things, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met. Some licensees' procedures were developed when the predecessor to 10 CFR 35.41, called Quality Management Program, was initiated in the 1990s, and licensees may not have updated these procedures even though administration methods and assessments may have changed. For instance, prior to 1990, many licensees implanted sources for prostate treatments without pre-planning or post-planning dosimetry. Today, many licensees perform extensive imaging and dosimetry to prescribe and evaluate doses to not only intended tissue (e.g., prostate), but also to nearby tissue (e.g., rectum, bladder, or urethra). Therefore, licensees are reminded that procedures should correctly document the program currently in place. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

Additionally, under 10 CFR 35.457 and 10 CFR 35.657, the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

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

Licensees may find the list of INs summarizing reported medical events in Appendix AA of this NUREG useful in developing written directive procedures.

Response from Applicant: No response required.

8.10.15 Safe Use of Unsealed Licensed Material

Regulations: 10 CFR 20.1101, 10 CFR 20.1201, 10 CFR 30.33(a)(2)

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

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

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

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

- use of syringe shields and/or vial shields, specific to the energy emitted (e.g., PET shields should be used when handling high-energy fluorine-18)
- wearing laboratory coats and gloves when handling unsealed byproduct material
- monitoring hands after handling unsealed byproduct material
- designing equipment and facilities to protect health and minimize danger to life or property in accordance with 10 CFR 30.33(a)(2)

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

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

8.10.16 Safety Procedures for Treatment When Patients are Hospitalized

Regulations: 10 CFR 20.1201, 10 CFR 20.1301, 10 CFR 20.1501, 10 CFR 20.1801, 10 CFR 35.315, 10 CFR 35.404(b), 10 CFR 35.415, 10 CFR 35.604(a), 10 CFR 35.615, 10 CFR 35.1000

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

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

Discussion: Under 10 CFR 35.315, 10 CFR 35.415, 10 CFR 35.615, and 10 CFR 35.1000, licensees are required to take certain safety precautions for uses of byproduct material involving radiopharmaceutical therapy, manual brachytherapy, remote afterloader brachytherapy, or emerging technologies involving patients who cannot be released in accordance with 10 CFR 35.75. The precautions described below are provided to help ensure compliance with the exposure limits in 10 CFR Part 20.

Under 10 CFR 35.404(b) and 10 CFR 35.604(a), licensees are required to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. When sources are placed within the patient's body, 10 CFR 35.615(e) requires that licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source. In addition, applicants must take the following steps for patients who cannot be released under 10 CFR 35.75:

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

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

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

- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation survey meter set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or handle them as radioactive waste (10 CFR 35.315 and 10 CFR 20.1501).

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

Licensees are required to perform adequate surveys to evaluate the extent of radiation levels in accordance with 10 CFR 20.1501. Therefore, licensees must evaluate the exposure rates around patients who cannot be released under the requirements of 10 CFR 35.75 and are hospitalized following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

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

In order to control exposures to individuals, in accordance with 10 CFR 20.1201 and 10 CFR 20.1301, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

Response from Applicant: No response is necessary.

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

8.10.17 Mobile Medical Service

Regulations: 10 CFR 35.2, 10 CFR 35.80, 10 CFR 35.647, 10 CFR Part 71, 10 CFR 150.20, 49 CFR Parts 171-178

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

Discussion: Applicants for licensure of mobile medical services, as defined in 10 CFR 35.2, should review other sections of this NUREG for information to be submitted as part of their applications; many other requirements are relevant to the use of byproduct material by mobile medical service providers, with details being dependent upon the scope of such programs. "Temporary jobsite" means a location, other than the specific location(s) of use authorized on the license, where mobile medical services are conducted for limited periods of time. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should be located on the client's property that is under the client's control. Mobile PET medical service licensees must consider a "quiet room" as an area of use if the patients in the "quiet room" cannot be released under the provisions of 10 CFR 35.75.

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

The general types of services provided as mobile medical services are

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

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

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

Refer to Appendix V of this NUREG for additional guidance on information to provide in applications and Appendix Z of this NUREG for information on transportation requirements (10 CFR Part 71 and 49 CFR Parts 171-178).

Agreement State licensees that request reciprocity for activities conducted in NRC States are subject to the general license provisions described in 10 CFR 150.20. This general license authorizes persons holding a specific license from an Agreement State to conduct the same activity in NRC States if the specific license issued by the Agreement State does not limit the authorized activity to specific locations or installations. Licensees should contact the appropriate NRC Regional Office for reciprocity information.

An NRC licensee who wishes to conduct operations at temporary jobsites in an Agreement State should contact that State's Radiation Control Program Office for information about State regulations, including notification requirements, whether the AU meets the requirements to be an AU in that State, and if mobile medical services are allowed within the Agreement State through reciprocity. The licensee should contact the appropriate Agreement State using the NRC's Agreement State Directory. To ensure compliance with Agreement State reciprocity requirements, an NRC licensee shall request authorization well in advance of scheduled work. In addition to the requirements specified in 10 CFR 150.20, "Reciprocity," applicants requesting a mobile medical service license should contact all States where they plan to conduct mobile medical services, to clarify requirements, including training and experience requirements for AUs, as well as requirements associated with an authorization to practice medicine within the State's jurisdiction.

Response from Applicant: The applicant should review the guidance in Appendix V of this NUREG to determine the response required.

8.10.18 Release of Patients or Human Research Subjects

Regulations: 10 CFR 35.75

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

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

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

- guidance on the interruption or discontinuation of breastfeeding
- information on the potential consequences of failure to follow the guidance

Appendix U of this NUREG provides guidance to the applicant for determining when

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (See Section U.1 in Appendix U of this NUREG).
- Instructions to the patient are required by 10 CFR 35.75(b). (See Appendix U.2 of this NUREG)

Appendix U of this NUREG lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

The NRC has issued additional information on controlling exposures to members of the public. Licensees should review RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011, for NRC's policy on the release of I-131 therapy patients to locations other than private residences. Licensees should also review RIS 2008-11, "Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administration of Iodine-131," May 12, 2008, for precautions that should be taken to protect infants and young children who may come in contact with patients released after administration of therapeutic amounts of I-131.

Response from Applicant: No response required.

8.10.19 Minimization of Contamination

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

Regulations: 10 CFR 20.1406 and 10 CFR 35.67

Criteria: Applicants must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste in accordance with 10 CFR 20.1406.

Discussion: Applicants should consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed byproduct material. As described in Section 8.10.5, "Spill/Contamination Procedures," cleanup procedures should be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in Appendix R, Tables R–2 and R–3 of this NUREG.

Sealed sources and devices that are approved by the NRC or an Agreement State and located and used according to their SSD registration certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD registration certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to NRC requirements in 10 CFR 35.67. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant: A response from applicants is not required under the following condition: The NRC will consider that the above criteria have been met if the information provided in the applicant's responses satisfy the criteria in Sections 8.9, 8.9.1, 8.10, 8.10.7, 8.10.15, and 8.11, on the following topics: facility and equipment, facility diagram, radiation protection program, and waste management.

8.10.20 Records of Dosages and Use of Brachytherapy Sources

Regulations: 10 CFR 30.51, 10 CFR 35.63, 10 CFR 35.204,

10 CFR 35.2063, 10 CFR 35.2204, 10 CFR 35.2406

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

Criteria: Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years, in accordance with 10 CFR 30.51.

Discussion: Licensees are required to make and maintain records of each dosage and administration prior to medical use. In accordance with 10 CFR 35.2063, the records must include:

- radiopharmaceutical
- patient's or human research subject's name or identification number (if one has been assigned)

- prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq [30 µCi]
- date and time of dosage determination
- name of the individual who determined the dosage

In accordance with 10 CFR 35.63, dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements or an NRC or Agreement State medical use licensee authorized under 10 CFR 30.32(j) to produce PET radioactive drugs. If molybdenum-99 (Mo-99) concentration is measured under 10 CFR 35.204, records of Mo-99 concentration must be made under 10 CFR 35.2204 and must include, for each measured elution of Tc-99m:

- ratio of the measurements expressed as kilobecquerel (kBq) (µCi) of Mo-99 per MBq (mCi) of Tc-99m
- date and time of the measurement
- name of the individual who made the measurement

If Sr-82 and strontium-85 (Sr-85) concentrations are measured under 10 CFR 35.204, "Permissible molybdenum-99, strontium-82, and strontium-85 concentrations," records of Sr-82 and Sr-85 concentrations must be made under 10 CFR 35.2204, "Records of molydenum-99, strontium-82, and strontium-85 concentrations," and must include for each measured elution of Rb-82:

- ratio of the measurements expressed in kBq (µCi) of Sr-82 per MBq (mCi) of Rb-82 chloride and kBq (µCi) of Sr-85 per MBq (mCi) of Rb-82
- date and time of the measurement
- name of the individual who made the measurement

Licensees who use Rb-82/Sr-82 generators should also refer to the CardioGen-82 Highlights of Prescribing Information for further guidance on documentation and recordkeeping.

If the licensee uses manual brachytherapy sources, the following records of use must be kept in accordance with 10 CFR 35.2406:

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

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

Response from Applicant: No response is necessary.

8.10.21 Recordkeeping

Regulations: 10 CFR Part 20, Subpart L; 10 CFR 30.51; 10 CFR Part 35, Subpart L; 10 CFR 37.23, 37.31, 37.43, 37.75, and 37.103.

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

Criteria: Licensees must maintain records as provided in 10 CFR Part 20, Subpart L; 10 CFR 30.51; and 10 CFR Part 35, Subpart L. In accordance with 10 CFR Part 37, licensees authorized to possess Category 1 or Category 2 quantities of radioactive material must maintain records as provided in 10 CFR 37.23, 37.31, 37.43, 37.75, and 37.103.

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

Response from Applicant: No response is necessary.

8.10.22 Reporting

Regulations: 10 CFR Part 20, Subpart M; 10 CFR 21.21; 10 CFR 30.50; 10 CFR 31.5; 10 CFR Part 35, Subpart M

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

Criteria: Licensees are required to report to the NRC via telephone, written report, or both, in the event that the safety or security of byproduct material may be compromised. The specific events that require reporting are explained in 10 CFR Part 35, Subpart M; 10 CFR Part 20, Subpart M; and in 10 CFR 21.21, 30.50, and 31.5. The timing and type of report are specified within these parts.

Discussion: The NRC requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, 10 CFR Parts 20, 21, 30, 31, and 35 include provisions that describe reporting requirements associated with the medical use of byproduct material. A table of reporting requirements appears in Appendix Y of this NUREG.

Response from Applicant: No response is necessary.

8.10.23 Transportation

Regulations: 10 CFR 30.41; 10 CFR 37, Subpart D; 10 CFR 71.5; 10 CFR 71.13; 10 CFR 71.17; 10 CFR 71.37; 10 CFR 71, Subpart H; 49 CFR Parts 171-178

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

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

In accordance with 10 CFR Part 37 (Subpart D), licensees must also preplan, coordinate and provide advance notification of the shipment of Category 1 quantities of radioactive material and coordinate the shipment of Category 2 quantities of radioactive material.

Discussion: Most packages of licensed material for medical use contain quantities of radioactive material that require the use of Type A packages. Many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the "Limited Quantity" criteria described in 49 CFR 173.421, "Excepted Packages for Limited Quantities of Class 7 (Radioactive) Materials," and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met {e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv/h [0.5 mrem/h]}.

The general license in 10 CFR 71.17, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC. This general license is subject to certain conditions. The requirements for transportation of licensed material are set forth in 10 CFR 71.5, "Transportation of Licensed Material." The regulations in 10 CFR 71.13 exempt from the requirements in 10 CFR 71.5 any physician licensed by a State to dispense drugs in the practice of medicine, who is also licensed under 10 CFR Part 35 or the equivalent Agreement State regulations. This exemption applies to transport by the physician of licensed material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or GSR) may need to ship licensed material in Type B packages. The Type B package requirements for transporting or delivering the package to a carrier for transport are set forth in 10 CFR Part 71. These include registration as a user of the package and the requirement to have an NRC-approved quality assurance (QA) plan. See 10 CFR 71.17(c)(3) for registration information and 10 CFR 71.101 for QA plan information. For information about these QA programs, see RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," March 2005. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Division of Spent Fuel Management by calling NRC toll-free at 800-368-5642, extension 415-9956. For information about associated fees, visit the NRC License Fees Web site.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee) then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and

DOT regulations. Licensees who do this must ensure that the manufacturer (or service licensee):

- is authorized to possess the licensed material (see 10 CFR 30.41)
- actually takes possession of the licensed material under its license

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

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

Appendix Z of this NUREG lists major DOT regulations that apply to medical use licensees.

Medical use licensees are reminded of the following:

- The licensee must properly block and brace the transportation case when transporting byproduct material to ensure that the material does not shift during transport.

- The licensee must have emergency response information, including current emergency response telephone numbers that meet the requirements of Subpart G, "Emergency Response Information," of 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans."

- Initial and recurrent training must be given to all employees who transport byproduct material per the requirements of Subpart H, "Training," of 49 CFR Part 172.

- The licensee shall maintain transportation shipping records in accordance with the requirements of Subpart C, "Shipping Papers," of 49 CFR Part 172, including the proper shipping name, hazard class (Class 7), United Nations identification number, the name of the shipper, and the name and activity of each radionuclide.

Licensees shipping or transferring a Category 1 or Category 2 quantity of radioactive material are subject to the 10 CFR Part 37, Subpart D ("Physical Protection in Transit"). For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

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

8.10.24 Security Program for Category 1 and Category 2 Radioactive Material

Regulations: 10 CFR Part 37

Criteria: Licensees must ensure the security of Category 1 and Category 2 radioactive material.

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

Note: The regulations in 10 CFR Part 37 apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material. The specific radionuclides subject to 10 CFR Part 37 requirements are listed in Table 1 of Appendix A to 10 CFR Part 37.

Discussion:

Requirements in 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material"

In accordance with 10 CFR Part 37, licensees that possess aggregated Category 1 or Category 2 quantities of radioactive material must establish, implement, and maintain an access authorization program (Subpart B) and a security program (Subpart C) to ensure physical protection of the radioactive material.

Table 1 of Appendix A, "Category 1 and Category 2 Radioactive Materials," to 10 CFR Part 37 lists Category 1 and Category 2 threshold quantities of radioactive material. The applicant should refer to this table to determine whether its proposed activities would be subject to the 10 CFR Part 37 requirements.

Before giving individuals unescorted access to Category 1 or Category 2 quantities of radioactive material (as defined in 10 CFR 37.5), licensees must conduct background investigations of these individuals, to determine that they are trustworthy and reliable, in accordance with 10 CFR 37.25.

In accordance with 10 CFR 37.41(b), licensees must establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

Per 10 CFR Part 37, Subpart D, licensees must provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the Subpart D requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.

Applicants and licensees are required to implement the 10 CFR Part 37 security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

Any licensee that has not previously been made subject to the provisions of 10 CFR Part 37, Subpart C, shall notify the NRC regional office specified in 10 CFR 30.6 in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold. Pursuant to 10 CFR 37.43(b), as part of the security program, the licensee must develop and maintain written procedures that document how the requirements of Subpart C will be met. These written procedures may be subject to NRC review and inspection.

For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Response from Applicant: No response is required from an applicant or licensee. Compliance with access authorization and security program requirements may be reviewed during NRC inspections.

Note: In accordance with 10 CFR 37.41(a)(3), any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C, shall notify the NRC in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

8.11 Item 11: Waste Management

Regulations: 10 CFR 20.1101, 10 CFR 20.1301, 10 CFR 20.1302, 10 CFR 20.1501, 10 CFR 20.1902, 10 CFR 20.1904, 10 CFR 20.2001-2008, 10 CFR 30.3, 10 CFR 30.41(b), 10 CFR 31.11; 10 CFR 35.92, 10 CFR 37.11(c), 10 CFR 61.3

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

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

- transfer to an authorized recipient (10 CFR 30.41(b), 20.2006, 20.2008)
- decay-in-storage (10 CFR 35.92)
- release in effluents within the limits in 10 CFR 20.1301 or
- as authorized under 10 CFR 20.2002 through 20.2005

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 10 CFR 20.1101 must include provisions for waste disposal of licensed material. Appendix W of this NUREG contains model procedures that represent one way to provide for decay-in-storage and generator or other licensed material

return. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

- The NRC has concluded that materials with half-lives of less than or equal to 120 days are appropriate for decay-in-storage (DIS) and interim storage. The holding time of the waste should be based on the radionuclide(s), half life, and the activity present when the waste was placed into storage. Such waste may be disposed of as in-house trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. In accordance with 10 CFR 20.1904(b), all radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed. Applicants must maintain accurate records of such disposals.

- Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with 10 CFR 20.2001(b), 10 CFR 20.2006, or in applicable regulations in 10 CFR 30.3 or 10 CFR 61.3. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.

- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location and appropriately posted in accordance with 10 CFR 20.1902. In addition, all storage containers must be appropriately labeled in accordance with 10 CFR 20.1904. ***Note:*** Some short half-life radionuclide products (e.g., samarium-153, Tc-99m/Mo-99 generator columns and Y-90 microspheres) may contain long half-life contaminants that may preclude disposal by decay-in-storage. Long-lived contaminants need not be listed on an NRC license; however, licensees need to perform surveys and dispose of the material in accordance with 10 CFR Parts 20 and 35 requirements. Licensees using Y-90 microspheres should review IN 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities," for applicability.

- Check and calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) may not be held for decay-in-storage and must be disposed of in accordance with 10 CFR Part 20.

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

- In accordance with 10 CFR 20.1302, consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of

material into air and water under 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," and 20.2003, "Disposal by Release into Sanitary Sewerage," respectively.

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

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

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

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

- Applicants that wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Section 8.9.1, Facility Diagram:

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

— the types, quantities, and concentrations of the waste to be compacted

— an analysis of the potential for airborne release of radioactive material during compaction activities

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

— methods used to monitor worker breathing zones and/or exhaust systems

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

— the instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, and methods of handling uncompacted waste and examining containers for defects

Note: Before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), if licensees are authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form, the licensees must, in accordance with 10 CFR 30.51(e), transfer the following records to the new licensee:

- records of disposal of licensed material made under:
  - — 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures"
  - — 10 CFR 20.2003, "Disposal by release into sanitary sewerage"
  - — 10 CFR 20.2004, "Treatment or disposal by incineration
  - — 10 CFR 20.2005, "Disposal of specific wastes"

- records required by 20.2103(b)(4) of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment

Nuclear pacemakers: Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify the NRC and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee that implanted the device is responsible for the follow-up, explanation, and return of the pacemaker to the manufacturer for proper disposal. IN 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

Waste Return from Landfills or Medical Incinerators: Medical licensees are periodically contacted by the waste broker after receipt of potentially contaminated medical waste. As described in IN 99-33, "Management of Wastes Contaminated with Radioactive Materials," December 21, 1999, licensees must evaluate waste in accordance with 10 CFR 20.1501, "Surveys and Monitoring," and manage the storage and or disposal of the waste in accordance with applicable regulations and license conditions.

In accordance with 10 CFR 37.11(c), a licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material as defined in 10 CFR 37.5 is exempt from the requirements of 10 CFR Part 37, Subparts B, C, and D. However, any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of 10 CFR Part 37. For additional guidance on implementing 10 CFR Part 37 requirements, see NUREG–2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG–2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

A licensee possessing radioactive waste that is exempt under 10 CFR 37.11(c) from the requirements of 10 CFR Part 37, Subparts B, C, and D must implement the following requirements to secure the radioactive waste:

- use continuous physical barriers that allow access to the radioactive waste only through established access control points;
- use a locked door or gate with monitored alarm at the access control point;
- assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
- immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains Category 1 or Category 2 quantities of radioactive material.

Please note, under 10 CFR Part 37, security plans are not submitted to the NRC, but may be subject to review and inspection.

Response from Applicant: For other treatment or disposal of waste, provide the following statement:

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

Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration.

References and Resources:

- Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," dated March 1994
- Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," dated January 1994

- Information Notice 84-94, "Reconcentration of Radionuclides Involving Discharges into Sanitary Sewage Systems Permitted Under 10 CFR 20.203 (now 10 CFR 20.2003)," dated December 1984

- Information Notice 90-09, "Extended Interim Storage of Low Level Radioactive Waste by Fuel Cycle and Materials Licensees," dated February 1990

- Regulatory Issue Summary 2008-12, "Considerations For Extended Interim Storage Of Low Level Radioactive Waste By Fuel Cycle And Materials Licensees"

- Regulatory Issue Summary 2011-09, "Available Resources Associated With Extended Storage Of Low Level Radioactive Waste"

- Policy and Guidance Directive PG 8-10, "Disposal of Incineration Ash as Ordinary Waste," January 1997, ADAMS Accession Nos. ML003744979 and ML003752866 and Addendum, ADAMS Accession Nos. ML003744984 and ML003744988.

- NRC Regulatory Issue Summary 2004 17, Revision 1, Revised Decay-In-Storage Provisions For The Storage Of Radioactive Waste Containing Byproduct Material, September 2005

- State and Tribal Communication Letter FSME 12-025 dated March 13, 2012 "Clarification of the Authorization for Alternative Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR" (ADAMS Accession No. ML12065A038)

8.12 Item 12: License Fees

Regulation: 10 CFR 170.31

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

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

Direct all questions about the NRC's fees or completion of Item 12 of NRC Form 313 to the Office of the Chief Financial Officer at NRC Headquarters in Rockville, MD, 301-415-7554. Information about fees may also be obtained by calling NRC's toll free number, 800-368-5642, extension 415-7554. The e-mail address for fees questions is Fees.Resource@nrc.gov.

8.13 Item 13: Certification

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

A representative of the corporation or legal entity filing the application must sign and date NRC Form 313. The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in Chapter 3, "Management Responsibility," signing the application acknowledges management's commitment to and responsibility for the radiation protection program. The NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to knowingly and willfully make a false statement or representation on applications or correspondence (18 U.S.C. 1001).

- When an application references commitments, those items will be incorporated into the license and, therefore, will become binding regulatory requirements.

9 LICENSE AMENDMENTS AND RENEWALS

9.1 Timely Submittals of Amendments and Renewals

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

Regulations: 10 CFR 2.109(a), 10 CFR 30.36, 10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.12, 10 CFR 35.13, 10 CFR 35.14, 10 CFR 35.24(c)

Criteria: It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date [10 CFR 2.109(a), 10 CFR 30.36(a)].

Discussion: Under Title 10 of the *Code of Federal Regulations* (CFR)10 CFR 35.13, "License amendments," a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- receiving or using byproduct material for a type of use permitted by 10 CFR Part 35, but not authorized on the licensee's current Part 35 license
- permitting anyone to work as an authorized user (AU) for medical uses, authorized medical physicist (AMP), or authorized nuclear pharmacist (ANP), unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) [information required to document training and experience may be provided on the appropriate U.S. Nuclear Regulatory Commission (NRC) Form 313A series of forms for change or addition of AU for medical uses, AMP, ANP, or radiation safety officer (RSO)]
- changing the RSO
- receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than currently authorized on the NRC license
- changing an area or address of use identified in the application or on the license; includes additions and relocations
- revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety

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

Response from Applicant: No response is required from an applicant for a new license. Applicants for license amendment or renewal should do the following:

- Use the most recent guidance in preparing an amendment or renewal request.

- Submit either an NRC Form 313 or a letter requesting an amendment or renewal. (10 CFR 30.37, 10 CFR 30.38, 10 CFR 35.12)

- Provide the license number and docket number.

For renewals, provide a complete and up-to-date application, including all required program elements outlined in Appendix C of this NUREG. The licensee may reference recent documents that have been previously accepted. Training documentation for personnel currently listed on the license does not need to be submitted as part of the renewal application.

9.2 Timely Notification of Transfer of Control

9.2.1 Transfer of Control

Regulation: 10 CFR 30.34(b)

Criteria: Licensees must provide all supporting information and obtain the NRC's prior, *written consent* before transferring control of the license, also referred to as a "change of ownership" and/or "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the NRC's intent to interfere with the business decisions of licensees, under 10 CFR 30.34(b) and the Atomic Energy Act, licensees must obtain prior NRC written consent before transferring control of the license to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses or Agreement State licenses.

- Materials are properly handled and secured.

- Persons using these materials are capable, competent, and committed to implementing appropriate radiological controls.

- A clear chain of custody is established to identify who is responsible for disposition of records and licensed material.

- Adequate financial assurance is provided for compliance with the applicable NRC requirements, if required.

- Public health and safety are not compromised by the use of such materials.

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer to NUREG–1556, Volume 15, "Consolidated Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," for more information about transfer of control (i.e., ownership).

Reference: For further information, see Regulatory Issue Summary (RIS) 2014-08, Rev. 1 "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses," dated May 5, 2016.

9.2.2 Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h)

Criteria: Immediately following the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of the filing.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable NRC regulatory requirements. The NRC must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The NRC shares the results of its determinations with other involved entities (e.g., trustee), so that health and safety issues can be resolved before bankruptcy actions are completed and may request that the U.S. Department of Justice represent the NRC's interests in the bankruptcy proceeding.

Response from Applicant: None is required at the time of application for a new license. Licensees must immediately notify the NRC, in writing, following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

Reference: See NUREG–1556, Volume 15, "Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses."

9.2.3 Other

Licensees are required to notify the NRC of program changes as noted below:

- decommissioning activities in accordance with 10 CFR 30.36(d)
- new AUs, AMPs, and ANPs who meet the criteria in 10 CFR 35.14(a)
- current AUs, AMPs, ANPs, and RSOs permanently discontinuing duties in accordance with 10 CFR 35.14(b)(1)
- temporary RSOs in accordance with 10 CFR 35.14(b)(2) and 35.24(c)
- change in mailing address in accordance with 10 CFR 35.14(b)(3)
- name change that does not constitute a transfer of control in accordance with 10 CFR 35.14(b)(4)
- new areas of use or changes to the areas of use where 10 CFR 35.100 and 200 materials are used in accordance with 10 CFR 35.14(b)(5)
  Note: an amendment is needed to release for unrestricted use

10 APPLICATIONS FOR EXEMPTIONS

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

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

Criteria: Licensees may request exemptions from U.S. Nuclear Regulatory Commission (NRC) regulations. The licensee must demonstrate that the exemption is authorized by law; will not endanger life, property, or the common defense and security; and is otherwise in the public interest.

Discussion: Various sections of the NRC's regulations address requests for exemptions (e.g., Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 19.31, "Applications for exemptions;" 10 CFR 20.2301, "Applications for exemptions;" 10 CFR 30.11, "Specific Exemptions;" and 10 CFR 35.19, "Specific Exemptions"). These regulations state that the NRC may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations or to apply to large classes of licensees and are generally limited to unique situations. Requests for exemptions submitted to the NRC must identify the regulation for which the exemption is being requested and include a justification for the requested exemption.

Unless the NRC has granted an exemption in writing, licensees must comply with all applicable regulations.

Type A broad scope licensees are granted certain exemptions as described in 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope."

11 TERMINATION OF ACTIVITIES

Regulations: 10 CFR 20 Subpart E, 10 CFR 30.34(b), 10 CFR 30.35(g), 10 CFR 30.36, 10 CFR 30.51, 10 CFR 40.42, 10 CFR 40.51, 10 CFR 40.61

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

Criteria: In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 30.36(d) and 10 CFR 40.42(d), the licensee must do the following:

- Notify the U.S. Nuclear Regulatory Commission (NRC), in writing, within 60 days of the occurrence of any of the following:
  - — expiration of its license
  - — a decision to permanently cease principle activities[1] at the entire site
  - — for licensees subject to 10 CFR 30.36, a decision to permanently cease principle activities[1] in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
  - — for licensees subject to 10 CFR 40.42, a decision to permanently cease principal activities[1] in any separate building or outdoor area
  - — no principal activities[1] under the license have been conducted for a period of 24 months
  - — no principal activities[1] have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or area is unsuitable for release according to NRC requirements
- Submit a decommissioning plan, if required by 10 CFR 30.36(g) or 10 CFR 40.42(g).
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j) or 10 CFR 40.42(h) and (j).
- Submit, to the appropriate NRC regional office, a completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and information demonstrating that the premises are suitable for release for unrestricted use (e.g., results of final surveys and results of leak tests of sealed sources).
- Before a license is terminated, send the records important to decommissioning that are required by 10 CFR 30.35(g) and/or 10 CFR 40.36(f) to the appropriate NRC regional office, in accordance with 10 CFR 30.51(d) and (f) or 10 CFR 40.61(d) and (f).

[1] 'Principal activities' are activities that are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

- Before a license is terminated, send records of disposal of licensed material made under 10 CFR 20.2002, 20.2003, 20.2004, 20.2005, and the results of measurement and calculations used to evaluate the release of radioactive effluents to the environment to the appropriate NRC regional office in accordance with 10 CFR 30.51(d) and/or 10 CFR 40.61(d), if authorized to possess byproduct material with a half-life greater than 120 days in an unsealed form and/or source material in an unsealed form, respectively.

Discussion: To comply with the above criteria, before a licensee can decide whether it must notify the NRC under 10 CFR 30.36(d), the licensee must determine whether residual radioactivity is present and, if so, whether the levels make the building or outdoor area unsuitable for release, according to the NRC requirements. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection. For information about requirements that apply to the timeliness of decommissioning, see Regulatory Issue Summary (RIS) 2015-19, Revision 1, "Decommissioning Timeliness Rule Implementation and Associated Regulatory Relief," dated September 27, 2016.

In general, most medical licensees use licensed material with short half-lives [e.g., technetium-99m (Tc-99m) with a 6-hour half-life] and sealed sources (e.g., dose calibrator sources and manual brachytherapy sources). In addition, most medical licensees do not dispose of licensed material to the sanitary sewer. Therefore, in these instances, the licensees should submit the following:

- area radiation level surveys, including a description of instruments used, showing that all areas previously used are at background

- area contamination wipes, including a description of instruments used, showing that all areas previously used are at background

- leak tests for all sealed sources transferred or disposed

- transfer or disposal documentation for all sealed sources (and unsealed material, if applicable)

If the half-life of the licensed material used is sufficiently short compared to the time of last use, area surveys and contamination wipes may be unnecessary. For instance, if only Tc-99m has ever been used and the last use was a month ago, surveys would not be warranted.

For guidance on the disposition of licensed material, see Section 8.11, "Waste Management." For guidance on decommissioning records, see Section 8.5.2, "Financial Assurance and Recordkeeping for Decommissioning."

For regulations governing radiological criteria for license termination, licensees should refer to 10 CFR Part 20 Subpart E.

NUREG–1757, Volume 1, "Decommissioning Process for Materials Licensees," September 2006, contains the current regulatory guidance concerning decommissioning of facilities and termination of licenses. NUREG–1757, Volume 2, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria," September 2006, may also be useful guidance in describing the disposition of licensed material and facilities.

Response from Applicant: The applicant is not required to submit a response to the NRC during the initial application. The licensee's obligations in this matter begin when the license expires or at the time the licensee ceases operations, whichever is earlier. These obligations are to undertake the necessary decommissioning activities, to submit NRC Form 314 or equivalent information, and to perform any other actions summarized in "Criteria" above.

Reference: NRC Form 314 is available at http://www.nrc.gov/reading-rm/doc-collections/forms.

APPENDIX A

SAFETY CULTURE POLICY STATEMENT

Safety Culture

The safety culture policy statement was published in the *Federal Register* (76 FR 34773) on June 14, 2011, and can be found at: http://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf. It is also posted in the U.S. Nuclear Regulatory Commission (NRC) Agencywide Documents Access and Management System Accession Number ML11146A047.

Safety Culture Policy Statement

The purpose of this Statement of Policy is to set forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States, Agreement State licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy.

Nuclear Safety Culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The NRC will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort versus safety. It should be noted that although the term ''security'' is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

(1) *Leadership Safety Values and Actions* – Leaders demonstrate a commitment to safety in their decisions and behaviors;

(2) *Problem Identification and Resolution* – Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;

(3) *Personal Accountability* – All individuals take personal responsibility for safety;

(4) *Work Processes* – The process of planning and controlling work activities is implemented so that safety is maintained;

(5) *Continuous Learning* – Opportunities to learn about ways to ensure safety are sought out and implemented;

(6) *Environment for Raising Concerns* – A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;

(7) *Effective Safety Communication* – Communication maintains a focus on safety;

(8) *Respectful Work Environment* – Trust and respect permeate the organization; and

(9) *Questioning Attitude* – Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes.

It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy.

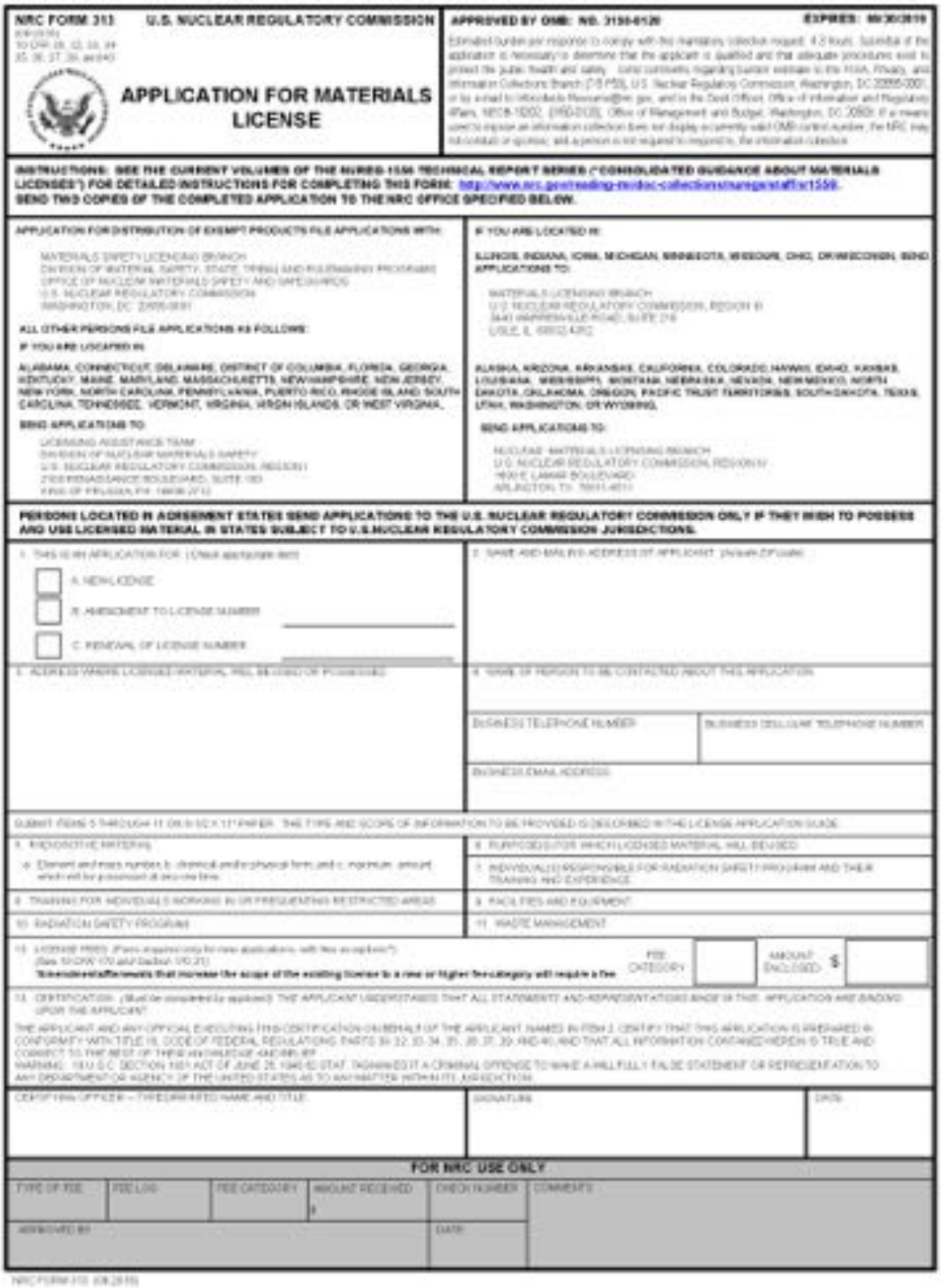
APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION FORM 313

1

U.S. Nuclear Regulatory Commission Form 313

Please use the most current version of this form, which may be found at:
http://www.nrc.gov/reading-rm/doc-collections/forms/



NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120 EXPIRES:

APPLICATION FOR MATERIALS LICENSE

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/.
SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKINGS PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

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

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
612 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

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

1. THIS IS AN APPLICATION FOR: (Check appropriate item)
   - A. NEW LICENSE
   - B. AMENDMENT TO LICENSE NUMBER
   - C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

BUSINESS TELEPHONE NUMBER | BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

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

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSE FEES (Fees are required only for new applications, with few exceptions)
(See 10 CFR 170 and Section 170.31)
Amendments/renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY | AMOUNT ENCLOSED: $

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFUL FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED OR PRINTED NAME AND TITLE | SIGNATURE | DATE

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
ASSIGNED TO			DATE		

NRC FORM 313 (08-2010)

APPENDIX C

LICENSE APPLICATION CHECKLISTS

License Application Checklists

This Appendix contains links and checklists that may be used to assist in organizing an application, including the U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License," and the NRC Form 313A series, "Medical Use Training and Experience and Preceptor Attestation," which can be found on the Medical Uses Licensee Toolkit.

Items 1-4 and 12-13 may be completed on NRC Form 313. Table C–1 may be used to describe Item 5 (Radioactive Material) and Item 6 (Purpose of Use), and Table C–2 may be used to describe Items 7 and 8 (Training and Experience), Item 9 (Facilities and Equipment), Item 10 (Radiation Safety Program), and Item 11 (Waste Management). Table C–3, Applicable Appendices Describing Model Procedures, may be helpful to applicants in developing procedures for inclusion in their radiation safety program. Please note that the procedures provided are not all-inclusive (e.g., full calibration and emergency procedures for therapy devices are not included and only references to American Association of Physicists in Medicine and American National Standards Institute standards are made in this NUREG document). In addition, uses conducted under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.1000 may require procedures specific to the emerging technology; however, the procedures described in the document may be helpful in developing these procedures. Finally, Appendix X, Y, and Z of this NUREG are not model procedures; however, they are included in Table C–3 to remind licensees of recordkeeping, reporting, and transportation requirements.

Table C–1 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for the type of radioactive material requested and the purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required," or 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," then the applicant should check the "yes" column next to 10 CFR 35.100 and 35.200 in Table C–1. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

The applicant should review the guidance in Chapter 6, "Identifying and Protecting Sensitive Information," and mark security-related sensitive information appropriately.

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390" ❑ **Yes** ❑ **No**			
Radionuclide	**Form or Mfr/Mod No.**	**Max Qty**	**Purpose of Use**
❒Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
❒Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
❒Any byproduct material permitted by 10 CFR 35.300 (Note: Check this box if using all radionuclides covered by 35.300; otherwise, check subsequent boxes if limiting use by radionuclide).	Any	_____ millicuries (mCi)	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300. ❒inpatient (facility diagram attached) ❒outpatient (Note: Check the inpatient box if keeping patients in-house who are not releasable pursuant to 10 CFR 35.75. If releasable, check outpatient.)
❒Iodine-131 permitted by 10 CFR 35.300	Any	___mCi	Oral administration of sodium iodide iodine-131. ❒inpatient (facility diagram attached) ❒outpatient
❒Samarium-153 permitted by 10 CFR 35.300	Any	___mCi	Parenteral administration of samarium-153 ❒inpatient (facility diagram attached) ❒outpatient
❒Other Radionuclide permitted by 10 CFR 35.300 _____	Any	___mCi	Purpose of Use ❒inpatient (facility diagram attached) ❒outpatient
❒Iodine-125 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No._____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒outpatient
❒Palladium-103 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒outpatient

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390" ❑ **Yes** ❑ **No**			
Radionuclide	**Form or Mfr/Mod No.**	**Max Qty**	**Purpose of Use**
❒Iridium-192 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒inpatient (facility diagram attached)
❒Cesium-131 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒outpatient
❒Cesium-137 permitted by 10 CFR 35.400	Sealed sources (Manufacturer _____, Model No. _____)	___mCi	Any manual brachytherapy procedure permitted by 10 CFR 35.400. ❒inpatient (facility diagram attached)
❒Strontium-90 permitted by 10 CFR 35.400	Sealed source (Manufacturer _____, Model No._____)	___mCi	Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
❒Iodine-125 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
❒Barium-133 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
❒Cesium-137 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390" ❑ **Yes** ❑ **No**			
Radionuclide	**Form or Mfr/Mod No.**	**Max Qty**	**Purpose of Use**
❒Gadolinium-153 permitted by 10 CFR 35.500	Sealed sources (Manufacturer _____, Model No. _____) Device (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
❒Iridium-192 permitted by 10 CFR 35.600	Sealed sources (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ remote afterloader unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
Note: If requesting an individual source activity of greater than 10 curies, see the Medical Uses Licensee Toolkit for the current models approved for a higher activity.			
❒Cobalt-60 permitted by 10 CFR 35.600	Sealed sources (Manufacturer _____, Model No._____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.

Table C–1. Items 5 and 6 on NRC Form 313: Radioactive Material and Use (Continued) This response includes security-related sensitive information that is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390" ❑ **Yes** ❑ **No**			
Radionuclide	**Form or Mfr/Mod No.**	**Max Qty**	**Purpose of Use**
❒Cobalt-60 permitted by 10 CFR 35.600	Sealed sources (Manufacturer _____, Model No. _____)	___curies per source and ___curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ gamma stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery device.
❒Any byproduct material permitted by 10 CFR 31.11	Prepackaged kits	___mCi	*In vitro* studies.
❒Depleted uranium	Metal	___kilograms	Shielding in a linear accelerator.
❒Any radionuclide in excess of 30 mCi for use in calibration. List radionuclide: _____	Sealed source	___mCi	For use in a Manufacturer _____, Model No. _____ for calibrations and checking of licensee's survey instruments.
❒Americium-241	Sealed source (Manufacturer _____, Model No. _____)	___mCi	For use as an anatomical marker.
❒Other	Form or Manufacturer/ Model No. _____	___mCi	Purpose of use _____.

Table C–2 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name of the radiation safety officer (RSO) in Table C–2 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application. Personal information about employees or other individuals should not be submitted unless specifically requested by the NRC. Examples of private information are social security number, home address, home telephone number, date of birth, and radiation dose information. If private information is submitted, it should be separated from the public portion of the application and clearly marked: "Privacy Act Information—Withhold Under 10 CFR 2.390." See Chapter 6, "Identifying and Protecting Sensitive Information," for more information.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal

Item 7: Radiation Safety Officer (RSO)
RSO Name:

❒ Listed on previous license as an RSO within the last 7 years

- Provide NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope

OR

❒ Board certified by an NRC-recognized board

- Attach copy of board certification which includes prescribed language and shows issuance within specified dates

OR

❒ Has classroom/laboratory training and supervised radiation safety experience

- Attach completed NRC Form 313A (RSO) or equivalent documentation

AND

❒ Except for an RSO previously listed on a license/permit for the same types of uses, has radiation safety training for each type of medical use documented

- Attach Table 3.c. of NRC Form 313A (RSO) or equivalent documentation
- Attach Preceptor Attestation

AND

❒ If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

AND

❒ For consultant-RSO or contractor, attach statements regarding the following:

- Commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. The statement should include the consultant-RSO's minimum amount of onsite time (hours per week).

AND

- Identification of an in-house representative who will serve as the point of contact during the RSO's absence.

A description of the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of radiation safety program and related regulatory requirements. Specification of the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his/her presence.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 7: Authorized Users (AUs)
Authorized User(s) Name(s):

❒ Provide state or territory where licensed

❒ Listed on previous license as an AU for the same type of use(s) requested within the last 7 years

- Provide NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope

OR

❒ Board certified by an NRC-recognized board

- Attach copy of board certification which includes prescribed language and shows issuance within specified dates

OR

❒ Has classroom/laboratory training and supervised radiation safety experience

- Attach completed NRC Form 313A (AUD, AUT, AUS) or equivalent documentation

AND

❒ Except for an AU previously listed on a license/permit for the same types of uses, has radiation safety training for each type of medical use documented

- Attach casework experience for 10 CFR 35.300
- Attach vendor training documentation or equivalent for each device requested under 10 CFR 35.600 – see Table 3.e. of NRC Form 313A (AUS)
- Attach Preceptor Attestation

AND

❒ If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

❒ For emerging technologies requested in accordance with 10 CFR 35.1000, documented training submitted in accordance with the applicable guidance found on the Medical Uses Licensee Toolkit.

❒ Listed on previous license as an AMP for the same type of use(s) requested within the last 7 years

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 7: Authorized Medical Physicist (AMP) Authorized Medical Physicist(s) Name(s):
• Provide NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope **OR** ❒ Board certified by an NRC-recognized board • Attach copy of board certification which includes prescribed language and shows issuance within specified dates **OR** ❒ Has degree, medical physics training, and medical physics work experience • Attach completed NRC Form 313A (AMP) or equivalent documentation, which includes: — Master's degree or doctorate in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university — Documentation of 1 year of full-time training in medical physics — Documentation of 1 year of full-time work experience in medical physics **AND** ❒ Except for an AU previously listed on a license/permit for the same types of uses, has radiation safety training for each type of medical use documented • Attach vendor training documentation or equivalent for each device requested under 10 CFR 35.600 – see Table 3.e. of NRC Form 313A (AMP) • Attach Preceptor Attestation **AND** ❒ If applicable, recently received related training, if the original training and experience was received greater than 7 years ago ❒ For emerging technologies requested in accordance with 10 CFR 35.1000, documented training submitted in accordance with the applicable guidance found on the Medical Uses Licensee Toolkit.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 7: Authorized Nuclear Pharmacist (ANP) Authorized Nuclear Pharmacist(s) Name(s):
❒ Provide state or territory where licensed AND ❒ Listed on previous license as an AMP for the same type of use(s) requested within the last 7 years • Provide NRC License #_____ or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC Master Materials License broad scope **OR** ❒ Board certified by an NRC-recognized board • Attach copy of board certification which includes prescribed language and shows issuance within specified dates **OR** ❒ Has classroom/laboratory training and supervised practical experience in nuclear pharmacy • Attach completed NRC Form 313A (ANP) or equivalent documentation **AND** ❒ Except for an ANP previously listed on a license/permit, has radiation safety training for each type of medical use documented • Attach Preceptor Attestation **AND** ❒ If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 8: Training for Individuals Working In or Frequenting Restricted Areas
A response is not required. Refer to Section 8.8, "Training for Individuals Working in or Frequenting Restricted Areas."

Item 9: Facility Diagram

❒ A diagram(s) is enclosed that describes the facilities. For Positron Emission Tomography (PET), radiopharmaceutical therapy, manual brachytherapy, and all therapy devices, identify activities conducted in all contiguous areas surrounding the area(s) of use, including areas above and below. On the diagram, indicate: the scale used; the designated areas of use, storage, or preparation; room numbers; and principal use of each room and contiguous area.

❒ A diagram(s) is enclosed that describes therapy in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use.

❒ Guidance in Chapter 6, "Identifying and Protecting Sensitive Information," was reviewed and security-related sensitive information provided is marked accordingly.

❒ Shielding calculations are enclosed for:

- PET facilities
- In-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use
- High Dose-Rate/Pulsed Dose-Rate & Low Dose-Rate Remote Afterloaders
- Teletherapy
- Gamma stereotactic radiosurgery (GSR)

❒ The shielding calculations include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations also include the workload assumptions used.

❒ For teletherapy facilities direction(s) of primary beam use and, in the case of an isocentric unit, the plane of beam rotation is identified in the shielding calculations.

❒ Occupancy factors are provided for contiguous areas and whether surrounding areas are restricted or unrestricted as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Radiation Monitoring Instruments

❒ A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

AND/OR

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

AND

❒ A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

AND

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

Item 9: Dose Calibrator and Other Dosage Measuring Equipment

For the administration of alpha-, gamma- and beta-emitting unsealed byproduct materials, we are providing the following:

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

❒ A description of the equipment used to measure the dosages.

For alpha-emitters where gamma or beta emissions are not measureable:

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

OR

❒ We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 9: Therapy Unit - Calibration and Use ❒ We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application. **Item 9: Other Equipment and Facilities** ❒ Guidance in Chapter 6, "Identifying and Protecting Sensitive Information," was reviewed and security-related sensitive information provided is marked accordingly. ❒ Attached is a description of additional facilities and equipment. ❒ For manual brachytherapy facilities, we are providing a description of the emergency response equipment. For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: ❒ Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; ❒ Area radiation monitoring equipment; ❒ Viewing and intercom systems (except for low dose-rate units); ❒ Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, x-ray machine) is in the treatment room; ❒ Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and ❒ Emergency response equipment. **Item 10: Emergency Procedures for Therapy Devices Containing Sealed Sources** ❒ Attached are procedures required by 10 CFR 35.610. ❒ Guidance in Chapter 6, "Identifying and Protecting Sensitive Information," was reviewed and security-related sensitive information provided is marked accordingly

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)
Item 10: Occupational Dose ❒ A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in a year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG–1556, Vol. 9, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " **OR** ❒ A description of an alternative method for demonstrating compliance with the referenced regulations. **Item 10: Leak Tests** ❒ No response is necessary, if leak testing is performed in-house. If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits and/or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit." **Item 10: Area Surveys** ❒ A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70." **Item 10: Safe Use of Unsealed Licensed Material** ❒ A statement that: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301." **Item 10: Spill/Contamination Procedures** ❒ A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

Table C–2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

❒ Name of the proposed employee and types of activities requested:

_____

_____

AND

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

AND

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

Item 10: Minimization of Contamination

A response is not required under the following condition: The NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfies the criteria in Sections 8.9, 8.9.1, 8.10, 8.10.7, 8.10.15, and 8.11, on the topics: facilities and equipment, facility diagram, radiation protection program, safety program, and waste management.

Item 11: Waste Management

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

❒ Attached is a description of the radioactive waste incinerator facility and related portions of the radiation safety program (10 CFR 20.2004).

Table C–3 is provided to help applicants determine which procedures must be developed, implemented, and maintained for the type of medical use requested. Several appendices in this report present sample procedures that applicants may use in developing their procedures.

Table C–3. Applicable Appendices Describing Model Procedures

Appendix	Topic	35.100 35.200	35.300	35.400	35.500	35.600
G	Dose Calibrator Calibration	x	X			
H	Remote Afterloader Spot-Checks					x
I	Radiation Safety Officer Duties, Responsibilities, and Delegation	x	X	x	x	x
J	Training Program	x	X	x	x	x
K	General Radiation Monitoring Instrument Specifications and Calibration	x	X	x	x	x
L	Medical Licensee Audit	x	X	x	x	x
M	Occupational Dose Program	x	X	x	x	x
N	Emergency Procedures	x	X			
O	Ordering and Receiving Packages	x	X	x	x	x
P	Safely Opening Packages Containing Radioactive Material	x	X	x	x	x
Q	Leak Tests	x	X	x	x	x
R	Area Surveys	x	X	x	x	x
S	Developing, Maintaining, and Implementing Written Directives		X	x		x
T	Safe Use of Unsealed Licensed Material	x	X			
U	Release of Patients	x	X	x		
V	Mobile Medical Service	x	X		x	x
W	Waste Disposal	x	X	x	x	x
X	Recordkeeping	x	X	x	x	x
Y	Reporting	x	X	x	x	x
Z	Transportation	x	X	x	x	x

APPENDIX D

DOCUMENTATION OF TRAINING AND EXPERIENCE TO IDENTIFY INDIVIDUALS ON A LICENSE

Documentation of Training and Experience to Identify Individuals on a License

Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), or radiation safety officer (RSO) to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the U.S. Nuclear Regulatory Commission (NRC) or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material broad scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review and the individual meets the recentness of training criteria described in Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 35.59, "Recentness of training." When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Ra-226, or Both, for Medical or Nuclear Pharmacy Uses

The NRC implemented a waiver for Naturally-Occurring and Accelerator-Produced Radioactive Material, which has expired. Specifically, the NRC "grandfathered" RSOs, physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, under states where the material was formerly licensed or registered need to apply under a different pathway listed in this section.

Applications that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by the NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC Form 313A (RSO) for the Radiation Safety Officer; NRC Form 313A (AMP) for the authorized medical physicist; NRC Form 313A (ANP) for the authorized nuclear pharmacist; NRC Form 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, and/or 35.500; NRC Form 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC Form 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, or RSO. The first is by means of certification by a board recognized by the NRC

and listed on the NRC Web site as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a). Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H. Additional training may also need to be documented for RSOs, AMPs, and AUs under 10 CFR 35.600.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. In some cases, there may be additional training and experience routes for recognized AUs, ANPs, AMPs, or RSOs to seek additional authorizations.

Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience for physicians include the following:

- successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use

- practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization

- practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization

- for therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant

General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms [i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)]. Also, if the applicant requests that a physician be authorized for both HDR remote afterloader and gamma stereotactic radiosurgery (GSR) under 10 CFR 35.600, only NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad scope license or broad scope permit of a Master Materials License, provide a copy of the permit issued by the broad scope licensee/permittee. Alternatively, provide a statement signed by the RSO or chairperson of the RSC similar to the following: "_____ (name of supervising individual or

preceptor) is authorized under _____ (name of licensee/permittee) broad scope license number_____ to use_____ (materials) during _____ (time frame)."

INTRODUCTORY INFORMATION

Name of Individual

Provide the individual's complete name so that the NRC can distinguish the training and experience received from that received by others with a similar name.

***Note**:* Do not include personal or private information (e.g., date of birth, social security number, home address, personal telephone number) as part of your qualification documentation.

State or Territory Where Licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the U.S., the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of "physician," "dentist," "podiatrist," and "pharmacist" in 10 CFR 35.2, "Definitions").

Requested Authorization(s)

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by the NRC. Specialty board certifications recognized by the NRC are posted on the Medical Uses Licensee Toolkit.

***Note**:* An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding board certifications other than those listed on the Medical Uses Licensee Toolkit will also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework, as indicated on the specific form of the NRC Form 313A series.

All applicants under this pathway (except for 10 CFR 35.500 uses) must submit a completed Part II Preceptor Attestation.

Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework, as indicated on the specific form of the NRC Form 313A series. (***Note**:* This section does not include individuals who are authorized only on foreign licenses.)

All applicants under this pathway must submit a completed Part II Preceptor Attestation.

Item 3. Alternate Pathway for Training and Experience for Proposed New Authorized Individuals

This pathway is used for those individuals not listed on the license as authorized individuals or do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (i) classroom and laboratory training, and (ii) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (i) classroom and laboratory training, or (ii) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the “classroom and laboratory training,” provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed authorized individual may obtain the required “classroom and laboratory training” in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the “supervised work experience” sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements to confirm that the listed subject areas were included in the supervised work experience.

The “supervised work experience” for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For nuclear pharmacists, under the "supervised practical experience" section, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

***Note**:* If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Part II. Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. The preceptor language in NRC Forms 313A (AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual has the knowledge to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - Select One of Four Methods Below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and a completed preceptor attestation). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above

Provide the requested information [i.e., documentation of specific radiation safety training (complete the table in 3.c) and a completed preceptor attestation in Part II]. As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO. This is documented in Section 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his or her qualifications.

Provide the requested information [i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c)]. Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Submit a completed Preceptor Attestation in Part II.

Item 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on the Licensee's License

Provide the requested information [i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 3.c)]. As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an RSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's training or identification on the license as an AU, AMP, or ANP is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation for the individual's competency to function independently as an RSO for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO on a medical use license, in addition to the preceptor's signature.

The preceptor for a new proposed RSO must fill out all four sections.

The preceptor for an RSO seeking authorization to be recognized as an RSO for the additional medical use(s) must fill out the second, third, and fourth sections.

VII. AUTHORIZED MEDICAL PHYSICIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)

See Section V, "General Instructions and Guidance for Filling Out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - Select one of the Three Methods Below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of device-specific training in the table in 3.c, and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If

more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience, which cannot be concurrent. This is documented in Section 3.b by providing the ranges of dates for training and work experience.

If the proposed AMP had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an AMP, the applicant must provide documentation that the supervising individual meets the requirements in 10 CFR 35.51, “Training for an authorized medical physicist,” and 10 CFR 35.59, “Recentness of training.”

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his or her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the proposed AMP’s training is in the first section.

The attestation for the device-specific training is in the second section.

The attestation of the individual's competency to function independently as an AMP for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new AMP must fill out all four sections of this page. The preceptor for an AMP seeking additional authorizations must complete the last three sections.

VIII. AUTHORIZED NUCLEAR PHARMACIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (ANP)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - Select One of the Two Methods Below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed Sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in Section 2.b.

Submit a completed Preceptor Attestation.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections. The preceptor must select either the board certification or the structured educational program when filling out the first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material, in addition to the preceptor's signature.

IX. 10 CFR 35.100, 35.200, AND 35.500 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUD)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Current 35.390 Authorized User Seeking Additional 10 CFR 35.290 Authorization

(a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.

(b) Provide a description of the proposed user's experience that meets the requirements of 10 CFR 35.290(c)(1)(ii)(G) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name, and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

***Note**:* Providing the training and experience information required under 10 CFR 35.290 will allow the individual to be authorized to use materials permitted by both 10 CFR 35.100 and 10 CFR 35.200.

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 10 CFR 35.500 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 10 CFR 35.500 uses.

Submit a completed Preceptor Attestation, except for 10 CFR 35.500 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections. The attestations for training and experience requirements in 10 CFR 35.190 and 10 CFR 35.290 are found in the first section. The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature. The preceptor must fill out both sections.

***Note**:* The attestation to the proposed user's training and competency to function independently under 10 CFR 35.190 covers the use of material permitted by 10 CFR 35.100 only. The attestation for the proposed user's training and competency to function independently under 10 CFR 35.290 will allow the individual to be authorized to use material permitted by both 10 CFR 35.100 and 10 CFR 35.200.

X. 35.300 AUTHORIZED USER - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUT)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

If the applicant is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.300 on NRC's Web site, provide the requested information [i.e., a copy of the board certification, documentation of supervised clinical experience (complete the table in section 3.c), and a completed Preceptor Attestation]. As indicated on the form, additional information is needed if the board certification or supervised clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is a radiation oncologist whose board certification is not listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's Web site, documentation of training and supervised work experience with unsealed materials requiring a written directive (WD) (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name, and include the license showing the supervising individual as an AU.

Item 2. Current 10 CFR 35.300, 10 CFR 35.400, or 10 CFR 35.600 Authorized User Seeking Additional Authorization

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the applicant is currently authorized for a subset of clinical uses under 10 CFR 35.300, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name, and include the license showing the supervising individual as an AU.

If the applicant is currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meets the requirements in 10 CFR 35.396, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a WD (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The attestations for training and experience requirements in 10 CFR 35.390, 10 CFR 35.392, and 10 CFR 35.394 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for competency to function independently as an AU for specific uses are in the third section.

The attestation for training and experience requirements and competency to function independently for a radiation oncologist meeting the requirements in 10 CFR 35.396 is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

There are seven possible categories of individuals seeking AU status under this form. Follow the instructions for the applicable category.

The preceptor for a proposed AU who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on the Medical Uses Licensee Toolkit must complete the first, second, third, and fifth sections.

The preceptor for a proposed AU for all the uses listed in 10 CFR 35.390(b)(1)(ii)(G) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on the Medical Uses Licensee Toolkit must complete the first, second, third, and fifth sections.

The preceptor for a proposed AU for 10 CFR 35.390(b)(1)(ii)(G)(iii) and (iv) uses who is a radiation oncologist with a board certification listed under 10 CFR 35.490 or 10 CFR 35.690 on the Medical Uses Licensee Toolkit must complete the fourth and fifth sections.

The preceptor for an AU who is currently authorized for a subset of clinical uses under 10 CFR 35.300 must complete the second, third, and fifth sections of this part, except for an AU

meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394.

The preceptor for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394 must complete the first, second, third, and fifth sections.

The preceptor for an AU currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meeting the requirements in 10 CFR 35.396 must complete the fourth and fifth sections.

The preceptor for a proposed new AU must complete the first, second, third, and fifth sections.

XI. 35.400 AND 35.600 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUS)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification) for 10 CFR 35.600 uses, documentation of device-specific training in the table in 3.e, and for all uses, a completed Preceptor Attestation. As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users or either a supervising AU or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 2. Current 10 CFR 35.600 Authorized User Requesting Additional Authorization for 10 CFR 35.600 Use(s) Checked Above

Provide the requested information [i.e., documentation of device-specific training (complete the table in 3.e)] and a completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience were completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 10 CFR 35.400 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 (Sr-90) for ophthalmic use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of Sr-90 for ophthalmic use. If more than one supervising AU provided the supervised clinical experience, identify each supervising individual by name and provide his or her qualifications.

Submit a completed Section 3.d for each requested 10 CFR 35.600 use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his or her qualifications.

Submit a completed Section 3.e for each specific 10 CFR 35.600 device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his or her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The attestation to the training and individual's competency for 10 CFR 35.400 uses or Sr-90 eye applicator use is in the first section.

The attestation to the training for the proposed AU for 10 CFR 35.600 uses is in the second section.

The attestation for the 10 CFR 35.600 device-specific training is in the third section.

The attestation of the individual's competency to function independently as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

The preceptor for a 10 CFR 35.400 proposed AU must fill out the first and fifth sections.

The preceptor for a 10 CFR 35.600 proposed AU must fill out the second, third, fourth, and fifth sections.

The preceptor for an AU seeking additional 10 CFR 35.600 authorizations must complete the third, fourth, and fifth sections.

APPENDIX E

U.S. NUCLEAR REGULATORY COMMISSION FORM 313A (AUD)

U.S. Nuclear Regulatory Commission Form 313A (AUD)

Please use the most current version of this form, which may be found at:
http://www.nrc.gov/reading-rm/doc-collections/forms/

NRC FORM 313A (AUD) (MM-YYYY) | U. S. NUCLEAR REGULATORY COMMISSION | APPROVED BY OMB: NO. 3150-0120 EXPIRES: (MM/DD/YYYY)

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed

Requested Authorization(s) *(check all that apply)*

☐ 35.100 Uptake, dilution, and excretion studies ☐ 35.200 Imaging and localization studies

☐ 35.500 Sealed sources for diagnosis (specify device) _____

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

(iii) Stop here.

☐ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

☐ 35.290 ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G) ☐ 35.57 for 35.200 uses

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NRC FORM 313A (AUD)
(MM-YYYY)

U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

☐ 3. **Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use *(not required for 35.590)*			
Radiation biology			
Total Hours of Training: ☐			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience **Total Hours of Experience:** ☐

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

☐ 35.55 ☐ 35.57 for 35.200 uses

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

NRC FORM 313A (AUD) (MM-YYYY) U. S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each use requested:

For 35.190

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290 (c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses under 10 CFR 35.100 and 35.200.

Second Section

Complete one of the following for attestation and signature:

☐ Authorized User:

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience ☐ 35.57 for 35.200 uses

OR

☐ Residency Program Director:

☐ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience ☐ 35.57 for 35.200 uses

☐ I affirm that this facility member concurs with the attestation I am providing as program director.

☐ I affirm that the residency training program is approved by the:

☐ Residency Review Committee of the Accreditation Council for Graduate Medical Education

☐ Royal College of Physicians and Surgeons of Canada

☐ Committee on Post-Graduate Training of the American Osteopathic Association

☐ I affirm that the residency training program includes training and experience specified in:

☐ 35.190 ☐ 35.290

Name of Facility:	License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
Signature		

APPENDIX F

CHECKLIST FOR REQUESTS TO WITHHOLD PROPRIETARY INFORMATION FROM PUBLIC DISCLOSURE (UNDER 10 CFR 2.390)

Checklist for Requests to Withhold Proprietary Information from Public Disclosure (Under 10 CFR 2.390)

In order to request that the U.S. Nuclear Regulatory Commission (NRC) withhold information from public disclosure, the applicant or licensee must submit the information, including an affidavit, in accordance with Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding." The applicant should submit all of the following:

☐	A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the nonproprietary portions intact. This copy should **not** be marked as proprietary.
☐	An affidavit that:
☐	Is notarized.
☐	Clearly identifies (such as by name or title and date) the document to be withheld.
☐	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information the organization is seeking to withhold and is authorized to apply for withholding on behalf of the organization.
☐	States that the organization submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	Provides a rational basis for holding the information in confidence.
☐	Fully addresses the following issues:
☐	Is the information submitted to, and received by, the NRC in confidence? Provide details.
☐	To the best of the applicant's knowledge, is the information currently available in public sources?
☐	Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your organization, the amount of effort or money expended in developing the information, and the ease or difficulty for others to acquire the information.

APPENDIX G

MODEL PROCEDURES FOR DOSE CALIBRATOR CALIBRATION

Model Procedures for Dose Calibrator Calibration

The model procedure provides acceptable methods for dose calibrator testing when measuring photon-emitting radionuclides. Applicants may either adopt this model procedure or develop an alternative procedure in accordance with manufacturer's instructions or a nationally recognized standard.

The tests should be performed at the indicated frequency:

- constancy, at least once each day prior to assay of patient dosages (+/- 10%)
- linearity, at installation and at least annually thereafter (+/- 10%)
- geometry dependence, at installation (+/- 10%)
- accuracy, at installation and at least annually thereafter (+/- 10%)

The dose calibrator will be repaired, replaced, or corrected arithmetically if the dose calibrator falls outside the suggested tolerances. For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 megabecquerels (MBq) or 30 microcurie (μCi)] if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use.

Constancy means reproducibility in measuring a constant source over a long period of time. At least one relatively long-lived source, such as cesium-137 (Cs-137), cobalt-60, cobalt-57 (Co-57), or radium-226 will be assayed using reproducible geometry each day before using the calibrator. Two or more sources with different photon energies and activities will also be used.

1. Assay each reference source using the appropriate dose calibrator setting (e.g., use the Cs-137 setting to assay Cs-137).

2. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

3. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.

4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings. Record (e.g., plot, log) the results.

5. Notify the radiation safety officer (RSO) or the authorized user if the test results fall outside +/- 10% of the expected results.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 1.1 MBq [30 μCi]. This test will be performed using a vial or syringe of technetium-99m (Tc-99m) whose activity is at least as large as the maximum activity normally assayed for administration.

Time Decay Method

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the next activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.

2. Repeat the assay at approximately 4-hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 1.1 MBq [30 µCi]. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

3. Convert the time and date information you recorded to hours elapsed since the first assay.

4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

5. Notify the RSO, if the deviation is more than $^{+}/_{-}$ 10%.

Shield Method

"Sleeves" of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1 percent of decay of Tc-99m).

2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4. Continue for all sleeves.

5. Complete the decay method linearity test Steps 2 through 5 above.

6. From the data recorded in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.

7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step 3.

8. Continue for all sleeves.

9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity. Record the net activity.

2. Steps 3 through 5 below must be completed within 6 minutes.

3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

5. Continue for all sleeves.

6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.

7. Notify the RSO if the worst deviation is more than +/- 10%.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections or administrations, and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and your predetermined safety margin is +/-10%. If 5 cc syringes, 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

***Note**:* If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 millicuries (mCi)/milliliter. Set out a second small beaker or vial with water.

2. To test the geometry dependence for a 3 cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.

3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water and assay again. Record the volume and activity indicated.

4. Repeat the process until you have assayed a 2.0 cc volume.

5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen “standard volume.”

6. Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.

7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

8. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.

9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water and assay again. Record the volume and activity indicated.

10. Repeat the process until a 19.0 cc volume has been assayed. The entire process must be completed within 10 minutes.

11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."

12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.

13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g., Co-57 or barium-133) will be used. At least one reference source whose activity is within the range of activities normally assayed will be used.

1. Assay a calibrated reference source at the appropriate settings (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.

2. The measurement should be within +/- 10% of the certified activity of the reference source, mathematically corrected for decay.

3. Repeat the procedure for any other calibrated reference sources possessed.

4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its

activity, the date of the test, the results of the test, and the name of the individual who performed the test.

5. Notify the RSO if the test results do not agree, within +/- 10%, with the certified value of the reference source(s).

6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.

APPENDIX H

MODEL PROCEDURES FOR REMOTE AFTERLOADER SPOT-CHECKS

Model Procedures for Remote Afterloader Spot-Checks

This model provides acceptable procedures for performing spot-checks of Remote Afterloader units, equipment, and facilities. Applicants may either adopt these model procedures or develop alternative procedures.

Periodic Spot-Checks for Remote Afterloader Units

Before the first use on a given day (or before each patient treatment for low-dose-rate remote afterloaders) and after each source installation, the following spot-checks will be performed:

- Electrical Interlocks at Each Room Entrance

Proper functioning of the treatment room door interlock will be performed using the remote afterloader source.

Expose the remote afterloader source inside the treatment room, open the treatment room door, and verify that the source retracts. The source should retract immediately, the area radiation monitor should alarm, and the control console should indicate that the door is open. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Source Exposure Indicator Lights

  — Treatment Console Indicators and Status Lamps

    Turn on the remote afterloader unit and verify that the indicator lights flash to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the treatment console are lit to indicate an exposed source.

  — Remote Afterloader Indicators and Status Lamps

    Turn on the remote afterloader unit and verify that the indicator lights flash on the remote afterloader to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the remote afterloader are lit to indicate an exposed source.

- Viewing and Intercom Systems

  — Viewing System

    Turn on the camera(s). Check that the camera(s) is (are) operable and that the treatment area can be viewed from the treatment console. Adjust, if necessary.

  — Intercom System

    Turn on the intercom system. The intercom system will be tested using a two-person method. One person will be at the treatment console while another person is in the treatment room. Both individuals will speak and confirm that the other is heard.

- Emergency Response Equipment

Verify the presence of the emergency equipment within the treatment room. This equipment includes but is not limited to a mobile lead container large enough to hold the largest applicator, long-handled forceps, wire cutter, flashlight, suture removal kit, and timer (timer located at unit console). If a portable radiation survey meter is included, verify the presence of the meter and check the operability using a radioactive check source.

- Radiation Monitors Used to Indicate the Source Position

Verify that the area radiation monitor located inside the treatment room is on with the indicator light flashing green. Expose the remote afterloader source inside the treatment room with the door closed and verify that the indicator light flashes red; indicating the presence of radiation. This test will be performed with the area radiation monitor on *A/C* power and on battery backup power.

- Timer Accuracy

Expose the remote afterloader source inside the treatment room with the door closed. Immediately start a stopwatch when the control console indicates that the source is exposed. Stop the stopwatch when the control console indicates that the source is retracted. Compare the stopwatch measured time to the irradiation time indicated on the control console. Verify that the comparison is within 1 percent.

- Clock Date and Time in the Remote Afterloader's Computer

Verify clock date and time printed on the control console documentation of the pretreatment checks against the actual date and time. The date must be exact and the time may be within 1 hour.

- Decayed Source Activity in the Remote Afterloader's Computer

Verify the source activity (or decay factor) displayed on the remote afterloader control console matches to within 0.5 percent of the manufacturer's provided decay table for today's date.

If the results of the above checks indicate the malfunction of any system, the control console shall be locked in the off position, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.643(e), and not used except as may be necessary to repair, replace, or check the malfunctioning system.

In addition, consideration will be given to testing the following before the first use of the remote afterloader unit on a given day:

- Treatment Interrupt Button

Press the "Interrupt" button on the control console while source is exposed. Verify that the source retracts immediately and the control console indicates an alarm. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Emergency Off Button

  Press the “Stop” button on the control console while the source is exposed. Verify that the source retracts immediately and the control console indicates an alarm. Repeat the test for all wall-mounted “Stop” buttons. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Dual Use Switch

  An x-ray unit is also used in the remote afterloader treatment room, and a selector switch to limit operation to only one unit at a time is installed.

  With the key switch on the wall set to x-ray, attempt to expose the remote afterloader source. Verify that the area radiation monitor and the control console source indicator lights do not illuminate; indicating that the source did not expose. Switch the key to remote afterloader. Expose the remote afterloader source and confirm that the area radiation monitor illuminates. With the remote afterloader source still exposed, switch the key back to x-ray, and confirm that the remote afterloader source retracts and the area radiation monitor flashes green. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Misconnected or Missing Transfer Tube and/or Applicator

  Misconnect a transfer tube to the remote afterloader. This may either be performed by connecting the transfer tube to the wrong channel or by not fully inserting the transfer tube into the correct channel. Attempt to expose the remote afterloader source and verify that the source does not expose as indicated by the area radiation monitor. Additionally, verify that an error is indicated on the control console for the misconnection. Repeat the test with an applicator intentionally misconnected to a transfer tube that is correctly inserted into the remote afterloader.

- Mechanical Integrity of Applicators, Transfer Tubes, Connectors

  Perform a visual inspection of all applicators, transfer tubes, and connectors to be used for patient treatments that day. Check for any potential mechanical defects. Replace if a defect is noted.

- Position of Remote Afterloader Within the Treatment Room

  For some remote afterloader units located within minimally shielded rooms, the location of use within the room may have been specified in the application to ensure that the regulatory limits in 10 CFR 20.1301 will be met. If this is the case, verify that the positioning of the remote afterloader unit within the treatment room is in accordance with the commitments made in the application.

APPENDIX I

RADIATION SAFETY OFFICER DUTIES, RESPONSIBILITES, AND DELEGATION

Radiation Safety Officer Duties, Responsibilities, and Delegation

Typical Duties and Responsibilities of the Radiation Safety Officer

The radiation safety officer's (RSO's) duties and responsibilities include ensuring radiological safety and compliance with U.S. Nuclear Regulatory Commission (NRC) and U.S. Department of Transportation (DOT) regulations and the conditions of the license. Typically, these duties and responsibilities include ensuring the following:

- Stop activities involving licensed material that the radiation safety officer (RSO) considers unsafe.
- Ensure that radiation exposures are kept as low as is reasonably achievable (ALARA).
- Oversee all activities involving radioactive material, including monitoring and surveying all areas in which radioactive material is used.
- Ensure that up-to-date operating, emergency, and security procedures are developed, implemented, maintained, and distributed.
- Ensure that possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the Sealed Source and Device (SSD) registration certificate(s), and the manufacturer's recommendations and instructions.
- Ensure individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license.
- Ensure personnel training is conducted and is commensurate with the individual's duties regarding licensed material.
- Ensure documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided.
- When necessary, ensure personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Properly secure radioactive material.
- If the licensee possesses an aggregated Category 1 or Category 2 quantity of radioactive material, support development and implementation of a security program for radioactive material in accordance with 10 CFR 37.
- Ensure documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR Part 20.1301, "Dose limits for individual members of the public."

- Notify proper authorities of incidents, such as damage to or malfunction of sources/devices, loss of licensed material, fire, theft, etc.

- Serve as a point of contact for the NRC's and licensee's management during routine operations, emergencies, or incidents.

- Medical events and precursor events are investigated and reported to the NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.

- Perform and document periodic audits, at least annually, of the radiation safety program to ensure that the licensee is complying with all applicable NRC regulations and the terms and conditions of the license.

- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for 3 years after the record is made) and provided to management for review; ensure that prompt action is taken to correct deficiencies.

- Ensure that the audit results and corrective actions are communicated to all personnel who use licensed material.

- When the licensee identifies violation(s) of regulations or license conditions or program weaknesses, ensure corrective action(s) are developed, implemented, and documented.

- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of 10 CFR Part 20 and 30 limits are investigated and reported to NRC and other appropriate authorities, if required, within the required time limits.

- Ensure licensed material is transported, or offered for transport, in accordance with all applicable NRC and DOT requirements.

- Ensure radioactive waste is disposed of in accordance with NRC regulations and license conditions. Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records. Oversee the storage of radioactive material not in current use, including waste.

- Perform/oversee the inventory and leak testing on all sealed sources.

- Oversee the calibration of radiation survey instruments.

- Supervise decontamination operations.

- Maintain up-to-date copies of NRC regulations, the license, revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the NRC during the licensing process.

- Submit amendment and renewal requests in a timely manner.

Model Delegation of Authority

Memo To: (Name of Radiation Safety Officer)
From: (Name of Chief Executive Officer or other ranking official)
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe and secure use of radiation and radioactive material. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations when justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the U.S. Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____

Signature of Management Representative Date
I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Names of affected department head

APPENDIX J

MODEL TRAINING PROGRAM

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and background knowledge of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet U.S. Nuclear Regulatory Commission (NRC) requirements. Guidance on requirements for training and experience for authorized medical physicists (AMP) and authorized users (AU) for medical use who engage in certain specialized practices is also included.

Model Training Program for Medical and Non-medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for 3 years. The training records will include the date of the instruction or training, a brief outline of subjects covered, and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Medical Use of Byproduct Material

Training for professional staff [e.g., AU, AMP, authorized nuclear pharmacist, radiation safety officer (RSO), nurse, dosimetrist, technologist, therapist] may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues).
- Basic radiation protection to include concepts of time, distance, and shielding.
- Concept of maintaining exposure as low as is reasonably achievable. (10 CFR 20.1101)
- Risk estimates, including comparison with other health risks.
- Posting requirements. (10 CFR 20.1902)
- Proper use of personnel dosimetry (when applicable).
- Access control procedures. (10 CFR 20.1601, 10 CFR 20.1802)
- Proper use of radiation shielding, if used.
- Patient release procedures (10 CFR 35.75)

- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care. (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)

- Occupational dose limits and their significance. (10 CFR 20.1201)

- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy. (10 CFR 20.1208)

- Worker's right to be informed of occupational radiation exposure. (10 CFR 19.13)

- Each individual's obligation to report unsafe conditions to the RSO. (10 CFR 19.12)

- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12)

- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination. (10 CFR 19.11)

- Proper recordkeeping required by NRC regulations. (10 CFR 19.12)

- Appropriate surveys to be conducted. (10 CFR 20.1501)

- Proper calibration of required survey instruments. (10 CFR 20.1501)

- Emergency procedures.

- Decontamination and release of facilities and equipment. (10 CFR 20.1406, 10 CFR 30.36)

- Dose to individual members of the public. (10 CFR 20.1301)

- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing). (10 CFR 35.27)

- Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material. (49 CFR Part 172)

Training for Individuals Involved in Nonmedical Use of Byproduct Material

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. All training should be commensurate with the individual's duties.

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), *commensurate with their duties*:

- leak testing of sealed sources (10 CFR 35.67)
- emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
- operating instructions (10 CFR 35.27, 10 CFR 35.610)
- computerized treatment planning system (10 CFR 35.657)
- dosimetry protocol (10 CFR 35.630)
- detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610)
- safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410)
- patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
- visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610)
- licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for gamma stereotactic radiosurgery (GSR), correct positioning of the helmet) (10 CFR 35.40, 10 CFR 35.41)
- proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610)
- size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610)
- previous incidents, events, and/or accidents
- for remote afterloaders, teletherapy units, and GSR units, initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes
  - — design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms

— hands-on training in actual operation of the device under the direct supervision of an experienced user, including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures

— a method, such as practical examinations, to determine each trainee’s competency to use the device for each type of proposed use

Additional Training for Authorized Medical Physicists

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.51(b)(1). Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of strontium-90sources used for ophthalmic treatments (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 10 CFR 35.51(c).

Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, and 10 CFR 35.690, attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in 10 CFR 35.390, 35.490, 35.491, and 35.690.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/or housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 millisievert [100 millirem] will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel.

Topics of instruction may include the following:

- storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12)

- potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12)

- the applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12)

- responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12)

- appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12)

- radiation exposure reports that workers may request, as per 10 CFR 19.13, "Notifications and reports to individuals" (10 CFR 19.12)

References and Resources:

- National Council on Radiation Protection and Measurements (NCRP) Report No. 105, "Radiation Protection for Medical and Allied Health Personnel," 1989.

- NCRP Report No. 134, "Operational Radiation Safety Training," October 2000.

- International Commission on Radiological Protection (ICRP) Report No. 75, "General Principles for the Radiation Protection of Workers," 1997.

APPENDIX K

GENERAL RADIATION MONITORING INSTRUMENT SPECIFICATIONS AND SURVEY INSTRUMENT CALIBRATION PROGRAM

General Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

The following provides acceptable guidelines for radiation survey instrument calibrations. Licensees may either adopt these guidelines or develop their own to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20 and 10 CFR 35.61.

Radiation Monitoring Instrument Specifications

The specifications in Table K–1 may help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies). Except where indicated by an asterisk below, the information in Table K–1 was extracted from "The Health Physics and Radiological Health Handbook," Revised Edition, 1992.

Table K–1. Typical Survey Instruments

Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Exposure Rate Meters	Gamma, X-ray	milliroentgen (mR)-roentgen (R)	N/A
Count Rate Meters			
Geiger-Mueller (GM)	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate
Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter [sodium iodide (NaI)]*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Equipment Selection

Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes should be taken and counted on a liquid scintillation counter to verify potential contamination.

Medium- to high-energy beta emitters, such as phosphorus-32 and calcium-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.

Low-energy gamma emitters, such as iodine-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the NaI probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.

Medium- to high-energy gamma emitters, such as iodine-131 (I-131), can be detected with either GM or NaI probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for NaI probes.

Model Radiation Survey Instrument Calibration Program

Training

Before independently calibrating radiation survey instruments, an individual shall have sufficient training and experience to perform independent radiation survey instrument calibrations in accordance with 10 CFR 35.61.

- Classroom training may be in the form of lecture, video, computer-based, or self-study and will cover the following subject areas:
  - — principles and practices of radiation protection
  - — radioactivity measurements, monitoring techniques, and the use of radiation detection instruments
  - — mathematics related to the use and measurement of radioactivity
  - — biological effects of radiation
- On-the-job training will be considered complete if the individual has completed both of the following:
  - — observing authorized personnel performing radiation survey instrument calibration
  - — conducting radiation survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations

Facilities and Equipment

To reduce doses received by individuals not calibrating radiation survey instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.

The calibration source used for calibrating dose and dose rate measuring instruments should be well-collimated, and the calibration area should be designed to minimize scatter of radiation, which could affect the calibration process.

The calibration area should be appropriately controlled so that persons entering the area will be aware if a radiation source is in use. Evaluate posting of the calibration area with appropriate radiation warning signs, as required by Subpart J of 10 CFR 20.

Individuals conducting radiation survey instrument calibrations will wear assigned dosimetry.

Individuals conducting calibrations will use a calibrated and operable radiation survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Frequency of Calibration of Radiation Measurement Instruments

A licensee committed to a routine or emergency radiation survey program should perform an acceptable calibration of all radiation measurement instruments and equipment at the frequency specified in U.S. Nuclear Regulatory Commission (NRC) regulations, annually, or at the frequency recommended by the manufacturer, whichever period is shorter.

Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a radiation measurement instrument have changed, by repair or alteration, or whenever system performance is observed to change significantly. (Battery changes are not considered as a repair or alteration.)

Routine maintenance of radiation measurement instruments should be performed as recommended by the manufacturer.

Primary or secondary standard instruments used to calibrate radiation measurement instruments should be inspected frequently for consistency of performance.

Calibration Sources for Dose and Dose Rate Measuring Instruments

Radiation survey instruments will be calibrated with a radioactive source, in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. A radioactive sealed source(s) will be used for calibrating dose and dose rate measuring radiation survey instruments, and this source will have the following characteristics:

- The source should approximate a point source.
- Calibration fields from gamma sources should be known with an accuracy when compared to secondary or primary national standards of 5 percent for dose rates greater than or equal to 1.0 microGray/hour (µGy)/h [0.1 millirad (mrad)/h] and 10 percent for dose rates less than 1.0 µGy/h [0.1 mrad/h].
- The source should contain a radionuclide that emits radiation of identical or similar type and energy [e.g., cesium-137 (Cs-137), cobalt-60) as the environment in which the calibrated device will be used.
- Provides a radiation dose rate sufficient to reach the full scale (less than 1,000 mR/h) of the instrument calibrated.

- The source should be strong enough to give an exposure rate of at least 7.7 microcoulomb per kilogram per hour [30 milliroentgen per hour] at 100 centimeters [e.g., 3.1 gigabecquerels (85 millicuries) of Cs-137 or 780 megabecquerels (21 millicuries) of cobalt-60].

***Note**:* Inverse square and radioactive decay laws should be used to correct for changes in exposure rate due to changes in distance or source decay. Instrument readings should be within ± 10% of known radiation values at calibration points; however, readings within ± 20% are acceptable if a calibration chart or graph is prepared and made available with the instrument.

Calibration of Dose or Dose Rate Measuring Instruments

There are three kinds of scales frequently used on dose or dose-rate survey meters. These are calibrated as follows:

- **Linear readout instruments** with a single calibration control for all scales should be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale should be adjusted on each scale. After adjustment, check the response of the instrument at approximately 20 percent and 80 percent of full scale. Instrument readings shall be within ± x of the conventionally true value for the following ranges:
  - — Background to 10 µGy/h [1.0 mrad/h]; ±x = ±30%
  - — 10 µGy/h [1.0 mrad/h] to 1.0 milliGray (mGy)/h [100 mrad/h]; ±x = ±20%
  - — 1.0 mGy/h [100 mrad/h] to 10 gray/h [1,000 Rad/h]; ±x = ±10%
- **Logarithmic readout instruments**, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. Adjust the instrument for each scale according to site specifications or the manufacturer's specifications. After adjustment, check the calibration at a minimum of one point on each decade. Instrument readings should have a maximum deviation from the conventionally true value as described for linear readout instruments.
- **Digital readout instruments** should be calibrated the same as linear readout instruments. Digital readout instruments without scale switching for indicating exposure rates shall be checked at two points on each decade.
- **Integrating instruments** shall be checked at two dose rates at approximately 20% and 80% of the stated dose rate range. Instrument readings shall be within the same ± x of the conventionally true value as described for linear readout instruments.

***Note**:* Readings above 2.58×10^{-4} coulomb/kilogram/hour [1R/h] need not be calibrated, unless the licensee expects to make measurements at higher dose rates; regardless, such scales may be checked for operation and response to radiation.

***Note**:* Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured.

Calibration of Surface Contamination Measurement Instruments

Instruments used to detect surface contamination usually consist of a count-rate meter and a detector that is appropriate for the type of radiation(s) being measured.

The efficiency of radiation survey meters must be determined by using radiation sources with similar energies and types of radiation that users of the radiation survey instrument intend to measure.

If each scale has a calibration potentiometer, the reading should be adjusted to respond to the calibration source at approximately 80 percent of full scale, and the response at approximately 20 percent of full scale should be observed. If only one calibration potentiometer is available, the response should be adjusted at mid-scale on one of the scales, and response on the other scales should be observed. The instrument efficiency factor [e.g., counts per minute (cpm)/disintegrations per minute (dpm)] thus obtained should have a signal-to-noise ratio, including the compilation of source and instrument uncertainties, of ±x for the following ranges:

- alpha measurement

  0.01 becquerel (Bq)/square centimeter (cm^2) to 2.0 Bq/cm^2 [60 to 12,000 $dpm/100\ cm^2$]; ±x = ±20%

  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 $dpm/100\ cm^2$]; ±x = ±10%

- beta measurement

  0.05 Bq/cm^2 to 2.0 Bq/cm^2 [300 to 12,000 $dpm/100\ cm^2$]; ±x = ±20%

  2.0 Bq/cm^2 to 200 Bq/cm^2 [12,000 to 1,200,000 $dpm/100\ cm^2$]; ±x = ±10%

Calibration of Analytical Instruments Such As Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multichannel Analyzers

Analytical instruments used to determine radioactivity in a sample may be specialized equipment according to the type of samples to be analyzed and the types and quantities of radioactivity to be measured. Typically, the sample sizes and activities are very small, and can be difficult to measure. Sample collection and preparation may differ for the various analytical instruments, so manufacturer procedures and industry standard practices should be followed. Such analytical instruments should be calibrated in accordance with the manufacturer's instructions. Analytical instruments typically require routine maintenance and verification procedures to ensure that they are operating properly when used.

As with calibration of other radiation measurement instruments, calibration of analytical instruments use a radioactive sealed source(s). These should be suitable for the geometry of the sample(s) to be analyzed. The calibration source(s) should have a known activity(ies) and be of similar type and energy as the radioactive materials to be analyzed. The analysis should be sensitive enough to detect the lowest levels of radioactivity desired. Correction of results for quenching, self-absorption, and other factors may be required, depending on the analytical instrument, the samples type, and other environmental conditions.

Calibration Records

A record must be made of each radiation survey instrument calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061).

Calibration records for all radiation survey instruments should indicate the procedure used and the results of the calibration. The records should include the following:

- the owner or user of the radiation survey instrument
- a description of the radiation survey instrument that includes the manufacturer's name, model number, serial number, and type of detector
- a description of the NIST-traceable calibration source, including the calibration procedure, exposure rate, distance at which it was measured, and date of measurement
- for each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the radiation survey instrument
- the efficiency of the radiation survey instrument for each radionuclide the instrument will be used to measure, if efficiency is not calculated before each use
- the exposure reading indicated with the radiation survey instrument in the "battery check" mode, if available on the instrument
- for radiation survey instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
- for radiation survey instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument
- for radiation detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure
- the exposure rate from a check source, if used
- the name of the person who performed the calibration and the date it was performed

The following information will be attached to the radiation survey instrument as a calibration sticker or tag:

- for dose and dose rate measuring instruments, the source radionuclide that was used to calibrate the instrument (with correction factors) for each scale
- the proper deflection in the battery check mode, unless this is clearly indicated on the instrument
- special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated)
- for each scale or decade not calibrated, an indication that the scale or decade was checked only for function but not calibrated
- the date of calibration and the next calibration due date

- the apparent exposure rate or count rate from the check source, if used
- sensitivity of counting system

Follow the procedures in Appendix Q of this NUREG to determine minimum detectable activity (MDA) if there is a question concerning the ability to measure small quantities of radioactivity.

Calculating the Efficiency of Sodium Iodide (Thallium Doped) Uptake Probes

Sodium iodide (thallium doped) uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of liquid NaI. Refer to 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage" for the ALIs and DACs for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, µCi) when performing bioassays to determine thyroid burdens of radioiodine.

Use the following procedure to calibrate the probe for uptake measurements:

- Check the instrument's counting efficiency using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate the efficiency of the instrument.

For example:

$$Eff_a = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcuries)}$$

where: Eff_a = efficiency[1],
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag, and the following information should be included:

- the due date of the next efficiency test
- results of efficiency calculation(s)

[1]The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and is much less dependent on the counting geometry.

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources, and areas where unsealed byproduct material is prepared, administered, or stored. Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for assaying wipe tests on an annual basis, before first use, and/or after repair, using the following procedure:

- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards will be within ± 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

- Calculate the efficiency of the instrument.

For example:

$$Eff = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcuries)}$$

where: Eff = efficiency, in cpm/microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

Operational and calibration checks, using a dedicated check source, should be conducted each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- the due date of the next efficiency test

- results of efficiency calculation(s)

References:

- Detailed information about portable radiation survey instrument calibration may be obtained by referring to American National Standards Institute (ANSI) N323AB-2013, "American National Standard for Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the ANSI eStandards Store.

- National Council on Radiation Protection and Measurements (NCRP) Report No. 112, "Calibration of Survey Instruments Used in Radiation Protection for the Assessment of Ionizing Radiation Fields and Radioactive Surface Contamination," 1991.

APPENDIX L

MODEL MEDICAL LICENSEE AUDIT

Model Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

***Note**:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Also, the audit notes may not be complete for nonmedical uses authorized on the license. Licensees should review audit lists in other volumes of the NUREG–1556 series, as appropriate, when completing the audit list that is specific to nonmedical uses.

Date of this audit: _____

Date of last audit: _____

Date of next audit: _____

Auditor:

_____

Signature *Date*

Management review:

_____

Signature *Date*

All references are to Title 10 of the *Code of Federal Regulations* (CFR) Parts unless noted otherwise.

License (License Condition)

1. License Number.

2. Current Amendment Number.

3. Are all of the tie-down documents on file?

4. Has the Legal Entity having control over licensed activities changed since the last audit? Are materials, uses, and locations of use confined to those specifically described in the license?

Audit History

1. Were previous audits conducted annually [20.1101(c)]?
2. Were records of previous audits maintained [20.2102(b)]?
3. Were any deficiencies identified during previous audit?
4. Were corrective actions taken? (Look for repeated deficiencies.)
5. Any previous problem/deficiency not corrected or repeated?

Organization and Scope of Program

1. Radiation Safety Officer (RSO)

   a. If the RSO was changed, was the license amended [35.13(c)]?

   b. Does the new RSO meet U.S. Nuclear Regulatory Commission (NRC) training requirements [35.50, 35.57, 35.59]?

   c. If the scope of the program expanded, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?

   d. Is the RSO fulfilling all duties [35.24(e)]?

   e. If the scope of the program expanded, have the RSO duties been updated to reflect the scope of the program [35.24(e)]?

   f. Is the written agreement in place for the new RSO [35.24(b)]?

   g. Has NRC been notified about a temporary RSO [35.14(b)(2)]?

   h. Are the written agreements and duties and responsibilities in place for the temporary RSO [35.24(b), (c), (e), (g), and (h)]?

2. Multiple places of use? If yes, list locations. (License Condition [L/C])

3. Are all locations listed on license? (L/C)

4. Were annual audits performed at each location? If no, explain.

5. Describe the scope of the program (staff size, number of procedures performed, etc.)

6. Licensed Material: (L/C)

   a. Isotope, chemical form, physical form, quantity, and use as authorized?

   b. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is financial assurance current based on NUREG–1757, Volume 3 ?

   c. Calibration, transmission, and reference sources [35.65]?

      i. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 1.11 GBq [30 millicuries (mCi)] each [35.63(a) and (b)]?

      ii. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq [15 mCi] [35.65(c)]?

iii. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq [200 microcuries (μCi)] or 1,000 times the quantities in Appendix B of Part 30 [35.65(d)]?

iv. Technetium-99m (Tc-99m) in individual amounts as needed [35.65(e)]?

d. Unsealed materials used under 10 CFR 35.100, 35.200, and 35.300 are:

i. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

ii. Obtained from a producer of Positron Emission Tomography radioactive drugs under 10 CFR 30.32(j)?

OR

iii. Prepared by a physician authorized user (AU), an authorized nuclear pharmacist (ANP), or an individual under the supervision of an ANP or physician AU?

OR

iv. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?

7. Are the sealed sources possessed and used as described in the Sealed Source and Device Registry registration certificate in 10 CFR 32.210, 35.400, 35.500, 35.600? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

8. Are the actual uses of medical devices consistent with the authorized uses listed on the license? (L/C)

9. If places of use/storage changed, was the license amended [35.13(e)]?

10. If control of the license was transferred or bankruptcy filed, was NRC's prior consent obtained or notification made [30.34(b) and 30.34(h), respectively]?

11. Is radioactive material regulated under 10 CFR 35.1000 used in accordance with the license conditions and tie-down commitments? (L/C)

Radiation Safety Program

1. Minor changes to program [10 CFR 35.26 or license condition for 10 CFR 35.1000 medical uses]?

2. Records of changes maintained for 5 years [35.2026(a)]?

3. Content and implementation reviewed annually by the licensee [20.1101(c)]?

4. Records of reviews maintained [20.2102(a)(2)]?

Nationally Tracked Sources

1. Reports of transactions involving nationally tracked sources submitted to National Source Tracking System (10 CFR 20.2207)?

Use by Authorized Individuals (L/C)

1. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59]:

    a. Listed on a facility license?

2. Authorized user [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690]:

    a. Listed on a facility license?

    b. Each AU only uses material for which they are authorized?

3. Authorized medical physicist (AMP) [35.51, 35.57, 35.59]:

    a. Listed on a facility license?

    b. Each AMP only uses material for which they are authorized?

4. Non-medical use authorized users [30.33(a)(3)]:

    a. Listed on facility license for same materials and uses?

Mobile Medical Service

1. Operates services per 35.80, 35.647?

2. Compliance with public dose limits evaluated and met [20.1301, 20.1302]?

3. Are all base locations listed on the license? (L/C)

4. Mobile Medical Agreement letter signed by management of each client [35.80(a)]?

5. Licensed material not delivered to client's address, unless client was authorized [35.80(b)]?

6. Dosage measuring instruments checked for proper function before use at each address of use or on each day of use, if more frequent [35.80(a)]?

7. Survey instruments checked for proper operation before use at each address of use [35.80(a)]?

8. Survey all areas of use prior to leaving each client address [35.80(a)]?

9. Adequate security maintained for mobile trailer? Keypad codes changed or keys retrieved when an employee terminates employment [20.1801, 20.1802]?

10. AUs briefed on responsibilities for supervising the use of licensed material [35.27]?

11. Compliance with additional technical requirements for mobile remote afterloaders evaluated and met [35.647]?

Amendments Since Last Audit [35.13]

1. Any Amendments since last audit [35.13]?

2. Security-related sensitive information was properly marked [10 CFR 2.390]?

Notifications Since Last Audit [35.14]

1. Any Notifications since last audit [35.14]?

2. Appropriate documentation provided to NRC for ANP, AMP, or AU, no later than 30 days after the individual starts work [35.14(a), 30.34(j)(4)]?

3. NRC notified within 30 days after: AU, ANP, AMP, or RSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 10 CFR 35.100 or 35.200 use [35.14].

Training, Retraining, and Instructions to Workers

1. Is the training program implemented? Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?

2. Is the individual's understanding of current procedures and regulations adequate?

3. Do appropriate individuals have adequate understanding of appropriate:

    a. Operating procedures [35.27, 35.310, 35.410, 35.610]?

    b. Emergency procedures [35.27, 35.310, 35.410, 35.610]?

4. Do appropriate individuals have an up-to-date copy of the licensee's operating use and emergency procedures?

5. Periodic training required and implemented [35.310, 35.410, 35.610]?

6. Were all workers who are likely to exceed 1 millisievert (mSv) [100 millirem (mrem)] in a year instructed and was refresher training provided, as needed [19.12]?

7. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives (WD), as appropriate [35.27]?

8. Are initial and periodic training records maintained for each individual [35.2310]?

9. Briefly describe training program.

10. Hazardous Materials (HAZMAT) training [49 CFR Part 172]

11. Do additional therapy device instructions/training include:

    a. Unit operation, inspection, associated equipment, survey instruments?
    b. License conditions applicable to the use of the unit?
    c. Emergency drills [35.610]?

12. 10 CFR Part 20 – Are workers cognizant of requirements for:

    a. Radiation Safety Program [35.24, 35.26, 20.1101]?
    b. Annual dose limits [20.1201, 20.1301, 20.1302]?
    c. NRC Forms 4 and 5?
    d. 10% monitoring threshold [20.1502]?
    e. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
    f. “Grave Danger” Posting [20.1902(c)]?
    g. Procedures for opening packages [20.1906]?

13. Is supervision of individuals by AU and/or ANP in accordance with 10 CFR 35.27?

14. Was training provided for workers involved with emerging technologies in accordance with the NRC license and tie-downs?

Training for Manual Brachytherapy and Use of Unsealed Byproduct Material for Which a Written Directive Is Required

1. Does safety instruction to personnel include [35.310, 35.410]:

    a. Control of patient and visitors?
    b. Routine visitation to patients in accordance with 10 CFR 20.1301?
    c. Contamination control and size/appearance of sources?
    d. Safe handling and shielding instructions?
    e. Waste control?
    f. RSO and AU notification if patient had a medical emergency or died?
    g. Records retained [35.2310]?

Facilities

1. Facilities as described in license application? (L/C)

2. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?

3. Emergency source recovery equipment available [35.415, 35.615]?

4. Storage areas:

    a. Materials secured from unauthorized removal or access [20.1801]?

    b. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802]?

c. Locations appropriately shielded to control public and occupational exposures in accordance with 10 CFR Part 20?

5. Therapy unit operation:

a. Unit, console, console keys, and treatment room controlled adequately [20.1801, 20.1802, 35.610(a)(1)]?

b. Restricted to certain source orientations and/or gantry angles? (L/C)

c. Ceases to operate in restricted orientation(s)? (L/C)

d. Only one radiation device can be placed in operation at a time within the treatment room [35.610(a)(3)]?

Dose or Dosage Measuring Equipment

1. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [35.60]:

a. Types of equipment listed?

b. Approved procedures for use of instrumentation followed?

c. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?

d. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., ±10%)?

e. Records maintained and include required information [35.2060]?

2. Determination of dosages of unsealed byproduct material [35.63]?

a. Each dosage determined and recorded prior to medical use [35.63(a)][1]?

b. Measurement of unit dosages of alpha-, beta-, or photon-emitting radionuclides made either by direct measurement [35.63(b)] or by decay correction of the activity provided by the licensed producer [32.72]?

c. For other than unit dosages of alpha-, beta-, or photon-emitting radionuclides, measurement made by direct measurement of radioactivity [35.63(c)] or by combination of radioactivity or volumetric measurement and calculation using the activity provided by the licensed producer [32.72]?

3. Licensee uses generators?

[1]See Sections 8.9.3 and 8.10.20 for additional information regarding Rb-82 generators.

a. First eluate after receipt tested for molybdenum-99 (Mo-99) breakthrough [35.204(b)]?

b. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 kbq per Mbq [0.15 µCi per mCi] of Tc-99m [35.204(a)(1)]?

c. First eluate after receipt tested for strontium-82 (Sr-82) and strontium-85 (Sr-85) when eluting rubidium-82 (Rb-82) [35.204(c)]?

d. No radiopharmaceuticals administered with Sr-82 concentrations over 0.02 kbq per MBq [0.02 µCi per mCi] of Rb-82 or Sr-85 concentrations over 0.2 kbq per MBq [0.2 µCi per mCi] of Rb-82 [35.204(a)(2)]?

e. Records maintained [35.2204]?

4. Confirmation of source output or activity for manual brachytherapy sources? Alternatively, the manufacturer's measurements may be accepted if the criteria in 10 CFR 35.432(b) have been met.

5. Dosimetry Equipment [35.630]:

a. Calibrated system available for use [35.630(a)]?

b. Calibrated by National Institute of Standards and Technology or an American Association of Physicists in Medicine (AAPM)-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 10 CFR 35.630(a)(2)?

c. Calibrated within the previous 4 years [35.630(a)(2)]?

d. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?

e. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

Radiation Protection and Control of Radioactive Material

1. Use of radiopharmaceuticals:

a. Protective clothing worn?
b. Personnel routinely monitor their hands?
c. No eating/drinking in use/storage areas?
d. No food, drink, or personal effects kept in use/storage areas?
e. Proper dosimetry worn?
f. Radioactive waste disposed of in proper receptacles?
g. Syringe shields and vial shields used and are specific to the energy emitted?
h. Proper use of remote handling tools and radiation shields?

2. Leak tests and inventories:

   a. Leak test performed on sealed sources and brachytherapy sources at appropriate intervals [35.67(b)(1) or leak test license condition]?

   b. Inventory of sealed sources and brachytherapy sources performed semiannually [35.67(g)]?

   c. If applicable, transactions associated with nationally tracked sources entered into the National Source Tracking System, including annual reconciliation [10 CFR 20.2207]?

   d. Records maintained [35.2067]?

Radiation Survey Instruments

1. Survey instruments used to show compliance with 10 CFR Part 20 and 10 CFR 30.33(a)(2):

   a. Appropriate operable survey instruments possessed or available [10 CFR Part 20]?

   b. Calibrations [35.61(a) and (b)]:

      i. Before first use, annually, and after repairs?
      ii. Within 20% on each scale or decade of interest, as applicable?
      iii. Instrument sent to a licensed instrument service provider?
      iv. Copy of instrument service provider license on file?

   c. Records maintained [35.2061]?

2. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [20.1501, 35.70]?

   a. Daily in all areas where radiopharmaceuticals requiring a WD are prepared or administered (except patient rooms) [35.70]?

   b. Weekly in all areas where radiopharmaceuticals or wastes are stored?

   c. Weekly for wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?

   d. Trigger levels established?

   e. Corrective action taken and documented if trigger level exceeded?

   f. Techniques can detect 0.1 milliroentgen/hour, 2,000 disintegrations per minute?

   g. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the sources(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry [35.652(a)] and records maintained [35.2652]?

i. After new source installation?

ii. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

1. Is licensed material used in a manner to keep doses below 1 mSv [100 mrem] in a year [20.1301(a)(1)]?

2. Has a survey or evaluation been performed per 20.1501(a)?

3. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

4. Do unrestricted area radiation levels exceed 0.02 mSv [2 mrem] in any one hour [20.1301(a)(2)]?

5. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [20.1801 and 20.1802]?

6. Are records maintained [20.2103, 20.2107]?

Patient Release

1. Individuals released when total effective dose equivalent (TEDE) is less than 5 mSv [0.5 rem] [35.75(a)]?

2. Instructions to the released individual, including breastfeeding women, include required information [35.75(b)]?

3. Release records maintained [35.2075(a)]?

4. Records of instructions given to breastfeeding women maintained, if required [35.2075(b)]?

Unsealed Byproduct Material for Which a Written Directive Is Required

1. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [35.315(a)]?

2. RSO and AU promptly notified if patient had a medical emergency or died [35.315(b)]?

Brachytherapy or Brachytherapy Source Use

1. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [35.415]?

2. Survey immediately after implant [35.404(a)]?

3. Patients surveyed immediately after removing the last temporary implant source [35.404(b)]?

4. RSO and AU promptly notified if patient had a medical emergency or died [35.415(c)]?

5. Records maintained [35.2404]?

Radioactive Waste

1. Disposal:

   a. Decay-in-storage [35.92]?
   b. Procedures followed?
   c. Labels removed or defaced [20.1904, 35.92]?

2. Special procedures performed as required?

3. Authorized disposals [20.2001]?

4. Records maintained [20.2103(a), 20.2108, 35.2092]?

5. Effluents:

   a. Release to sanitary sewer [20.2003]?

      i. Material is readily soluble or readily dispersible [20.2003(a)(1)]?

      ii. Monthly average release concentrations do not exceed 10 CFR Part 20, Appendix B, Table 2 values?

      iii. No more than 5 curies (Ci) of H-3, 1 Ci of C-14, and 1 Ci of all other radionuclides combined, released in a year [20.2003]?

      iv. Procedures to ensure representative sampling and analysis implemented [20.1501]?

   b. Release to septic tanks [20.2003]? Within unrestricted limits [10 CFR Part 20, Appendix B, Table 2]?

   c. Waste incinerated?

      i. License authorizes [20.2004(a)(3)]?
      ii. Exhaust directly monitored?
      iii. Airborne releases evaluated and controlled [20.1302, 20.1501]?

   d. Air effluents and ashes controlled [20.1101, 20.1201, 20.1301, 20.1501, 20.2001]? (See also Inspection Procedure 87102, RG 8.37.)

      i. Air effluent less than 0.10 mSv [10 mrem] constraint limit [20.1101]?

         1. If no, reported appropriate information to the NRC?
         2. If no, corrective actions implemented and on schedule?

ii. Description of effluent program:

1. Monitoring system hardware adequate?

2. Equipment calibrated, as appropriate?

3. Air samples/sampling technique (e.g., charcoal, high-efficiency particulate air) analyzed with appropriate instrumentation?

6. Waste storage:

a. Protection from elements and fire?
b. Control of waste maintained [20.1801and 20.1802]?
c. Containers properly labeled and area properly posted [20.1902, 20.1904]?
d. Package integrity adequately maintained?

7. Waste disposal:

a. Sources transferred to authorized individuals [20.2006, 20.2001, 30.41]?
b. Name of organization: _____ .
c. Copy of waste disposal recipient's license on file?

8. Records of surveys and material accountability maintained [20.2103, 20.2108, 35.2092]?

Receipt and Transfer of Radioactive Material

1. Description of how packages are received and by whom?

2. Written package-opening procedures established and followed [20.1906(e)]?

3. All incoming packages with a U.S. Department of Transportation (DOT) label monitored for radioactive contamination, unless exempted (gases and special form) [20.1906(b)(1)]?

4. Incoming packages surveyed [20.1906(b)(2)]?

5. Monitoring in (C) and (D) performed within time specified [20.1906(c)]?

6. Transfer(s) performed per [30.41]?

7. All sources surveyed before shipment and transfer [20.1501(a)]?

8. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51]?

9. Package receipt/distribution activities evaluated for compliance with 20.1301?

Transportation (10 CFR 71.5(a) and 49 CFR 171-178)

1. Shipments are:

a. Delivered to common carriers?
b. Transported in own private vehicle?

c. Both?
d. No shipments since last audit?

2. Return radiopharmacy doses to drug manufacture or commercial nuclear pharmacy or sealed sources to source or device manufacturer?

a. Licensee assumes shipping responsibility?

b. If "NO," describe arrangements made between licensee and radiopharmacy for shipping responsibilities.

3. Packages:

a. Authorized packages used [49 CFR 173.415, 416]?
b. Performance test records on file?

i. DOT-7A packages
ii. special form sources

c. Two labels (White-I, Yellow-II, Yellow-III) with Transport Index (TI), Nuclide, Activity, and Hazard Class?

d. Properly marked [Shipping Name, United Nations (UN) Number, Weight, Package Type, Reportable Quantity, "This End Up" (liquids), Name and Address of consignee] [49 CFR 172.403, 172.441, 173.471]?

e. Closed and sealed during transport [49 CFR 173.475(f)]?

4. Shipping Papers:

a. Prepared and used [49 CFR 172.200(a)]?

b. Contain proper entries (Shipping Name; Hazard Class; Identification Number (UN Number); Total Quantity; Package Type; Nuclide; Reportable Quantity; Physical and Chemical Form; Activity; Category of Label; TI; Shipper's Name, Certification and Signature; Emergency Response Telephone Number; "Limited Quantity" {if applicable); "Cargo Aircraft Only" (if applicable)} [49 CFR 172.200-204]?

c. Readily accessible during transport [49 CFR 177.817(e)]?

5. Any incidents reported to DOT [49 CFR 171.15, 171.16]?

Teletherapy and Gamma Stereotactic Radiosurgery

1. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.655(a)]?

2. Needed service arranged for as identified during the inspection?

3. Service performed by persons specifically authorized to do so [35.655(b)]?

4. Were security requirements implemented, if applicable? [10 CFR Part 37]

Full Calibration-Therapeutic Medical Devices

1. Proper protocol(s) used (e.g., AAPM Task Group (TG)–21 (TG-21), AAPM 54, AAPM TG-56, AAPM TG-40)?

2. Performed prior to first patient use [35.632(a)(1), 35.633(a)(1), 35.635(a)(1)]?

3. At intervals not to exceed 1 year for teletherapy, gamma stereotactic radiosurgery (GSR), and low dose-rate (LDR) remote afterloader; at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate (MDR), and pulsed dose-rate (PDR) remote afterloaders [35.632(a)(3), 35.633(a)(3) and (4), 35.635(a)(3)]?

4. Whenever spot-checks indicate output differs from expected by ±5% [35.632(a)(2)(i), 35.635(a)(2)(i)]?

5. After source exchange, relocation, and major repair or modification [35.632(a)(2), 35.633(a)(2), 35.635(a)(2)]?

6. Performed with properly calibrated instrument [35.632(c), 35.633(c), 35.635(c)]?

7. Includes:

    a. For teletherapy:

        i. Output measured within ±3% of expected for the range of field sizes, range of distances [35.632(b)(1)]?

        ii. Coincidence of radiation field and field light localizer [35.632(b)(2)]?

        iii. Uniformity of radiation field and beam angle dependence [35.632(b)(3)]?

        iv. Timer accuracy and linearity over the range of use [35.632(b)(4)]?

        v. On-off error [35.632(b)(5)]?

        vi. Accuracy of all measuring and localization devices [35.632(b)(6)]?

    b. For remote afterloaders:

        i. Output measured within ±5% of expected [35.633(b)(1)]?

        ii. Source positioning accuracy within ±1 millimeter [35.633(b)(2)]?

        iii. Source retraction with backup battery upon power failure [35.633(b)(3)]?

        iv. Length of source transfer tubes [35.633(b)(4)]?

        v. Timer accuracy and linearity over the typical range of use [35.633(b)(5)]?

        vi. Length of the applicators [35.633(b)(6)]?

vii. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [35.633(b)(7)]?

viii. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [35.633(e)]?

c. For gamma stereotactic radiosurgery:

i. Output measured within ±3% of expected [35.635(b)(1)]?

ii. Helmet factors [35.635(b)(2)]?

iii. Isocenter coincidence [35.635(b)(3)]?

iv. Timer accuracy and linearity over the range of use [35.635(b)(4)]?

v. On-off error [35.635(b)(5)]?

vi. Trunnion centricity [35.635(b)(6)]?

vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [35.635(b)(7)]?

viii. Helmet microswitches [35.635(b)(8)]?

ix. Emergency timing circuit [35.635(b)(9)]?

x. Stereotactic frames and localizing devices (trunnions) [35.635(b)(10)]?

8. Output corrected mathematically for decay [35.632(e), 35.633(g), 35.635(e)]?

9. Records maintained [35.2632]?

Periodic Spot-Checks for Therapeutic Devices

1. Performed at required frequency [35.642(a), 35.643(a), 35.645(a)]?

2. Procedures established by AMP [35.642(b), 35.643(b), 35.645(b)]?

3. Procedures followed?

4. Medical physicist reviews results within 15 days [35.642(c), 35.643(c), 35.645(b)]?

5. Performed with properly calibrated instrument [35.642(a)(5), 35.645(c)(2)(i)]?

6. Output and safety spot-checks include:

a. For teletherapy:

i. Timer accuracy and linearity over the range of use [35.642(a)(1)]?

ii. On-off error [35.642(a)(2)]?

iii. Coincidence of radiation field and field light localizer [35.642(a)(3)]?

iv. Accuracy of all measuring and localization devices [35.642(a)(4)]?
v. The output for one typical set of operating conditions [35.642(a)(5)]?
vi. Difference between measured and expected output [35.642(a)(6)]?
vii. Interlock systems [35.642(d)(1)]?
viii. Beam stops [35.642(d)(2)]?
ix. Source exposure indicator lights [35.642(d)(3)]?
x. Viewing and intercom systems [35.642(d)(4)]?
xi. Treatment room doors, inside and out [35.642(d)(5)]?
xii. Electrical treatment doors with power shut off [35.642(d)(6)]?

b. For remote afterloaders:

i. Interlock systems [35.643(d)(1)]?
ii. Source exposure indicator lights [35.643(d)(2)]?
iii. Viewing and intercom systems, except for LDR [35.643(d)(3)]?
iv. Emergency response equipment [35.643(d)(4)]?
v. Radiation monitors used to indicate source position [35.643(d)(5)]?
vi. Timer accuracy [35.643(d)(6)]?
vii. Clock (date and time) in the unit's computer [35.643(d)(7)]?
viii. Decayed source(s) activity in the unit's computer [35.643(d)(8)]?

c. For gamma stereotactic radiosurgery:

i. Treatment table retraction mechanism [35.645(c)(1)(i)]?

ii. Helmet microswitches [35.645(c)(1)(ii)]?

iii. Emergency timing circuits [35.645(c)(1)(iii)]?

iv. Stereotactic frames and localizing devices [35.645(c)(1)(iv)]?

v. The output for one typical set of operating conditions [35.645(c)(2)(i)]?

vi. Difference between measured and expected output [35.645(c)(2)(ii)]?

vii. Source output compared against computer calculation of output [35.645(c)(2)(iii)]?

viii. Timer accuracy and linearity over the range of use [35.645(c)(2)(iv)]?

ix. On-off error [35.645(c)(2)(v)]?

x. Trunnion centricity [35.645(c)(2)(vi)]?

xi. Automatic positioning system?

xii. Interlock systems [35.645(d)(1)]?

xiii. Source exposure indicator lights [35.645(d)(2)]?

xiv. Viewing and intercom systems [35.645(d)(3)]?

xv. Timer termination [35.645(d)(4)]?

xvi. Radiation monitors used to indicate room exposures [35.645(d)(5)]?

xvii. Emergency off buttons [35.645(d)(6)]?

7. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [35.642(e), 35.643(e), 35.645(f)]?

8. Records maintained [35.2642, 35.2643, 35.2645]?

Installation, Maintenance, and Repair of Therapy Devices

1. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [35.605, 35.655]? Name of organization/individual.

2. License verification?

3. Records maintained [35.2605, 35.2655]?

Emergency Procedures for Therapy Devices

1. Instructions on location of emergency procedures and emergency response telephone numbers posted at the device console [35.610(c)]?

2. Copy of the entire procedures physically located at the device console [35.610(b)]?

3. Procedures include:

   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [35.610(a)(4)]?

   b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [35.610(a)(4)]?

   c. The names and telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally [35.610(a)(4)]?

4. AMP and AU:

   a. Physically present during initiation of patient treatment with remote afterloaders? (***Note**:* for MDR and PDR, an appropriately trained physician under the supervision of the AU may be physically present instead of the AU) [35.615(f)(1) and (2)].

   b. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [35.615(f)(3)]?

Patient Surveys and Therapy Devices

1. Radiation survey of patient is performed to ensure source is returned to shielded position [35.604(a)]?

2. RSO and AU promptly notified if patient had a medical emergency or died [35.615(f)(4)]?

3. Records of radiation surveys maintained for 3 years [35.2404]?

Personnel Radiation Protection

1. Exposure evaluation performed [20.1501]?

2. As low as is reasonably achievable (ALARA) program implemented [20.1101(b)]?

3. External Dosimetry:

   a. Monitors workers per [20.1502(a)]?

   b. External exposures account for contributions from airborne activity [20.1203]?

   c. Supplier _____ Frequency

   d. Supplier is National Voluntary Laboratory Accreditation Program -approved [20.1501(c)]?

   e. Dosimeters exchanged at required frequency?

4. Internal Dosimetry:

   a. Monitors workers per 20.1502?

   b. Program for monitoring and controlling internal exposures [20.1701, 20.1702] briefly described?

   c. Monitoring/controlling program implemented (includes bioassays)?

   d. Respiratory protection equipment [20.1703]?

5. Review of Records and Reports:

   a. Reviewed by _____ Frequency_____

   b. Auditor reviewed personnel monitoring records for period _____ to _____

   c. Prior dose determined for individuals likely to receive doses [20.2104]?

   d. Maximum exposures TEDE _____ Other _____

   e. Maximum committed dose equivalents (CDEs) _____ Organs

   f. Maximum CEDE _____

   g. Internal and external summed [20.1202]?

   h. Occupational limits met for adults [20.1201]?

i. If applicable, occupational limits met for minors [20.1202]?

j. NRC forms or equivalent [20.2104(d), 20.2106(c)]?

i. NRC-4 Complete:

ii. NRC-5 Complete:

k. If a worker declared her pregnancy during the audit period, was the dose in compliance [20.1208] and were the records maintained [20.2106(e)]?

6. Any planned special exposures (number of people involved and doses received) [20.1206, 20.2104, 20.2105, 20.2204]?

7. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 20.2103, 20.2106]?

Security Program for Category 1 and Category 2 Materials [10 CFR Part 37]

1. Background investigations and access control program [10 CFR Part 37, Subpart B]?

2. Security program content and implementation reviewed annually and maintain records for 3 years [10 CFR 37.55]

3. Physical protection in transit [10 CFR Part 37, Subpart D]?

4. Records [10 CFR Part 37, Subpart F]?

Confirmatory Measurements

1. Detail location and results of confirmatory measurements.

Medical Events

If medical events meeting the criteria in 35.3045 have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering WDs using the existing guidance.

1. Event date _____ Information Source _____

2. Notifications:

❑ NRC Ops Center	❑ NRC Region
❑ Referring Physician	❑ Patient
❑ In writing	❑ By telephone

If notification did not occur, why not?

3. Written Reports [35.3045]: Submitted to Region within 15 days?

4. Patient intervention that resulted in the total dose or dosage not being administered? Describe each intervention.

Notification and Reports

1. In compliance with 10 CFR 19.13, and 10 CFR 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?

2. In compliance with 10 CFR 20.2201, and 10 CFR 30.50 (theft or loss)?

3. In compliance with 10 CFR 20.2202, and 10 CFR 30.50 (incidents)?

4. In compliance with 10 CFR 20.2203, and 10 CFR 30.50 (overexposure and high radiation levels)?

5. Licensee in compliance with 10 CFR 21.21 (device defect)?

6. Aware of NRC Operations Center telephone number?

7. In compliance with 10 CFR 20.2203 (constraint on air emissions)?

Posting and Labeling

1. NRC Form 3, “Notice to Workers” is posted [19.11]?

2. 10 CFR Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to 10 CFR Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]?

3. Other posting and labeling per 10 CFR 20.1902, 20.1904, and not exempted by 20.1903, 20.1905?

Recordkeeping for Decommissioning

1. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)]?

2. Records include all information outlined in 10 CFR 30.35(g)?

Bulletins and Information Notices (IN)

1. Bulletins, INs, Newsletters, etc., received? To receive these documents electronically, subscribe to the Medical List Server by sending an e-mail to “Medical-GC.Resource@nrc.gov” with the word ‘subscribe’ in the subject line.

2. Appropriate action in response to Bulletins, Generic Letters, etc.?

Special License Conditions or Issues (L/C)

Special license condition or issues to be reviewed:

a. If authorized for 10 CFR 35.1000 medical uses, review the program for conformance with license application commitments, license conditions, and regulations.

b. Other special license conditions.

Performance-Based Review

1. Conduct performance-based reviews of radiation workers performing licensed activities:

   a. to assess the capability of the radiation workers to maintain exposures ALARA;

   b. to assess that radiation workers follow the operating procedures;

   c. to assess the effectiveness of the operating procedures and compliance with the regulations, license conditions and the licensee commitments submitted in support of a license (and incorporated by “tie-down” conditions);

   d. to ensure the safe and secure use of radioactive material;

   e. to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and maintain exposures ALARA; and

   f. to ensure that emergency procedures have been developed for all likely scenarios.

2. Take the necessary actions to address programmatic and performance deficiencies with radiation workers and facilitate immediate corrective actions.

Evaluation of Other Factors

1. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight?

2. RSO has sufficient time to perform radiation safety duties and is not too busy with other assignments?

3. Licensee has sufficient staff?

Audits and Findings

1. Summary of findings.
2. Corrective and preventive actions.
3. Amendment required?

1

APPENDIX M

MODEL PROCEDURES FOR OCCUPATIONAL DOSE PROGRAM

Model Procedures for Occupational Dose Program

This model provides acceptable procedures for an external occupational dose program and references and resources for developing an internal occupational dose program. Applicants may either adopt these model procedures for an external occupational dose program or develop alternative procedures to meet the requirements of Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 20.1101 and Subparts C ("Occupational Dose Limits") and F ("Surveys and Monitoring") of 10 CFR Part 20. The model includes guidance as well as a discussion of regulatory requirements that are to be reflected in the elements of an occupational dose program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 10 CFR 20.1502(a). The occupational dose limits for adults are provided in 10 CFR 20.1201, while 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," provides, in part, that adults likely to receive in a year a dose in excess of 10% of those dose limits must be provided with dosimetry. Definitions of relevant terms such as total effective dose equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in 10 CFR 20.1003, "Definitions." In addition, if monitoring is required pursuant to 10 CFR 20.1502, each licensee shall maintain records of doses received (see 10 CFR 20.2106, "Records of individual monitoring results") and individuals must be informed of their doses on at least an annual basis (see 10 CFR 19.13(b), "Notifications and reports to individuals").

The licensee must consider the dose that an individual may receive in the current year from all sources of employment where the individual's assigned duties involve exposure to sources of radiation.

If an individual is likely to receive more than 10% of the annual dose limits, the NRC requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his or her dose.

The As-Low-As-Reasonably-Achievable "ALARA" Program

Regulations in 10 CFR 20.1101 state that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities" and "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally, 10 CFR 20.1101 requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels.

Providing for the safe use of radioactive materials and radiation is a management responsibility. It is important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 10 CFR 20.1201 that apply to external exposure: deep dose to the whole body [5 rem or 0.05 Sievert (Sv)], shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in 10 CFR 20.1003, the DDE to the whole body is considered to be at a tissue depth of 1 centimeter (cm) [1,000 milligram (mg)/square centimeters (cm^2)], shallow-dose equivalent (SDE) to the skin or extremities at 0.007 cm [7 mg/cm^2], and eye dose equivalent at 0.3 cm [300 mg/cm^2]. In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Under 10 CFR 20.1502(a), the use of individual monitoring devices is required for the following:

- Adults likely to receive, in a year, from sources external to the body, a dose in excess of 10% of the occupational dose limits in 10 CFR 20.1201(a). Monitoring devices are accordingly required for adults with an annual dose in excess of
  - 0.5 rem [0.005 Sv] DDE
  - 1.5 rem [0.015 Sv] eye dose equivalent
  - 5 rem [0.05 Sv] SDE to the skin
  - 5 rem [0.05 Sv] SDE to any extremity
- Minors who are likely to receive an annual dose in excess of:
  - 0.1 rem [1.0 millisievert (mSv)] DDE
  - 0.15 rem [1.5 mSv] eye dose equivalent
  - 0.5 rem [5 mSv] SDE to the skin, or
  - 0.5 rem [5 mSv] SDE to any extremity
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem [1.0 mSv] DDE during the entire pregnancy.
- Individuals entering a high- or a very-high-radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, the NRC does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

- Prior Experience: Reviews of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits.
- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys [e.g., using a radiation survey meter or area thermoluminescent dosimeters (TLDs)] in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable “accident” scenarios should also be evaluated).

- The licensee performs a reasonable calculation, based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters, or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program-approved, as required by 10 CFR 20.1501.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year [10 CFR 20.1201(c)]. When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly nonuniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

Under 10 CFR 20.2106, individual monitoring must be recorded on NRC Form 5, "Occupational Dose Record for a Monitoring Period," or equivalent. Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record in order to demonstrate compliance with occupational dose limits in 10 CFR 20.1201. Sometimes the most reliable method for estimating an individual's dose is to use his or her recent dose history. In other cases, particularly if the individual does nonroutine types of work, it may be better to use doses of coworkers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in International Commission on Radiological Protection (ICRP) Report 26, "Recommendations of the International Commission on Radiological Protection," Investigational

Levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's dose or the dose for a group of workers needs to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table M–1 (i.e., 10% of the annual limit for occupational exposure), the radiation safety officer (RSO) or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds the Investigational Level II in Table M–1 (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table M–1. Investigational Levels

Part of Body	Investigational Level I (mrem/yr)	Investigational Level II (mrem/yr)
whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee	500 [5 mSv]	1,500 [15 mSv]
hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin	5,000 [50 mSv]	15,000 [150 mSv]
lens of the eye	1,500 [15 mSv]	4,500 [45 mSv]

Review and record on NRC Form 5, "Occupational Dose Record for a Monitoring Period," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table M–1 are reached:

- Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than Table M–1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements or additional safety measures are needed to reduce exposures. Evaluate, in the context of ALARA program quality, and record the results of investigations and evaluations.

- Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. The RSO should consider actions to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Reestablishment of Investigational Level II to a level above that listed in Table M–1.

Declared Pregnancy and Dose to Embryo/Fetus

Regulations in 10 CFR 20.1208, "Dose equivalent to an embryo/fetus," state that the licensee shall ensure that the dose to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv]. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo or fetus shall be taken as the sum of

- the DDE to the declared pregnant woman

- the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman

Licensees should reference RG 8.13, "Instructions Concerning Prenatal Radiation Exposure," June 1999, for information to help pregnant women and other personnel make decisions regarding radiation exposure during pregnancy and RG 8.36, "Radiation Dose to the Embryo/Fetus," July 1992, for calculating the radiation dose to the embryo/fetus.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in a year (10 CFR 20.1502). Terms for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) are provided in 10 CFR Part 20.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in microcurie (μCi)/milliliter that, if an occupational worker were to be continuously exposed to it for 2,000 hours (1 year), would result in either a CEDE of 5 rem [0.05 Sv] to the whole body or a committed dose equivalent of 50 rem [0.5 Sv] to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in Appendix B of 10 CFR Part 20.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem [0.05 Sv] or a committed dose equivalent of 50 rem [0.5 Sv] to any individual organ or tissue; again, with no consideration for the contribution of external dose.

The TEDE concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers in 10 CFR Part 20 reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per 10 CFR Part 20, Appendix B, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities, require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include

- adequate equipment to perform bioassay measurements
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or µCi units
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue)
- the interval between bioassays
- action levels
- the actions to be taken at those levels

For additional guidance on developing occupational dose programs refer to the following:

- Regulatory Guide (RG) 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," July 1993.
- RG 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 87, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," February 1987.
- NUREG/CR–4884, "Interpretation of Bioassay Measurements," July 1987.
- NUREG–1400, "Air Sampling in the Workplace," September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.2106. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," November 2005.

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, "Compliance with requirements for summation of external and internal doses," the external and internal doses must be summed if required to monitor both under 10 CFR 20.1502. Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," April 16, 2002, contains helpful information regarding occupational doses.

APPENDIX N

MODEL EMERGENCY PROCEDURES

Model Emergency Procedures

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

This model provides acceptable procedures for responding to emergencies involving spills or patients administered therapeutic amounts of radionuclides. Applicants using unsealed licensed material may either adopt this model or develop alternative procedures to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101. Applicants using therapeutic sealed sources should develop procedures specific to each use.

General Safety Procedures to Handle Spills

The name and telephone number of the radiation safety officer (RSO) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies. Licensee should have emergency equipment readily available for handling spills. Spill/contamination kits should include the following items:

- disposable gloves
- disposable lab coats
- disposable head coverings
- disposable shoe covers
- roll of absorbent paper with plastic backing
- masking tape
- plastic trash bags with twist ties
- “radioactive material” labeling tape
- marking pen
- prestrung “Radioactive Material” labeling tags
- contamination wipes
- instructions for “Emergency Procedures”
- clipboard with copy of Radioactive Spill Report Form
- pencil
- appropriate survey instruments, including batteries

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest annual limit on intake (ALI), an alternative spill/contamination procedure may be to restrict access pending complete decay. In most cases, determination of a major versus minor spill should be based on the lowest ALI.

The licensee should estimate the amount of radioactivity spilled and initiate a major or minor spill/contamination procedure. Use Table N–1 as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills above these millicurie (mCi) amounts are considered major, and spills below these levels are considered minor.

Table N–1 Relative Hazards of Common Radionuclides			
Radionuclide	**mCi**	**Radionuclide**	**mCi**
nitrogen-13	100	technetium-99m	100
carbon-14	10	indium-111	10
oxygen-15	100	iodine-123	10
fluorine-18	100	iodine-125	1
phosphorus-32	1	iodine-131	1
gallium-67	10	samarium-153	10
rubidium-82	10	ytterbium-169	10
strontium-82	1	mercury-197	10
strontium-85	10	gold-198	10
strontium-89	1	thallium-201	100
yttrium-90	1	Alpha emitters	*
*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions.			

***Note**:* A report to U.S. Nuclear Regulatory Commission (NRC) may be required pursuant to 10 CFR 30.50.

Minor Spills of Liquids and Solids

Instructions to Workers

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper.
- Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a bag labeled "caution radioactive material" for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detection instrument sufficiently sensitive to detect the radionuclide. Survey for removable contamination to ensure contamination levels are below trigger levels. Survey the area around the spill.
- Survey hands, clothing, and shoes for contamination prior to leaving the area.
- Report the incident to the RSO promptly.
- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Follow up on the decontamination activities and document the results.

- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

- If necessary, notify the NRC.

Major Spills of Liquids and Solids

Instructions to Workers

- Clear the area. Notify all persons not involved in the spill to vacate the room.

- Prevent the spread of contamination by covering the spill with absorbent paper labeled "caution radioactive material," but do not attempt to clean it up. Paper should be dampened, if solids are spilled. To prevent further spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.

- Shield the source only if it can be done without further contamination or a significant increase in radiation exposure.

- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.

- Notify the RSO immediately.

- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap.

- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Supervise and confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

- Document decontamination results, including all surveys, location of surveys, and decontamination results.

- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.

- If necessary, notify the NRC.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

For emergency surgery or autopsy of patients administered byproduct material, National Council on Radiation Protection and Measurements (NCRP) Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," 1991, may contain helpful information.

If emergency surgery is performed within the first 24 hours following the administration of iodine-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).

The radiation safety staff will direct personnel in methods to keep doses as low as reasonable achievable (ALARA) during surgical procedures.

If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

- Immediately notify the authorized user (AU) in charge of the patient and the RSO upon death of a therapy patient.

- An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.

- Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with phosphorus-32 and yttrium-90.

- Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accordance with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.

- If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Autopsy or Cremation of Patients Who Have Permanent Implants

Patients treated with seed implants will not usually represent a radiation hazard to persons dealing with the body unless there is to be an autopsy or cremation. For autopsy or cremation

of patients with permanent implants, NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information.

If an autopsy or cremation is to be performed

- Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
- Consult and get permission from the RSO.
- Instruct pathologist to excise tissue containing radioactive seeds.
  - — Make pathologist aware seeds may have migrated and additional tissue may need to be removed.
  - — Instruct pathologist to consult with RSO about possibility of slicing through a seed and contaminating the facility.
- Seek municipal approval, if required, because the very high temperatures used in modern crematoria may cause seeds to burst, releasing radioactivity into the plume.

Nuclear Pacemakers

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify the NRC and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee that implanted the device is responsible for the follow-up, explanation, and return of the pacemaker to the manufacturer for proper disposal. Information Notice (IN) 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

APPENDIX O

MODEL PROCEDURES FOR ORDERING AND RECEIVING PACKAGES

Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- Authorize, through a designee (e.g., radiation safety officer), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user (AU) and that possession limits are not exceeded.

- Establish and maintain a system for ordering and receiving radioactive material; include the following information:

  — records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier

  — confirmation, through the above records, that material received was ordered through proper channels

- For deliveries during normal working hours, instruct carriers to deliver radioactive packages directly to a specified area and provide contact information to the carrier for any questions (e.g., delivery area not accessible, staff not present to receive package).

- For deliveries during off-duty hours, instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package _____, and relock the door. If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

	NAME	**HOME TELEPHONE**
Radiation Safety Officer	_____	
Director of Nuclear Medicine	_____	
Nuclear Medicine Technologist Supervisor	_____	
Nuclear Medicine Technologist on call (call/page operator at extension ___)	_____	
Nuclear Medicine Physician on call (call/page operator at extension ___)	_____	

APPENDIX P

MODEL PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Model Procedures for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1906.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in Table A–1 in Appendix A of 10 CFR Part 71. Such packages must be received expeditiously when the carrier offers them for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt, if received during working hours, or no later than 3 hours from the beginning of the next working day, if received after working hours, in accordance with the requirements of 10 CFR 20.1906(c). Notify the final delivery carrier and the U.S. Nuclear Regulatory Commission (NRC) Operations Center, (301) 816-5100, by telephone, when

- removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i)
- external radiation levels exceed the limits of 10 CFR 71.47

Model Procedure

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and immediately notify the radiation safety officer (RSO) or the designee of the RSO, if the RSO is not present.

3. Monitor the external surfaces of a labeled[1] package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4, "Definitions."

4. Monitor the external surfaces of a labeled package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A–1 in Appendix A of 10 CFR Part 71. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

5. Remove the packing slip.

6. Open the outer package, following any instructions that may be provided by the supplier.

7. Open the inner package and verify that the contents agree with the packing slip.

[1]Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

8. Check the integrity of the final source container. Notify the RSO or the RSO's designee of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

9. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. Use an appropriate instrument with sufficient sensitivity to assay the sample. For example, a sodium iodide crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. Convert wipe sample from counts per minute to disintegrations per minute.
***Note**: A dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.

10. Check the user request to ensure that the material received is the material that was ordered.

11. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding.

12. Make a record of the receipt.

For packages received under the general license in 10 CFR 31.11, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO or the RSO's designee immediately.

2. Check to ensure that the material received is the material that was ordered.

APPENDIX Q

MODEL LEAK TEST PROGRAM

Model Leak Test Program

This model program provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

Training

Before allowing an individual to perform leak testing, the licensee must ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak testing and sample analysis independently in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 30.33(a)(3). Records for training on the applicable leak test procedures should be maintained. See Appendix X of this NUREG for recordkeeping requirements.

Classroom training may be in the form of lecture, online, video, or self-study, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations used for measuring radioactivity
- biological effects of radiation

Appropriate on-the-job training consists of the following:

- observing authorized personnel collecting and analyzing leak test samples

- collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak test and sample analysis

Facilities and Equipment

- To ensure the required sensitivity of measurements is achieved, analyze leak tests in a low background area.

- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.

- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (e.g., sodium iodide well-counter system for gamma emitters, liquid scintillation detector for beta emitters, or gas-flow proportional counters for alpha emitters).

- Instrumentation used to analyze leak test samples must be capable of detecting 185 becquerels (Bq) [0.005 microcuries (µCi)] of radioactivity.

- If the sensitivity of the counting system is unknown, determine the minimum detectable activity (MDA). The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{(bkg \times t)}}{t \times E}$$

where: MDA = minimum detectable activity in disintegrations per minute (dpm)
bkg = background count rate in counts per minute (cpm)
t = background counting time in minutes
E = detector efficiency in counts per disintegration

For example:

where: bkg = 200 cpm
E = 0.1 counts per disintegration (10% efficient)
t = 2 minutes

$$MDA = \frac{2.71 + 4.65\sqrt{(200\ cpm \times 2\ minutes)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$= \frac{2.71 + 4.65\ (20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$= 478.55 \frac{\text{disintegrations}}{\text{minute}}$$

$$Bq = \frac{1\ \text{disintegration}}{\text{second}}$$

$$Bq = \frac{478.55\ \text{disintegration}}{\text{minutes}} \times \frac{\text{minute}}{60\ \text{seconds}} = 7.976\ Bq$$

***Note**:* The MDA equation shown assumes that counting times for the background measurement and for the sample will be equal. MDA equations for nonequal counting times, as well as derivations of equations and discussions of limitations, can be found in "Decommissioning Health Physics—A Handbook for MARSSIM Users," Eric W. Abelquist, published by Taylor & Francis Group, 2001.

Reference:

- National Council on Radiation Protection and Measurements (NCRP) Report No. 58, "A Handbook of Radioactivity Measurement Procedures," Second Edition, 1985.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests will be conducted at the frequency specified in the respective Sealed Source and Device registration certificate. If a sealed source is not registered, leak tests should be conducted at 6 month intervals, unless a different interval is established during the licensing process. Leak testing of sealed sources may be required by license condition.

Procedure for Performing Leak Testing and Analysis [on all sealed sources except individual radium-226 (Ra-226) sealed sources]

- Follow the manufacturer's instructions for performing the leak test.
- For each sealed source to be tested, list identifying information such as sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Use a radiation survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking, but do not wipe the surface of a plated or foil source (see manufacturer's instructions).

Procedure for Performing Gaseous Emanation Test for Individual Ra-226 Sealed Sources (ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification," Appendix A, Section A.2.1.5)

- For each source to be tested, list identifying information such as sealed source serial number, manufacturer, model number, radionuclide, and activity.
- Number each container to correlate information for each source.
- Wear gloves.
- Put each Ra-226 sealed source into a separate small, gas-tight container with activated carbon or two cotton filters.
    - — Leave source in airtight container for 24 hours.
    - — Remove source.
    - — Close container.
- Measure immediately the activity of the Absorber. (See "Model Procedure for Analysis of Gaseous Emanation and Leak Test" below for (i) how to analyze the absorber, (ii)

required records, (iii) leakage determination, and (iii) required response to a leaking source.)

- If the wipe test reveals 37 Bq [1 nano curie (Ci)] or greater of radon or daughter products

  — Notify the RSO.

  — Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67 or standard license condition].

  — File a report within 5 days of the leak test, in accordance with 10 CFR 35.3067, "Report of a leaking source," or standard license condition.

Procedure for Analysis of Leak Test and Gaseous Emanation

- Select an instrument that is sensitive enough to detect 185 Bq [0.005 µCi] of the radionuclide and ensure that its calibration is current.

- Using the selected instrument, count and record background count rate.

- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. The calibration source should be in the same configuration as the sample. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by the National Institute of Standards and Technology.

- Calculate efficiency of the instrument.

For example:

$$Eff = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ Bq)}$$

where:

Eff	=	efficiency, in cpm/Bq
cpm	=	counts per minute
std	=	standard
bkg	=	background
Bq	=	becquerel

- Count each wipe (or absorber for a Ra-226 sealed source) sample; determine net count rate.

- For each sample, calculate and record activity in Bq (or µCi).

The activity of the sample in becquerels may be calculated using the following formula:

$$\text{Activity on wipe sample [Bq]} = \frac{[(cpm \text{ from wipe sample}) - (cpm \text{ from } bkg)]}{\left(Eff \text{ in} \frac{cpm}{Bq}\right)}$$

- Leak test records (which include the gaseous emanation test) will be retained in accordance with 10 CFR 35.2067, "Records of leak tests and inventory of sealed sources and brachytherapy sources," or standard license condition for 3 years. Licensees should include the following in records:

  — the model number and serial number (if assigned) of each source tested
  — the identity of each source radionuclide and its estimated activity
  — the measured activity of each test sample expressed in μCi
  — a description of the method used to measure each test sample
  — the date of the test
  — the name of the individual who performed the test

- If the wipe test reveals 185 Bq [0.005 μCi] [or 37 Bq [1 nano Ci] of radon or daughter products] or greater:

  — Notify the RSO.

  — Immediately withdraw the sealed source from use and store it, dispose of it, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67 or standard license condition].

  — File a report within 5 days of the leak test, in accordance with 10 CFR 35.3067, "Report of a leaking source," or standard license condition.

APPENDIX R

MODEL PROCEDURES FOR AREA SURVEY

Model Procedures for Area Survey

This model provides acceptable methods for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1101, 10 CFR 20.1501, and 10 CFR 35.70, "Surveys of ambient radiation exposure rate." Guidance for developing alternate trigger levels for contamination in restricted areas is included below. Before use of survey instrumentation, perform a daily check with a dedicated check source and battery checks.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70):

- Perform surveys of dose rates in locations where
  - — Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or
  - — An individual is working in an environment with a dose rate of 0.0025 millisievert (mSv)/h [2.5 millirem/hour (h)] or more [5 rem/year (yr) divided by 2,000 h/yr].
- Regulations in 10 CFR 20.1301 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 millisievert (mSv) [0.1 rem] in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem] in any one hour. Appropriate surveys will be conducted to ensure that the requirements of 10 CFR 20.1301 are met.
- Perform radiation level surveys with a radiation survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR)/h in the following areas, at the frequency specified:
  - — Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive [e.g., all therapy dosages and any iodine 131 (I-131) dosage exceeding 30 microcuries (µCi)].
  - — Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (less than 200 µCi at a time).
  - — Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms [e.g., bone scan injections, technetium 99m (Tc-99m) heart agents] and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table R–1.

Table R–1. Ambient Dose Rate Trigger Levels		
Type of Survey	**Area Surveyed**	**Trigger Level**
Ambient Dose Rate	Unrestricted	0.1 mR/h
Ambient Dose Rate	Restricted	5.0 mR/h

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. The section of Table K–1, entitled "Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples," provides examples of appropriate instruments.

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of byproduct materials are used:
  - — to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
  - — after any spill or contamination event
  - — when procedures or processes have changed
  - — to evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
  - — in unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly
  - — in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables R–2 for restricted areas and R–3 for unrestricted areas [e.g., 200 disintegrations per minute (dpm)/100 square centimeters (cm^2) for isotopes of I-131 in unrestricted areas]. Table R–3 for unrestricted areas is based on Regulatory Guide (RG) 1.86, "Termination of Operating Licenses for Nuclear

Reactors." Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

— Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.

— Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (less than 200 µCi at a time).

— Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in counts per minute) to dpm.

- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted areas are presented in Table R–2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table R–2. Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

Area, clothing	Restricted areas, protective clothing used only in restricted area
alpha emitters	200
P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	2000
Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201	20000

Table R–3. Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)

Nuclide*	Average†, ‡, §	Maximum†, ‖, §	Removable†, ¶, §
I-123, I-125, I-129, Ra-223, Ra-224, Ra-226	100	300	20
I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except those noted above.	5000	15000	1000

*Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

†As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

‡Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

§The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/h at 1 cm and 1.0 millirad/h at 1 c**entimeter, respectively, measured through not more than 7 milligram/cm^2 of total absorber.**

‖ The maximum contamination level applies to an area of not more than 100 cm^2.

¶The amount of removable radioactive material per 100 cm^2 of surface area should be determined by swiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally, and the entire surface should be wiped.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables R–1 and R–2:

Alternate action levels for cleanup of contamination in restricted areas may be developed without prior NRC approval if

- acceptable unrestricted area trigger levels are implemented (e.g., Tables R–1 and R–3)
- the action levels maintain occupational doses as low as is reasonably achievable
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste)

Contents of Survey Records

- a diagram of the area surveyed
- a list of items and equipment surveyed
- specific locations on the survey diagram where wipe tests were taken
- ambient radiation levels with appropriate units
- contamination levels with appropriate units
- make and model number of instruments used
- background levels
- name of the person making the evaluation and recording the results and date

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX S

MODEL PROCEDURES FOR DEVELOPING, MAINTAINING, AND IMPLEMENTING WRITTEN DIRECTIVES

Model Procedures for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives (WD). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 10 CFR 35.41 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 megabecquerels [30 microcuries], any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040, "Records of written directives."

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a high dosage-rate treatment, the delivery process may involve a team of medical professionals, such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, and film verifications to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be completed before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which 10 CFR 35.40 requires, or would require, a WD (as defined in 10 CFR 35.2, "Definitions"), the

licensee should develop, implement, and maintain written procedures to meet the requirements and objectives of 10 CFR 35.40, 35.41, and 35.63, outlined below:

- Confirm that the WD is signed and dated by the AU prior to the administration, in accordance with 10 CFR 35.40(b), including the name of the patient or human research subject.
- Verify the identity of the patient or human research subject prior to each administration.
- Verify that the administration is in accordance with the treatment plan, if applicable, and the WD.
- Check both manual and computer-generated dose calculations.
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices.
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcuries of Iodine-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

- An AU must date and sign a WD prior to the administration of any dose or dosage. WDs may be maintained in patients' charts.
- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (e.g., radionuclide, total dose or dosage) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include (i) measuring the activity in the dose calibrator, (ii) checking the serial number of the sealed sources behind an appropriate shield, (iii) using color-coded sealed sources, or (iv) using clearly marked storage locations.

Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under 10 CFR 35.40 and 10 CFR 35.41 to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)

2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)

3. for manually-generated dose calculations, verifying

    a. no arithmetical errors
    b. appropriate transfer of data from the WD, treatment plan, tables, and graphs
    c. appropriate use of nomograms (when applicable)
    d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

After implantation but before completion of the procedure, record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose), as required by 10 CFR 35.40(b)(6). For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The WD may be maintained in the patient's chart.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations.

Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either

1. an individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630)

2. an AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%

For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

For emerging technologies (e.g., Yttrium-90 Microsphere Brachytherapy, Leksell Gamma Knife Perfextion), the licensee should review the applicable guidance on the Medical Uses Licensee Toolkit to ensure the written directive contains all necessary components.

A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes (i) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (ii) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused and must be relabeled in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). The number of patient cases to be sampled should be based on the principles of statistical

acceptance sampling and be representative of each treatment modality performed in the institution.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by 10 CFR 35.41, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Medical Events

Notify by telephone the U.S. Nuclear Regulatory Commission (NRC) Operations Center at 301-816-5100 no later than the next calendar day after discovery of a medical event and submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6, "Communications," within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045, "Report and notification of a medical event." Also notify the referring physician and the patient as required by 10 CFR 35.3045.

APPENDIX T

MODEL PROCEDURES FOR SAFE USE OF UNSEALED LICENSED MATERIAL

Model Procedures for Safe Use of Unsealed Licensed Material

This model[1] provides acceptable procedures for safe use of unsealed licensed material. Applicants may either adopt this model procedure or develop their own procedure. Some of the health physics practices listed below may also apply to sealed sources.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the radiation safety officer. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey all areas of licensed material use, including the generator storage, kit preparation, and injection areas, for contamination using a survey instrument each day of use. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 35.70 (except when administering therapy dosages in patients' rooms when patients are confined).
- Store radioactive solutions in shielded containers that are clearly labeled.

[1] NCRP Report No. 30, "Safe Handling of Radioactive Materials," March 1964.

- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69, "Labeling of vials and syringes," and 10 CFR 20.1904, "Labeling containers."

- Syringes and unit dosages must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to 10 CFR Part 20, "Quantities of Licensed Material Requiring Labeling," the syringe or vial need only be labeled to identify the radioactive drug (10 CFR 35.69). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.

- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (10 CFR 35.63).

- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.

- When measuring the dosage, licensees need not consider the radioactivity that adheres to the syringe wall or remains in the needle.

- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive (WD), the patient's identity must be verified and the administration must be in accordance with the WD (10 CFR 35.41).

- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

- Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the U.S. Nuclear Regulatory Commission license (or such individual's designee).

APPENDIX U

MODEL PROCEDURES FOR RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS

Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials

In this Appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient." This model provides acceptable procedures for the release of patients, under Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR 35.75, who are administered radioactive materials. Regulations in 10 CFR Part 35.75 permit a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv) (0.5 rem)." However, a patient who meets the release criteria in 10 CFR 35.75 is not required to be released immediately following administration of radioactive materials. Inpatient treatment is always an option and may be the appropriate choice, given the patient's specific situation.

Licensees should review Information Notice (IN) 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations," December 9, 2003, and Supplement 1, July 29, 2009, in developing instructions for patients that still contain detectable amounts of radiation and provide patients with an appropriate explanation about the potential of alarming radiation monitoring equipment.

Special Considerations and Guidance for Release of Patients Following I-131 Therapy

Although the regulations are not explicit, licensees should consider implementing the 5 mSv [0.5 rem] as an annual limit for multiple administrations during a calendar year. For more information on this topic see Regulatory Issue Summary (RIS) 2008-07, "Dose Limits for Patient Release Under 10 CFR 35.75," March 27, 2008.

Although 10 CFR 35.75 does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the U.S. Nuclear Regulatory Commission (NRC) strongly discourages this practice, because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 10 CFR 35.75(a) and may result in doses that are not as low as is reasonably achievable (ALARA). For more information on this topic, see RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011.

Licensees should take into account whether the released patient may come in contact with infants or young children. In such a situation, in order to protect infants and young children from possible iodine-131 (I-131) contamination, the licensee should provide the patient with additional instructions. These additional instructions are listed in Section U.2.3.1, "Instructions Regarding Radiopharmaceutical Administrations." For more information on this topic see RIS 2008-11, "Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administrations of Iodine-131," May 12, 2008.

Release Equation

The activity at which patients could be released was calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic

Amounts of Radionuclides." This report uses the following equation to calculate the exposure until time *t* at a distance *r* from the patient:

Equation U–1:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_P\,(1 - e^{-0.693t/T_P})}{r^2}$$

where: $D(t)$ = Accumulated exposure at time t, in roentgens (R)
34.6 = Conversion factor of 24 hours/day times the total integration of decay (1.44)
Γ = Specific gamma ray constant for a point source, R/millicuries (mCi)-h at 1 centimeter (cm)
Q_0 = Initial activity of the point source in mCi, at the time of the release
T_p = Physical half-life in days
r = Distance from the point source to the point of interest, in cm
t = Exposure time in days.

This Appendix uses the NCRP equation (Equation U–1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1\text{-}e^{-0.693t/Tp})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 mSv [1 rem].
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Table U–5.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation U–1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U–2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, *E*, of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation U–2:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0 T_p (0.25)}{(100\ \text{cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation U–3:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0 T_p (1)}{(100\ \text{cm})^2}$$

Equations U–2 and U–3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (i.e., less than a few percent), relative to the external gamma dose. For some radionuclides, such as sodium iodide I-131, it may be necessary to also consider the internal dose from exposure to a released patient. The internal and external doses must be summed to determine the total dose. See Supplement B.3, "Internal Dose" for equations. Further, the equations above do not apply to the dose to breastfeeding infants or children who continue to breastfeed. Patients who are breastfeeding an infant or child must be considered separately, as discussed in Section U.1.1, "Release of Patients Based on Administered Activity."

U.1 Release Criteria

Licensees should use one of the following options (U.1.1, U.1.2. or U.1.3.) to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements.

Licensees should perform an assessment in advance of the treatment to validate the factors used in release equations, including confirmation that default values used are appropriate for the patient's situation. Licensees should have a program that includes a structured series of questions and maintain documentation of responses. Examples of items to consider in the assessment can be found in "Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine ^{131}I: Practice Recommendations of the American Thyroid Association."

U.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table U–1. The activities in Table U–1 are based on a TEDE of 5 mSv [0.5 rem] to an individual using the following conservative assumptions:

- administered activity
- physical half-life

- occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day

- no shielding by tissue

Because the values in Table U–1 are based on Equations U–2 and U–3, licensees should perform patient-specific dose calculations, if it is determined that a different occupancy factor is appropriate for the patient's situation. See Section U.1.3 and Supplement B for details on patient-specific dose calculations.

The TEDE is approximately equal to the external dose because the internal dose is a small fraction of the external dose. See Section B.3, "Internal Dose," of Supplement B. In this case, no record of the release of the patient is required unless the patient is breastfeeding an infant or child, as discussed in Section U.3.2, "Records of Instructions for Breastfeeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table U–1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table U–1. In this case, 10 CFR 35.75(c) requires a record because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table U–1 were calculated using either Equation U–2 or U–3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table U–1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 mSv [0.5 rem]. Equation U–2 or U–3 may be used, as appropriate, to calculate the activity Q corresponding to 5 mSv [0.5 rem].

The release activities in Column 1 of Table U–1 do not include consideration of the dose to a breastfeeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breastfeeding an infant or child, the activities in Column 1 of Table U–1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Sections U.2.2 and U.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breastfeeding infant or child in excess of 5 mSv [0.5 rem], a record that instructions were provided is required by 10 CFR 35.75(d).

U.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table U–1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U–1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table U–1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 mSv [0.5 rem] dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation U–2

or U–3, as appropriate, because the dose rate at 1 meter is equal to Γ Q / 10,000 square centimeters.

Because the values in Table U–1 are based on Equations U–2 and U–3, patient-specific dose calculations should be performed, if it is determined that a different occupancy factor is appropriate for the patient's situation. See Section U.1.3 and Supplement B for details on patient-specific dose calculations.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv [0.5 rem], the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table U–1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table U–1. Activities and Dose Rates for Authorizing Patient Release*

Radionuclide	Column 1		Column 2	
	GBq	mCi	mSv/h	mrem/h
silver-111	19	520	0.08	8
gold-198	3.5	93	0.21	21
chromium-51	4.8	130	0.02	2
copper-64	8.4	230	0.27	27
copper-67	14	390	0.22	22
gallium-67	8.7	240	0.18	18
iodine-123	6	160	0.26	26
iodine-125	0.25	7	0.01	1
iodine-125 implant	0.33	9	0.01	1
iodine-131	1.2	33	0.07	7
indium-111	2.4	64	0.2	20
iridium-192 implant	0.074	2	0.008	0.8
phosphorus-32	†	†	†	†
Pd-103 implant	1.5	40	0.03	3
rhenium-186	28	770	0.15	15
rhenium-188	29	790	0.2	20
scandium-47	11	310	0.17	17
selenium-75	0.089	2	0.005	0.5
samarium-153	26	700	0.3	30
tin-117m	1.1	29	0.04	4

Table U–1. Activities and Dose Rates for Authorizing Patient Release* (Continued)				
	Column 1		Column 2	
Radionuclide	GBq	mCi	mSv/h	mrem/h
stontium-89	†	†	†	†
technetium-99m	28	760	0.58	58
thallium-201	16	430	0.19	19
yttrium-90	†	†	†	†
ytterbium-169	0.37	10	0.02	2

*The activity values were computed based on 5 mSv [0.5 rem] TEDE.
†Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.
Note: If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Section U.3.1, "Records of Release," for information on records.

Notes:

- The mCi values were calculated using Equations U–2 and U–3 and the physical half-life. The gigabecquerel (GBq) values were calculated using the mCi values and the conversion factor from mCi to GBq. The dose rate values are calculated using the mCi values and the exposure rate constants.

- In general, the values are rounded to two significant figures; however, values less than 0.37 GBq [10 mCi] or 0.1 mSv [10 millirem (mrem)] per hour are rounded to one significant figure. Details of the calculations are provided in NUREG–1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

- Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

U.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. Licensees may either adopt these model instructions or develop their own instructions to meet the requirements of 10 CFR 35.75.

U.2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released. NRC cannot enforce patient compliance with the instructions, nor is it the licensee's responsibility to do so. Column 1 of Table U–2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table U–2 may be used for determining when instructions must be given. If the patient is breastfeeding an infant or child, additional instructions may be necessary. (See Section U.2.2, "Additional Instructions for Release of Patients Who Could Be Breastfeeding after Release.")

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 mSv [0.1 rem].

If a radionuclide not listed in Table U–2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 mSv [0.1 rem]. Equation U–2 or U–3, as appropriate, may be used.

U.2.2 Additional Instructions for Release of Patients Who Could Be Breastfeeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breastfeeding, and the consequences of failing to follow the recommendation, presumes the licensee will inquire, as appropriate, regarding the breastfeeding status of the patient.

***Note**:* The NRC does not intend to enforce patient compliance with the instructions, nor is it the licensee's responsibility to do so. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breastfeeding an infant or child when the dose to the infant or child could exceed 5 mSv [0.5 rem], if there is no interruption of breastfeeding.

If the patient could be breastfeeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table U–3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breastfeeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breastfeeding infant or child. Table U–3 also provides recommendations for interrupting or discontinuing breastfeeding to minimize the dose to below 1 mSv [0.1 rem] if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table U–3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table U–3 is administered to a patient who could be breastfeeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant in an article by Michael Stabin entitled "Internal Dosimetry in Pediatric Nuclear Medicine," published in *Pediatric Nuclear Medicine* (edited by S. Treves, Springer Verlag, New York, 1995).

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine therapy, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to Sections U.2.3.1 and U.2.3.2).

Table U–2. Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	**Column 1 Activity Above Which Instructions Are Required**		**Column 2 Dose Rate at 1 Meter Above Which Instructions Are Required**	
	(GBq)	**(mCi)**	**(mSv/h)**	**(mrem/h)**
silver-111	3.8	100	0.02	2
gold-198	0.69	19	0.04	4
chromium-51	0.96	26	0.004	0.4
copper-64	1.7	45	0.05	5
copper-67	2.9	77	0.04	4
gallium-67	1.7	47	0.04	4
iodine-123	1.2	33	0.05	5
iodine-125	0.05	1	0.002	0.2
iodine-125 implant	0.074	2	0.002	0.2
iodine-131	0.24	7	0.02	2
indium-111	0.47	13	0.04	4
iridium-192 implant	0.011	0.3	0.002	0.2
phosphorus-32	†	†	†	†
Pd-103 implant	0.3	8	0.007	0.7
rhenium-186	5.7	150	0.03	3
rhenium-188	5.8	160	0.04	4
scandium-47	2.3	62	0.03	3
selenium-75	0.018	0.5	0.001	0.1
samarium-153	5.2	140	0.06	6
tin-117m	0.21	6	0.009	0.9
stontium-89	†	†	†	†
technetium-99m	5.6	150	0.12	12
thallium-201	3.1	85	0.04	4
yttrium-90	†	†	†	†
ytterbium-169	0.073	2	0.004	0.4

*The activity values were computed based on 1 mSv [0.1 rem] TEDE.
†Activity and dose rate limits are not applicable in this case, because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes:

- The values for activity were calculated using Equations U–2 and U–3 and the physical half-life. The values given in International System of Units (GBq values) were using conversion factors.

- In general, values are rounded to two significant figures; however, values less than 0.37 GBq [10 mCi] or 0.1 mSv [10 mrem] per hour are rounded to one significant figure. Details of the calculations are provided in NUREG–1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

- Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

Table U–3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child

Radio-pharmaceutical	Column 1 Activity Above Which Instructions Are Required		Column 2 Activity Above Which a Record is Required		Column 3* Examples of Recommended Duration of Interruption of Breastfeeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation for this infant or child
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq [10 mCi] 12 hours for 150 MBq [4 mCi]
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 MBq [4 mCi]
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq [30 mCi] 12 hours for 440 MBq [12 mCi]
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2000	50	6 hours for 740 MBq [20 mCi]
Tc-99m Red Blood Cell *In Vitro* Labeling	1000	30	6000	150	
Tc-99m Sulfer Colloid	300	7	1000	35	6 hours for 440 MBq [12 mCi]
Tc-99m DTPA Aerosol	1000	30	6000	150	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq [30 mCi] 12 hours for 440 MBq [12 mCi]

Table U–3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child (Continued)					
Radio-pharmaceutical	Column 1 Activity Above Which Instructions Are Required		Column 2 Activity Above Which a Record is Required		Column 3* Examples of Recommended Duration of Interruption of Breastfeeding
	(MBq)	(mCi)	(MBq)	(mCi)	
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq [4 mCi] 2 weeks for 50 MBq [1.3 mCi] 1 week for 7 MBq [0.2 mCi]
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq [0.5 mCi]
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq [3 mCi]
*The duration of interruption of breastfeeding is selected to reduce the maximum dose to a newborn infant to less than 1 mSv [0.1 rem], although the regulatory limit is 5 mSv [0.5 rem]. The actual doses that would be received by most infants would be far below 1 mSv [0.1 rem]. Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.					

***Notes**:*

- Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG–1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

- If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breastfeeding.

- Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

U.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

You have been administered radioactive material for therapeutic medical purposes. To minimize exposure to radiation to others from the radioactive material inside your body, you should do the following for_____days:

- Maintain distance from other persons (e.g., use separate sleeping arrangements, no cuddling or holding children).
- Minimize time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Reduce the spread of radioactive contamination (e.g., do not share towels or washcloths; wash linens separately; and do not share cups, glasses, plates, or eating utensils).

Refrain from returning to work for _____ days.

Additionally for some types of therapy:

- Drink one glass of water each hour and use the bathroom as soon as possible to empty bladder.
- Men should sit on the toilet while urinating to decrease splashing.
- Use a tissue to wipe up any urine on the toilet bowl and flush twice.
- Wash hands after urinating.
- Rinse the sink and tub after each use.
- Minimize time with children and pregnant women.
- Avoid direct or indirect contact (e.g., indirect contact includes contamination from shared living space) with infants and young children for a specific period of time (e.g., consider having children stay outside the home with other family members).
- Establish adequate living space at home (e.g., bedroom, bathroom) that can be used exclusively by the patient for a specific period of time.
- For women who are breastfeeding, consult physician before resuming breastfeeding.

Licensees should consider not releasing patients administered I-131, whose living conditions may result in the contamination of infants and young children. The licensee should provide information on the potential consequences, if any, from failure to follow these instructions (e.g., could result in significant doses to the child's thyroid and potentially raise the risk of subsequent radiation-induced thyroid cancer).

If additional instructions are required because the patient is breastfeeding, the instructions should include appropriate recommendations on whether to interrupt breastfeeding, the length of time to interrupt breastfeeding, or, if necessary, the discontinuation of breastfeeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The consequences should be

explained so that the patient will understand that, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving sodium iodide I-131 is that continued breastfeeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breastfeeding. The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breastfeeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in providing detailed instructions and recommendations.

U.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for_____days:

- Stay at a distance of _____ feet from other individuals.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out
  - — Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
  - — Place the container with the seed or pellet in a location away from people.
  - — Notify _____ at telephone number _____.

U.3 Records

U.3.1 Records of Release

- There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table U–1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or

attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information: **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this Appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

- **For Immediate Release of a Patient Based on Measured Dose Rate**: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

- **For Delayed Release of a Patient Based on Radioactive Decay Calculation**: The time of the administration, the date and time of release, and the results of the decay calculations.

- **For Delayed Release of a Patient Based on Measured Dose Rate**: The results of the radiation survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality; that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

U.3.2 Records of Instructions for Breastfeeding Patients

If failure to interrupt or discontinue breastfeeding could result in a dose to the infant or child in excess of 5 mSv [0.5 rem], a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table U–3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breastfeeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breastfeeding an infant or child.

U.4 Summary Table

Table U–4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table U–4. Summary of Release Criteria, Required Instructions to Patients, and Records To Be Maintained				
Patient Group	**Basis for Release**	**Criteria for Release**	**Instructions Needed?**	**Release Records Required?**
All patients, including patients who are breastfeeding an infant or child	Administered activity	Administered activity ≤Column 1 of Table U–1	Yes – if administered activity > Column 1 of Table U–2	No
	Retained activity	Retained activity ≤ Column 1 of Table U–1	Yes – if retained activity > Column 1 of Table U–2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table U–1	Yes – if dose rate > Column 2 of Table U–2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv [0.5 rem]	Yes – if calculated dose > 1 mSv [0.1 rem]	Yes
Patients who are breastfeeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table U–3 or Licensee calculated dose from breastfeeding > 1 mSv [0.1 rem] to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table U–3 or Licensee calculated dose from continued breastfeeding > 5 mSv [0.5 rem] to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this Appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this Appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

Supplement A

Table U–5. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide	**Physical Half-Life (days)***	**Exposure Rate Constant† (R/mCi-h at 1 cm)**
silver-111	7.45	0.15
gold-198	2.696	2.3
chromium-51	27.704	0.16
copper-64	0.529	1.2
copper-67	2.578	0.58
gallium-67	3.261	0.753
iodine-123	0.55	1.61
iodine-125	60.14	1.42
iodine-125 implant‡	60.14	1.114
iodine-131	8.04	2.2
indium-111	2.83	3.21
iridium-192 implant‡	74.02	4.594
phosphorus-32	14.29	N/A§
Pd-103 implant‖	16.96	0.865
rhenium-186	3.777	0.2
rhenium-188	0.708	0.26
scandium-47	3.351	0.56
selenium-75	119.8	2
samarium-153	13.61	1.48
tin-117m	50.5	N/A§
stontium-89	0.251	0.756
technetium-99m	3.044	0.447
thallium-201	32.01	1.83

Table U–5. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine (Continued)		
Radionuclide	**Physical Half-Life (days)***	**Exposure Rate Constant† (R/mCi-h at 1 cm)**
yttrium-90	2.67	N/A§
ytterbium-169	32.01	1.83

*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, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

†Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, p. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D. E. Barber, J. W. Baum, and C. B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG–1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

‡R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

§S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

‖Not applicable (N/A) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table U–1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential TEDE to any individual would be no greater than 5 mSv [0.5 rem].

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by 10 CFR 35.75(c). The following equation can be used to calculate doses:

Equation B–1:

$$D(t) = \frac{34.6\ \Gamma\ Q_0 TE\left(1 - e^{-0.693t/T_p}\right)}{(r)^2}$$

where: $D(t)$ = Accumulated dose to time t, in rem;

	34.6	=	Conversion factor of 24 hours/day times the total integration of decay (1.44);
	Γ	=	Exposure rate constant for a point source, R/mCi x h at 1 cm;
	Q_0	=	Initial activity at the start of the time interval;
	T_p	=	Physical half-life, in days;
	E	=	Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
	r	=	Distance in cm. This value is typically 100 cm; and
	t	=	Exposure time in days.

This calculation considers only the external dose to an individual from exposure to a released patient. For some radionuclides, such as sodium iodide I-131, it may be necessary to also consider the internal dose from exposure to a released patient. The internal and external doses must be summed to determine the total dose. See Section B.3, "Internal Dose," for a discussion of internal dose.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table U–1

In Table U–1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior [as discussed in the supporting regulatory analysis (Ref. B-11)], suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table U–1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, *E*, at 1 meter, may be useful for patient-specific calculations:

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- E = 0.25 when an effective half-life is greater than 1 day, if the patient has been given instructions, such as
  - — Maintain a prudent distance from others for at least the first 2 days.
  - — Sleep alone in a room for at least the first night.
  - — Do not travel by airplane or mass transportation for at least the first day.
  - — Do not travel on a prolonged automobile trip with others for at least the first 2 days.
  - — Have sole use of a bathroom for at least the first 2 days.
  - — Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as
  - — Follow the instructions for E = 0.25 above.
  - — Live alone for at least the first 2 days.
  - — Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of sodium iodide I-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely external dose to an individual exposed to a patient who has received 2,220 megabecquerels (MBq) [60 mCi] of sodium iodide I-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay (t = ∞) is calculated based on the physical half-life using Equation B–1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0 T_p E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\left(2.2\ R\ \cdot \frac{cm^2}{mCi} \cdot hr\right)(60mCi)(8.04\ d)(0.125)}{(100\ \text{cm})^2}$$

D (∞) = 4.59 mSv [0.459 rem]

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3, "Internal Dose," for a discussion of internal dose and sample calculations. Unless the internal dose is likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose.

If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 0.41 mSv [0.041 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. The patient may be released, but 10 CFR 35.75(b) requires that instructions be given to the patient on maintaining doses to others ALARA. A record of the calculation must be maintained, pursuant to 10 CFR 35.75(c), because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 10 CFR 35.75. The effective half-life is defined as

Equation B–2:

$$T_{eff}\ \frac{T_b \times T_p}{T_b + T_P}$$

where: T_b = Biological half-life of the radionuclide and

T_p = Physical half-life of the radionuclide.

The behavior of sodium iodide I-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

Equation B–3:

$$T_{1eff}\ \frac{T_{b1} \times T_p}{T_{b1} + T_P}$$

Equation B–4:

$$T_{2eff}\frac{T_{b2}\times T_p}{T_{b2}+T_P}$$

where: T_{b1} = Biological half-life for extrathyroidal iodide;

T_{b2} = Biological half-life of iodide following uptake by the thyroid; and

T_p = Physical half-life of I-131.

However, simple exponential excretion models do not account for (i) the time for the I-131 to be absorbed from the stomach to the blood; and (ii) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of I-131.

Thus, an equation to calculate the dose from a patient administered sodium iodide I-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B–1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of I-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B–5.

Equation B–5:

$$D(\infty)=\frac{34.6\ \Gamma\ Q_0}{(100\,cm)^2}\left\{E_1\ T_p\ (0.8)(1-e^{-0.693(0.33)/T_p})\right.$$
$$\left.+\quad e^{-0.693(0.33)/T_p}E_2\ F_1\ T_{1eff}+e^{-0.693(0.33)/T_p}\ E_2\ F_2\ T_{2eff}\right\}$$

where: F_1 = Extrathyroidal uptake fraction;

F_2 = Thyroidal uptake fraction;

E_1 = Occupancy factor for the first 8 hours; and

E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B–1, B–3, and B–4. Acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} are shown in Table U–6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by 10 CFR 35.75(c) is described in Section U.3.1 of this Appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely external dose to an individual exposed to a patient to whom 5,550 MBq [150 mCi] of sodium iodide I-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose will be calculated by using Equation B–5 to account for the elimination of I-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table U–5. The uptake fractions and effective half-lives are from Table U–6. An occupancy factor, *E*, of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because (i) the effective half-life associated with the dominant component is greater than 1 day; and (ii) patient-specific questions were provided to the patient to justify the occupancy factor. See Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this Supplement.

Table U–6. Uptake Fractions and Effective Half-Lives for Sodium-Iodide Iodine-131 Treatments

	Extrathyroidal Component		Thyroidal Component	
Medical Condition	**Uptake Fraction F_1**	**Effective Half-Life T_{1eff} (day)**	**Uptake Fraction F_2**	**Effective Half-Life T_{2eff} (day)**
Hyperthyroidism	0.201*	0.322†	0.801*	5.21*
Post-Thyroidectomy for Thyroid Cancer	0.953‡	0.322†	0.053‡	7.32†

*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. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.

†International Commission on Radiological Protection (ICRP) Publication No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

‡The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC Medical Visiting Fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B–5, the dose to total decay is

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100\ cm)^2}\{(0.75)(8.04)(0.8)\left(1 - \mathrm{e}^{-\frac{0.693(0.33)}{8.04}}\right) + \mathrm{e}^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.95)(0.32) + \mathrm{e}^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.05)(7.3)\}$$

D(∞) = 3.40 mSv [0.340 rem]

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3, "Internal Dose," for a discussion of internal dose and sample calculations. Unless the internal dose is likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose.

If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 1.6 mSv [0.160 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. This patient would not have to remain under licensee control and could be released under 10 CFR 35.75, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the sum of the internal and external doses is not greater than 5 mSv [0.5 rem].

In the example above, the thyroidal fraction, F_2 = 0.05, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely external dose to an individual exposed to a patient to whom 2,035 MBq [55 mCi] of sodium iodide I-131 have been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, the dose will again be calculated using Equation B–5, Table U–5, and Table U–6, to account for the elimination of I-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, *E*, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor. See Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations."

Substituting the appropriate values into Equation B–5, the dose to total decay is

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100\ cm)^2}\{(0.75)(8.04)(0.8)\left(1 - \mathrm{e}^{-\frac{0.693(0.33)}{8.04}}\right) + e^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.20)(0.32) + \mathrm{e}^{-\frac{0.693(0.33)}{8.04}}(0.25)(0.80)(5.2)\}$$

D(∞) = 4.86 mSv [0.486 rem]

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3 for a discussion of internal dose and sample calculations. Unless the internal dose is likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose. If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 0.14 mSv [0.014 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. The patient would not have to remain under licensee control and could be released under 10 CFR 35.75 when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction F_2 = 0.8 is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as sodium iodide I-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B–6.

Equation B–6:

$$D_i = Q(10^{-5})(DCF)$$

where:

D_i	=	Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;
Q	=	Activity administered to the patient in mCi;
10^{-5}	=	Assumed fractional intake; and
DCF	=	Dose conversion factor to convert an intake in mCi to an internal committed effective dose equivalent[1]

Equation B–6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb[2] was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies[3,4] regarding the intakes of individuals exposed to patients administered sodium iodide I-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

[1] Such as tabulated in K.F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

[2] *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*

[3] 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.

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

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 MBq [33 mCi] of sodium iodide I-131 have been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B–6. The dose conversion factor DCF for the ingestion pathway is 53 rem/mCi from Table 2.2 of K.F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

Substituting the appropriate values into Equation B–6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv } [0.017 \text{ rem}]$$

Using Equation B–1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv [0.5 rem]. Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose, if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients." The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see NUREG–1492.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5,550 MBq [150 mCi] of sodium iodide I-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose is again calculated using Equation B–6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B–6, the maximum internal dose to the person is

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv } [0.08 \text{ rem}]$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 mSv [0.34 rem], while the internal dose would be about 0.80 mSv [0.08 rem]. Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose: 4.2 mSv [0.42 rem].

Other Reference Documents

- American National Standards Institute (ANSI) N13.54, “Fetal Radiation Dose Calculations,” January 2008.
- ICRP Publication No. 53, “Radiation Dose to Patients from Radiopharmaceuticals,” 1987.
- ICRP Report No. 80, “Radiation Dose to Patients from Radiopharmaceuticals (Addendum to ICRP Publication 53)”, 1998.
- ICRP Report No. 106, “Radiation Dose to Patients from Radiopharmaceuticals (Addendum 3 to ICRP Publication 53),” 2008.
- NCRP Report No. 128, “Radionuclide Exposure of the Embryo/Fetus,” 1998.
- Regulatory Guide (RG) 8.39, “Release of Patients Administered Radioactive Materials,” April 1997.

Regulatory Analysis

- NUREG–1492, “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,” February 1997, provides the regulatory basis and examines the costs and benefits.

APPENDIX V

RADIOACTIVE MATERIALS GUIDANCE FOR MOBILE MEDICAL SERVICES

Radioactive Materials Guidance for Mobile Medical Services

Before submitting information to the U.S. Nuclear Regulatory Commission (NRC), review Chapter 6, "Identifying and Protecting Sensitive Information," of this document for guidance on identifying and protecting sensitive information. All security-related sensitive information in the application should be identified and properly marked.

Mobile medical service providers must comply with all applicable sections of Title 10 of the *Code of Federal Regulations* (10 CFR) 10 CFR Part 30 and 35 as well as U.S. Department of Transportation (DOT) regulations regarding approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with 10 CFR Part 35, Subpart H. The sections below describe the type of information that should be submitted when requesting to conduct mobile medical service provider activities.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of byproduct material within a transport vehicle (e.g., in-van or trailer use). A second type is transportation of byproduct material to a client's facility for use within a client's facility by either the mobile medical service's employees (i.e., transport and use) or the client's employees (i.e., transport only).

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the byproduct material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the byproduct material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the byproduct material use and patient treatments upon transfer of the byproduct material to the client's possession.

A Positron Emission Tomography (PET) mobile medical service provider that uses a "quiet room" and/or a patient waiting area in the client's facility may either be authorized for "in-van or trailer use only" or "transport and use," depending on whether the PET patients meet the criteria for release described in 10 CFR 35.75 while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile medical service licensee and should be under their control while onsite. In addition, for mobile nuclear medicine and PET imaging, the licensee should take into account the possibility of using the client's bathroom dedicated for their use for PET patients and finding the bathroom with low levels of radioactive contamination during the end-of-day surveys. In this event, the mobile licensee must provide direction to the client for restricting access to the bathroom until follow up surveys show the bathroom free of contamination (e.g., post and close off the patient bathroom for a designated period of time to allow for radioactive decay). The mobile medical service provider should also survey "quiet rooms," provided for their use at the client's site, for contamination and radiation levels to ensure that public dose limits are not exceeded and that these areas are left free of contamination following use.

The locations of use for mobile medical services are of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other

type of location is the temporary jobsite at client facilities. The following two sections describe the type of information necessary for base locations and temporary jobsites.

Mobile Medical Service Agreement

Regulations in 10 CFR 35.80(a)(1) require, in part, that a licensee providing mobile medical service shall obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by 10 CFR 35.80(c) and 10 CFR 35.2080, "Records of mobile medical services." Additionally, as required by 10 CFR 35.80(a)(4), the licensee must survey to ensure compliance with the requirements in 10 CFR Part 20 (e.g., ensure that all byproduct material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

The following is provided as an example of a PET mobile medical service agreement.

SAMPLE PET MOBILE MEDICAL SERVICE AGREEMENT

In accordance with 10 CFR 35.80(a)(1), management designee, Sam Curie of ABC Hospital, Inc. acknowledges that mobile medical service provider, PET Mobile, Inc., will use byproduct material at client address 456 Rad Road, Somewhere, WV. Service will be provided every Monday beginning February 1, 2014. All radioactive material will be removed from the client facility prior to leaving the site. PET Mobile, Inc. will abide by all NRC and Agreement State regulations while on-site.

The following authority and responsibilities are delegated to the client:

- ordering of radioactive dosages

The following authority and responsibilities are delegated to the mobile medical service provider:

- Package receipt and return surveys.
- Quality control testing on equipment used to measure radioactive dosages (e.g., dose calibrator).
- Quality control testing and calibration of survey instrumentation (e.g., radiation survey meter, well counter).
- Sealed source inventories and leak testing.
- Shipping papers.
- Radiation safety and hazardous materials (HAZMAT) training for mobile medical service personnel.
- Radiation safety training for client staff involved in: (i) controlling patient waiting areas used by the mobile medical service provider in the hospital; (ii) performing surveys to

support release of the patient bathroom located in the hospital; and (iii) providing patient escort.

- Surveys of all interior PET trailer areas.

- Surveys of areas exterior to the PET trailer to ensure compliance with 10 CFR 20.1301 and roping off of any area (if necessary) to ensure that the dose rate is less than 0.02 mSv [2 millirem (mrem)] in any one hour.

- Surveys of patient waiting area in the hospital to ensure compliance with 10 CFR 20.1301 (0.02 mSv [2 mrem] in any one hour and 1 mSv [0.1 rem] in a year) since the patient has not yet been released under 10 CFR 35.75 and is awaiting scanning.

- Surveys of dedicated PET patient bathroom located within the hospital prior to leaving client site.

- Decay in storage and disposal of radioactive material/waste. Radioactive waste will be removed to the PET trailer for storage. Non-radioactive waste that has been surveyed and shown to be at background may be disposed into the normal waste stream at the client's site.

- Confirming that AUs designated on the application are cognizant that they will be responsible for supervising the use of licensed material.

- Providing dosimetry to staff that would require it in accordance with 10 CFR 20.1502.

- Maintaining security of mobile PET trailer (e.g. keys, keypad codes).

- Ensuring that all radioactive material is accounted for and removed from the client at the end of the day of service.

- Radiation safety program audits, including use at client sites, in accordance with 10 CFR 20.1101.

***Note**:* In the event that bathroom contamination is found in the dedicated PET bathroom on hospital property and cannot be cleaned to below trigger levels for an unrestricted area, the mobile medical service provider will block off the bathroom and post it as a radiation area. The contamination will be reported to the client manager. The bathroom will be surveyed with a calibrated radiation survey meter the next day and released for unrestricted use if radiation levels are below trigger levels for an unrestricted area described in the mobile medical service provider license.

This agreement will be retained by the licensee for 3 years after the last provision of service, in accordance with 10 CFR 35.2080.

_____	_____
Signed and Dated	Signed and Dated
Vice President of Operations	President
ABC Hospital	PET Mobile, Inc.

Base Location

The base location (e.g., nuclear medicine hot lab or storage location for the remote afterloader) for the mobile medical service must be specified. A "base location" is one that is identified on the license, while a "temporary jobsite" (or client site) is a location that is other than a location of use identified on the license and where work is conducted for a limited period of time. The base location can be in a medical institution, noninstitutional medical practice, commercial facility, or mobile van or trailer. Applicants should specify in what type of facility the proposed base location is sited. A mobile licensee cannot provide a service to a private practice (nonlicensee) located within a licensed medical institution (e.g., hospital). The medical institution's management (i.e., hospital management) must be consulted in this event. As required by 10 CFR 30.33 and 10 CFR 35.12, applicants must submit a description and diagram(s) of the proposed base location and associated equipment in accordance with Item 9 of this report. The description and diagram of the proposed base location should demonstrate that the building (or van or trailer) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301 (e.g., shielding and roping off of areas greater than 0.02 mSv [2 mrem] in any one hour). Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van or trailer, the description of the van or trailer should address radiation levels in the van or trailer driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults."

- Applicants may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.

  — For diagnostic uses, the mobile medical service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered to the base location without their personnel present.

- Base locations can include the use of a mobile van or trailer. When the base location is in the van or trailer, and there is no permanent structure for the byproduct material storage, provide for the following:

  — Secured off-street parking is under licensee control. Public rights-of-way are not considered part of the address of the client.

  — Secured storage facilities are available for storage of byproduct material and radioactive waste if the van or trailer is disabled.

- Byproduct material is delivered directly to the van or trailer parked at a site owned by the mobile medical service provider occupied by licensee personnel. In addition, for diagnostic uses only, the mobile medical service provider may arrange to have licensed

material delivered to the van or trailer parked at a client site only if the mobile medical service provider submits information clearly demonstrating that they will have their personnel at the van or trailer to accept delivery and ensure the security and control of the licensed material.

- The mobile medical service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered to the base location without their personnel present.

- If a base location is in a residential area, provide the following information:

  — Justification of the need for a private residence location rather than for a commercial location.

  — Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the base location in the event of contamination. Provisions for decontamination of the mobile medical service van or trailer, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.

  — A description of the program demonstrating compliance with 10 CFR 20.1301, "Dose limits for individual members of the public."

  — Verification that restricted areas do not contain residential quarters.

- Perform surveys necessary to show that exposure rates do not exceed 0.02 mSv [2 mrem] in any one hour nor 1 mSv/yr [100 mrem/yr].

Client Site for Diagnostic Uses

In general, client facility information does not need to be submitted; however, the mobile medical service provider may arrange to have licensed material delivered to the client site only if the licensee submits information clearly demonstrating that the mobile medical service provider licensee will have its own personnel at the client site to accept delivery and ensure the security and control of the licensed material.

Alternatively, the mobile medical service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile medical service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile medical service provider may arrange to have licensed material delivered

to the base location without their personnel present and must provide an example contract that will be used with clients to designate these areas.

In addition, as described above, the client may designate “quiet rooms” for use by PET mobile medical service providers. These areas must also be described in the contract with the client and the applicant must provide an example contract that will be used with clients to designate these areas.

Client Site for Therapeutic Uses

This section applies only to therapeutic uses of byproduct material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained byproduct material services (e.g., in-van or trailer), the following additional facility information should be provided:

- For therapy treatments with byproduct material [e.g., high dosage-rate (HDR) remote afterloader], provide a separate drawing for each client site showing the location of the treatment device and vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public.

- As delineated in the letter required by 10 CFR 35.80(a), a signed agreement that the location of the treatment device and vehicle will be on client-owned or controlled property.

- The protection from vehicular traffic that could adversely affect patient treatment(s), which could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility or site drawings provided.

- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If transportable services will be provided to the client’s site for use within the client’s facility by the mobile medical service’s employees, the following client facility information and commitment should be provided:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 10 CFR 20.1301. Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.

- A commitment, as delineated in the letter required by 10 CFR 35.80(a), that the mobile medical service licensee has full control of the treatment room during byproduct material use for each client.

- The initial installation records and function checks of a remote afterloader device for each site of use, as required by 10 CFR 35.633, "Full calibration measurements on remote afterloader units;" 10 CFR 35.643, "Periodic spot-checks for remote afterloader units;" and 10 CFR 35.647, "Additional technical requirements for mobile remote afterloader units."

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:

- Each client is properly licensed for medical use of byproduct material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.

- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of byproduct material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the byproduct material for patient treatments. The responsibilities for supervising individuals who use the byproduct material, set forth in 10 CFR 35.27, "Supervision," transfer to the client's authorized users (AU) upon transfer of the device to the client by the mobile medical service provider.

- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).

- As required by 10 CFR 30.51, "Records," a formal record of the transfer of control of the byproduct material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of byproduct material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in 10 CFR 19.12, 10 CFR 35.27 requires that instructions be given to supervised individuals in written radiation protection procedures, written directive

procedures, regulations, and license conditions with respect to the use of byproduct material. Additionally, 10 CFR 35.27 requires the supervised individual to:

- Follow the instructions of the supervising AU for medical uses of byproduct material.
- Follow the instructions of the supervising Authorized Nuclear Pharmacist or supervising AU for preparation of byproduct material for medical uses.
- Follow the written radiation protection procedures and written directive procedures established by the licensee.
- Comply with the provisions of 10 CFR Part 35 [e.g., 10 CFR 35.80 and 10 CFR 35.647 (if applicable)], and the license conditions with respect to the mobile medical use of byproduct material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27, 10 CFR 35.310, 10 CFR 35.410, and 10 CFR 35.610 (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, as low as is reasonably achievable (ALARA), basic radiation protection, and emergency response.

Survey Instrument and Dose Measurement Instrument Checks

As required by 10 CFR 35.80, instruments should be checked for proper operation before use at each address of use. Dosage measurement instruments should be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Byproduct Material

Byproduct material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of byproduct material ordered. Additionally, if the mobile medical service provider is specifically licensed for receipt and storage in the client's facility, byproduct material may be delivered to the client's address. Delivery of byproduct material to a van or trailer that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, licensees may pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

The mobile medical service provider applicant should commit to develop, implement, and maintain emergency procedures, in accordance with the radiation protection program required by 10 CFR 20.1101. Indicate typical response times of the radiation safety officer (RSO) and AU in the event of an incident, and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire that results in damage to exterior or interior portions of the

vehicle or the byproduct material used in the mobile medical service. The transportation emergency response plan should cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous-material (HAZMAT)-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel.

- The emergency contact numbers for the NRC's Operation Center and all appropriate State radiological protection agencies.

- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.

- Procedures for retrieving and securing any byproduct material, including a sealed source that may become detached or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers.

- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios.

- Preplanned decontamination procedures, including ready access to all necessary materials.

- A calibrated, operational radiation survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys.

- Security of the transport vehicle against unauthorized access, including the driver's compartment.

- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or authorized medical physicist. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 10 CFR 30.50, "Reporting requirements," will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

***Note**:* The type of response should be consistent with the level of the incident. The response may range from telephone contact for minor spills to prompt onsite response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

The mobile medical service provider applicant should commit to develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170–178, "Transportation." Procedures will include
  - use of approved packages
  - use of approved labeling
  - conduct of proper surveys
  - complete and accurate shipping papers
  - bracing of packages
  - security provisions
  - written emergency instructions
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. Describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

***Note**:* The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Appendix Z of this NUREG summarizes DOT requirements for Transportation of Licensed Material.

Radioactive Waste Management

If waste will be stored in vans or trailers, they must be properly secured and posted as byproduct material storage locations. Ensure that the van or trailer will be secured against unauthorized access and that the waste storage location will be posted as a byproduct material storage area.

Develop, document, and implement final waste disposal procedures in accordance with Section 8.11 of this report.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewer system, in accordance with 10 CFR 20.2003. However, collecting excreta from patients in a van or

trailer restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van or trailer for patient use, submit the following information for NRC review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van or trailer, and the driver of the van or trailer; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any iodine-131 will be held in the tank.

- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 10 CFR 20.1201 and 20.1301, that the external surfaces of the van or trailer do not exceed 0.02 mSv/h [2 mrem/h], and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.

- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services With Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Conduct safety checks on a remote afterloader device and facility. The procedure will include the periodic spot-checks required by 10 CFR 35.643 and the additional spot-checks required by 10 CFR 35.647 before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.

- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.

- Such tests should be performed in accordance with written procedures.

- As required by 10 CFR 35.2647 and 10 CFR 35.2643, records showing the results of the above safety checks must be maintained for NRC inspection and review for a period of 3 years.

- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of an HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

APPENDIX W

MODEL PROCEDURES FOR WASTE DISPOSAL BY DECAY-IN-STORAGE, GENERATOR RETURN, AND LICENSED MATERIAL RETURN

Model Procedures for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

This model provides acceptable procedures for waste disposal. Most licensees will dispose of material that fall within these procedures. Note that some short half-life radionuclide products [e.g., technetium-99m (Tc-99m)/molybdenum-99 (Mo-99) generator columns and some yttrium-90 (Y-90) microspheres] may contain long half-life contaminants that may preclude disposal by decay-in-storage and may require disposal by alternate methods, such as return to the manufacturer. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Subpart K, "Waste Disposal," to Title 10 of the *Code of Federal Regulations* (CFR) 10 CFR Part 20, 10 CFR 20.1101, and 10 CFR 35.92.

Model Procedure for Decay-In-Storage

Regulations in 10 CFR 35.92 describe the requirements for decay-in-storage. Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at as low as is reasonably achievable levels. Storage areas must be in a secure location.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.

- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.

- Store liquid and solid wastes should be stored separately.

- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.

- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container.

- The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container. The container should be labeled in accordance with 10 CFR 20.1904 and 10 CFR 20.1905. The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.

- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.

- Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:

  — Use a survey instrument that is appropriate for the type and energy of the radiation being measured.

  — Check the radiation survey meter for proper operation and current calibration status.

  — Monitor in a low-level radiation area away from all sources of radioactive material, if possible.

  — Remove any shielding from around the container or generator column.

  — Monitor, at contact, all surfaces of each individual container.

  — Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in 10 CFR 35.92).

  — Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

  — Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized byproduct material recipient.

  — Short half-life radionuclide products such as samarium-153 (Sm-153), Tc-99m/Mo-99 generator columns, and Y-90 microspheres may contain long half-life contaminants that may preclude disposal by decay-in-storage. Licensees need to perform surveys and dispose of long half-life contaminants in accordance with 10 CFR Parts 20 and 35 requirements.

Note: Check for any calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153), as these may not be held for decay-in-storage and must be disposed of in accordance with 10 CFR Part 20 and 10 CFR Part 30.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m, strontium-82/rubidium-82, or germanium-68/gallium-68 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and U.S. Department of Transportation (DOT) regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.

- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with 10 CFR 30.51, "Records."

Model Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with 10 CFR 30.41(a)(5), confirm that persons are authorized to receive byproduct material prior to transfer (e.g., obtain a copy of the transferee's U.S. Nuclear Regulatory Commission license or Agreement State license that authorizes the byproduct material).
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.
- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 10 CFR Part 20, Appendix B.
- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 10 CFR 20.2003(a)(4) and 10 CFR Part 20, Appendix B, Table 3.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 10 CFR Part 20, Appendix B, Table 3 must not exceed unity.

- Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 gigabecquerel (GBq) [5 Curies (Ci)] of H-3 (tritium), 37 GBq [1 Ci] of C-14, and 37 Gbq [1 Ci] of all other radionuclides combined.

- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.

- Liquid waste should be discharged only via designated sinks, toilets, or other release points.

- Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.

- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.

- Decontaminate all areas or surfaces if found to be contaminated.

- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

APPENDIX X

RECORDKEEPING REQUIREMENTS

Recordkeeping Requirements

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 declared pregnant woman	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 information important to the decommissioning of a facility		30.35(g)	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
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

Table X–1. Typical Records and Retention Times (Continued)			
Record	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
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 after date of release
Mobile medical services	35.80(a)(1)	35.2080(a)	3 years after last provision of service
Surveys of client facilities	35.80(a)(4)	35.2080(b)	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 after last use of source
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
Emergency procedures for therapy devices containing sealed sources	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

Table X–1. Typical Records and Retention Times (Continued)			
Record	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit
Documentation regarding the trustworthiness and reliability of individual employees		37.23(h)(1)	3 years from the date the individual no longer requires unescorted access
Current access authorization program procedures		37.23(h)(2)	3 years after the procedure is superseded or no longer needed
List of persons approved for unescorted access authorization		37.23(h)(3)	3 years after the list is superseded or replaced
Documentation supporting relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations		37.31	3 years from the date the individual no longer requires unescorted access
Copy of current security plan		37.43(a)(4)	3 years after the plan is superseded or no longer required
Copy of current implementing procedure		37.43(b)(3)	3 years after the procedure is superseded or no longer required
Documentation of initial and refresher training		37.43(c)(4)	3 years from the date of the training
Documentation for preplanning and coordination of shipment		37.75(e)	3 years
Record retention when a retention period is not otherwise specified		37.103	duration of license

APPENDIX Y

REPORTING REQUIREMENTS

Reporting Requirements

***Note**:* The following list of notification and reporting requirements is provided to inform licensees about typical notification and reporting requirements that apply to their licensed activities. Licensees should note that the list is incomplete in that not all potentially applicable requirements have been included. Also, notification and reporting requirements change; therefore, licensees should consult the regulations for definitive information about current requirements.

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)
Package received with removable radioactive surface contamination exceeding the limits of Title 10 of the *Code of Federal Regulations* (10 CFR) 71.87(i) or external radiation levels exceeding the limits of 10 CFR 71.47	immediate [U.S. Nuclear Regulatory Commission (NRC) and final delivery carrier must be notified]	none	20.1906(d)
Theft or loss of material	Immediate	30 days	10 CFR 20.2201(a)(1)(i) 10 CFR 20.2201(b)(1)
Whole body dose greater than 0.25 Sieverts (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) 10 CFR 20.2203 (a)
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 (Continued)			
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) 10 CFR 21.21(d)(3)(ii)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate (not more than 4 hours after discovery)	30 days	10 CFR 30.50(a) 10 CFR 30.50(c)(2)
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) 10 CFR 30.50(c)(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)
Generally licensed devices	None	30 days	10 CFR 31.5(c)(14)
Licensee permits individual to work as authorized users (AU), authorized nuclear pharmacists (ANP), or authorized medical physicist (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)
Temporary Radiation Safety Officer	None	30 days	10 CFR 35.14(b)(2)
Licensee's mailing address changes	None	30 days	10 CFR 35.14(b)(3)
Licensee's name changes without constituting a transfer of control	None	30 days	10 CFR 35.14(b)(4)
Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license	None	30 days	10 CFR 35.14(b)(5)
Medical event	1 day	15 days	10 CFR 35.3045(c) 10 CFR 35.3045(d)
Dose to an embryo/fetus that is greater than 50 millisieverts (mSv) [5 rem] dose equivalent	1 day	15 days	10 CFR 35.3047(c)
Dose to a nursing child that is greater than 50 mSv [5 rem] or resulted in unintended permanent functional damage	1 day	15 days	10 CFR 35.3047(d)
Leaking source	None	5 days	10 CFR 35.3067

Table Y–1. Typical NRC Notifications and/or Reports (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Determination that any licensee that has not previously implemented the Security Orders (i.e., orders issued by the NRC to require licensees to implement interim security measures) or been subject to the provisions of 10 CFR Part 37, Subpart C will aggregate radioactive material to a quantity that equals or exceeds the Category 2 threshold	None	90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold	10 CFR 37.41(a)(3)
Coordination with local law enforcement agency (LLEA) has failed, either because the LLEA has not responded or because the LLEA does not plan to participate	3 business days	Submittal of a written report concerning failures of coordination with LLEA as described in 10 CFR 37.45(b) is not required; however, licensees must document their efforts to coordinate with the LLEA and keep this documentation for 3 years	10 CFR 37.45(b)
Determination that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material	As soon as possible (but not at the expense of causing delay or interfering with the LLEA response), but no later than 4 hours after discovery	30 days	10 CFR 37.57(a)&(c)
Assessment of any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material	As soon as possible, but no later than 4 hours after notifying the LLEA	none	10 CFR 37.57(b)
Determination that a shipment containing a Category 1 quantity of material is lost or missing in transport	Within 1 hour of the determination. Also, notify LLEA within 1 hour of determination	30 days and periodic updates [10 CFR 37.79(c)]	10 CFR 37.81(a)&(g)
Determination that a shipment containing a Category 2 quantity of material is lost or missing in transport	Within 4 hours of the determination and again within 24 hours if the material has not yet been located and secured	30 days	10 CFR 37.81(b)&(g)

Table Y–1. Typical NRC Notifications and/or Reports (Continued)			
Event	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Discovery along the route of any actual or attempted theft or diversion, or suspicious activity, related to a Category 1 quantity of material in transport	Upon discovery, as soon as possible. Also notify LLEA as soon as possible upon discovery	30 days (except no report for suspicious activity)	10 CFR 37.81(c)&(g)
Discovery of any actual or attempted theft or diversion, or suspicious activity, related to a Category 2 quantity of material in transport	As soon as possible	30 days (except no report for suspicious activity)	10 CFR 37.81(d)&(g)
Upon recovery of any lost or missing Category 1 quantity of material	As soon as possible. Also notify the LLEA as soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(e)&(h)
Upon recovery of any lost or missing Category 2 quantity of material	As soon as possible	To be included in the 30-day report of an event described in 10 CFR 37.81(g), if recovered during that time	10 CFR 37.81(f)&(h)

***Note**:* Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100, except as noted.

APPENDIX Z

SUMMARY OF DOT REQUIREMENTS FOR TRANSPORTATION OF TYPE A, TYPE B, OR LIMITED QUANTITIES OF LICENSED MATERIAL

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

Note: The reference charts included at the end of this Appendix are for reference only and are not a substitute for U.S. Department of Transportation (DOT) and U.S. Nuclear Regulatory Commission (NRC) transportation regulations.

Licensed material must be transported in accordance with DOT regulations. Applicants and licensees should review the most recent regulations in Title 49 of the *Code of Federal Regulations* (49 CFR). The following are the major areas in DOT regulations most relevant for medical use licensees transporting licensed material:

- Table of Hazardous Materials and Special Provisions—Subpart B
  - — 49 CFR 172.101—Purpose and Use of Hazardous Materials Table [proper shipping name, hazard class, identification number]
  - — Table 2, Appendix A to 49 CFR 172.101—List of Hazardous Substances and Reportable Quantities [for radionuclides]
- Shipping Papers—Subpart C
  - — 49 CFR 172.201—Preparation and retention of shipping papers
  - — 49 CFR 172.202—Description of hazardous material on shipping papers
  - — 49 CFR 172.203—Additional description requirements
  - — 49 CFR 172.204—Shipper's certification [if applicable]
- Markings—Subpart D
  - — 49 CFR 172.301—General marking requirements for non-bulk packagings
  - — 49 CFR 172.304—Marking requirements
  - — 49 CFR 172.310—Class 7 (radioactive) materials
  - — 49 CFR 172.324—Hazardous substances in non-bulk packagings [designation of "reportable quantities" with the letters "RQ"]
- Labeling—Subpart E
  - — 49 CFR 172.400—General labeling requirements
  - — 49 CFR 172.400(a)—Exceptions from labeling
  - — 49 CFR 172.403—Class 7 (radioactive) material
  - — 49 CFR 172.406—Placement of labels
  - — 49 CFR 172.436, 172.438, 172.440, 172.450—Labels [White-1, Yellow-2, Yellow-3, Empty]
- Placarding—Subpart F
  - — 49 CFR 172.504—General placarding requirements
  - — 49 CFR 172.516—Visibility and display of placards
  - — 49 CFR 172.556—RADIOACTIVE placard

- Emergency Response Information—Subpart G
  - 49 CFR 172.600—Applicability and general requirements
  - 49 CFR 172.602—Emergency response information
  - 49 CFR 172.604—Emergency response telephone number
- Training—Subpart H
  - 49 CFR 172.702—Applicability and responsibility for training and testing
  - 49 CFR 172.704—Training requirements [types of training, frequency, recordkeeping]
- Safety and Security Plans – Subpart I
  - 49 CFR 172.800 – Purpose and applicability
  - 49 CFR 172.802 – Components of a security plan
- Shippers—General Requirements for Shipments and Packaging—49 CFR Part 173
  - Class 7 (Radioactive Materials) – Subpart I.
    - 49 CFR 173.25—Authorized packagings and overpacks
    - 49 CFR 173.403—Definitions
    - 49 CFR 173.410—General design requirements
    - 49 CFR 173.412—Additional design requirements for Type A packages
    - 49 CFR 173.413—Requirements for Type B packages
    - 49 CFR 173.415—Authorized Type A packages
    - 49 CFR 173.416—Authorized Type B packages [includes packaging certification requirements]
    - 49 CFR 173.421—Excepted packages for limited quantities of Class 7 (radioactive) materials
    - 49 CFR 173.422—Additional requirements for excepted packages containing Class 7 (radioactive) materials
    - 49 CFR 173.425—Table of activity limits—excepted quantities and articles [limited quantity]
    - 49 CFR 173.431—Activity limits for Type A and Type B packages
    - 49 CFR 173.435—Table of A_1 and A_2 values for radionuclides [for determination of package type]
    - 49 CFR 173.441—Radiation level limitations and exclusive use provisions
    - 49 CFR 173.443—Contamination control
    - 49 CFR 173.471—Requirements for U.S. Nuclear Regulatory Commission approved packages
    - 49 CFR 173.476—Approval of special form Class 7 (radioactive) materials [includes requirement for documentation of special form status]
- Carriage by Public Highway—49 CFR Part 177
  - General Information and Regulations-Subpart A
    - 49 CFR 177.817—Shipping papers [location of shipping papers during transport]

- Loading and Unloading – Subpart B

  — 49 CFR 177.842—Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

Applicants should visit the DOT Web site for additional information on transportation requirements: http://www.dot.gov/.

1. Minimum Required Packaging for Class 7 (Radioactive) Material[1] (49 CFR 173 and 10 CFR 71)[2]

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Minimum Packaging Required for Radioactive Materials other than Low Specific Activity (LSA) Material and Surface Contaminated Objects (SCO) based on Activity of Package Contents

Radioactive Material Quantity[3]		Excepted Quantities and Articles	Type A[4]	Type B
Activity Restrictions		≤ the limits specified in Table 4 of §173.425	≤ A_1 for special form ≤ A_2 for normal form	> A_1 for special form > A_2 for normal form
Contents of Package	Non-fissile and Fissile Excepted	Excepted Package	Type A Package	Type B(U) or Type B(M) package
	Fissile	N/A	Type AF package	Type B(U)F or Type B(M)F package

Minimum Packaging Required for LSA Material and SCO[5,6]

Type(s) of LSA and/or SCO	LSA-I	LSA-II	LSA-III	SCO-I	SCO-II
Category of Package for Domestic or International Transport[7,8]	Unpackaged[9] IP-1: solids, or liquids/exclusive use IP-2 : liquids/non-exclusive use Specification tank cars or cargo tank motor vehicles: liquids/exclusive use	- - IP-2: exclusive use IP-3: liquids or gases/non-exclusive use	- - IP-2: exclusive use IP-3: non-exclusive use	Unpackaged[9] IP-1 - -	- - IP-2 -
Alternative Provisions for Domestic only Transport[10]	Packaging shall meet the requirements of §§173.24, 24a, and 410 Transportation shall be an exclusive use shipment Activity per shipment must be less than an A_1 quantity				

[1] Additional provisions may apply for radioactive materials that are pyrophoric, oxidizing, fissile excepted, or uranium hexafluoride.
[2] Each NRC licensee shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397 (see §71.5).
[3] Materials that contain radionuclides, where both the activity concentration and the total activity in the consignment exceed either the values specified in the table in §173.436 or the values derived according to the instructions in §173.433, must be regulated in transport as Class 7 (radioactive) material.
[4] Except for LSA material and SCO, a Type A package may not contain a quantity of Class 7 (radioactive) materials greater than A_1 or A_2.
[5] The external dose rate from LSA material or SCO in a single package may not exceed 10 mSv/h (1 rem/h) at 3 m from the unshielded material or objects (see §173.427(a)(3)).
[6] LSA material and SCOs that are or contain fissile material in quantities that are not fissile excepted must be packaged in appropriate Type AF or Type BF packages. For alternate domestic transport provisions, see §173.427(b)(4). For comprehensive guidance on packaging and transportation of LSA material and SCO, see NUREG-1608.
[7] For LSA material and SCO, transport of combustible solids, all liquids and all gases classified as LSA-II and LSA-III material, and transport of all SCO-I and SCO-II is limited to a maximum activity of 100 A_2 in a conveyance (see §173.427(a)(2)).
[8] Unless excepted by §§173.427(c) or (d), the material or object(s) shall be appropriately packaged in a Type IP, DOT-7A Type A or Type B package.
[9] Certain LSA-I and SCO-I may be transported unpackaged under the conditions specified in §173.427(c).

2. Radiation Level, TI and CSI Limits for Transportation by Road, Rail and Air[1] (49 CFR 172 - 177, and 10 CFR 71)

Type of Transport	Non-exclusive use	Exclusive use		
Mode of Transport	Road, Rail, Vessel and Air	Road and Rail	Vessel	Air (cargo only)
Radiation Level Limits[2]				
Package Surface[3]	2 mSv/h (200 mrem/h)	2 mSv/h (200 mrem/h): other than closed vehicles 10 mSv/h (1000 mrem/h): closed vehicles	None specified	2 mSv/h (200 mrem/h)[3]
Conveyance[4]	N/A	2 mSv/h (200 mrem/h): outer surfaces (sides, top and underside) of vehicle[5]	N/A	N/A
		0.1 mSv/h (10 mrem/h): at any point two (2) m (6.6 ft) from sides of the vehicle[5]	N/A	N/A
Occupied position	N/A	0.02 mSv/h (2 mrem/h): at any normally occupied area[6]	Requirement of §176.708 applies	N/A
Transport Index (TI) Limits[2]				
Package[1,7]	3: passenger aircraft 10: road, rail, vessels and cargo aircraft	No limit		10
Conveyance[4]	50: road, rail and passenger aircraft 50 to No limit: vessels[7] 200: cargo aircraft	No limit		200
Overpack	N/A: for road, rail 50 to 200: vessels[7] 3: passenger aircraft; 10: cargo aircraft	N/A	No limit[8]	N/A
Criticality Safety Index (CSI) Limit for fissile material[2]				
Package[1,7]	50	100	100	100
Conveyance[4]	50: road, rail and air 50: for holds, compartments or defined deck areas of vessels[7] 200 to No limit: for a total vessel[7]	100	200 to No limit; for a total vessel[7]	100
Overpack	50: road, rail, vessels[7] and air	N/A		

[1] The limits in this table do not apply to excepted packages.
[2] In addition to any applicable radiation level, TI and CSI limits, separation distance requirements apply to packages, conveyances, freight containers and overpacks, to occupied positions, and to materials stored in transit. Separation distances are based on the sum of the TIs and, for fissile materials, also the sum of the CSIs.
[3] Higher package surface radiation levels may be allowed through an approved special arrangement.
[4] Conveyance is, for transport by public highway or rail, any transport vehicle or large freight container; and for transport by air, any aircraft.
[5] The outer surfaces (sides, top and underside) of vehicles are defined for road and rail vehicles in §179.441.
[6] For rail, normally occupied areas include the transport vehicle and adjacent rail cars. The 0.02 mSv/h (2 mrem/h) limit does not apply to carriers operating under a State or federally regulated radiation protection program where personnel wear radiation dosimetry devices.
[7] Additional TI and CSI limits apply for individual packages when non-fissile radioactive material packages are mixed with fissile material packages. Also, see CSI limits established by §71.59.
[8] For details on TI and CSI limits for transport by vessel, see §176.708.

3. Contamination Limits and Quality Control for Class 7 (Radioactive) Materials: (49 CFR 173.443 and 173.475, and 10 CFR 71)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Maximum Permissible Limits for Non-fixed Radioactive Contamination on Packages When Offered for Transport

The level of non-fixed (removable) radioactive contamination on external surfaces of packages offered for transport must be kept as low as reasonable achievable, and shall not exceed the values shown in the following table:

Contaminant	Maximum permissible limits (§173.443(a), Table 9)		
	Bq/cm^2	µCi/cm^2	dpm/cm^2
Beta, gamma and low toxicity alpha emitters	4	10^{-4}	220
All other alpha emitting radionuclides	0.4	10^{-5}	22

The non-fixed contamination shall be determined by:

(a) wiping, with an absorbent material using moderate pressure, sufficient areas on the package to obtain a representative sampling of the non-fixed contamination;
(b) ensuring each wipe area is 300 cm^2 in size;
(c) measuring the activity on each single wiping material and dividing that value by the surface area wiped and the efficiency of the wipe procedure, where an actual wipe efficiency may be used, or it may be assumed to be 0.10.

Alternatively, the contamination level may be determined using alternative methods of equal or greater efficiency.

Provisions for Control of Contamination on Radioactive Material Packages Prior to Shipment

Prior to shipment, the non-fixed contamination on each package of radioactive material:

- must be kept as low as reasonable achievable; and
- may not exceed the limits set forth in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Excepted and Empty Radioactive Material Packages

- The non-fixed radioactive surface contamination on the external surface of excepted and empty packages shall not exceed the limits specified in §173.443(a), Table 9 (as shown above).
- The internal contamination of an empty package must not exceed 100 times the limits in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination on Packages and in Rail and Road Vehicles used for Exclusive Use Shipments of Radioactive Material

- The levels of non-fixed radioactive contamination on the packages (a) at the beginning of transport, may not exceed the levels prescribed in the above table, and (b) at any time during transport, may not exceed ten times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each transport vehicle used for transporting the radioactive material packages must be surveyed with appropriate radiation detection instruments after each use. If contamination values exceed acceptable levels, the transport vehicle may not be returned to service until the radiation dose rate at each accessible surface is demonstrated to be 0.005 mSv/h (0.5 mrem/h) or less, and that there is no significant non-fixed radioactive surface contamination specified in §173.443(a), Table 9 (as shown above).

Provisions for Non-fixed (Removable) Contamination in Closed Rail and Road Vehicles that are used Solely for the Transportation of Radioactive Material

- The contamination levels must not exceed 10 times the levels prescribed in §173.443(a), Table 9 (as shown above).
- Each vehicle shall be stenciled with the words "*For Radioactive Materials Use Only*" in letters at least 76 mm (3 in) high in a conspicuous place on both sides of the exterior of the vehicle.
- A survey of the interior surfaces of the empty closed vehicle must show that the radiation dose rate at any point does not exceed 0.1 mSv/h (10 mrem/h) at the surface or 0.02 mSv/h (2 mrem/h) at 1 m (3.3 feet) from the surfaces.
- Each vehicle shall be kept closed except for loading or unloading.

Provisions for Quality Control Prior to Each Shipment of Radioactive Material (§173.475)

- Before each shipment of any radioactive materials package, the offeror must ensure, by examination or appropriate tests, that:
  (a) the packaging is proper for the contents to be shipped;
  (b) the packaging is in unimpaired physical condition, except for superficial marks;
  (c) each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;
  (d) for fissile material, each moderator and neutron absorber, if required, is present and in proper condition;
  (e) each special instruction for filling, closing, and preparation of the packaging for shipment has been followed;
  (f) each closure, valve, or other opening of the containment system is properly closed and sealed;
  (g) each packaging containing liquid in excess of an A_2 quantity and intended for air shipment has been tested to show that it will not leak under an ambient atmospheric pressure of not more than 25 kPa, absolute (3.6 psia), where the test must be conducted on the entire containment system, or on any receptacle or vessel within the containment system, to determine compliance with this requirement;
  (h) the internal pressure of the containment system will not exceed the design pressure during transportation; and
  (i) the external radiation and contamination levels are within the allowable limits specified in §173.441 and 443.

4. Hazard Communications for Class 7 (Radioactive) Materials: Shipping Papers (49 CFR 172, Subpart C)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Shipping Paper Entries

Always Required	Sometimes Required	Optional Entries
Basic description (in sequence): • **UN Identification number** • **Proper Shipping Name** • **Hazard Class (7)** • **Total activity contained in each package in SI units** (e.g. Bq, TBq, etc.), or in both SI and customary units (e.g. Ci, mCi, etc.) with customary units in parentheses following the SI units • **Number and type of packages** Additional description: • **Name of each radionuclide**[1] • **Description of physical and chemical form** (unless special form) • **Category of label** used • **Transport index (TI)** of each package bearing a Yellow-II or Yellow-III label Additional entry requirements: • 24 hour **emergency telephone number** • **Shipper's Certification** shall be provided by each person offering radioactive material for transportation[2] • Proper page numbering (e.g. Page 1 of 4)	Materials-based Requirements: • The criticality safety index (CSI) or "Fissile Excepted" for fissile material • The words "Highway route controlled quantity" or the term "HRCQ" entered in the basic description for highway route controlled quantities • The letters "RQ" entered on the shipping paper either before or after the basic description for each hazardous substance (see §171.8) • Enter applicable subsidiary hazard class(es) in parentheses immediately following the primary hazard class when a subsidiary hazard label is required • A hazardous waste manifest and the word "Waste" preceding the proper shipping name is required for radioactive material that is hazardous waste Package-based Requirements: • The applicable DOE or NRC package approval identification marking for certified Type AF and Type B packages • The International Atomic Energy Agency (IAEA) Certificate of Competent Authority identification marking for export shipment or shipment in a foreign made package Shipment- and Administrative-based Requirements: • Specify "exclusive use shipment" as required • Specify instructions for maintaining exclusive use controls for shipments of LSA material or SCO under exclusive use • Specify the notation "DOT–SP" followed by the special permit number[3] for a special permit shipment	• The weight in grams or kilograms of radionuclides may be inserted instead of activity units for fissile radionuclides, except for Pu-239 and Pu-241 • The weight in grams of Pu-239 and Pu-241 may be inserted in addition to the activity units • The words "RESIDUE: Last Contained * * *" may be included in association with the basic description of the hazardous material last contained in the packaging • Other information is permitted provided it does not confuse or detract from the proper shipping name or other required information

Special Considerations/Exceptions for Shipping Papers

- For shipments of multiple cargo types, any HAZMAT entries must appear as the first entries on the shipping papers, or be entered in a color that readily contrasts with any description on the shipping papers or highlighted on the shipping papers in a contrasting color, or be designated by an "X" (or "RQ" if appropriate).
- Emergency response information consistent with §§172.600-606 shall be readily available on the transport vehicle.
- Shipments of limited quantities of radioactive material in excepted packages, under UN2908, 2909, 2910 and 2911, are excepted from shipping paper requirements if (a) the package does not contain fissile material unless excepted by §173.453, and (b) the limited quantity of radioactive material is not a hazardous substance or hazardous waste.
- For road transport, the shipping papers shall be (a) readily available to authorities in the event of accident or inspection, (b) stored within the driver's immediate reach while he is restrained by the lap belt, (c) readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle, and (d) either in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat.

[1] For mixtures of radionuclides, the radionuclides to be shown must be determined in accordance with §173.433(g), which is commonly known as the 95% rule; abbreviations (symbols) are authorized.

[2] The shipper's certification shall satisfy the requirements of either §§172.204(a)(1) or 204(a)(2); or if transported by air of §172.204(c); but is not required if the shipper is a private carrier and the shipment is not reshipped or transferred from one carrier to another.

[3] Shipments made under an exemption or special permit issued prior to October 1, 2007 may bear the notation "DOT–E" followed by the number assigned.

5. Hazard Communication for Class 7 (Radioactive) Materials: Marking of Packagings: (49 CFR 172, Subpart D; and 49 CFR 178.3 and 178.350)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Markings on Packages

Markings Always Required Unless Excepted[1]	Additional Markings Sometimes Required	Optional Markings

Markings for Non-bulk Packagings:
• Proper shipping name
• Identification number (preceded by "UN" or "NA," as appropriate)
• Name and address of consignor or consignee, unless the package is:
  • highway only and no motor carrier transfers; or
  • part of a rail carload or truckload lot or freight container load, and entire contents of railcar, truck, or freight container are shipped from one consignor to one consignee
Markings for Bulk Packages:
• Identification number on orange rectangular panel:
  • on each side and each end, if the packaging has a capacity of 3,785 L (1,000 gallons) or more, or
  • on two opposing sides, if the packaging has a capacity of less than 3,785 L (1,000 gallons), or
  • on each side and end of motor vehicle carrying cylinders permanently installed on a tube trailer
	Package-based marking requirements:
	• Gross mass, including the unit of measurement (which may be abbreviated) for each package with gross mass greater than 50 kg (110 lb)
	• Package type as appropriate, i.e., "TYPE IP–1," "TYPE IP–2," "TYPE IP–3," "TYPE A," "TYPE B(U)" or "TYPE B(M)"[1]
	• Marked with international vehicle registration code of country of origin for IP–1, IP–2, IP–3 or Type A package design [2]
	• Radiation (trefoil) symbol[3] on outside of outermost receptacle of each Type B(U) or Type B(M) packaging design
	• For NRC or DOE packaging, model number, serial number, gross weight, and package identification number for each certified package (Type AF, Type B(U), Type B(M), Type B(U)F, and Type B(M)F)
	• For Specification 7A packaging, mark on the outside with "USA DOT 7A Type A", and the name and address or symbol of the manufacturer satisfying §178.3 and §178.350.
	Materials-based requirements:
	• For non-bulk IP-1 package containing a liquid, use underlined double arrow symbol indicating upright orientation[4], where the symbol is placed on two opposite sides of the packaging
	• If a hazardous substance in non-bulk package, mark outside of each package with the letters "RQ" in association with the proper shipping name
	Administrative-based requirements:
	• For each Type B(U), Type B(M) or fissile material package destined for export shipment, mark "USA" in conjunction with specification marking, or certificate identification; and package identification indicated in U.S. Competent Authority Certificate
	• Mark "DOT–SP" followed by the special permit number assigned for each package authorized by special permit
	• Competent authority identification marking and revalidation for foreign made Type B(U), Type B(M), Type C, Type CF, Type H(U), Type H(M), or fissile material package for which a Competent Authority Certificate is required
		• Both the name and address of consignor and consignee is recommended.
		• Other markings on packages such as advertising are permitted, but must be located away from required markings and labeling.

Special Considerations for Marking Requirements

- All markings are to be (a) on the outside of each packaging, (b) durable and legible, (c) in English, (d) printed on or affixed to the surface of a package or on a label, tag, or sign, (e) displayed on a background of sharply contrasting color, and (f) unobscured by labels or attachments.

[1] Some exceptions exist as specified in §§172.301(a) and 302(a); and in §§173.421(a), 422(a).

[2] The international vehicle registration code for packages designed by a U.S. company or agency is the symbol "USA."

[3] The radiation symbol shall be resistant to the effects of fire and water, plainly marked by embossing, stamping or other means resistant to the effects of fire and water that conform to the requirements of Appendix B to Part 172.

[4] The arrows must be either black or red on white or other suitable contrasting background and commensurate with the size of the package; depicting a rectangular border around the arrows is optional.

6. Hazard Communications for Class 7 (Radioactive) Materials:

Labeling of Packages (49 CFR 172.400-450)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Requirements for Labels [1]

- Label each package except for (a) excepted packages containing a limited quantity of radioactive material; and (b) Low Specific Activity (LSA) material and Surface Contaminated Objects (SCO), packaged or unpackaged, when transported domestically and when material or object contains less than an A_2 quantity.
- Labeling is required to be (a) printed or affixed to a surface other than the bottom of the package, (b) placed near the proper shipping name marking, (c) printed or affixed to a background of contrasting color or have a dotted or solid line outer border, (d) clearly visible, (e) un-obscured by markings or other attachments, and (f) representative of hazardous material content.
- Display duplicate labels on at least two opposite sides or two ends (other than the bottom) of all non-bulk packages of radioactive material except as noted above for excepted packages, and packaged or unpackaged LSA material and SCO.

Radioactive Category Labels [2]			Other Labels [2]	
				
White-I	**Yellow-II**	**Yellow-III**	**Fissile**	**Empty**
Radiation Surface Level (RSL):			Fissile labels required for each package containing fissile material, other than fissile-excepted material, and labels must be affixed adjacent to radioactive category labels.	Empty labels required for shipments of empty Class 7 (radioactive) packages satisfying §173.428; and any previously-used labels cannot be visible
mSv/h: **RSL** ≤ 0.005	0.005 < **RSL** ≤ 0.5	0.5 < **RSL** ≤ 2 [5]		
mrem/h: **RSL** ≤ 0.5	0.5 < **RSL** ≤ 50	50 < **RSL** ≤ 200 [5]		
Transport Index (TI): [3]				
TI = 0 [3]	0 [3] < **TI** ≤ 1	1 < **TI** ≤ 10 [4, 5]		

Contents on Labels

- Each radioactive category label must contain: (a) Except for LSA-I material, the names of the radionuclides in the package where, for mixtures of radionuclides, the names listed must be in accordance with the 95% rule specified in §172.433(g); and, for LSA-I material, the term "LSA-I"; (b) activity in appropriate SI units (*e.g.* Bq, TBq), or appropriate customary units (e.g. Ci, mCi) in parentheses following SI units; and (c) for Yellow-II or Yellow-III labels the Transport Index (TI). Abbreviations and symbols may be used. Except for Pu-239 and Pu-241, the weight in g or kg of fissile radionuclides may be inserted instead of activity units; for Pu-239 and Pu-241, the weight in g of fissile radionuclides may be inserted in addition to the activity units.
- Each fissile label must contain the relevant Criticality Safety Index (CSI).

[1] Additional labeling may be required if the radioactive material also meets the definition of one or more other hazard classes. See §§172.402 and 403 for details on label requirements. See §§172.403, 421 and 427 for details when labels are not required, and see §172.407 for details on label design, size, color, form identification, exceptions, etc.

[2] An additional "Cargo Aircraft Only" label is required for each package containing a hazardous material which is authorized for cargo aircraft only.

[3] The category of the label must be the higher of the two values specified for RSL and TI; see §172.403(b).

[4] The TI is determined from radiation level 1 m from package surface; see definition for TI in §173.403 for details. If the measured TI is not greater than 0.05, the value may be considered to be zero.

[5] RSLs less than or equal to 10 mSv/h (1000 mrem/h), and TIs more than 10 are allowed for shipments under exclusive-use; see §§172.403(a) – 403(c). In addition; any package containing a Highway Route Controlled Quantity (HRCQ) must bear a YELLOW-III label.

7. Hazard Communications for Class 7 (Radioactive) Materials: Placarding (49 CFR 172, Subpart F)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.
NOTE: IAEA, IATA/ICAO, and IMO may require additional hazard communication information.

Conditions when Display of Radioactive Placards is Required [§§172.504, 507(a), 508 and 512(b)(2)]

- On bulk packages, road transport vehicles, rail cars, and freight containers, and on aircraft unit load devices having a capacity of 640 cubic feet or more[1], on each side and each end when they contain either a package with a Radioactive Yellow-III label, or low specific activity (LSA) material or surface contaminated objects (SCO) being transported under exclusive use.
- On a square background on any motor vehicle used to transport a package containing Highway Route Controlled Quantity (HRCQ) Class 7 (radioactive) materials[2].

Visibility and Display of Radioactive Placards [§172.516]

- Placards are required to:
  - be clearly visible, on a motor vehicle and rail car, from the direction they face, except from the direction of another transport vehicle or rail car to which the motor vehicle or rail car is coupled[3];
  - be securely attached or affixed thereto or placed in a holder thereon;
  - be located clear of appurtenances and devices such as ladders, pipes, doors, and tarpaulins;
  - be located, so far as practical, so dirt or water is not directed to it from transport vehicle wheels;
  - be located at least 3 inches (76.0 mm) away from any marking (e.g. advertising) that could reduce its effectiveness;
  - have authorized words or identification number printed on it displayed horizontally, reading from left to right;
  - be maintained by the carrier so format, legibility, color, and visibility of the placard will not be substantially reduced due to damage, deterioration, or obscurement by dirt or other matter;
  - be affixed to background of contrasting color, or dotted or solid line outer border which contrasts with the background color.

Radioactive Placards

PLACARD (FOR OTHER THAN HRCQ)	PLACARD FOR HRCQ
	
White triangular background color in the lower portion with yellow triangle in the upper portion; trefoil symbol, text, class number and inner and outer borders in black. [see §172.556 for detailed requirements]	Square background must consist of a white square surrounded by black border. The placard inside the square is identical to that for other than HRCQ. [see §172.527 for detailed requirements]

Special Considerations/Exceptions for Placarding

- Placards must conform to the specifications set forth in §172.519.
- A corrosive placard is required for more than 454 kg (1001 pounds) or more gross weight of fissile or low specific activity uranium hexafluoride.

[1] See §172.512 for exceptions and variations to the placarding requirements for freight containers and aircraft unit load devices.

[2] See §173.403 for definition of Highway Route Controlled Quantity (HRCQ). A package containing an HRCQ must be labeled with RADIOACTIVE Yellow-III labels; see §172.507(a).

[3] Required placarding of the front of a motor vehicle may be on the front of a truck tractor instead of or in addition to the placarding on the front of the cargo body to which a truck tractor is attached; §172.516(b).

8. Requirements/Guidance for Registration, Emergency Response and Action for Class 7 (Radioactive) Materials: (49 CFR 107, Subpart G, 49 CFR 171.15 and 49 CFR 172, Subparts G and H)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Provisions for Persons Who Offer or Transport Class 7 (Radioactive) Materials (49 CFR 107, Subpart G)

- Any person, other than those excepted by §107.606, who offers for transportation, or transports, in foreign, interstate or intrastate commerce any of the following Class 7 (radioactive) materials must satisfy registration and fee requirements of Part 107, Subpart G:
  - a highway route-controlled quantity of radioactive material;
  - a shipment in a bulk packaging with a capacity ≥ 13,248 L (3,500 gallons) for liquids or gases, or > 13.24 cubic meters (468 cubic feet) for solids; or
  - any quantity of radioactive material that requires placarding, under provisions of Part 172, Subpart F.
- Any person required to register must submit a complete and accurate registration statement on DOT Form F 5800.2 by June 30th for each registration year, or in time to have on file a current Certificate of Registration in accordance with §107.620.
- Each registrant or designee must maintain for a period of 3 years from the date of issuance a copy of the registration statement and Certificate of Registration issued by PHMSA and must furnish its Certificate of Registration (or a copy thereof) and related records to an authorized representative or special agent of DOT upon request.
- Each motor carrier subject to registration requirements of this subpart must carry a copy of its current Certificate of Registration or another document bearing the registration number on board each truck and truck tractor, and the Certificate of Registration or document must be made available, upon request, to enforcement personnel.
- The amount of fees to be paid and procedures to be followed are found at §§107.612 and 616.

Provisions for Providing and Maintaining Emergency Response Information (49 CFR 172, Subpart G)

- When shipping papers for the transportation of radioactive materials are required (see Part 172, Subpart C), emergency response information shall:
  - be provided and maintained during transportation and at facilities where materials are loaded for transportation, stored incidental to transportation, or otherwise handled during any phase of transportation;
  - be provided by persons who offer for transportation, accept for transportation, transfer or otherwise handle hazardous materials during transportation;
  - be immediately available for use at all times the hazardous material is present; and
  - include and make available the emergency response telephone number (see §172.604) to any person, representing a Federal, State or local government agency, who responds to an incident involving the material or is conducting an investigation which involves the material.
- Emergency response information is information that can be used in mitigating an incident involving radioactive materials. It must contain at least the information specified in §§172.602 and 604; and includes an emergency response telephone number that is monitored at all times the material is in transportation by (a) knowledgeable person, or (b) a person who has immediate access to a knowledgeable person, or (c) an organization capable of accepting responsibility for providing the necessary detailed information concerning the material.
- Each carrier who transports or accepts for transportation radioactive material for which a shipping paper is required shall instruct, according to the requirements of §172.606, the operator of a conveyance to contact the carrier in the event of an incident involving the material.

Actions to be Taken in the Event of Spillage, Breakage, or Suspected Contamination by Radioactive Material

- Except for a road vehicle used solely for transporting Class 7 (radioactive) material, if radioactive material has been released in a road, rail, or air transport conveyance, the conveyance must be taken out of and remain out of service until the radiation dose rate at every accessible surface is less than 0.005 mSv/h (0.5 mrem/h) and the non-fixed radioactive surface contamination levels are below the values the limits in §173.443(a), Table 9 [see Chart 3].
- Each aircraft used routinely, and each motor vehicle used, for transporting radioactive materials under exclusive use, must be (a) periodically checked for radioactive contamination, (b) taken out of service if contamination levels are above acceptable limits, and (c) remain out of service until the radiation dose rates at accessible surfaces are less than 0.005 mSv/h (0.5 mrem/h) and non-fixed radioactive surface contamination levels are below the limits in §173.443(a), Table 9 [see Chart 3].
- Following any breakage, spillage, release or suspected radioactive contamination incident, any rail or air carrier shall notify, as soon as possible, the offeror (i.e. the consignor); special provisions apply for buildings, areas, and equipment that might become contaminated during rail transport. Alternative provisions may apply for motor vehicles transporting radioactive materials under exclusive use. [see §§174.750(a) and 750(e), and §177.843(b)]

Provisions for Immediate Notification for Reportable Incidents Involving Radioactive Materials (§§171.15 and 16)

- Each person in physical possession of radioactive material must provide notice in the event of a reportable incident (see §171.15(b)) as soon as practical, but no later than 12 hours after the occurrence of the reportable incident, to the National Response Center (NRC) by telephone at 800–424–8802 (toll free) or 202–267–2675 (toll call) or online at http://www.nrc.uscg.mil.
  - Each notice must include the information specified in §171.15(a)(1) – (a)(7).
- A detailed incident report must also submitted as required by §171.16.

Guidance on Responding to Emergencies (Emergency Response Guidebook)

- The DOT issues guidance to aid first responders in quickly identifying the specific or generic hazards of the dangerous goods involved in an accident or incident, and for protecting themselves and the general public during the initial response to the accident or incident. For each name or UN ID Number, the user is led to a specific guide that provides insight into potential hazards and steps to be taken for public safety and emergency response.
- The current Emergency Response Guidebook is available at the following URL:
  http://www.phmsa.dot.gov/hazmat/library/erg

9. Requirements for Training and Security for Class 7 (Radioactive) Materials: (49 CFR 172, Subparts H and I, and 49 CFR 173)

These are basic reference charts; refer to current U.S. DOT & NRC regulations for complete requirements.

Provisions for Training (49 CFR 172, Subpart H)

- For any person who is employed by an employer or is self-employed, and who directly affects radioactive materials transportation safety, a systematic program shall be established to ensure that the person:
  - has familiarity with the general provisions of Part 172, Subpart H;
  - is able to recognize and identify radioactive materials;
  - has knowledge of specific requirements of Part 172 that are applicable to functions performed by the employee;
  - has knowledge of emergency response information, self protection measures and accident prevention methods and procedures; and
  - does not perform any function related to the requirements of Part 172 unless instructed in the requirements that apply to that function.
- The person shall be trained pursuant to the requirements of §§172.704(a) and (b), may be trained by the employer or by other public or private sources, and shall be tested by appropriate means. The training must include the following:
  - (a) general awareness training providing familiarity with applicable regulatory requirements;
  - (b) function-specific training applicable to functions the employee performs;
  - (c) safety training concerning emergency response information, measures to protect the employee from hazards, and methods and procedures for avoiding accidents;
  - (d) security awareness training providing awareness of security risks and methods designed to enhance transportation security; and
  - (e) in-depth security training if a security plan is required for the shipment(s) involved.
- Initial and recurrent training shall comply with the requirements of §172.704(c).
- Records of training shall be created and retained in compliance with the requirements of §172.704(d).

Provisions for Security (49 CFR 172, Subpart I and 49 CFR 173)

- A security plan for hazardous materials that conforms to the requirements of Part 172, Subpart I must be developed and adhered to by each person who offers for transportation in commerce or transports in commerce in a motor vehicle, rail car, or freight container any of the following radioactive materials:
  - (a) IAEA Code of Conduct Category 1 and 2 materials (see §172.800(b)(15));
  - (b) a highway route controlled quantity (HRCQ) of radioactive material as defined in §173.403 (see §172.800(b)(15));
  - (c) known radionuclides in forms listed as radioactive material quantities of concern (RAM–QC) by the NRC (see §172.800(b)(15)); or
  - (d) a quantity of uranium hexafluoride requiring placarding under §172.505(b) (see §172.800(b)(14)).
- The security plan must include an assessment of possible transportation security risks and appropriate measures to address the assessed risks.
- Specific measures put into place by the plan may vary commensurate with the level of threat at a particular time.
- At a minimum, a security plan must address personnel security, unauthorized access, and en route security.
- The security plan must be
  - (a) in writing;
  - (b) retained for as long as it remains in effect;
  - (c) available as copies or portions thereof to the employees who are responsible for implementing it, consistent with personnel security clearance or background investigation restrictions and a demonstrated need to know;
  - (d) revised and updated as necessary to reflect changing circumstances; and
  - (e) maintained (all copies) as of the date of the most recent revision, when it is updated or revised.
- Security plans that conform to regulations, standards, protocols, or guidelines issued by other Federal agencies, international organizations, or industry organizations may be used to satisfy the requirements in Part 172, provided such security plans address the requirements specified in Part 172, Subpart I.
- Additional security planning requirements may apply for rail transport of a highway route controlled quantity of radioactive material (see §§172.820 and 173.403).

APPENDIX AA

LIST OF REFERENCES AND RESOURCES

List of References and Resources

Some sections of the guidance include references to other documents or resources that may be useful to the applicant or licensee. This Appendix provides a complete list of documents used to prepare or referenced in the guidance. If reference or resource documents include information conflicting with current regulations, the regulations in Title 10 of the *Code of Federal Regulations* (CFR) apply. For example, some references or resources may include alternate limits for occupational and public dose; however, licensees should note that the limits in 10 CFR Part 20 are applicable. Many of these documents may be accessed online at the U.S. Nuclear Regulatory Commission Library or using the links provided for each section below. See the Notice of Availability on the inside front cover of this report for more information.

Title 10 of the *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
16. Title 49 of the *Code of Federal Regulations*

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

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

19. Part 177 – Carriage by Public Highway

20. Part 178 – Specifications for Packaging

NRC Regulatory Guides

21. RG 1.86, "Termination of Operating Licenses for Nuclear Reactors," June 1974.

22. RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Revision 2, March 2005.

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11. ABSTRACT (200 words or less)

This technical report contains information intended to provide program-specific guidance and assist applicants and licensees in preparing applications for materials licenses for the medical use of byproduct material. In particular, it describes the types of information needed to complete U.S. Nuclear Regulatory Commission (NRC) Form 313, "Application for Materials License," and the NRC Form 313A series for authorized users (AU), authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), and Radiation Safety Officers (RSO). This document describes both the methods acceptable to the NRC license reviewers in implementing the regulations and the techniques used by the reviewers in evaluating the application to determine if the proposed activities are acceptable for licensing purposes.

The document contains appendices that include (i) copies of necessary forms; (ii) a sample license application for different types of medical uses of byproduct materials; and (iii) examples of the types of supporting documents, such as procedures, that may need to be prepared by applicants. Guidance in this document represents one means acceptable to NRC staff of complying with NRC regulations and is not intended to be the only means of satisfying requirements for a license.

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