U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1556
Vol. 9, Rev. 2

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

Final Report

Office of Federal and State Materials and
Environmental Management Programs

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Manuscript Completed: January 2008
Date Published: January 2008

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Office of Federal and State Materials and
Environmental Management Programs

ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) consolidated and updated numerous guidance documents into a single comprehensive repository, as described in NUREG-1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign," dated April 1996, and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance," dated April 1996. NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," is the third version of the ninth program-specific guidance document developed for the new process; it is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States.

This document contains information that is intended to assist those preparing applications for licenses for the medical use of byproduct material. In particular, it describes the types of information needed to complete NRC Form 313, "Application for Materials License," and the NRC Form 313A series of forms: NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and 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]"; and 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]."

The document provides an overview of the types of licenses issued by the NRC, the commitments and responsibilities that must be undertaken by a licensee, applicable regulations, the process for filing a license application, and the contents of applications for different types of medical uses of byproduct material. In particular, this document provides a description, on an item-by-item basis, of the information to be provided by an applicant on NRC Form 313. Because of the wide variety in the types of medical uses of byproduct material, indicators have been placed in the document to alert applicants for particular types of medical uses to material that pertains to those types of uses.

The document also contains appendices that include (1) copies of necessary forms; (2) a sample license application and sample licenses for different types of medical uses of byproduct materials; (3) examples of the types of supporting documents, such as implementing procedures, that may need to be prepared by applicants; and (4) information required by regulation for requesting authorization for preparation of Positron Emission Tomography (PET) radioactive drugs for noncommercial distribution to other members of a consortium. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and to allow implementation by licensees that may be specific to their needs while meeting the regulatory requirements. By supplying examples, the NRC seeks to provide information to meet the needs of applicants for

licensure, without being prescriptive. 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.

The original Volume 9 of NUREG-1556 provided guidance for licensure under revised Title 10, Part 35, "Medical Use of Byproduct Material." It combined and superseded guidance found in the documents listed below:

- Regulatory Guide (RG) 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs";
- Appendix X to RG 10.8, Revision 2, "Guidance on Complying With New Part 20 Requirements";
- Draft RG DG-0009, "Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs";
- Draft RG FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs";
- RG 8.23, "Radiation Safety Surveys at Medical Institutions, Revision 1";
- RG 8.33, "Quality Management Program";
- RG 8.39, "Release of Patients Administered Radioactive Materials";
- Policy and Guidance Directive (P&GD) 03-02, "Licensing Lixiscope and BMA";
- Policy and Guidance Directive (P&GD) 03-08, "Standard Review Plan for Teletherapy";
- Policy and Guidance Directive (P&GD) 3-17, "Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants";
- Policy and Guidance Directive (P&GD) FC 87-2, "Standard Review Plan for License Applications for the Medical Use of Byproduct Material";
- Policy and Guidance Directive (P&GD) FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices";
- Addendum to Revision 1 to P&GD FC 86-4, "Information Required for Licensing Remote Afterloading Devices-Increased Source Possession Limits";
- Policy and Guidance Directive (P&GD) FC 92-01 "Information Required for Licensing Mobile Nuclear Medicine Services"; and
- Policy and Guidance Directive (P&GD) 3-15, "Standard Review Plan for Review of Quality Management Programs."

Revision 1 of NUREG-1556, Volume 9, revised Volume 9 to reflect the March 30, 2005, Final Rule, Medical Use or Byproduct Material – Recognition of Specialty Boards (70 FR 16336), that revised the training and experience requirements for recognition of specialty boards. Revision 2 of NUREG-1556, Volume 9, revises Volume 9 to provide additional guidance to reflect regulatory changes made by the Naturally Occurring and Accelerator-Produced Material (NARM) Rule, "Requirements for Expanded Definition of Byproduct Material" (72 FR 55864),

replaces NRC Form 313A with six new NRC Form 313A forms, makes additional changes to enhance clarification of the training and experience requirements, and removes all references to, and information contained in, 10 CFR Part 35, Subpart J, which expired on October 25, 2005.

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FOREWORD

This report, NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," is one of twenty-one volumes in NRC's NUREG-1556 series addressing its materials licensing process. This report is intended for use by applicants, licensees, NRC license reviewers, and other NRC license personnel addressing the medical use of byproduct material. Below is a list of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1, Rev. 1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3, Rev. 1	Applications for Sealed Source and Device Evaluation and Registration	Final Report
4	Program-Specific Guidance About Fixed Gauge Licenses	Final Report
5	Program-Specific Guidance About Self-Shielded Irradiators Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiators Licenses	Final Report
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope	Final Report
8	Program-Specific Guidance About Exempt Distribution Licenses	Final Report
9, Rev.2	Program-Specific Guidance About Medical Use Licenses	Final Report
10	Program-Specific Guidance About Master Materials Licenses	Final Report
11	Program-Specific Guidance About Licenses of Broad Scope	Final Report
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution	Final Report
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14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses	Final Report
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees	Final Report
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Final Report

Vol. No.	Volume Title	Status
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)	Final Report
20	Guidance About Administrative Licensing Procedures	Final Report
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator	Final Report

Questions and Answers on the implementation of Part 35 of Title 10 of the Code of Federal Regulations (CFR) are posted on the NRC's Web site on the Medical Uses Licensee Toolkit http://www.nrc.gov/materials/miau/med-use-toolkit.html, serving as another source of guidance about implementation of revised 10 CFR Part 35.

After the October 2002 publication of NUREG-1556, Volume 9, the NRC amended 10 CFR Part 35, "Medical Use of Byproduct Material" (March 30, 2005; 70 FR 16335). The licensing guidance contained in NUREG-1556, Volume 9, Revision 1, included updated guidance on requirements for training and experience appearing in the amended rule. The guidance also reflected the extension of the effective date of Subpart J to October 24, 2005 (69 FR 55736).

Following the May 2005 publication of NUREG-1556, Volume 9, Revision 1, the NRC developed six new 313A Forms to record the training and experience of six different groups of individuals seeking recognition as authorized users, radiation safety officers, authorized nuclear pharmacists, and authorized medical physicists. On March 27, 2006, the NRC published a final rule to correct several minor errors in the CFR, update the address for Region III, and remove all references to Subpart J in 10 CFR Parts 32 and 35. Revision 2 of NUREG-1556, Volume 9, includes the new NRC Form 313A series of forms, provides guidance on how to fill them out, and removes references to 10 CFR Part 35, Subpart J.

On November 30, 2007, the NRC amended its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of byproduct material to include:

- any discrete source of radium-226 (Ra-226),
- any material made radioactive by use of a particle accelerator, and
- any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials described in the EPAct,

determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226

that are extracted or converted after extraction for use for a commercial, medical, or research activity.

In so doing, these materials were placed under the NRC's regulatory authority. Also as authorized by the EPAct, the NRC issued a waiver on August 31, 2005, to allow continued use and possession of naturally-occurring and accelerator-produced radioactive materials (NARM) while the NRC developed a regulatory framework for regulation of the new byproduct material. The NRC will terminate the waiver in phases, beginning November 30, 2007, and ending on August 7, 2009. On November 30, 2007, the NRC terminated the waiver for Federal Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. Waiver terminations for Connecticut, New Jersey, Pennsylvania, Vermont, Virginia, West Virginia, Michigan, Missouri, Alaska, Hawaii, Idaho, Pacific Trust Territories, and South Dakota will be executed for groups of States and U.S. Territories in phases between November 30, 2007 and August 7, 2009.

Upon waiver termination, all persons who possess the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with NRC regulations. Being in compliance with the NRC regulations means that such persons are responsible for the proper handling, transfer, and disposal of these new byproduct materials as specified in the NRC's regulations. Some radioactive materials that fall under the newly expanded definition of byproduct materials may already be authorized on an existing NRC license, since the term "byproduct materials" will include the new NARM material. For those radioactive materials and uses of the new byproduct material that are not already on an NRC license, the person will either be required to: (1) apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, or (2) submit a new license application for the new byproduct material within 12 months from the date the waiver is terminated. The person may continue to use the materials until NRC takes final licensing action, provided the amendment or new license request was made during the required time periods.

Revision 2 of NUREG-1556, Volume 9, includes updated guidance on requirements for licensing the accelerator-produced radioactive materials and discrete sources of radium-226 now included in the expanded definition of byproduct material.

In addition to combining and updating the guidance for applicants and licensees previously found in numerous Regulatory Guides, Policy and Guidance Directives, draft Regulatory Guides, Standard Review Plans, and Information Notices, this guidance incorporates input from stakeholders received in public workshops and written comments.

This report follows the risk-informed, performance-based approach adopted for revisions to 10 CFR Part 35. It reduces the amount of information submitted by an applicant seeking to possess and use certain quantities of byproduct material for medical use. In a number of instances, the regulations found in 10 CFR Part 35 and reflected in this report do not require the

submission of detailed procedures. Instead, applicants are requested to confirm that they have developed and will implement and maintain procedures required by Part 35, but they are not required to submit those procedures as part of their license application. This report contains appendices containing suggested procedures that applicants may consider. The risk-informed, performance-based approach to the regulation of NRC-licensed materials is also being emphasized in the inspection and enforcement arena.

This document addresses those topics that an applicant must provide in preparing a license application on NRC Form 313. The report also includes descriptions of certain key elements of a medical use program that do not require a response on Form 313. This material is presented for clarification only.

Revision 2 of NUREG-1556, Volume 9, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only. Guidance in this document represents one means acceptable to the staff of complying with NRC regulations and is not intended to be the only means of satisfying the requirements for licensing.

The NRC's "Procedures for Recognizing Certification Processes of Specialty Boards" may be found on NRC's Web site on the Medical Uses Licensee Toolkit http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Complementary guidance on Inspection Procedures for inspections of medical use licensees is contained in the following documents available at NRC's Web site on the Medical Uses Licensee Toolkit http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Inspection Procedures in the 87100 series:

- "Nuclear Medicine Programs — Written Directive Not Required,"
- "Nuclear Medicine Programs — Written Directive Required,"
- "Brachytherapy Programs,"
- "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs," and
- "Medical Broad-Scope Programs."

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ACKNOWLEDGMENTS

The guidance development team thanks the individuals listed below for assisting in the development and review of the report. All participants provided valuable insights, observations, and recommendations.

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The team also thanks Justine Cowan, Loleta Dixon, Agi Seaton, and Roxanne Summers of Computer Sciences Corporation for their assistance in the preparation of this document.

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We acknowledge both the assistance of Francis X. "Chip" Cameron for leading two facilitated round-table discussions and the participation of stakeholders in public meetings held at NRC headquarters on April 25 and 30, 2002.

The following individuals are recognized for their contribution to supporting documents that formed a basis for the original report:

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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ACR	American College of Radiology
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
bkg	background
BPR	Business Process Redesign
Bq	bequerel
CFR	Code of Federal Regulations
Ci	curie
cc	centimeter cubed
cm^2	square centimeter
Co-57	cobalt-57
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
DAC	derived air concentration
DOT	United States Department of Transportation
dpm	disintegrations per minute
EPAct	Energy Policy Act of 2005
F-18	fluorine-18
FDA	United States Food and Drug Administration
GM	Geiger-Mueller
GPO	Government Printing Office
GSR	gamma stereotactic radiosurgery
HDR	high dose-rate

I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
Mo-99	molybdenum-99
mR	milliroentgen
mrem	millirem
mSv	millisievert
N–13	nitrogen-13
NaI(Tl)	sodium iodide (thallium doped)
NARM	Naturally Occurring and Accelerator-Produced Material
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
O-15	oxygen-15
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically stimulated luminescence dosimeters
PET	Positron Emission Tomography
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
P&GD	Policy and Guidance Directive
QA	quality assurance
Ra-226	radium-226
Ru-82	rubidium-82

RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unités)
Sr-82	strontium-82
Sr-85	strontium-85
Sr-90	strontium-90
SSDR	Sealed Source and Device Registry
std	standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	Transport Index
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
Xe-133	xenon-133
Y-90	yttrium-90
μCi	microcurie
%	percent

1 OVERVIEW

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

1.1 PURPOSE OF REPORT

This report is intended to provide guidance on three topics to individuals who are preparing an application for a license for the medical use of byproduct material as well as to NRC staff who review applications:

(1) Preparation of a license application using NRC Form 313 "Application for Materials License," including supplemental forms:

- 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]"; and
- 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]."

(2) NRC criteria for evaluating a medical use license application. This report 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 is not required under 10 CFR 35.40 (see Subpart D, 10 CFR 35.100-190);
- Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required under 10 CFR 35.40 (see Subpart D, 10 CFR 35.200-290);
- Use of unsealed byproduct material for which a written directive 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); and

- Other medical uses of byproduct material or radiation from byproduct material not specifically covered by 10 CFR Part 35, Subparts 35.100 through 35.600 (see 10 CFR 35.1000, Subpart K).

(3) The NRC criteria for evaluating an application for authorization of a medical facility to prepare PET radioactive drugs under 10 CFR 30.32(j) for noncommercial transfer to medical use licensees within its consortium.

To assist license applicants, this guide includes text boxes at the beginning of each section to indicate the type of use to which the guidance pertains (identified by the pertinent section of 10 CFR Part 35). 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 check indicates that applicants for that type of use should review the guidance section. Some of the checks have asterisks next to them. These asterisks indicate that there are conditions or limitations in that particular section of the guidance relating to the applicants who are subject to the checked section of the rule. Table 1.1 summarizes the material in the text boxes. The Table also includes Appendix AA because it includes information the applicant needs when requesting authorization under 10 CFR 30.32(j). Because this authorization is not an authorization for medical use, none of the medical uses were marked.

Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.1	License Action Type	•	•	•	•	•	•	•
8.2	Applicant's Name and Mailing Address	•	•	•	•	•	•	•
8.3	Address(es) Where Licensed Material Will Be Used or Possessed	•	•	•	•	•	•	•
8.4	Person to Be Contacted about This Application	•	•	•	•	•	•	•
8.5	Radioactive Material	•	•	•	•	•	•	•
8.6	Sealed Sources and Devices (including Ra-226 Sealed Sources and Devices)				•	•	•	•
8.7	Discrete Source of Ra-226 (other than Sealed Sources)	•	•	•				•
8.8	Recordkeeping for Decommissioning and Financial Assurance	•	•	•	•	•	•	•
8.9	Purpose(s) for which Licensed Material Will Be Used	•	•	•	•	•	•	•
8.10	Individual(s) Responsible for Radiation Safety Program and their Training and Experience	•	•	•	•	•	•	•
8.11	Radiation Safety Officer (RSO)	•	•	•	•	•	•	•

Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.12	Authorized User (AU)	●	●	●	●	●	●	●
8.13	Authorized Nuclear Pharmacist (ANP)	●	●	●				●
8.14	Authorized Medical Physicist (AMP)				●		●	●
8.15	Facilities and Equipment	●	●	●	●	●	●	●
8.16	Facility Diagram	●	●	●	●	●	●	●
8.17	Radiation Monitoring Instruments	●	●	●	●	●	●	●
8.18	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material	●	●	●				●
8.19	Therapy Unit - Calibration and Use				●		●	●
8.20	Other Equipment and Facilities	●	●	●	●	●	●	●
8.21	Radiation Protection Program	●	●	●	●	●	●	●
8.22	Safety Procedures and Instructions						●	●
8.23	Occupational Dose	●	●	●	●	●	●	●
8.24	Area Surveys	●	●	●	●	●	●	●
8.25	Safe Use of Unsealed Licensed Material	●	●	●				●
8.26	Spill/Contamination Procedures	●	●	●	●	●	●	●
8.27	Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						●	●
8.28	Minimization of Contamination	●	●	●	●	●	●	●
8.29	Waste Management	●	●	●	●	●	●	●
8.30	Fees	●	●	●	●	●	●	●
8.31	Certification	●	●	●	●	●	●	●
AA	Authorization under 10 CFR 30.32(j) to Prepare PET Radioactive Drugs for Noncommercial Transfer							
PROGRAM-RELATED GUIDANCE - NO RESPONSE FROM APPLICANTS ON NRC FORM 313								
8.32	Safety Instruction for Individuals Working In or Frequenting Restricted Areas	●	●	●	●	●	●	●
8.33	Public Dose	●	●	●	●	●	●	●
8.34	Opening Packages	●	●	●	●	●	●	●
8.35	Procedures for Administrations When a Written Directive Is Required			●	●		●	●

Table 1.1 Sections of NUREG-1556, Volume 9, Revision 2, that Applicants for a Particular Type of Use Should Review

NUREG-1556 - Volume 9, Rev. 2 Section:		Type of Use						
		100	200	300	400	500	600	1000
8.36	Release of Patients or Human Research Subjects			•	•			•
8.37	Mobile Medical Service	•	•	•	•	•	•	•
8.38	Audit Program	•	•	•	•	•	•	•
8.39	Operating and Emergency Procedures	•	•	•	•	•	•	•
8.40	Material Receipt and Accountability	•	•	•	•	•	•	•
8.41	Ordering and Receiving	•	•	•	•	•	•	•
8.42	Sealed Source Inventory	•	•	•	•	•	•	•
8.43	Records of Dosages and Use of Brachytherapy Source	•	•	•	•			•
8.44	Recordkeeping	•	•	•	•	•	•	•
8.45	Reporting	•	•	•	•	•	•	•
8.46	Leak Tests	•	•	•	•	•	•	•
8.47	Safety Procedures for Treatments When Patients Are Hospitalized			•	•		•	•
8.48	Transportation	•	•	•	•	•	•	•

Applicants also should 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 that relate to radiation safety;
- Provisions of 10 CFR Part 30 that relate to licensing (e.g., §30.33); and
- Provisions of 10 CFR 30.32(j) and 30.34(j) for preparation for noncommercial transfer of PET radioactive drugs to medical use licensees within a consortium.

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 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Licenses of Broad Scope," dated April 1999, provides additional licensing guidance on medical use programs of broad scope. Section 1.2.1 below provides a general discussion on specific licenses of broad scope.

- 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations."
- 10 CFR Part 20, "Standards for Protection Against Radiation," and other regulatory requirements potentially applicable to medical use licensees listed in Section 4 below.
- 10 CFR Part 21, "Reporting of Defects and Noncompliance."
- This report does not address the commercial aspects of manufacturing, distribution, and service of sources containing byproduct material in devices. Volumes 12, 13, and 18 of NUREG-1556, provide additional licensing guidance.
- This report does not address the accelerator production of radionuclides by the medical use licensee for either commercial or noncommercial distribution of radionuclides. Volume 21 of NUREG-1556, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator," provides licensing guidance to applicants requesting a license to produce radioactive materials using an accelerator.
- This report does not describe the licensing, possession, or use of pacemakers, which are licensed under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." However, a sample pacemaker license is included in Appendix F.

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 their 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 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 their 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.

Sections 1 through 7 of this document provide background information. Section 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 judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – provides suggested response(s) or indicates that no response is needed on that topic during the initial licensing process.

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

When NRC Form 313 does not have sufficient space to provide full responses to Items 5-11, provide the information on separate attachments, label the attachments to indicate which item is being addressed, and submit the attachments with the completed NRC Form 313.

Appendix AA contains background information and item-by-item information that should be provided in Items 1 through 11 of NRC Form 313 for applicants requesting authorization under 10 CFR 30.32(j) for the production of PET radioactive drugs for noncommercial transfer to other medical use licensees within a consortium.

Other appendices to this report provide the following supplementary information:

- Appendices A and B provide sample application forms;
- Appendix C provides license application checklists for responding to Items 5-11 on NRC Form 313;
- Appendix D describes how to fill out the NRC Form 313A series of forms;
- Appendix E includes a sample application;
- Appendix F provides sample licenses;
- Appendices G and H provide information regarding required submissions;
- Appendices I through W provide model procedures;
- Appendices X through Z provide reference materials;
- Appendix BB, published as a separate document, provides a summary of public comments on drafts and NRC responses;
- Appendix CC provides a list of references; and
- Appendix DD provides a summary of public comments and NRC responses on draft NUREG-1556, Volume 9, Revision 2.

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 (TEDE). These quantities are defined in 10 CFR Part 20 and are expressed in units of rem and its SI equivalent, the Sievert (Sv) (1 rem = 0.01 Sv). (The quantities, absorbed dose and exposure, and their associated units, the rad and the roentgen, are not used in 10 CFR Part 20 to specify dose limits.) The byproduct materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of

1 rem. With the addition of accelerator-produced materials to the definition of byproduct material by the EPAct, licensees may see the development of alpha-emitting radioisotopes for medical uses that are under NRC jurisdiction. The quality factor used in 10 CFR Part 20 for alpha particles is 10.

This NUREG updates the information and guidance provided in Revision 2 of RG 10.8, "Guide for the Preparation of Applications for Medical Use Programs," revises the format in which the information is presented to assist with the preparation of a medical use license, and includes new guidance for the new byproduct material now under NRC jurisdiction in accordance with the expanded definition of byproduct material. Revision 2 of RG 10.8 was issued in August 1987 to provide guidance for the revised 10 CFR Part 35, which became effective April 1, 1987. Since then, 10 CFR Part 35 has been amended a number of times. Technology-specific information has been revised and expanded to include technologies that are now more commonly used; for example, computerized remote afterloading brachytherapy and gamma stereotactic radiosurgery (GSR). It has also been updated to include accelerator-produced radioactive materials and discrete sources of radium-226 (Ra-226) as a result of the expanded definition of byproduct material resulting from the EPAct.

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 Materials Using an Accelerator," and is not within the scope of this guidance for medical use licensees. Note that this guidance (Volume 9) 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 authorized nuclear pharmacist (ANP) or qualified authorized user (AU) for the applicant's medical use.

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). 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 (1) on an NRC or Agreement State license, (2) 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 (3) 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). Section 10 CFR 35.57(b) also recognizes as an AU a physician, dentist, or podiatrist using only accelerator-produced radioactive materials, discrete sources of Ra-226, or both, for medical use under the provisions of the NRC waiver of August 31, 2005, for those same materials and uses.

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), and
- 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).

The NRC usually issues a single byproduct materials license to cover an entire radionuclide program. (Note, however, that nuclear-powered pacemakers are licensed separately under 10 CFR Part 70.) A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units, and a license may include authorization for possession of sealed sources to be used to calibrate dose calibration devices.

The NRC may issue separate licenses to individual licensees for different medical uses. However, 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).

Positron Emission Tomography (PET) Radionuclide Production or Radioactive Drug Distribution Licenses and Authorizations

- A medical use licensee that possesses and uses an accelerator to produce radionuclides used in PET studies needs a separate license under 10 CFR Part 30 for the PET radionuclide production activities. Volume 21 of NUREG-1556 provides licensing guidance for this type of activity.

  A medical use licensee, using its PET radionuclide production facility in the preparation of PET radiopharmaceuticals for its own use, needs two licenses (i.e., the Part 30 production license and the Part 35 medical use license). The PET radioactive drugs are produced under the provisions of 10 CFR 35.100(b), 35.200(b), or 35.300(b), as appropriate.

- A medical use facility that is a member of a consortium that jointly owns, or shares in the operation and maintenance costs of, the PET radionuclide production facility, and receives PET radionuclides from that production facility to produce only PET pharmaceuticals for the consortium members' medical uses, needs an additional authorization under 10 CFR 30.32(j) for the noncommercial distribution of the PET radioactive drugs to its consortium members. See Appendix AA for additional information on this authorization.

- A medical use licensee with a PET radionuclide production facility that commercially distributes PET radionuclides to other licensees needs a 10 CFR Part 30 production license and an additional 10 CFR Part 32 commercial distribution license or authorization. Volume 12 of NUREG-1556 provides additional guidance on commercial distribution.
- A medical use facility that commercially distributes PET radioactive drugs to another medical use licensee needs a commercial medical distribution license either as a manufacturer or commercial nuclear pharmacy. Volumes 12 and 13 of NUREG-1556 provide additional guidance for this type of license application.

"Consortium" as used here and in 10 CFR Part 30 is defined as an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial 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.

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 NRC, when incorporated into a license by reference;
- Terms and conditions of the license; and
- NRC regulations.

In 10 CFR 30.9, the NRC requires that the information in the application be complete and accurate in all material aspects. 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, inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms and, 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, 10 CFR 35.647). 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: (1) have experience successfully operating under a specific license of limited scope, and (2) are engaged in medical research and routine diagnostic and therapeutic uses of byproduct material. Volume 11 of NUREG-1556 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.

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). Section 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," need be filed. Medical-use licensees authorized pursuant to 10 CFR Part 35 do not need to file the form.

The NRC limits possession to a total of 200 microcuries (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 to 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 microcuries (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," it is stated 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 Radiation Safety Officer (RSO) is responsible for the day-to-day operation of the Radiation Protection Program.

References: The following documents contain information, methods, and references useful to those who are establishing Radiation Protection Programs to maintain radiation exposures at ALARA levels in medical facilities:

- RG 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures ALARA."

- RG 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be ALARA."
- NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA."
- NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities."
- Information directly related to radiation protection standards in 10 CFR Part 20 is contained in NUREG 1736, "Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation."

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

1.3.2 WRITTEN DIRECTIVE PROCEDURES

In 10 CFR 35.41, certain medical use licensees are required to develop, implement, and maintain written procedures to provide high confidence that before each administration requiring a written directive (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 provides further information on developing these procedures.

1.3.3 TIMELY NOTIFICATION OF TRANSFER OF CONTROL

Under 10 CFR 30.34(b) and 10 CFR 35.14(b), licensees must provide full information and obtain NRC's *written consent* before transferring control of the license, or, as some licensees refer to the process, "transferring the license."

Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not NRC's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain NRC's written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid NRC licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the material; and
- Public health and safety are not compromised by the use of such materials.

As provided in 10 CFR 35.14(b), if only the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in

10 CFR 30.34(b), a licensee must file a written notification with NRC no later than 30 days after the date(s) of the change(s). Otherwise, prior NRC written consent must be given before the transfer.

Guidance on information to be supplied to the NRC when seeking approval for transfer of control of licensed material is available in Appendix G.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of IN 97-30, "Control of Licensed Material during Reorganizations, Employee-Management Disagreements, and Financial Crises," dated June 3, 1997, and NUREG-1556, Volume 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," dated November 2000.

These documents can also be accessed at NRC's Web site, in the Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1997/in97030.html and http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/. Appendix G, excerpted from Appendix F of NUREG-1556, Volume 15, identifies the information to be provided about transferring control.

1.3.4 TIMELY NOTIFICATION OF BANKRUPTCY PROCEEDINGS

Immediately following the filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee is required by 10 CFR 30.34(h) to notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of the filing.

Even though the licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. The NRC needs to know 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 entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," dated November 2000.

1.4 OFFICE OF MANAGEMENT AND BUDGET CLEARANCES

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

2 AGREEMENT STATES

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

Certain States, called Agreement States (see Figure 2.1), have entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders. Any applicant, other than a Federal agency or Federally recognized Indian tribe, 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 NRC.

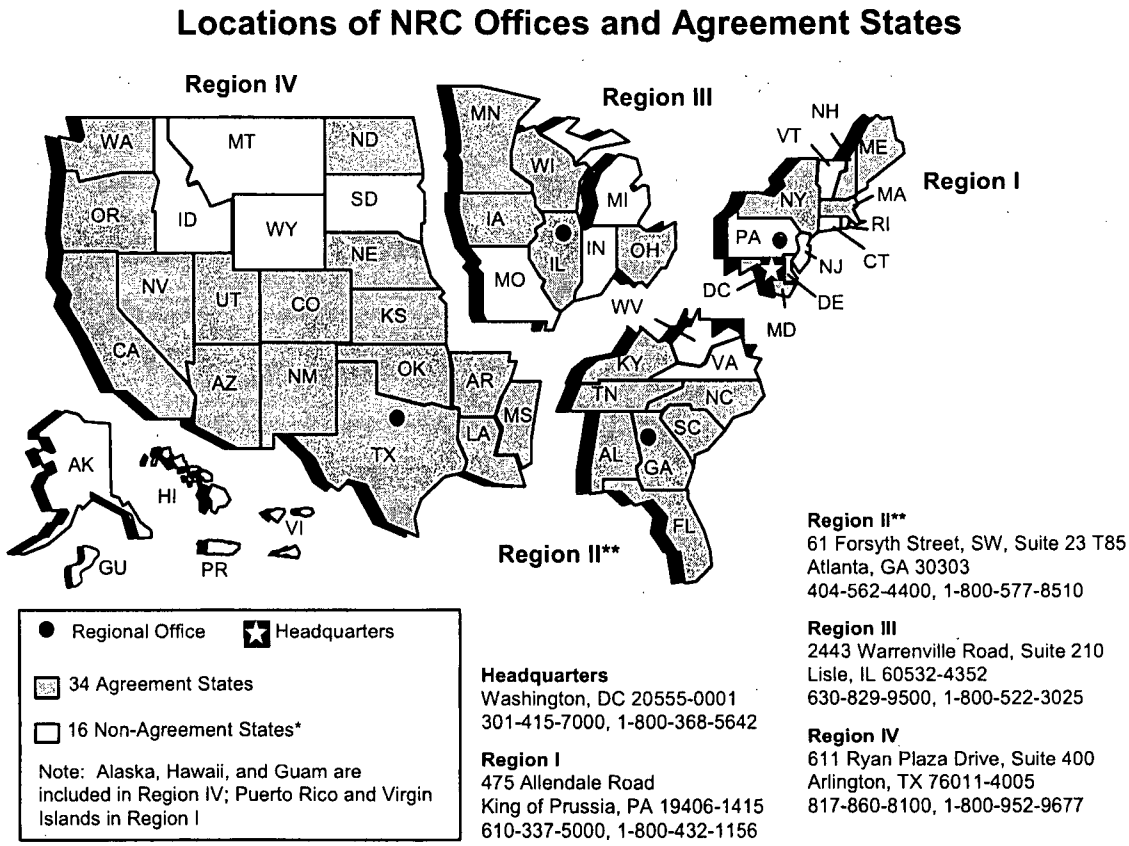

Figure 2.1 U.S. Map Location of NRC Offices and Agreement States.

Note: As of March 30, 2008, all Agreement States have to adopt the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. Before this date, some Agreement States may have additional training and experience criteria for certain medical uses such as the medical use of PET radiopharmaceuticals.

In the special situation of work at Federally controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. 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 finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. The NRC recommends that applicants ask their local contact for the Federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, in order to comply with NRC or Agreement State regulatory requirements, as appropriate. Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996, which is available at http://nrc-stp.ornl.gov/asletters/other/sp96022.pdf.

Table 2.1 provides a quick way to check on which agency has regulatory authority.

Table 2.1 Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency or Federally recognized Indian tribe[1] regardless of location (except the Department of Energy and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, District of Columbia, US territory, or possession, or in Offshore Federal Waters	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally controlled site ***not*** subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC

[1] NRC exercises jurisdiction as the regulatory authority on land where a Federally recognized Indian tribe has tribal jurisdiction. Section 274b Agreements do not give States authority to regulate nuclear material in these areas. Companies owned or operated by native American Indians or non-Indians wishing to possess or use licensed material in these areas would contact the appropriate NRC Regional Office to request a license application.

Reference: A current list of Agreement States is available at the Office of Federal and State Materials and Environmental Management Programs' (FSME) public Web site, which is located at http://nrc-stp.ornl.gov. As an alternative, request the list from an NRC Regional Office.

3 MANAGEMENT RESPONSIBILITY

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

Regulations: 10 CFR 30.9, 10 CFR 35.12, 10 CFR 35.24.

The NRC endorses the philosophy that effective Radiation Protection Program management is vital to safe operations that comply with NRC regulatory requirements (see 10 CFR 35.24).

"Management" refers to the chief executive officer or other individual having the authority to ***manage, direct, or administer the licensee's activities*** or that person's delegate or delegates (see 10 CFR 35.2).

To ensure adequate management involvement in accordance with 10 CFR 35.12(a) and 35.24(a), a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation protection, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation protection records and all information provided to NRC (10 CFR 30.9);
- Knowledge about the contents of the license application;
- Compliance with current NRC and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of 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;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- Approval of qualified individual(s) to serve as authorized medical physicists (AMPs), ANPs, and AUs for licensed activities.

For information on NRC inspection, investigation, enforcement, and other compliance programs, see the following:

- The NRC Enforcement Policy which is included on the NRC's Web site at http://www.nrc.gov/what-we-do/regulatory/enforcement/enforce-pol.html
- The NRC Inspection Manual, Chapter 2800, "Materials Inspection Program," and
- Inspection Procedures:

  83822 – "Radiation Protection,"

  84850 – "Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61,"

84900 – "Low-Level Radioactive Waste Storage,"

87130 – "Nuclear Medicine Programs — Written Directive Not Required,"

87131 – "Nuclear Medicine Programs — Written Directive Required,"

87132 – "Brachytherapy Programs,"

87133 – "Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs," and

87134 – "Medical Broad-Scope Programs."

For availability of these documents, see the Notice of Availability on the inside front cover of this report. In addition, the Inspection Manual and procedures are available at http://www.nrc.gov/materials/miau/med-use-toolkit.html.

4 APPLICABLE REGULATIONS

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

Regulations applicable to medical use licensees are listed below.

Applicants should ensure the use of up-to-date versions of regulations, which are available at NRC's Web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/ in the "Electronic Reading Room"; printed copies available from the U.S. Government Printing Office (GPO) are updated annually.

- 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 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 40, "Domestic Licensing of Source Material"
- 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" (for pacemaker devices)
- 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

  Part 71 requires that licensees or applicants who transport licensed material or who may offer such material to a carrier for transport must comply with the applicable DOT requirements in 49 CFR Parts 170 through 189.

- 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."

Availability: Copies of the above documents may be obtained by calling the GPO order desk in Washington, DC at (202) 512-1800, or online at http://www.bookstore.gpo.gov. A single copy of the above documents may be requested from NRC's Regional Offices (see Figure 2.1 for addresses and telephone numbers). In addition, 10 CFR Parts 1-199 can be found on NRC's Web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Note that NRC and all other Federal agencies publish amendments to their regulations in the *Federal Register*.

5 HOW TO FILE

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

5.1 PREPARING AN APPLICATION

Applicants for an NRC materials license should do the following:

- Use the most recent guidance in preparing an application, including Appendix AA of this document, if appropriate;
- Complete NRC Form 313 (Appendix A), 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;
- Complete the appropriate NRC Form 313A series of forms (Appendix B) to document training and experience, if electing to complete this optional form;
- Provide sufficient detail for 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 Form 313A series of forms or Appendix C, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- If submitted, proprietary information and other sensitive information must be clearly identified (see Section 5.2 below);
- Submit an original, signed application and one copy; and
- Retain one copy of the license application for future reference.

Applications must be signed by the applicant's or licensee's management as required by 10 CFR 35.12(a); see Section 8.31, "Certification."

5.2 IDENTIFYING AND PROTECTING SENSITIVE INFORMATION

All licensing applications, except for portions containing sensitive information, will be made available for review in NRC's Public Document Rooms and electronically at the Public Electronic Reading Room. More information on the Public Electronic Reading Room is available at www.nrc.gov.

Several types of sensitive information need to be identified, marked, and protected against unauthorized disclosure to the public. Key examples are as follows:

- Proprietary Information/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.
- Private information: Personal information about employees or other individuals should not be submitted unless specifically requested by 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."
- Security-Related Information: Following the events of September 11, 2001, the NRC changed its procedures to avoid release of information that terrorists could use to plan or execute an attack against facilities or citizens in the United States. 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, security-related sensitive information in an application should be marked as specified in Regulatory Issue Summary 2005-31, available at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf. Additional information on procedures and any updates are available at http://www.nrc.gov/reading-rm/sensitive-info.html.

5.3 PAPER FORMAT AND ELECTRONIC FORMAT

The NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. The NRC will continue to accept paper applications. However, these will be scanned through an optical character reader (OCR) to convert them to electronic format. To ensure a smooth transition to electronic applications, applicants should:

- Submit printed or typewritten – not handwritten – text on smooth, crisp paper that will feed easily into the scanner;
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman;
- Use 12-point or larger font;
- Avoid stylized characters such as script, italic, etc.;
- Use print that is clear and sharp;
- Ensure that there is high contrast between the ink and paper (black ink on white paper is best).

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via electronic media and through the Internet. Additional filing instructions will be provided as NRC implements these new mechanisms. When the electronic process becomes available, applicants may file electronically instead of on paper.

6 WHERE TO FILE

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

Applicants who wish to possess or use licensed material in any State or U.S. territory or possession subject to NRC jurisdiction must file an application with an NRC Regional Office for the locale in which the material will be possessed and/or used. Federally recognized Indian tribes must also file applications with the appropriate NRC Regional Office. Section 8.37 and Appendix V provide further information on filing procedures for applicants who wish to perform mobile medical services. Figure 2.1 shows NRC's four Regional Offices and their respective areas for licensing purposes, and identifies Agreement States. Note that all materials applications are submitted to Regions I, III, or IV. All applicants for materials licenses located in Region II's geographical area should send their applications to Region I.

In general, applicants for possession or use of byproduct material in an Agreement State must file an application with the Agreement State, not NRC. However, if work will be conducted at Federally controlled sites in Agreement States, applicants must first determine the jurisdictional status of the land in order to determine whether NRC or the Agreement State has regulatory authority. Section 2, "Agreement States," has additional information.

7 LICENSE FEES

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

Application fees are required for new license applications and some other licensing actions. Each application for which a fee is specified must be accompanied by the appropriate fee. Refer to 10 CFR 170.31 to determine the amount of the fee. The NRC will not issue the licensing action before it receives the appropriate payment. Consult 10 CFR 170.11 for information on exemptions from fees. Once technical review has begun, no fees will be refunded. Application fees will be charged regardless of NRC's disposition of an application or the withdrawal of an application.

Most NRC licensees are also subject to annual fees; refer to 10 CFR 171.16. 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."

Direct all questions about NRC fees or completion of Item 12 of NRC Form 313 (see Appendix A) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554 (or toll free at (800) 368-5642, extension 7554). Information about fees may also be obtained by calling this NRC toll-free number or by sending an e-mail to fees@nrc.gov.

Enter the fee category and the amount of the fee enclosed with the application on NRC Form 313.