
Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating 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, Vol. 9, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” dated October 2002, is the ninth program-specific guidance document developed for the new process and 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 applicants for licenses for the medical use of byproduct material in preparing their license applications. In particular, it describes the types of information needed to complete NRC Form 313, “Application for Material License” and NRC Form 313A, “Training and Experience and Preceptor Statement.” 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 completed licenses for some different types of medical uses of byproduct materials; and (3) examples of the types of supporting documents, such as implementing procedures, that may need to be prepared by applicants. 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 for the implementation by licensees that may be specific to their needs while meeting the regulatory requirements. By supplying examples, 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.

Volume 9 of NUREG-1556 provides guidance for licensure under revised Title 10, Part 35, “Medical Use of Byproduct Material.” It is also available for use by Agreement States and will combine and supercede guidance found in the documents listed below:

- Regulatory Guide (RG) 10.8, Revision 2, “Guide for the Preparation of Applications for Medical Use Programs;”

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- 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.”

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FOREWORD

This report, NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses,” dated October 2002, is one of twenty 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	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Industrial Radiography Licenses	Final Report
3	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 Irradiator Licenses	Final Report
6	Program-Specific Guidance About 10 CFR Part 36 Irradiator 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	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
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses	Final Report
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses	Final Report
15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses	Final Report
16	Program-Specific Guidance About Licenses Authorizing Distribution To General Licensees	Final Report
17	Program-Specific Guidance About Licenses for Special Nuclear Material of Less Than Critical Mass	Final Report
18	Program-Specific Guidance About Service Provider Licenses	Final Report
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

A team composed of NRC staff and staff from state departments of health prepared the initial draft of this document, which was published for public comment in August 1998. The NRC staff members were P.A. Lanzisera, A.R. Jones, R.G. Gattone, R.D. Reid. A revised draft was

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published in March 2002. Appendix Z of the March 2002 draft included a summary of comments on the 1998 draft and NRC responses. The NRC held two public workshops, on April 25 and April 30, 2002, to receive stakeholder comments on the March 2002 draft. The NRC also received written public comments during a 60-day comment period (April 5 to June 4, 2002). A summary and analysis of both sets of comments will be published as a separate document: Appendix BB to NUREG-1556 Vol. 9. This document will be available as noted inside the front cover of this document. Appendix BB to NUREG-1556, Vol. 9 will also be available on the NRC's web site <<http://www.nrc.gov>> in the Electronic Reading Room.

NRC staff is also producing a set of Questions and Answers (Q&As) on implementation of Part 35. Applicants may review the Q&As posted on the NRC's web page on the Medical Use of Byproduct Material <<http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html>> as another source of guidance about implementation of revised Part 35.

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 the public workshops and 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.

NUREG-1556, Vol. 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.

Complementary guidance on inspection procedures for inspections of medical use licensees is contained in the following documents available at the NRC's web page on the Medical Use of Byproduct Material <<http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.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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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	Becquerel
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
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

ABBREVIATIONS

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
NaI(Tl)	sodium iodide (thallium doped)
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
OCFO	Office of the Chief Financial Officer
OCR	optical character reader
OMB	Office of Management and Budget
OSL	optically stimulated luminescence dosimeters
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
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'Unites)

ABBREVIATIONS

Sr-90	strontium-90
SSDR	Sealed Source and Device Registration
std	standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
Xe-133	xenon-133
μCi	microcurie
%	percent

1 OVERVIEW

1.1 PURPOSE OF REPORT

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

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

- (1) Preparation of a license application using NRC Form 313 "Application for Material License," including supplemental NRC Form 313A, "Training and Experience and Preceptor Statement;" and
- (2) NRC's 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 35.300-390);
- Use of sources for manual brachytherapy (see Subpart F, 10 CFR 35.400-490);
- Use of sealed sources for diagnosis (see Subpart G, 10 CFR 35.500);
- 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 Subpart K, 10 CFR 35.1000).

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.

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

NUREG-1556 - Volume 9, 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				•	•	•	•
8.7 Recordkeeping for Decommissioning and Financial Assurance	•	•	•	•	•	•	•
8.8 Purpose(s) for which Licensed Material Will Be Used	•	•	•	•	•	•	•
8.9 Individual(s) Responsible for Radiation Safety Program and their Training and Experience	•	•	•	•	•	•	•
8.10 Radiation Safety Officer (RSO)	•	•	•	•	•	•	•
8.11 Authorized User (AU)	•	•	•	•	•	•	•
8.12 Authorized Nuclear Pharmacist	•	•	•				•
8.13 Authorized Medical Physicist (AMP)				•		•	•
8.14 Facilities and Equipment	•	•	•	•	•	•	•
8.15 Facility Diagram	•	•	•	•	•	•	•
8.16 Radiation Monitoring Instruments	•	•	•	•	•	•	•
8.17 Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Material	•	•	•				•
8.18 Therapy Unit - Calibration and Use				•		•	•
8.19 Other Equipment and Facilities	•	•	•	•	•	•	•
8.20 Radiation Protection Program	•	•	•	•	•	•	•
8.21 Safety Procedures and Instructions						•	•
8.22 Occupational Dose	•	•	•	•	•	•	•
8.23 Area Surveys	•	•	•	•	•	•	•
8.24 Safe Use of Unsealed Licensed Material	•	•	•				•
8.25 Spill Procedures	•	•	•	•	•		•

Table 1.1 (continued)

NUREG-1556 - Volume 9, Section	Type of Use						
	100	200	300	400	500	600	1000
8.26 Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						•	•
8.27 Minimization of Contamination	•	•	•	•	•	•	•
8.28 Waste Management	•	•	•	•	•	•	•
8.29 Fees	•	•	•	•	•	•	•
8.30 Certification	•	•	•	•	•	•	•
PROGRAM-RELATED GUIDANCE - NO RESPONSE FROM APPLICANTS ON NRC FORM 313							
8.31 Safety Instruction for Individuals Working In or Frequenting Restricted Areas	•	•	•	•	•	•	•
8.32 Public Dose	•	•	•	•	•	•	•
8.33 Opening Packages	•	•	•	•	•	•	•
8.34 Procedures for Administrations Requiring Written Directive			•	•		•	•
8.35 Patient or Human Research Subject Release			•	•			•
8.36 Mobile Medical Service	•	•	•	•	•	•	•
8.37 Audit Program	•	•	•	•	•	•	•
8.38 Operating and Emergency Procedures	•	•	•	•	•	•	•
8.39 Material Receipt and Accountability	•	•	•	•	•	•	•
8.40 Ordering and Receiving	•	•	•	•	•	•	•
8.41 Sealed Source Inventory	•	•	•	•	•	•	•
8.42 Records of Dosages and Use of Brachytherapy Source	•	•	•	•			•
8.43 Recordkeeping	•	•	•	•	•	•	•
8.44 Reporting	•	•	•	•	•	•	•
8.45 Leak Tests	•	•	•	•	•	•	•
8.46 Safety Procedures for Treatments When Patients are Hospitalized			•	•		•	•
8.47 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).

OVERVIEW

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).

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 of Noncompliance.”
- This report does not address the commercial aspects of manufacturing, distribution, and service of sources containing byproduct material in devices. NUREG-1556, Volumes 12, 13, and 18 provide additional licensing guidance.
- 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 AA 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 at 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 through 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.

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;
- Appendix D describes how to fill out NRC Form 313A;
- 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 AA provide reference materials; and
- Appendix BB, to be published as a separate document, will provide a summary of public comments on drafts and NRC responses.

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.) Furthermore, 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.

This NUREG not only updates the information and guidance provided in Revision 2 of RG 10.8, “Guide for the Preparation of Applications for Medical Use Programs,” but also revises the format in which it is presented to assist with the preparation of a medical use license. Revision 2 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).

1.2 TYPES OF LICENSES

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 10 CFR Part 35 and who is identified as an authorized user on an NRC or Agreement State license, on a permit issued by a Commission master material licensee or a Commission master material permittee that is authorized to permit the medical use of byproduct material; a permit issued by a Commission or Agreement State broad scope licensee authorized to permit the medical use of byproduct material that is authorized to permit the medical use of byproduct material (10 CFR 35.2).

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).

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 may not involve internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals (see Section 1.2.4).

NRC usually issues a single byproduct material 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.

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

Applicants should study this report, related guidance, and all applicable regulations carefully before completing NRC Forms 313 and 313A. NRC expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to NRC Form 313. When necessary, 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, 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

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 physician 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 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, 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. NUREG-1556, Vol. 11, offers additional guidance to applicants for a specific license of broad scope.

1.2.3 RESEARCH INVOLVING HUMAN SUBJECTS

10 CFR 35.2 defines “medical use” to include 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.

NRC limits possession to a total of 200 microcuries 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 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. 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 IS REASONABLY ACHIEVABLE (ALARA)” CONCEPT

10 CFR 20.1101, “Radiation Protection Programs,” states 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: 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 (WD) PROCEDURES

10 CFR 35.41 requires certain medical use licensees 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 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;
- 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 dates of the change(s). Otherwise, prior NRC written consent must be given prior to 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, Vol. 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, Vol. 15, identifies the information to be provided about transferring control.

1.3.4 TIMELY NOTIFICATION OF BANKRUPTCY PROCEEDINGS

Immediately following 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. 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). 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, Vol. 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses," dated November 2000.

1.4 OMB CLEARANCES

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

2 AGREEMENT STATES

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 who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that state for guidance on preparing an application. These applications are filed with state officials, not with NRC.

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

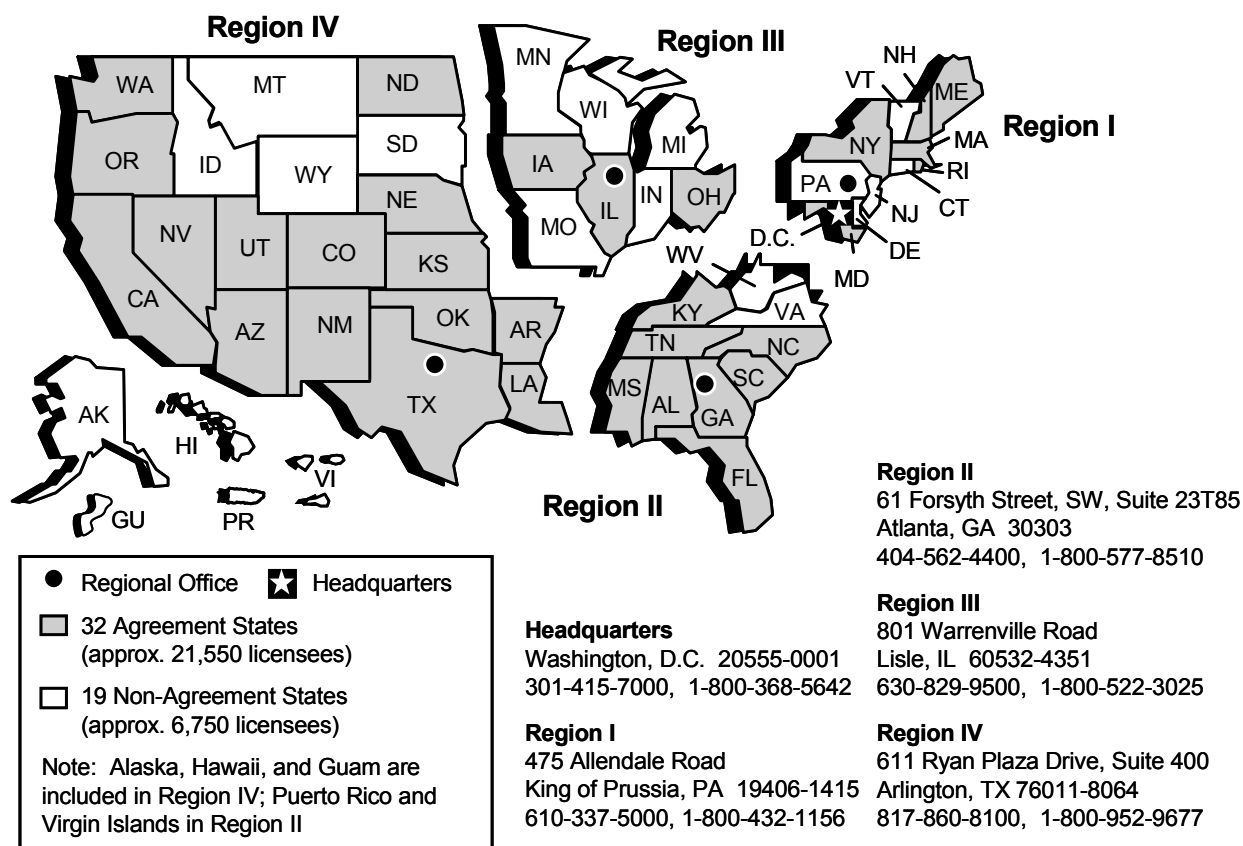
In the special situation of work at Federally-controlled sites in Agreement States, it is necessary to know the jurisdictional status of the land to determine whether NRC or the Agreement State has regulatory authority. NRC has regulatory authority over land determined to be under “exclusive Federal jurisdiction,” while the Agreement State has jurisdiction over non-exclusive Federal jurisdiction land. Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. NRC recommends that applicants and licensees ask their local contacts 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, so that licensees can 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 from NRC upon request.

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 regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	NRC

Locations of NRC Offices and Agreement States



* The 19 Non-Agreement States include the District of Columbia and three states that have filed letters of intent: Minnesota, Pennsylvania, and Wisconsin.

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

Reference: The identity of Agreement States shown in the map in Figure 2.1 may change over time. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from NRC’s Regional Offices. NRC Office of State and Tribal Programs (OSTP) also provides the current list of Agreement States at web site <<http://www.hsrdo.nrc.gov/nrc>>, under “Directories” and then under “State Program Directors.”

The All Agreement States Letter, SP-96-022, dated February 16, 1996, is available by calling NRC’s toll-free number at (800) 368-5642 and asking for OSTP. OSTP also provides this information at web site <<http://www.hsrdo.nrc.gov/nrc>>, under “NRC-State Letters.”

3 MANAGEMENT RESPONSIBILITY

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

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).

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

“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), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

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

- “General Statement of Policy and Procedures for NRC Enforcement Actions,” NUREG-1600;
- NRC Inspection Manual, Chapter 2800 “Materials Inspection Program;” and

MANAGEMENT RESPONSIBILITY

- 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.”

For availability of these documents see the Notice of Availability on the inside front cover of this report. NUREG-1600 is also available at NRC’s web site, <<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1600/>>.

4 APPLICABLE REGULATIONS

Regulations applicable to medical use licensees are listed below. Applicants should be sure to refer to 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 are updated annually.

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

- 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 requirements of the DOT that are found 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"

APPLICABLE REGULATIONS

- 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: The Notice of Availability on the inside front cover of this report provides information on how to request copies of the above documents. Applicants also may call the Government Printing Office (GPO) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, Code of Federal Regulations, Parts 0-50 and 51-199, from the GPO, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. You may also contact the GPO electronically through its web site at <<http://www.gpo.gov>>. Request single copies of the above documents from NRC’s Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers).

NRC publishes amendments to its regulations in the *Federal Register*. These updates may be requested from the appropriate Regional Office before they are included in the bound version of Title 10. Title 10 is also available on NRC’s web site at <<http://www.nrc.gov/reading-rm/doc-collections/cfr/>>.

5 HOW TO FILE

5.1 PREPARING AN APPLICATION

Applicants for an NRC materials license should do the following:

- Be sure to use the most recent guidance in preparing an application;
- 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 NRC Form 313A (Appendix B) to document training and experience;
- 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 NRC Form 313A and 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;
- If submitted, proprietary information must be clearly identified;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application and one copy; and
- Retain one copy of the license application for future reference.

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

Applications must be signed by the applicant's or licensee's management as required by 10 CFR 35.12(a), see Section 8.30, "Certification."

All license applications will be made available for review by the general public in NRC's Public Document Rooms and electronically at the Public Electronic Reading Room. For more information on the Public Electronic Reading Room, visit <http://www.nrc.gov>. If it is necessary to submit proprietary information, follow the procedure in 10 CFR 2.790. Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, and radiation dose information, should not be submitted unless specifically requested by NRC.

NRC's new licensing process will be faster and more efficient, in part, through acceptance and processing of electronic applications at some future date. 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.;
- Be sure the print is clear and sharp;
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5.2 ELECTRONIC APPLICATION

As the electronic licensing process develops, it is anticipated that NRC may provide mechanisms for filing applications via diskettes or CD-ROM 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

Applicants that 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 NRC Regional Office for the locale in which the material will be possessed and/or used. Section 8.36 and Appendix V provide further information on filing procedures for applicants that 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.

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

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

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. 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.

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. 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 (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 415-7554). Information about fees may also be obtained by calling this NRC toll-free number or by sending e-mail to fees@nrc.gov.

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

8 CONTENTS OF AN APPLICATION

This section explains, item by item, the information the applicants must provide on NRC Form 313 (see Appendix A) and NRC Form 313A (see Appendices B and D). The information needed to complete Items 5 through 11 on Form 313 describes the applicant's proposed 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.

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

If a particular part of a section does not apply, simply note "N/A" for "not applicable." If a particular section applies, but a procedure does not have to be developed, simply note "N" for "no response required." N/A, N, or short sentence responses to Items 5 through 10 should run consecutively on one or more sheets separate from responses provided on NRC Form 313. Lengthy responses should be appended as attachments.

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

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

8.1 ITEM 1: LICENSE ACTION TYPE

THIS IS AN APPLICATION FOR (Check appropriate item)

Type of Action	License No.
<input type="checkbox"/> A. New License	Not Applicable
<input type="checkbox"/> B. Amendment to License No.	XX-XXXXXX-XX
<input type="checkbox"/> C. Renewal of License No.	XX-XXXXXX-XX

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

Check A if the application is for a new license.

Check B for an amendment¹ to an existing license, and provide license number.

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

8.2 ITEM 2: APPLICANT’S NAME AND MAILING ADDRESS

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

List the legal name of the applicant’s corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity.

Provide the mailing address where correspondence should be sent. A post office box number is an acceptable mailing address. See Section 8.30, “Certification.”

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

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

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

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

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

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

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

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

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

8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

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

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

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

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

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

8.5 ITEM 5: RADIOACTIVE MATERIAL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8.6 ITEM 5: SEALED SOURCES AND DEVICES

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

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

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

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

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

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

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

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

8.7 ITEM 5: RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

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

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

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

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

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

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

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

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

Determining Need for Financial Assurance for Decommissioning

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONTENTS OF AN APPLICATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)

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

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

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

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

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

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

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

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

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

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

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

Response from Applicant: Provide the following:

- Name of the proposed RSO.

AND

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

OR

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

OR

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

OR

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

AND

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

AND

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

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).
- The licensee must notify NRC within 30 days if an RSO permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14 and to request an amendment to change an RSO under 10 CFR 35.13.
- An AU, AMP, or ANP may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities (see 10 CFR 35.50(c)) and, as required by 10 CFR 35.24(g), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subpart B or J are met. If the training and experience do not appear to meet the criteria in either Subpart B or J, NRC may request additional information from the applicant or may request the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI) in evaluating such training and experience.
- The training and experience for the RSO of a medical use broad scope license will be reviewed using the above criteria as well as criteria in 10 CFR Part 33.

8.11 ITEM 7: AUTHORIZED USERS (AUs)

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

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

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

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

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

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

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

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

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

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

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

Response from Applicant: Provide the following:

- Name of the proposed AU and uses requested.

AND

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

OR

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

OR

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

OR

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

AND

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

AND

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

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).
- Licensees must notify NRC within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.
- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet the 10 CFR Part 35 criteria, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

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

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)

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

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

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

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

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

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

Response from Applicant: Provide the following:

- Name of the proposed ANP.

AND

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

OR

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

OR

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

AND

- Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency
 - sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or
 - sufficient to independently operate a nuclear pharmacy (10 CFR 35.980).

AND

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

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).
- Licensees must notify NRC within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.

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- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subparts B and J are met. If the training and experience do not appear to meet the criteria in Subparts B and J, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP)

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

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

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

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

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

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

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

OR

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

OR

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

OR

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

AND

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

AND

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

Notes:

- NRC Form 313A may be used to document training and experience (see Appendix B; note that former NRC Form 313B, used for preceptor statements, was incorporated in NRC Form 313A in 2002, and use of NRC Form 313B has been discontinued).
- Licensees must notify NRC within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under 10 CFR 35.14.
- Subpart J will be retained in Part 35 until October 24, 2004, and, until then, licensees may follow this provision of the rule to meet training and experience requirements.
- Descriptions of training and experience will be reviewed using the criteria listed above. NRC will review the documentation to determine if the applicable criteria in Subparts B and J are met. If the training and experience do not appear to meet the criteria in Subparts B and J, NRC may request additional information from the applicant or may request the assistance of its ACMUI in evaluating such training and experience.

8.14 ITEM 9: FACILITIES AND EQUIPMENT

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

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

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in 10 CFR 30.33(a)(2), 35.12(b)(1), and 35.18(a).

Applications will be approved if, among other things, “the applicant’s proposed equipment and facilities are adequate to protect health and minimize danger to life or property.” Facility and equipment requirements depend on the scope of the applicant’s operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

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

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

8.15 ITEM 9: FACILITY DIAGRAM

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

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

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

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

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

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

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

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

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

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

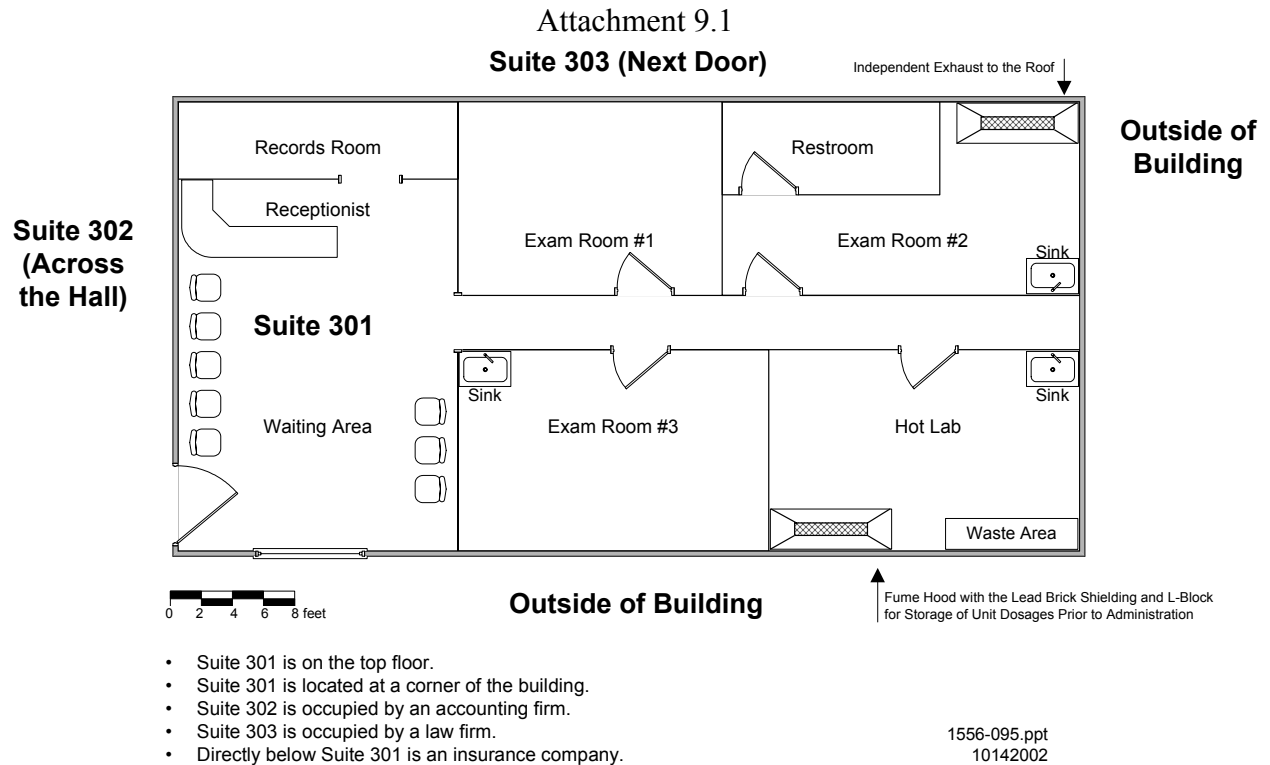


Figure 8.1: Facility Diagram for Nuclear Medicine Suite

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

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

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

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

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

- "For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall."
- "For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall."

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

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

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

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

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

8.16 ITEM 9: RADIATION MONITORING INSTRUMENTS

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

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

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

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

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

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

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

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

Response from Applicant: Provide the following:

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

AND/OR

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

AND

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

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

AND

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

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

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

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

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

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

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

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

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

- If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72, (and does not split, combine, or otherwise modify unit dosages) the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider’s dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- If the licensee performs direct measurements of dosages in accordance with 10 CFR 35.63 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

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

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

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

Response from Applicant: If applicable, provide the following:

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

8.18 ITEM 9: THERAPY UNIT — CALIBRATION AND USE

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.432; 10 CFR 35.630; 10 CFR 35.632; 10 CFR 35.633; 10 CFR 35.635; 10 CFR 35.642; 10 CFR 35.643; 10 CFR 35.645; 10 CFR 35.2432; 10 CFR 35.2630; 10 CFR 35.2632; 10 CFR 35.2642; 10 CFR 35.2643; 10 CFR 35.2645.

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

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

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

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

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

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

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

Full calibrations must be performed before first medical use², whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 10 CFR 35.632, 10 CFR 35.633, and 10 CFR 35.635. Manual brachytherapy sources must be calibrated only initially, prior to use.

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

Response from Applicant: Provide the following:

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

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

References:

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

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

8.19 ITEM 9: OTHER EQUIPMENT AND FACILITIES

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

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

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

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

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

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

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

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

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

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

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
 - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;

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- The “source safe and radiation present” signal should also be self-testing. If a “source not safe” input is received without a corresponding “radiation present” signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;
- The audible alarm should be sufficiently loud to be clearly heard by the facility’s responsible device/patient monitoring staff at all times; and
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

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

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

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

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

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; and

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

8.20 ITEM 10: RADIATION PROTECTION PROGRAM

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

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

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

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

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

8.21 ITEM 10: SAFETY PROCEDURES AND INSTRUCTIONS

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

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

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

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

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

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

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

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.
- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove

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

- Giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). **Note:** If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

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

References: None.

8.22 ITEM 10: OCCUPATIONAL DOSE

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

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

Criteria: Applicants must do either of the following:

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

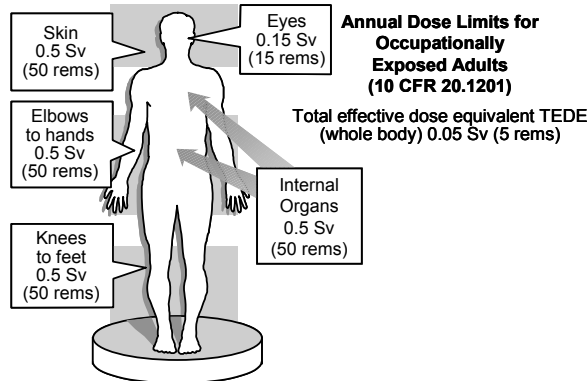


Figure 8.2 Annual Occupational Dose Limits for Adults

OR

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

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

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

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

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

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

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

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

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

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

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

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

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

Note: The definition of “shallow-dose equivalent” in 10 CFR 20.1003 was revised, effective June 4, 2002³ to change the area for averaging dose to skin from 1 square centimeter to 10 square centimeters (see NRC Regulatory Issue Summary 2002-10, “Revision of the Skin Dose Limit in 10 CFR Part 20”).

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

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

OR

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

³ 67 FR 16298

References:

- National Institute of Standards and Technology (NIST) Publication 810, “National Voluntary Laboratory Accreditation Program Directory,” is published annually and is available for purchase from GPO and on the Internet at <<http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm>>.
- Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <<http://www.ansi.org>>.
- NUREG/CR-4884, “Interpretation of Bioassay Measurements;”
- RG 8.9, Revision 1, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program;” Regulatory Issue Summary 2002-06;
- “Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;”
- NRC Regulatory Issue Summary 2002-06, “Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;”
- NRC Regulatory Issue Summary 2002-10, “Revision of the Skin Dose Limit in 10 CFR Part 20.”

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

8.23 ITEM 10: AREA SURVEYS

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

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 per year (100 millirem/year) and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour from licensed operations;

- Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 10 CFR 20.1201; and
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 10 CFR 20.1101.

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

There are many different kinds of surveys performed by licensees:

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

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

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas;

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- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; and
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

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

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

- Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted; and
- Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

In addition, licensees should also consider the following:

- The therapy patient's bed linens before removing them from the patient's room;
- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check);
- All trash exiting the patient's room; and
- Areas of public access in and around the patient's room.

Response from Applicant: Provide the following statement:

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

8.24 ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL

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

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/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

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

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

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

Response from Applicant: Provide the following statement:

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

8.25 ITEM 10: SPILL PROCEDURES

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

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

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

Response from Applicant: Provide the following statement:

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

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

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

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

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

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

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

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

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

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

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

AND

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

AND

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

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

8.27 ITEM 10: MINIMIZATION OF CONTAMINATION

Regulations: 10 CFR 20.1406; 10 CFR 35.67.

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

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

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

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

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

8.28 ITEM 11: WASTE MANAGEMENT

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

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));
- Decay-in-storage;
- Release in effluents within the limits in 10 CFR 20.1301; or
- As authorized under 10 CFR 20.2002 through 20.2005.

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

- Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with 10 CFR 20.2001(b), 10 CFR 20.2006, or in applicable regulations in 10 CFR Parts 30 or 61. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.
- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.
- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under 10 CFR 31.11 is exempt from waste disposal regulations in 10 CFR Part 20, as set forth in 10 CFR 31.11(f). Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under 10 CFR 20.1302 and 20.2003, respectively.
 - Regulations for disposal in the sanitary sewer appear in 10 CFR 20.2003. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see 10 CFR 20.2003(b)).
 - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix B to 10 CFR Part 20. These limits apply at the boundary of the restricted area.
 - Liquid scintillation-counting media containing 1.85 kBq (0.05 μ Ci) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (10 CFR 20.2005(a)(1)).

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- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with 10 CFR 20.2004. Contact the appropriate NRC Regional Office for guidance on treatment or disposal of material by incineration.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Item 8.16 (Facility Diagram):
 - A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer’s specifications, annotated sketches, photographs);
 - The types, quantities, and concentrations of the waste to be compacted;
 - An analysis of the potential for airborne release of radioactive material during compaction activities;
 - The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;
 - Methods used to monitor worker breathing zones and/or exhaust systems;
 - The types and frequencies of surveys that will be performed for contamination control in the compactor area;
 - The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompactable waste, and examining containers for defects.

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

Response from Applicant: Provide the following statement:

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

8.29 ITEM 12: FEES

Regulations: 10 CFR 170.31.

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

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

8.30 ITEM 13: CERTIFICATION

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

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

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

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

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

8.31 SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

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

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

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

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

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

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

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

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

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

Response from Applicant: No response is necessary.

8.32 PUBLIC DOSE

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

Criteria: Licensees must do the following:

- Ensure that licensed material will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in 1 year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour from licensed operations.
- Ensure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from these emissions.
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

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

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

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

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

The definition of “public dose” in 10 CFR 20.1003 does not include doses received due to exposure to patients released in accordance with 10 CFR 35.75. Dose to members of the public in waiting rooms was addressed in Informational Notice (IN) 94-09.⁴ The provisions of 10 CFR 20.1301(a) should not be applied to radiation received by a member of the general public from patients released under 10 CFR 35.75. If a patient is released pursuant to 10 CFR 35.75, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 0.02mSv (2mrem) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in 10 CFR 35.75.

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

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

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

Response from Applicant: No response required.

8.33 OPENING PACKAGES

Regulations: 10 CFR 20.1906; 10 CFR 20.2103.

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

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

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.

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

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

Response from Applicant: No response required.

8.34 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

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

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

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

Response from Applicant: No response required.

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

8.35 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

Regulations: 10 CFR 35.75; 10 CFR 35.2075.

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

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

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

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

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

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

Response from Applicant: No response required.

8.36 MOBILE MEDICAL SERVICE

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

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

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

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

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

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

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

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

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

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

Response from Applicant: No response required.

8.37 AUDIT PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102.

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

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

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

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

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

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

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

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

Response from Applicant: No response is necessary.

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

8.38 OPERATING AND EMERGENCY PROCEDURES

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

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.

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

- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.21);
- Steps to take if a therapy patient undergoes emergency surgery or dies.

AND

The licensee should consider the following:

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage);
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).
- When developing the procedures described above, the licensee is reminded that 10 CFR 20.1101(b) requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- When receiving and using byproduct material, the licensee is reminded that it must be licensed to possess the byproduct material and that the radioactive material must be secured (or controlled) and accounted for at all times.

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

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

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

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

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

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

Response from Applicant: No response is necessary.

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

8.39 MATERIAL RECEIPT AND ACCOUNTABILITY

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

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

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

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

Response from Applicant: No response is necessary.

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

8.40 ORDERING AND RECEIVING

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

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

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

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

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

Response from Applicant: No response is necessary.

8.41 SEALED SOURCE INVENTORY

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

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

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

Response from Applicant: No response is necessary.

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

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

8.42 RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

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

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

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

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

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

PROGRAM-RELATED GUIDANCE

- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μ Ci);
- Date and time of dosage determination; and
- Name of the individual who determined the dosage.

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

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

- Ratio of the measurements expressed as kBq (μ Ci) of molybdenum-99 per MBq (mCi) of technetium-99m;
- Date and time of the measurement; and
- Name of the individual who made the measurement.

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

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

Response from Applicant: No response is necessary.

8.43 RECORDKEEPING

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

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

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

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

A table of recordkeeping requirements appears in Appendix X.

Response from Applicant: No response is necessary.

8.44 REPORTING

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

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

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

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

A table of reporting requirements appears in Appendix Y.

Response from Applicant: No response is necessary.

8.45 LEAK TESTS

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

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

Discussion: Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with 10 CFR 35.67.

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

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

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

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

Response from Applicant: No response is necessary.

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

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

*If possess sealed sources under 35.65

8.46 SAFETY PROCEDURES FOR TREATMENTS WHEN PATIENTS ARE HOSPITALIZED

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

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

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

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

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

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

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: 10 CFR 35.315(a) allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (Note: 10 CFR 35.415 allows for a room shared with another brachytherapy patient);
- Visibly post a “Radioactive Materials” sign on the patient’s room and note on the door or in the patient’s chart where and how long visitors may stay in the patient’s room (10 CFR 35.315 and 10 CFR 35.415);
- Either monitor material and items removed from the patient’s room (e.g., patient linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished

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

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

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

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

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

Response from Applicant: No response is necessary.

8.47 TRANSPORTATION

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

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

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

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

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

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

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

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

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

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

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

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

References:

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

PROGRAM-RELATED GUIDANCE

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

9 AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: 10 CFR 35.13.

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

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

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

- Receipt or use of byproduct material for a type of use permitted by Part 35, but not authorized on the licensee's current Part 35 license;
- Permitting anyone to work as an AU, AMP, or ANP, unless the individual meets one of the exceptions listed in 10 CFR 35.13(b) (Supply information required to document training and experience on NRC Form 313A for change or addition of AU, AMP, ANP, or RSO);
- Changing the RSO;
- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than currently authorized on the NRC license;
- Changing an area or address of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 10 CFR 35.200; and
- Revising procedures required by 10 CFR 35.610, 35.642, 35.643, and 35.645, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the NRC regional materials licensing staff.

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

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

10 APPLICATIONS FOR EXEMPTIONS

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

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

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

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

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

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

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

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

11 TERMINATION OF ACTIVITIES

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

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

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

- Notify NRC, in writing, within 60 days of:
 - the expiration of its license;
 - a decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
 - a decision to permanently cease licensed activities in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements;
 - no principal activities having been conducted at the entire site under the license for a period of 24 months; and
 - no principal activities having been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to NRC requirements.
- Submit a decommissioning plan, if required by 10 CFR 30.36(g);
- Conduct decommissioning, as required by 10 CFR 30.36(h) and (j); and
- Submit, to the appropriate NRC Regional Office, a completed NRC Form 314, "Certificate of Disposition of Materials," (or equivalent information) and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the appropriate NRC Regional Office. If licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

TERMINATION OF ACTIVITIES

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

- NUREG-1727, "NMSS Decommissioning Standard Review Plan," dated September 2000.
- NUREG/BR-0241, "NMSS Handbook for Decommissioning Fuel Cycle and Materials Licenses," dated March 1997, contain the current regulatory guidance concerning decommissioning of facilities and termination of licenses.
- Appendix B of NUREG/BR-0241 contains a comprehensive list of NRC's decommissioning regulations and guidance. NUREG-1727 contains a list of superceded guidance; however, due to ongoing revisions, applicants are encouraged to consult with NRC staff regarding updates of decommissioning guidance.
- NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)," dated December 1997, should be reviewed by licensees who have large facilities to decommission.
- An acceptable computer code for calculating screening values to demonstrate compliance with the unrestricted dose limits is DandD, Version 2.1.0, (McFadden and others, 2001).
- NUREG-1727 includes a table (Table C2.2) of acceptable license termination screening values of common beta/gamma radionuclides for building surface contamination. NUREG-1727 also contains methods for conducting site-specific dose assessments for facilities with contamination levels above those in the table.

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

References:

- Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC's Regional Offices. (See Figure 2.1 for addresses and telephone numbers.)
- McFadden, K., D.A. Brosseau, W.A. Beyeler, and C.D. Updegraff, "Residual Radioactive Contamination from Decommissioning - User's Manual DandD Version 2.1," NUREG/CR-5512, Volume 2, U.S. Nuclear Regulatory Commission, Washington, DC, April 2001.

APPENDICES

APPENDICES A-H
FORMS AND SAMPLES

APPENDIX A

NRC Form 313 “Application for Material License”

<p>NRC FORM 313 (8-1999) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40</p> <p style="text-align: center;">U. S. NUCLEAR REGULATORY COMMISSION</p> <p style="text-align: center; font-size: 1.2em;">APPLICATION FOR MATERIAL LICENSE</p>	<p>APPROVED BY OMB: NO. 3150-0120</p> <p style="text-align: right; font-size: 0.8em;">EXPIRES: 10/10/31/2005</p> <p style="font-size: 0.8em;">Estimated burden per response to comply with this mandatory information collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-8 EB), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</p>				
<p>INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.</p>					
<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p style="font-size: 0.8em;">DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS U. S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:</p> <p style="font-size: 0.8em;">LICENSING ASSISTANT SECTION NUCLEAR MATERIALS SAFETY BRANCH U. S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415</p> <p>ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:</p> <p style="font-size: 0.8em;">SAM NUNN ATLANTA FEDERAL CENTER U. S. NUCLEAR REGULATORY COMMISSION, REGION II 61 FORSYTH STREET, S.W., SUITE 23T65 ATLANTA, GEORGIA 30303-8931</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p style="font-size: 0.8em;">MATERIALS LICENSING SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION III 801 WARRENVILLE RD. LISLE, IL 60532-4351</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:</p> <p style="font-size: 0.8em;">NUCLEAR MATERIALS LICENSING SECTION U. S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 76011-8064</p>				
<p>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.</p>					
<p>1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i></p> <p><input type="checkbox"/> A NEW LICENSE</p> <p><input type="checkbox"/> B AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include Zip code)</i></p>				
<p>3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p>TELEPHONE NUMBER _____</p>				
<p>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.</p>					
<p>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.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>				
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS</p>				
<p>9. FACILITIES AND EQUIPMENT</p>	<p>10. RADIATION SAFETY PROGRAM.</p>				
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSEE FEES <i>(See 10 CFR 170 and Section 170.31)</i></p> <table style="width:100%; border: none;"> <tr> <td style="border: none;">FEE CATEGORY _____</td> <td style="border: none;">AMOUNT ENCLOSED \$ _____</td> </tr> </table>	FEE CATEGORY _____	AMOUNT ENCLOSED \$ _____		
FEE CATEGORY _____	AMOUNT ENCLOSED \$ _____				
<p>13. CERTIFICATION. <i>(Must be completed by applicant)</i> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.</p> <p>THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</p> <p>WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.</p>					
<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p>	<p>SIGNATURE _____</p> <p>DATE _____</p>				
<p>FOR NRC USE ONLY</p>					
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY _____				DATE _____	

APPENDIX B

NRC Form 313A

“Training and Experience and Preceptor Statement”

NRC FORM 313A (10-2002)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2005	
TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT			
PART I -- TRAINING AND EXPERIENCE			
<p>Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.</p>			
1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)			
2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed			
3. CERTIFICATION			
Specialty Board	Category	Month and Year Certified	
<i>Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.</i>			
4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)			
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology			
Chemistry of Byproduct Material for Medical Use			
OTHER			

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

NRC FORM 313A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME TRAINING

- YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision
- N/A of _____ the RSO for License No. _____.

8. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of
- N/A _____ who meets requirements for Authorized Medical Physicists; and
- YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____
- N/A modality(ies) under the supervision of _____ who meets requirements for Authorized Medical Physicists for _____ modality(ies).

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

- A. Name of Supervisor _____
- B. Supervisor is:
 - Authorized User
 - Radiation Safety Officer
 - Authorized Medical Physicists
 - Authorized Nuclear Pharmacists
- C. Supervisor meets requirements of Part 35, Section(s) _____ for medical uses in Part 35, Section(s) _____.
- D. Address _____
- E. Materials License Number _____

NRC FORM 313A
(10-2002)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

Note: *This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.*

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in
 N/A 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s)
 N/A and Paragraph(s) _____.

YES 11b. The individual named in Item 1. is competent to independently function as an authorized
 N/A _____ for _____ uses.

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of _____
 or equivalent Agreement State requirements to be a preceptor authorized _____
 for the following uses of byproduct material: _____.

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR (*print clearly*)

D. SIGNATURE -- PRECEPTOR

E. DATE

APPENDIX C

License Application Checklists

License Application Checklists

This Appendix contains checklists that may be used to assist in organizing an application.

Table C.1, Applicability Table, may be used to determine if particular information must be provided or if “N/A” may be the response to each item that follows. To determine those items to which you must respond, “highlight” the columns under the categories of materials you requested in Item 5 (e.g., 35.300, 35.400, etc.). If any “Y” beside an item is highlighted, you must provide detailed information in response to that item. If the letters “N/A” (not applicable) are highlighted, you may respond “N/A” on your application. If any “N” beside an item is highlighted, no information in response is required, but NRC regulations that apply to the given category apply to your type of license. If any “P” beside an item is highlighted, you should provide a commitment as described in the section referenced in the body of this document. If any “G” beside an item is highlighted, see subsequent sections for required responses. “APP” indicates that an appendix found in this document addresses the item.

Table C.1 Applicability Table

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.5	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.8	Purpose(s) for Which Licensed Material Will be Used	Y	Y	Y	Y	Y	Y	
8.9	Training and Experience	G	G	G	G	G	G	
8.10	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	I, D

Table C.1 (continued)

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.11	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D
8.12	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.13	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
8.14	Facilities and Equipment	G	G	G	G	G	G	
8.15	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.16	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.17	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.18	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.19	Other Equipment and Facilities	N	N	N	N	Y	N	
8.20	Radiation Protection Program	G	G	G	G	G	G	
8.21	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.22	Occupational Dose	P	P	P	P	P	P	M
8.23	Area Surveys	P	P	P	P	P	P	R
8.24	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.25	Spill Procedures	P	P	P	N/A	N/A	P	N
8.26	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.27	Minimization of Contamination	N	N	N	N	N	N	
8.28	Waste Management	P	P	P	P	P	P	W
8.29	Fees	Y	Y	Y	Y	Y	Y	
8.30	Certification	Y	Y	Y	Y	Y	Y	
8.31	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.32	Public Dose	N	N	N	N	N	N	
8.33	Opening Packages	N	N	N	N	N	N	
8.34	Written Directive Procedures	N/A	N	N	N/A	N	N	S

Table C.1 (continued)

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.35	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.36	Mobile Medical Service	N	N	N	N	N	N	V
8.37	Audit Program	N	N	N	N	N	N	L
8.38	Operating and Emergency Procedure	N	N	N	N	N	N	N
8.39	Material Receipt and Accountability	N	N	N	N	N	N	
8.40	Ordering and Receiving	N	N	N	N	N	N	O
8.41	Sealed Source Inventory	N	N	N	N	N	N	
8.42	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.43	Recordkeeping	N	N	N	N	N	N	X
8.44	Reporting	N	N	N	N	N	N	Y
8.45	Leak Tests	N	N	N	N	N	N	Q
8.46	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.47	Transportation	N	N	N	N	N	N	Z

* Y beside item 8.13 for use under 35.400 applies to Sr-90 only.

** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and 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 or 35.200, then the applicant should check the “yes” column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	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 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	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.

Table C.2 (continued)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Byproduct material under 10 CFR 35.500 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe	Sealed source or 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	Sealed source or device (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 afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (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.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___ millicuries	<i>In vitro</i> studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.

Table C.2 (continued)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	As a component of Manufacturer _____ Model No. _____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/ Model No. _____	___ millicuries	Purpose of use _____.

Table C.3 is 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(s) of Radiation Safety Officer in Table C.3 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.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: _____	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.900(b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p> <p style="text-align: center;"><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual _____</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p style="text-align: center;">OR</p> <p>A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Names: _____</p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency</p> <ul style="list-style-type: none"> • sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or • sufficient to independently operate a nuclear pharmacy (10 CFR 35.980). <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Occupational Dose	<p>A statement that: “Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under “Criteria” in NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees,” dated October 2002.”</p> <p style="text-align: center;">OR</p> <p>A description of an alternative method for demonstrating compliance with the referenced regulations.</p>	<input type="checkbox"/> <input type="checkbox"/>
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.”	<input type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.”	<input type="checkbox"/>
Item 10: Spill 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.”	<input type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	<p>Name of the proposed employee and types of activities requested: _____</p> <p style="text-align: center;">AND</p> <p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p style="text-align: center;">AND</p> <p>Copy of the manufacturer’s training certification and an outline of the training in procedures to be followed.</p>	<input type="checkbox"/> <input type="checkbox"/>
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 satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92.”	<input type="checkbox"/>

APPENDIX D

**Documentation of Training and Experience
To Identify Individuals on a License as
Authorized User, Radiation Safety Officer,
Authorized Nuclear Pharmacist, or
Authorized Medical Physicist**

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Nuclear Pharmacist, or Authorized Medical Physicist

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer to its medical use license only needs to provide evidence that the individual is listed on a medical use license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material broad scope permittee before October 24, 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 10 CFR 35.59. When adding an experienced authorized nuclear pharmacist to the license, the applicant may also provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists. 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.

II. Applicants that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by NRC

Applicants should complete the appropriate sections on NRC Form 313A to show that the individuals meet the appropriate training and experience criteria in 10 CFR Part 35 subparts B, D, E, F, G, H, or J. NRC Form 313A was developed to provide a single location where six different professional groups (physicians, dentist, podiatrist, medical physicist, pharmacist, and radiation safety officer) and ten different medical sub-specialties could document completion of appropriate training and experience requirements. Therefore, some of the sections will not be applicable for each group.

There are two different training and experience routes recognized to qualify an individual as an authorized user, authorized medical physicist, authorized nuclear pharmacists, or radiation safety officer. The first is by means of certification by a professional board recognized by NRC 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), or until October 25, 2004, a professional board listed in 10 CFR Part 35 Subpart J.

The second route is by meeting the structured educational program, supervised work experience, and preceptor certification requirements in 10 CFR Part 35, subparts B, D, E, F, G, and H. Until October 25, 2004 this route also includes the classroom and laboratory training and supervised clinical or work experience requirements in 10 CFR Part 35, Subpart J.

III. Recentness of Training

The required training and experience 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 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; and
- 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.

IV. Instructions and Guidance for Filling Out NRC Form 313A

Note: Individuals who have been certified by boards recognized by the NRC need only complete items 1, 2 and 3 of NRC Form 313A. Information for all other individuals to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist or Radiation Safety Officer must be provided in subsequent sections of NRC Form 313A.

Part I. Training and Experience

Provide information for each individual for whom authorization is sought.

Item 1. Name of individual, proposed authorization, and applicable training requirements.

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name, specify the type authorization being requested (Radiation Safety Officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist), and applicable training requirements.

Note: Do not include personal or private information (e.g., date of birth, social security number) as part of your qualification documentation.

Item 2. State or territory where licensed

NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to

prescribe drugs in the practice of medicine, practice dentistry, practice podiatry, or practice pharmacy, respectively (see 10 CFR 35.2, “Definition”).

Item 3. Certification

The applicant should provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. The month and year certified is used to establish recentness of training, to confirm that NRC recognizes that board’s certifications, and to verify that the applicant meets the training requirements.

If an individual to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer cannot meet the Specialty Board certification route, the applicant must fill out the appropriate remaining sections of NRC Form 313A.

Item 4. “Didactic or Classroom and Laboratory Training”; 5a, “Work Experience with Radiation,” and 5b. “Supervised Clinical Case Experience.”

Applicants with individuals needing authorized user and authorized nuclear pharmacist recognition should consider the completion of Items 4 and 5 as a unit since the hours required for training and supervised work experience are usually added together to meet the requirement. Because the applicant is not required to receive the training described in Item 4 at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon that individual’s needs. Item 4 is optional for the medical physicist applicant because the regulations do not specify the specific training elements needed to be an authorized medical physicist.

Most applicants will only complete Item 5a because most individuals are required to have supervised work experience but are not required to have specific clinical case experience. Those individuals that have to document clinical case experiences (e.g., the Strontium-90 eye applicator users) may also have specific work experience elements that need to be documented in Item 5b, as part of the clinical case experience.

Note: Didactic or Classroom and Laboratory Training may be provided at medical teaching/university institutions. In some cases, a course may be specifically provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required “structural educational programs” or “training” may be obtained in any number of settings, locations, and educational situations. There are no specific requirements on who can provide the training or set hours for each of the training elements. If the applicant is seeking authorization under the requirements of 10 CFR Part 35 subparts B, D, E, F, G, and H, the preceptor is responsible for the initial determination of the adequacy of the training (and work experience) to permit the individual to function independently.

Item 6. Formal Training

This item is completed for individuals qualified to be medical physicists, therapy physicians meeting the requirements in 10 CFR 35.490, 35.690, 35.940 and 35.960, as well as radiation safety officers.

Item 7. Radiation Safety Officer – One Year Full-Time Work Experience

This item is used to document that the applicant meets the regulatory requirement of one full year of full time work experience in the areas which are listed in Item 5a.

Item 8. Medical Physicist – One-Year Full-Time Training and Experience

This section is used to document that the Medical Physicist has received one full year of full time training and one full year of work experience. Both are required to be under the supervision of an authorized medical physicist but they do not have to be under the same medical physicist.

Item 9. Supervising Individual

Item 9 need only be completed by an applicant seeking to have an individual listed on the license as an AU, RSO, or AMP under Part 35 Subparts B, D, E, F or H. If an applicant is following the training and experience requirements in Subpart J, it is sufficient to identify the supervising individual and licensed facility in Items 5a and 5b. In addition, the use of Item 9 is also dependent on whether information on the identity, qualifications and location (license number) of the supervising individual has already been provided elsewhere on NRC Form 313A (e.g., in Items 7, 8 or 12).

Note: If the individual had more than one supervisor, all supervising individual names must be listed in Items 5a and 5b and Item 9 filled out for each.

Note: The use of Item 9 is dependent on whether the information on the identity, qualifications, and locations (license number) are already provided elsewhere on NRC Form 313A (e.g., in Items 7, 8 or 12).

Note: The authorized nuclear pharmacist applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore the authorized nuclear pharmacist applicant does not need to identify a supervising individual in Item 5a or complete Item 9.

Part II Preceptor Statement

NRC defines the term “preceptor” in 10 CFR 35.2, “Definitions,” to mean “an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation Safety Officer.” 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 the training and experience required. The preceptor has to certify in writing that the

individual applying for recognition as an authorized user, authorized nuclear pharmacist, authorized medical physicist or radiation safety officer (pursuant to 10 CFR Part 35, Subparts B, C, D, E, F, or H and 10 CFR 35.980) has satisfactorily completed the appropriate training and experience criteria and can function independently. This preceptor also has to meet specific requirements.

NRC recognizes supervised work experience, such as that described in 10 CFR 35.290(c), conducted under a preceptor in a licensed material use program. A preceptor is an AU 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. Preceptorships may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in 10 CFR 35.490(b)(1), 10 CFR 35.491(b)(2), and 10 CFR 35.690(b)(1) must have been gained at a medical institution. When the supervised work experience is complete, the applicant should submit either the preceptor forms, NRC Form 313A as attachments to NRC Form 313, "Application for Material License," or a letter from the preceptor that indicates that the applicant has obtained all required experience elements.

Items 10, 11 and 12

An applicant requesting authorized nuclear pharmacist status for a pharmacist under 10 CFR 35.980(b) is required to provide a different certification statement than a pharmacist under Subpart B, 10 CFR 35.55(b). Item 10 confirms the certification needed to meet the requirements under 10 CFR Part 35, Subpart J and is applicable only for the pharmacist meeting the requirements in 10 CFR 39.980(b). Item 12 is to provide the preceptor authorized nuclear pharmacist's signature.

Items 11 and 12

Item 11 has two components: 11a. certifies that the applicant has satisfactorily completed the training and supervised work experience requirements and 11b. certifies that the applicant has the competency to function independently.

Note: 10 CFR Part 35 Subpart G does not require a preceptor statement.

Item 12 requires the preceptor's signature, and certification. The preceptor must indicate whether the preceptor is an Authorized Nuclear Pharmacist certifying the applicant under Subpart B (10 CFR 35.980(b) or Subpart B (10 CFR 35.55(b)), or whether the preceptor has another authorized position.

APPENDIX E

Sample License Application

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

APPLICATION FOR MATERIAL LICENSE

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
 OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
 U.S. NUCLEAR REGULATORY COMMISSION
 WASHINGTON, DC 20555-001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

NUCLEAR MATERIALS LICENSING SECTION
 U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
 611 RYAN PLAZA DRIVE, SUITE 400
 ARLINGTON, TX 76011-8084

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)

Dr. Noe Directive
 Suite 112
 2 Physician Circle Parkway
 Anytown, PA 02201

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Suite 112
 2 Physician Circle Parkway
 Anytown, PA 02201

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Noe Directive, MD

TELEPHONE NUMBER

(123) 456-7890

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

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7C AMOUNT ENCLOSED \$D, DDD.CC

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

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

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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE

Noe Directive, MD - President

SIGNATURE

Noe Directive

DATE

April 11, 2003

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED \$	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT

PART I -- TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Noe Directive, MD Authorized user, 10 CFR 35.190, 10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Pennsylvania Medical License PA-MD-XXYYY

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
N/A		

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Radiation 200 for Diagnostic Physicians Sample Medical School 4321 Broad Street	50	July 1 to August 15, 2002
Radiation Protection	Anytown, PA	50	"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	50	"
Radiation Biology	"	50	"
Chemistry of Byproduct Material for Medical Use	"	50	"
OTHER			

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
Ordering, receiving, and unpacking radioactive material safely and performing the related radiation surveys.	Thomas Group, D.O.	See item 9	August 2002 to March 2003 100
Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters.	"	"	100
Calculating, measuring, and safely preparing patient or human research subject dosages	"	"	100
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	50
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures.	"	"	50
Administering dosages of radioactive drugs to patients or human research subjects	"	"	100
Eluting generators, measuring and testing the eluate, and processing the eluate with reagent kits to prepare labeled radioactive drugs.	Jane Diagnostic, MD	See item 12	50
			Total > 700 hours

5b. SUPERVISED CLINICAL CASE EXPERIENCE - N/A

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
N/A					

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

7. RADIATION SAFETY OFFICER -- ONE-YEAR FULL-TIME TRAINING

- YES Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of
- N/A _____ the RSO for License No. _____.

8. MEDICAL PHYSICIST -- ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- YES Completed 1-year of full-time training in therapeutic radiological physics under the supervision of
- N/A _____ who meets requirements for Authorized Medical Physicists; and
- YES Completed 1-year of full-time work experience (for areas identified in item 5a) for _____
- N/A modality(ies) under the supervision of _____ who meets requirements for Authorized Medical Physicists for _____ modality(ies).

9. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each):

- A. Name of Supervisor Supervisor is:
- Thomas Group, D.O.** Authorized User Authorized Medical Physicists
- Radiation Safety Officer Authorized Nuclear Pharmacists
- C. Supervisor meets requirements of Part 35, Section(s) **35.290** _____
- for medical uses in Part 35, Section(s) **35.100 and 35.200** _____
- D. Address **Sample Medical-Institution Limited**
1234 Main Street
Anytown, PA 02120
- E. Materials License Number **99-02120-01**

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10.The individual named in item 1has satisfactorily completed the training requirements in
 N/A 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s) and
 N/A Paragraph(s) 35.190(c) and 35.290(c) .

YES 11b. The individual named in Item 1. is competent to independently function as an authorized
 N/A User for 10 CFR 35.100 and 200 uses.

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of 35.290
or equivalent Agreement State requirements to be a preceptor authorized User
for the following uses of byproduct material: 35.100 and 35.200

A.. Address

**Sample Medical Institution Limited
1234 Main Street
Anytown, PA 02120**

B. Materials License Number

99-02120-01

C.NAME OF PRECEPTOR (print clearly)

Jane Diagnostic, MD

D.SIGNATURE -- PRECEPTOR

Jane Diagnostic

E.DATE

4-11-03

Noe Directive, M.D. Attachment 1 of 6

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and 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 or 35.200, then the applicant should check the “yes” column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
<input checked="" type="checkbox"/>	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
<input checked="" type="checkbox"/>	Any byproduct 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	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer _____, Model No. _____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.

Noe Directive, M.D. Attachment 2 of 6

Table C.3 is 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(s) of Radiation Safety Officer in Table C.3 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.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: <u>Noe Directive, M.D.</u>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.</p> <p style="text-align: center;">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.900(b).</p> <p style="text-align: center;">OR</p> <p>Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.</p> <p style="text-align: center;">AND</p> <p>Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.</p> <p style="text-align: center;">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input checked="" type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

**Noe Directive, M.D. Attachment 3 of 6
Table C.3 (continued)**

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual <u>Noe Directive, M.D., 35.100; 35.200</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.</p> <p align="center">OR</p> <p>Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.</p> <p align="center">OR</p> <p>Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.</p> <p align="center">OR</p> <p>A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;</p> <p align="center">AND</p> <p>Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p align="center">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input checked="" type="checkbox"/></p> <p align="center"><input checked="" type="checkbox"/></p> <p align="center"><input type="checkbox"/></p>
<p>Item 7: Authorized Nuclear Pharmacists Names: <u>N/A</u></p>	<p>Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.</p> <p align="center">OR</p> <p>Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.51(a) or 10 CFR 35.980(a).</p> <p align="center">OR</p> <p>Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.</p> <p align="center">AND</p> <p>Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency</p> <ul style="list-style-type: none"> • sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or • sufficient to independently operate a nuclear pharmacy (10 CFR 35.980). <p align="center">AND</p> <p>If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.</p>	<p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p>

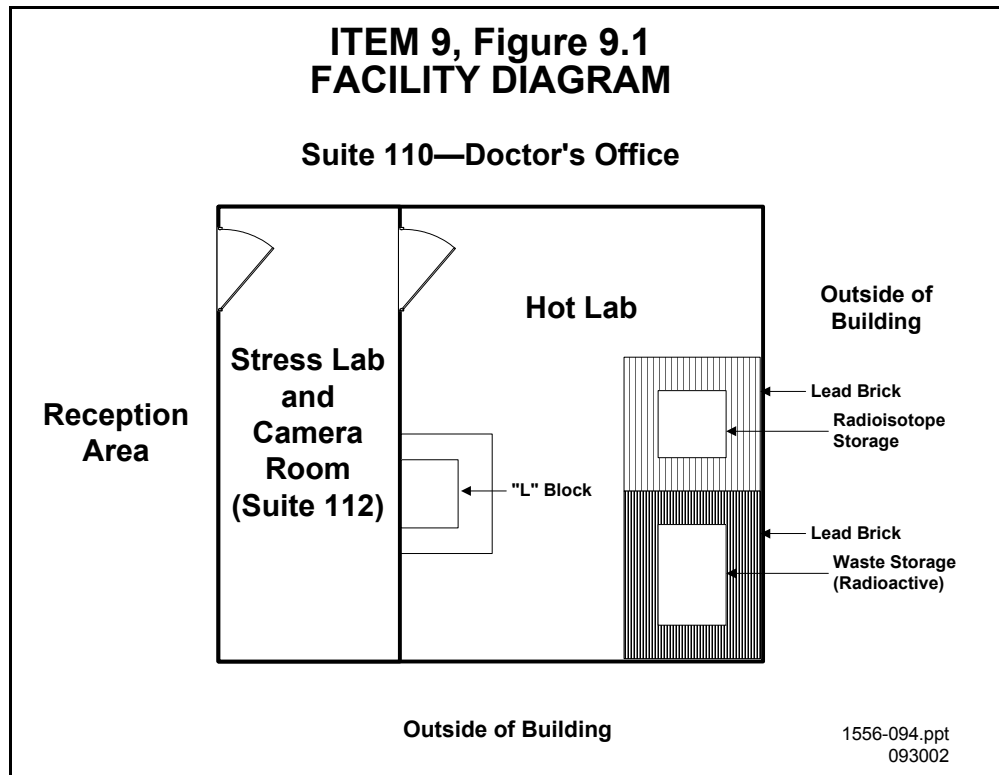
**Noe Directive, M.D. Attachment 3 of 6
Table C.3 (continued)**

Item Number and Title	Suggested Response	Check box to indicate material included in application
<p>Item 9: Radiation Monitoring Instruments</p> <p>Description of the instrumentation that will be used to perform required surveys: <u>Geiger Mueller-Range 1-1000 mR/hr and NaI Well Counter - sensitivity 22 dpm/cm²</u></p>	<p>A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."</p> <p align="center">AND/OR</p> <p>A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."</p> <p align="center">AND</p> <p>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.</p> <p align="center">AND</p> <p>A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."</p>	<p align="center"><input checked="" type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input checked="" type="checkbox"/></p> <p align="center"><input checked="" type="checkbox"/></p>
<p>Item 9: Dose Calibrator and Other Dosage Measuring Equipment N/A</p>	<p>A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."</p>	<p align="center"><input type="checkbox"/></p>
<p>Item 9: Therapy Unit - Calibration and Use N/A</p>	<p>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.</p>	<p align="center"><input type="checkbox"/></p>
<p>Item 9: Other Equipment and Facilities N/A</p>	<p>Attached is a description identified as Attachment 9.4, of additional facilities and equipment.</p> <p>For manual brachytherapy facilities, we are providing a description of the emergency response equipment.</p> <p>For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:</p> <ul style="list-style-type: none"> • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room; and • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons. • Emergency response equipment. 	<p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p>
<p>Item 10. Safety Procedures and Instructions N/A</p>	<p>Attached procedures required by 10 CFR 35.610</p>	<p align="center"><input type="checkbox"/></p>

**Noe Directive, M.D. Attachment 4 of 6
Table C.3 (continued)**

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Occupational Dose	<p>A statement that: “Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under “Criteria” in NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees,” dated October 2002.”</p> <p align="center">OR</p> <p>A description of an alternative method for demonstrating compliance with the referenced regulations.</p>	<p align="center"><input checked="" type="checkbox"/></p> <p align="center"><input type="checkbox"/></p>
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.”	<p align="center"><input checked="" type="checkbox"/></p>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: “We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.”	<p align="center"><input checked="" type="checkbox"/></p>
Item 10: Spill 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.”	<p align="center"><input checked="" type="checkbox"/></p>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources N/A	<p>Name of the proposed employee and types of activities requested:</p> <hr/> <p align="center">AND</p> <p>Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.</p> <p align="center">AND</p> <p>Copy of the manufacturer’s training certification and an outline of the training in procedures to be followed.</p>	<p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p> <p align="center"><input type="checkbox"/></p>
Item 10: Minimization of Contamination N/A	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 satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	<p align="center">N/A</p>
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 Subpart K to 10 CFR Part 20 and 10 CFR 35.92.”	<p align="center"><input checked="" type="checkbox"/></p>

Dr. Noe Directive



Notes:

- 1) *Radioactive material delivered to hot lab.*
- 2) *Counter surfaces are stainless steel and floors are seamless vinyl to facilitate cleanup and minimize permanent contamination.*
- 3) *Unoccupied basement located underneath facility and Suite 212 (a doctor's office) located above facility.*

APPENDIX F

Sample Licenses

Sample Licenses

The license conditions listed in the example licenses come from the standard conditions in NUREG 1556 Volume 20, “Guidance About Administrative Licensing Procedures,” with some modifications to reflect provisions of 10 CFR Part 35. The modified conditions are as follows:

- Standard tie-down condition (standard condition 38) modified to reflect 10 CFR 35.26
- Decay-in-storage condition (standard condition 140) modified to reflect 10 CFR 35.92
- Sealed sources leak test condition (standard condition 165) modified to reflect 10 CFR 35.67

When preparing licenses, please refer to the latest revision of NUREG 1556 Volume 20 for the most current versions of the license conditions.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Norma L. Vision, M.D.	3. License number 52-02210-01
2. Suite 201 1234 Bright Sun Drive Sun City, Puerto Rico 02210	4. Expiration date March 31, 2015
	5. Docket No. 030-02210 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Strontium 90 permitted by 10 CFR 35.400	A. Sealed Source (DuPont Merck Pharmaceutical Co. Model NB-1)	A. 120 millicuries

9. Authorized use:
A. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.

★ ★ ★ ★ ★
CONDITIONS

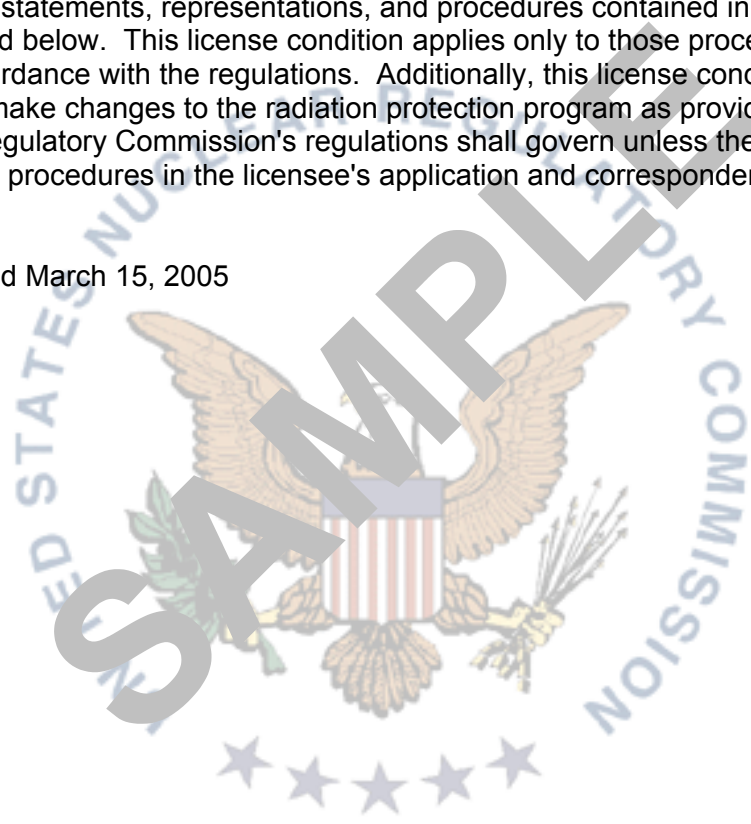
- 10. Licensed material may be used or stored only at the licensee's facilities located at Suite 201, 1234 Bright Sun Drive, Sun City, Puerto Rico.
- 11. The Radiation Safety Officer for this license is Cecil Source, Ph.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
 - B. Authorized user and use: Norma L. Vision, M.D. - Strontium 90 for ophthalmic radiotherapy.
 - C. Authorized medical physicist: Cecil Source, Ph.D.

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- 13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated March 15, 2005



For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Medical Broad Scope	3. License number 99-02110-01
2. 300 Main Street Anytown, Pennsylvania 02110	4. Expiration date March 31, 2013
	5. Docket No. 030-02110 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 1 through 83	A. Any	A. 200 millicuries per radionuclide and 15 curies total
B. Any byproduct material with atomic numbers 3 through 83	B. Sealed Sources	B. 1.5 curies per radionuclide and 15 curies total
C. Hydrogen 3	C. Any	C. 2 curies
D. Carbon 14	D. Any	D. 1 curie
E. Phosphorus 32	E. Any	E. 2 curies
F. Sulfur 35	F. Any	F. 2 curies
G. Chromium 51	G. Any	G. 500 millicuries
H. Molybdenum 99	H. Any	H. 10 curies
I. Technetium 99m	I. Any	I. 10 curies
J. Iridium 192	J. Sealed Sources (US Atomic Model IR-192HDR)	J. 12 curies per source and 24 curies total

9. Authorized use:
 A. through I. Medical diagnosis, therapy and research in humans in accordance with any applicable U.S. Food and Drug Administration (FDA) requirements. Research and development as defined

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in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in-vitro studies.

- J. One source for medical use described in 10 CFR 35.600, in a US Atomic Model IR-192THER remote afterloader unit. The source activity may not exceed 10 curies at the time of installation. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.

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10. Licensed material may be used or stored only at the licensee's facilities located at 300 Main Street, Anytown, Pennsylvania.
11. A. The Radiation Safety Officer for this license is Patty Melt, Ph.D.
- B. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- C. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- D. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.
12. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

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- D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
17. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism that prevents the foil temperature from exceeding that specified in the certificate of registration issued by NRC pursuant to 10 CFR 32.210 or the equivalent regulations from an Agreement State.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

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- 18. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, 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.
- 19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated December 20, 2002
 - B. Letter dated February 15, 2003

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Sample Medical Institution Limited 2. 1234 Main Street Anytown, Pennsylvania 02120	3. License number 99-02120-01 4. Expiration date October 31, 2012 5. Docket No. 030-02120 Reference No.
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6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.100 B. Any byproduct material permitted by 10 CFR 35.200 C. Any byproduct material permitted by 10 CFR 35.300 D. Any byproduct material permitted by 10 CFR 35.400 E. Any byproduct material permitted by 10 CFR 35.500 F. Any byproduct material permitted by 10 CFR 31.11 G. Phosphorus 32 H. Cesium 137	7. Chemical and/or physical form A. Any B. Any C. Any D. Sealed Sources (US Atomic Models Ir-192L, Cs-137V, and I-125M) E. Sealed Sources (US Atomic Model I-125P and GD-153A) F. Prepackaged Kits G. Sealed Sources (US Atomic Model P-32IVB) H. Sealed Source (US Atomic Model CS-137C)	8. Maximum amount that licensee may possess at any one time under this license A. As needed B. As needed C. 900 millicuries D. 2 curies E. 0.3 curie per source and 2 curies total F. 5 millicuries G. 600 millicuries per source assembly and 1.2 curies total H. 200 millicuries
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- | | | |
|---|--|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| I. Iridium 192 | I. Sealed Sources (US Atomic Model IR-192HDR2) | I. 10 curies per source and 20 curies total |
| J. Depleted Uranium | J. Metal | J. 999 kilograms |

9. Authorized use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. In vitro studies.
- G. One source assembly for medical use in a US Atomic Model INTRA intravascular brachytherapy remote afterloader unit. One source assembly in its shipping container as necessary for replacement of the source assembly in the intravascular brachytherapy remote afterloader unit.
- H. For use in a US Atomic Model CS-137SC for calibrations and checking of licensee's survey instruments.
- I. One source for medical use described in 10 CFR 35.600, in a US Atomic Model IR-192THER remote afterloading brachytherapy unit. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- J. Shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1234 Main Street, Anytown, Pennsylvania.
11. The Radiation Safety Officer for this license is Melba Physicist, M.S.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02120-01

Docket or Reference Number
030-02120

- B. The following individuals are authorized users for medical use:

	<u>Material and Use</u>
Jane Diagnostic, M.D.	35.100; 35.200; 35.300; 35.500; <i>In vitro</i> studies; Gadolinium-153 for patient attenuation correction
Thomas Group, D.O.	35.100; 35.200; 35.300 except Iodine-131
Gilbert Lawrence, M.D.	35.100; 35.200; 35.500; Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
John Therapy, M.D.	35.400; Phosphorus-32 for intravascular brachytherapy procedures; Iridium-192 for uses in a High Dose Rate Remote Afterloading Brachytherapy Unit; Depleted Uranium

- C. The following individuals are authorized users for non-medical uses:

	<u>Material and Use</u>
James Pathology	<i>In vitro</i> studies
Cecil Source, Ph.D.	Cesium-137 for calibration of instruments

- D. The following individual is an authorized medical physicist:

	<u>Material and Use</u>
Melba Physicist, M.S.	Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training

- E. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
99-02120-01Docket or Reference Number
030-02120

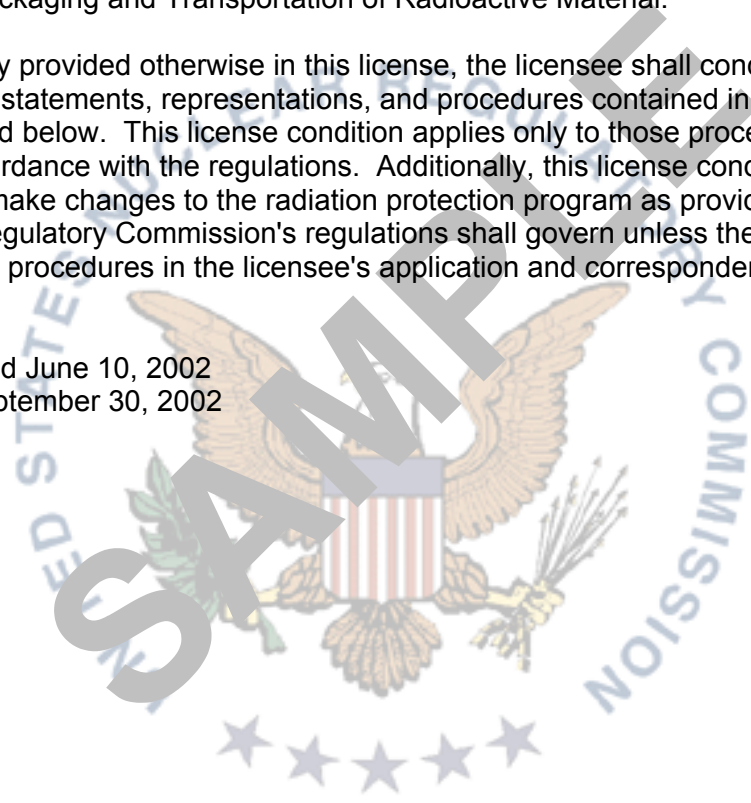
14. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.
15. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
 - D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
 - G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02120-01

Docket or Reference Number
030-02120

- 17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 18. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated June 10, 2002
 - B. Letter dated September 30, 2002



For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Thomas I. Royed, M.D.	3. License number 99-02200-01
2. Suite 301 2 Physician Circle Parkway Anytown, Pennsylvania 02200	4. Expiration date December 31, 2012
	5. Docket No. 030-02200 Reference No.

- | | | |
|---|----------------------------------|--|
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Iodine-131 permitted by 10 CFR 35.300 | A. Any | A. 500 millicuries |

9. Authorized use:
A. Any iodine-131 procedure permitted by 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.

★ ★ ★ ★ ★
CONDITIONS
★ ★ ★ ★ ★

10. Licensed material may be used or stored only at the licensee's facilities located at Suite 301, 2 Physician Circle Parkway, Anytown, Pennsylvania.
11. The Radiation Safety Officer for this license is Roger O. Blation, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02200-01

Docket or Reference Number
030-02200

B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users

Material and Use

Roger O. Blation, M.D.

Oral administration of sodium iodide I-131

Thomas I. Royed, M.D.

Oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries

- 13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated October 30, 2002

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Manuel U. Seeds	3. License number 99-02200-01
2. Suite 106 3 Physician Circle Parkway Anytown, Pennsylvania 02200	4. Expiration date September 30, 2014
	5. Docket No. 030-02200 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.400	A. Sealed Sources (US Atomic Model US-I-125-10L)	A. 500 millicuries

9. Authorized use:
A. Any manual brachytherapy procedure permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at Suite 106, 3 Physician Circle Parkway, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Manuel U. Seeds, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for the materials and uses indicated:

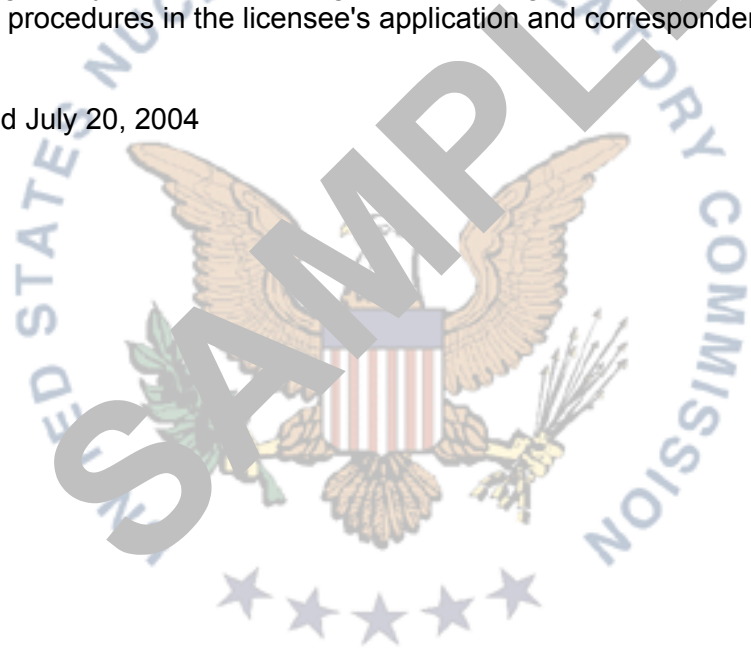
<u>Authorized Users</u>	<u>Material and Use</u>
Manuel U. Seeds, M.D.	10 CFR 35.400

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02200-01

Docket or Reference Number
030-02200

- 13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated July 20, 2004



For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Noe Directive, M.D.</p> <p>2. Suite 112 2 Physician Circle Parkway Anytown, Pennsylvania 02201</p>	<p>3. License number 99-02201-01</p> <hr/> <p>4. Expiration date June 30, 2013</p> <hr/> <p>5. Docket No. 030-02201 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any, except generators</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p>
<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. Any imaging and localization study permitted by 10 CFR 35.200.</p>		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at Suite 112, 2 Physician Circle Parkway, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Noe Directive, MD.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02201-01

Docket or Reference Number
030-02201

B. The following individuals are authorized users for the materials and uses indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Noe Directive, M.D.	35.100; 35.200

- 13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated April 11, 2003

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Mobile Nuclear Medicine 2. Suite 214 2 Physician Circle Parkway Anytown, Pennsylvania 02220	3. License number 99-02220-01	
4. Expiration date December 31, 2012	5. Docket No. 030-02220 Reference No.	
6. Byproduct, source, and/or special nuclear material A. Any byproduct material permitted by 10 CFR 35.100 B. Any byproduct material permitted by 10 CFR 35.200	7. Chemical and/or physical form A. Any B. Any, except generators	8. Maximum amount that licensee may possess at any one time under this license A. As needed B. As needed
9. Authorized use: A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100. B. Any imaging and localization study permitted by 10 CFR 35.200.		

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at Suite 214, 2 Physician Circle Parkway, Anytown, Pennsylvania and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

If the jurisdiction status of a Federal facility within an Agreement State is unknown, the licensee should contact the Federal agency controlling the job site in question to determine whether the proposed job site is an area of exclusive Federal jurisdiction. Authorization for use of radioactive materials at job sites in Agreement States not under exclusive Federal jurisdiction shall be obtained from the appropriate state regulatory agency.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02220-01

Docket or Reference Number
030-02220

11. Licensed material is only authorized for use by, or under the supervision of:

- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users

Material and Use

Thomas Group, D.O.

35.100; 35.200

12. The Radiation Safety Officer for this license is Thomas Group, D.O.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated November 15, 2002

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Sample Teletherapy	3. License number 99-02300-01
2. 200 Cobalt Street Anytown, Pennsylvania 02300	4. Expiration date June 30, 2013
	5. Docket No. 030-02300 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60 permitted by 10 CFR 35.600	A. Sealed Sources (US Atomic Model US-CO-60TELE)	A. 5,500 curies per source and 11,000 curies total
B. Depleted Uranium	B. Metal	B. 999 kilograms
9. Authorized use:		
A. One source for medical use permitted by 10 CFR 35.600, in a US Atomic Model TELE teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.		
B. Shielding in a teletherapy unit.		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 200 Cobalt Street, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Sarah Smith, M.S.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02300-01

Docket or Reference Number
030-02300

B. The following individual is an authorized user for medical use:

Material and Use

David Jones, M.D.

Cobalt-60 for medical uses in a Teletherapy Unit;
Depleted Uranium

C. The following individual is an authorized medical physicist:

Material and Use

Sarah Smith, M.S.

Cobalt-60 in a Teletherapy Unit for calibrations, spot-
checks, and training

- 13. The licensee is exempt from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.
- 14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated March 19, 2003

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Sample Gamma Stereotactic 2. 100 Main Street Anytown, Pennsylvania 02310	3. License number 99-02310-01 4. Expiration date March 31, 2013 5. Docket No. 030-02310 Reference No.	
6. Byproduct, source, and/or special nuclear material A. Cobalt 60 permitted by 10 CFR 35.600	7. Chemical and/or physical form A. Sealed Sources (US Atomic Model US-CO-60STER)	8. Maximum amount that licensee may possess at any one time under this license A. 33 curies per source and 10,000 curies total
9. Authorized use: A. For medical use permitted by 10 CFR 35.600, in a US Atomic Model STEREO gamma stereotactic radiosurgery unit. Sources in the shipping container as necessary for replacement of the sources in the gamma stereotactic radiosurgery unit.		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 100 Main Street, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Kimberly Therapy, Ph.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02310-01

Docket or Reference Number
030-02310

B. The following individuals are authorized users for medical uses:

Material and Use

John Smith, M.D.

Cobalt-60 for medical uses in a Gamma Stereotactic Radiosurgery Unit

Jessica Water, M.D.

Cobalt-60 for medical uses in a Gamma Stereotactic Radiosurgery Unit

C. The following individuals are authorized medical physicists:

Material and Use

Kimberly Therapy, Ph.D.

Cobalt-60 in a Gamma Stereotactic Radiosurgery Unit for calibrations, spot-checks, and training

Ronald Stereo, M.S.

Cobalt-60 in a Gamma Stereotactic Radiosurgery Unit for calibrations, spot-checks, and training

13. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 15, 2002

B. Letter dated March 4, 2003

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		
1. Sample Pacemaker License		3. License number SNM-22160
2. 100 Medical Center Drive Anytown, Pennsylvania 22160		4. Expiration date October 31, 2012
		5. Docket No. 070-22160 Reference No.
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium (principal radionuclide Pu-238)	A. Sealed Sources (US Atomic Model US-PU-238)	A. 5 curies per source and 50 curies total
9. Authorized use:		
A. As a component of US Atomic Model PACE nuclear-powered pacemakers for clinical evaluation in accordance with manufacturer's protocol dated October 19, 1995. This authorization includes: follow-up, explantation, recovery, and disposal, but not implantation.		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 100 Medical Center Drive, Anytown, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Chief Radiologist, M.D.
- 12. The physicians responsible for follow-up, explantation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are Chief Cardiosurgeon, M.D.
- 13. The specified possession limit for nuclear-powered pacemakers includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
SNM-22160

Docket or Reference Number
070-22160

- 14. The licensee shall continue patient follow-up and replacement procedures for the nuclear-powered pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear-powered pacemaker by return to the manufacturer shall be followed upon the death of the patient.
- 15. The licensee shall report to the U.S. Nuclear Regulatory Commission's Regional Office referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.
- 16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
- 17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated September 30, 2002
 - B. Letter dated October 15, 2002

For the U.S. Nuclear Regulatory Commission

Date _____

By _____

Division of Nuclear Materials Safety

APPENDIX G

Information Needed for Transfer of Control

Information Needed for Transfer of Control

The following information is taken from NUREG 1556 Volume 15, "Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Material Licenses."

Definitions

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of an NRC-licensed operation.

Transferor: A transferor is an NRC licensee selling or otherwise giving up control of a licensed operation.

Licensees must provide full information and obtain NRC's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom NRC may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

APPENDIX H

NRC Form 314 “Certificate of Disposition of Materials”

NRC FORM 314 <small>(7-2001)</small> <small>10 CFR 30.360(i); 40.420(i); 70.390(i), and 72.540(i)</small>	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0028 EXPIRES: 07/31/2004 <small>Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to ljs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0028), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</small>								
CERTIFICATE OF DISPOSITION OF MATERIALS										
LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER								
		LICENSE EXPIRATION DATE								
<p><input type="checkbox"/> This license has expired. <input type="checkbox"/> This license has not yet expired; please terminate it.</p> <p style="text-align: center;">A. LICENSE STATUS (Check the appropriate box)</p>										
<p style="text-align: center;">B. DISPOSAL OF RADIOACTIVE MATERIAL (Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments) The licensee, or any individual executing this certificate on behalf of the licensee, certifies that</p> <p><input type="checkbox"/> 1. No radioactive materials have ever been procured or possessed by the licensee under this license.</p> <p><input type="checkbox"/> 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner.</p> <p style="margin-left: 20px;"><input type="checkbox"/> a. Transfer of radioactive materials to the licensee listed below:</p> <p style="margin-left: 20px;"><input type="checkbox"/> b. Disposal of radioactive materials:</p> <p style="margin-left: 40px;"><input type="checkbox"/> 1. Directly by the licensee:</p> <p style="margin-left: 40px;"><input type="checkbox"/> 2. By licensed disposal site:</p> <p style="margin-left: 40px;"><input type="checkbox"/> 3. By waste contractor:</p> <p><input type="checkbox"/> c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.</p>										
<p style="text-align: center;">C. SURVEYS PERFORMED AND REPORTED</p> <p><input type="checkbox"/> 1. A radiation survey was conducted by the licensee. The survey confirms:</p> <p style="margin-left: 20px;"><input type="checkbox"/> a. the absence of licensed radioactive materials</p> <p style="margin-left: 20px;"><input type="checkbox"/> b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.</p> <p><input type="checkbox"/> 2. A copy of the radiation survey results:</p> <p style="margin-left: 20px;"><input type="checkbox"/> a. is attached; or <input type="checkbox"/> b. is not attached (Provide explanation); or <input type="checkbox"/> c. was forwarded to NRC on: _____ Date</p> <p><input type="checkbox"/> 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and</p> <p style="margin-left: 20px;"><input type="checkbox"/> a. The results of the latest leak test are attached; and/or <input type="checkbox"/> b. No leaking sources have ever been identified.</p>										
<p>The person to be contacted regarding the information provided on this form:</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:30%;">NAME</td> <td style="width:30%;">TITLE</td> <td style="width:20%;">TELEPHONE (Include Area Code)</td> <td style="width:20%;">E-MAIL ADDRESS</td> </tr> <tr> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </table> <p>Mail all future correspondence regarding this license to:</p>			NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS				
NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS							
<p>C. CERTIFYING OFFICIAL I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">PRINTED NAME AND TITLE</td> <td style="width:25%;">SIGNATURE</td> <td style="width:25%;">DATE</td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </table>			PRINTED NAME AND TITLE	SIGNATURE	DATE					
PRINTED NAME AND TITLE	SIGNATURE	DATE								
<p>WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.</p>										

CERTIFICATE OF DISPOSITION OF MATERIALS

PLEASE READ THESE INSTRUCTIONS BEFORE COMPLETING NRC FORM 314.

Subpart E of 10 CFR Part 20 establishes the radiological criteria for license terminations/decommissioning of facilities licensed under 10 CFR Parts 30, 40, 50, 60, 61, 70, and 72, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

INSTRUCTIONS

Section B, Item 2.

Licensees should describe the specific radioactive material transfer actions. If radioactive wastes were generated in terminating this license, the licensee should describe the disposal actions taken, including the disposition of low-level radioactive waste, mixed waste, greater-than-Class-C waste, and sealed sources.

Section B, Item 2.a.

The information provided concerning the transfer of radioactive material to another licensee should specify the date of the transfer, the name of the licensee recipient, an individual contact name and telephone number for the licensee recipient, and the recipient's NRC or Agreement State license number.

Section B, Item 2.b.

For disposal of radioactive materials, licensees should describe the specific disposal method or procedure (e.g., decay-in-storage). For those cases when radioactive materials are disposed of by a licensed disposal site or by a waste contractor, the licensee should specify the name, address, and telephone number of the licensed disposal site operator or waste contractor.

Section B, Item 2.c.

"Residual radioactivity," as defined in 10 CFR 20.1003, means radioactivity in 'areas' (structures, materials, soils, etc.) remaining as a result of activities (licensed and unlicensed) under the licensee's control from sources used by the licensee, excluding background radiation. ALARA is defined in 10 CFR 20.1003.

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

APPENDICES I-W

MODEL PROCEDURES FOR INFORMATION PURPOSES ONLY

The following model procedures provide one method of complying with the regulations and are not intended to be the only means for satisfying the requirements for licensees.

APPENDIX I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24.

Typically, these duties and responsibilities include ensuring the following:

- Stopping unsafe activities involving licensed material;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- 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, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

APPENDIX I

- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. 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 where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

Signature of Management Representative

Signature of Radiation Safety Officer

Date

Date

cc: Affected department heads

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 from 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 the state of learning (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 requires 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 NRC requirements. Guidance on requirements for training and experience for AMPs and AUs who engage in certain specialized practices is also included.

Model Training Program for 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 at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Usage of Byproduct Material

Training for professional staff (e.g., AU, AMP, ANP, 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 in the following topics, *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 ALARA (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); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (10 CFR 35.27).

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Therapeutic Quantities of Byproduct Material (Including Greater than 30 microcurie 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) in the following topics, *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 GSR, correct positioning of the helmet) (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; and
- 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 of determining each trainee's competency to use the device for each type of proposed use, such as practical examinations.

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 10 CFR 35.51(b)(1). Note, for example, that additional training is necessary for AMP planning tasks such as manual brachytherapy, remote afterloader therapy, teletherapy, GSR therapy and the use of the treatment planning system that applicants contemplate using.

Additional Training for Therapy Authorized Users

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 35.490, 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 system, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in Sections 35.390, 35.490, 35.491, and 35.690 of 10 CFR Part 35.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security and life-safety services. The training program for ancillary staff who perform duties that are likely to result in a dose in excess of 1 mSv (100 mrem) 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 (10 CFR 19.12).

APPENDIX K

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Model procedures for describing the specifications for monitoring instruments and a program for calibration of survey instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry, if required.

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 P-32 and Ca-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 I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide 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 I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with a *), extracted from “The Health Physics & Radiological Health Handbook,” Revised Edition, 1992, may be helpful in selecting instruments:

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	mR-R	N/A
Count Rate Meters			
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 (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

Model Procedure for Calibrating Survey Instruments

This model provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet the requirements of 10 CFR Part 20 and 10 CFR 35.61. (Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute at 1430 Broadway, New York, NY 10018 or by ordering electronically from <<http://www.ansi.org>>.

Procedures for calibration of survey instruments:

- Radiation survey instruments will be calibrated with a radioactive source in accordance with 10 CFR 35.61. Electronic calibrations alone are not acceptable. Survey meters must be

calibrated at least annually, before first use and after servicing or repairs which affect calibration. (Battery changes are not considered “servicing.”) 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. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta, or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.

- Use radioactive sealed source(s) that:
 - Approximates a point source;
 - Is certified, NIST-traceable, standard source that has an activity or exposure rate accurate to within 5%; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST;
 - Emit the type of radiation measured;
 - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed; and
 - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (10 CFR 20.2103(a) and 10 CFR 35.2061).
- Before use, perform daily check (with a dedicated check source) and battery checks.
- Instrument readings should be within $\pm 10\%$ of known radiation values at calibration points; however, readings within $\pm 20\%$ are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters should be calibrated as follows:
 - Calibrate Linear-Readout Instruments at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20% and 80%).
 - Calibrate Logarithmic-Readout Instruments at two points on each decade.
 - Calibrate Digital-Readout Instruments with either manual or automatic scale switching for indicating exposure rates at no fewer than two points on each scale. Check calibrations near the ends of each scale (at approximately 20% and 80% of each scale).

APPENDIX K

- Calibrate Digital-Readout Instruments without scale switching for indicating exposure rates at two points on each decade.
- Calibrate Integrating instruments at two dose rates (at approximately 20% and 80% of the dose rate range).
- Readings above 1000 mR/hr (250 microcoulomb/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:
 - A description of the instrument, including 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, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument;
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument);
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
 - For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;
 - For 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 should be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument;
 - 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);
 - The date of calibration and the next calibration due date;
 - The apparent exposure rate from the check source, if used.

Determining the Efficiency of NaI(Tl) Uptake Probes

Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. Refer to Appendix B to Part 20 for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (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 radioiodines. Use the following procedure to calibrate probe for uptake measurements:

- Frequency: perform calibrations annually, before first use and after repairs that affect calibrations;
- 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 $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

$$Eff_a = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(activity \text{ of } std \text{ in } microcurie)}$$

where:

Eff_a = efficiency¹,
 cpm = counts per minute,
 std = standard, and
 bkg = background.

¹The 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 has much less of a dependence on the counting geometry.

Operational and calibration checks, using a dedicated check source, should be conducted on 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 date of the next efficiency due;
- Results of efficiency calculation(s).

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 $\pm 5\%$ of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example,

$$Eff = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(activity \text{ of } std \text{ in } microcurie)}$$

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 on 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 date of the next efficiency due and
- Results of efficiency calculation(s).

Reference: Draft RG FC 413-4, "Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments," dated June 1985.

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 which 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.

Date of This Audit: _____ Date of Last Audit: _____

Next Audit Date: _____

Auditor: _____ Date: _____
(Signature)

Management Review: _____ Date: _____
(Signature)

Audit History

- A. Were previous audits conducted annually [20.1101]?
- B. Were records of previous audits maintained [20.2102]?
- C. Were any deficiencies identified during previous audit?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer:
 - 1. If the RSO was changed, was license amended [35.13]?
 - 2. Does new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
 - 3. Is RSO fulfilling all duties [35.24]?
 - 4. Is the written agreement in place for a new RSO [35.24(b)]?
- B. Multiple places of use? If yes, list locations.
- C. Are all locations listed on license?
- D. Were annual audits performed at each location? If no, explain.
- E. Describe scope of the program (staff size, number of procedures performed, etc.).
- F. Licensed Material:
 - 1. Isotope, chemical form, quantity and use as authorized?

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2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is financial assurance adequate?
3. Calibration, transmission, and reference sources [35.65]?
 - a. 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 30 millicurie each [35.65(a) and (b)]?
 - b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicurie [35.65(c)]?
 - c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcurie or 1000 times the quantities in Appendix B of Part 30 [35.65(d)]?
 - d. Technetium-99m in individual amounts as needed [35.65(e)]?
4. Unsealed materials used under 35.100, 200, and 300 are:
 - a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

- b. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?

OR

- c. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?
- G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [32.210, 35.400, 35.500, 35.600]? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
- H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- I. If places of use changed, was the license amended [35.13(e)]?
- J. If control of license was transferred or bankruptcy filed, was NRC prior consent obtained or notification made, respectively [30.34(b) and 30.34(h)]?

Radiation Safety Program

- A. Minor changes to program [35.26]?
- B. Records of changes maintained for 5 years [35.2026]?
- C. Content and implementation reviewed annually by the licensee [20.1101(c)]?
- D. Records of reviews maintained [20.2102]?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

- A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (*Note: Does not apply to facilities that are registered/licensed by FDA/State Agency as a Drug Manufacturer with distribution regulated under Part 32*):
- _____ 1. Certified by specialty board
 - _____ 2. Identified on NRC or Agreement State license
 - _____ 3. Identified on permit issued by broad scope or master materials licensee
 - _____ 4. Listed on facility license
- B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.491, 35.590, 35.690]:
- _____ 1. Certified by specialty board
 - _____ 2. Identified on NRC or Agreement State license
 - _____ 3. Identified on permit issued by broad scope or master materials licensee
 - _____ 4. Listed on facility license
- C. Authorized Medical Physicist [35.51, 35.57, 35.59]:
- _____ 1. Certified by specialty board
 - _____ 2. Identified on NRC or Agreement State license
 - _____ 3. Identified on permit issued by broad scope or master materials licensee
 - _____ 4. Listed on facility license

Mobile Medical Service

- A. Operates services per 35.80, 35.647?
- B. Compliance with 20.1301 evaluated and met?
- C. Letter signed by management of each client [35.80(a)]?
- D. Licensed material was not delivered to client's address (unless client was authorized) [35.80(b)]?
- E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [35.80(a)]?
- F. Survey instruments checked for proper operation before used at each address of use [35.80(a)]?
- G. Survey of all areas of use prior to leaving each client address [35.80(a)]?
- H. Additional technical requirements for mobile remote afterloaders per [35.647]?

Amendments Since Last Audit [35.13]

- A. Any Amendments since last audit [35.13]?

Notifications Since Last Audit [35.14]

- A. Any Notifications since last audit [35.14]?
- B. Appropriate documentation provided to NRC for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work [35.14(a)]?
- C. NRC notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, 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 35.100 or 35.200 use [35.14(b)]?

Training, Retraining, And Instructions to Workers

- A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?
- B. Is the individual's understanding of current procedures and regulations adequate?
- C. Training program implemented?
1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
 2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
 3. Periodic training required and implemented [35.310, 35.410, 35.610]?
 4. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [10 CFR 19.12]?
 5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [35.27]?
 6. Are initial and periodic training records maintained for each individual [35.2310]?
 7. Briefly describe training program:
- D. Additional therapy device instructions/training:
1. Unit operation, inspection, associated equipment, survey instruments?
 2. License conditions applicable to the use of the unit?
 3. Emergency drills [35.610]?
- E. Part 20 – Workers cognizant of requirements for:
1. Radiation Safety Program [35.24, 35.26, 20.1101]?
 2. Annual dose limits [20.1201, 20.1301, 20.1302]?
 3. NRC Forms 4 and 5?

4. 10% monitoring threshold [20.1502]?
 5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
 6. Grave Danger Posting [20.1902(c)]?
 7. Procedures for opening packages [20.1906]?
- F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 10 CFR 35.27?

Manual Brachytherapy And Unsealed Therapy Training

- A. Safety instruction to personnel provided include [10 CFR 35.310, 10 CFR 35.410]:
1. Control of patient and visitors?
 2. Routine visitation to patients in accordance with 10 CFR 20.1301?
 3. Contamination control and size/appearance of sources?
 4. Safe handling and shielding instructions?
 5. Waste control?
 6. RSO and AU notification in emergency or death?
 7. Records retained [35.2310]?

Facilities

- A. Facilities as described in license application?
- B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?
- C. Emergency source recovery equipment available [35.415, 35.615]?
- D. Storage areas:
1. Materials secured from unauthorized removal or access [20.1801]?
 2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802]?
- E. Therapy unit operation:
1. Unit, console, console keys, and treatment room controlled adequately [20.1801, 35.610(a)(1)]?
 2. Restricted to certain source orientations and/or gantry angles?
 3. Ceases to operate in restricted orientation(s)?
 4. 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

- A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [10 CFR 35.60]:
 - 1. List type of equipment used:
 - 2. Approved procedures for use of instrumentation followed?
 - 3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
 - 4. 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., $\pm 10\%$)?
 - 5. Records maintained and include required information [10 CFR 35.2060]?
- B. Determination of dosages of unsealed byproduct material [35.63]:
 - 1. Each dosage determined and recorded prior to medical use [35.63(a)]?
 - 2. Measurement of unit dosages made either by direct measurement or by decay correction [35.63(b)]?
 - 3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c)]?
- C. Licensee uses generators?
 - 1. First eluate after receipt tested for Mo-99 breakthrough [35.204(b)]?
 - 2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [35.204(a)]?
 - 3. Records maintained [35.2204]?
- D. Dosimetry Equipment [35.630]:
 - 1. Calibrated system available for use [35.630(a)]?
 - 2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 35.630(a)(2)?
 - 3. Calibrated within the previous 4 years [35.630(a)(2)]?
 - 4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?
 - 5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

Radiation Protection And Control of Radioactive Material

- A. Use of radiopharmaceuticals:
 - 1. Protective clothing worn?
 - 2. Personnel routinely monitor their hands?
 - 3. No eating/drinking in use/storage areas?
 - 4. No food, drink, or personal effects kept in use/storage areas?
 - 5. Proper dosimetry worn?
 - 6. Radioactive waste disposed of in proper receptacles?
 - 7. Syringe shields and vial shields used?
- B. Leak tests and Inventories:
 - 1. Leak test performed on sealed sources and brachytherapy sources [35.67(b)(1)]?
 - 2. Inventory of sealed sources and brachytherapy sources performed semiannually [35.67(g)]?
 - 3. Records maintained [35.2067]?

Radiation Survey Instruments

- A. Survey instruments used to show compliance with Part 20 and 30.33(a)(2):
 - 1. Appropriate operable survey instruments possessed or available [10 CFR Part 20]?
 - 2. Calibrations [35.61(a) and (b)]:
 - a. Before first use, annually and after repairs?
 - b. Within 20% on each scale or decade of interest?
 - 3. Records maintained [35.2061]?
- B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [20.1501, 35.70]?:
 - 1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [35.70]?
 - 2. Weekly in all areas where radiopharmaceuticals or waste is stored?
 - 3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
 - 4. Trigger levels established?
 - 5. Corrective action taken and documented if trigger level exceeded?
 - 6. Techniques can detect 0.1 mR/hr, 2000dpm?

7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [35.652(a)] and records maintained [35.2652]?
 - a. After new source installation?
 - b. 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

- A. Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year [10 CFR 20.1301(a)(1)]?
- B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour [10 CFR 20.1301(a)(2)]?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [10 CFR 20.1801 and 20.1802]?
- F. Records maintained [10 CFR 20.2103, 10 CFR 20.2107]?

Patient Release

- A. Individuals released when TEDE less than 0.5 rem [35.75(a)]?
- B. Instructions to the released individual, including breast-feeding women, include required information [35.75(b)]?
- C. Release records maintained [35.2075(a)]?
- D. Records of instructions given to breast-feeding women maintained, if required [35.2075(b)]?

Radiopharmaceutical Therapy

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [35.315(a)]?
- B. RSO and AU promptly notified if patient died or had a medical emergency [35.315(b)]?

Brachytherapy

- A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [35.415]?
- B. Survey immediately after implant [35.404(a)]?
- C. Patients surveyed immediately after removing the last temporary implant source [35.404(b)]?
- D. RSO and AU promptly notified if patient died or had a medical emergency [35.415(c)]?
- E. Records maintained [35.2404]?

Radioactive Waste

- A. Disposal:
 - 1. Decay-in-storage [35.92]
 - 2. Procedures followed?
 - 3. Labels removed or defaced [20.1904, 35.92]?
- B. Special procedures performed as required?
- C. Authorized disposals [20.2001]?
- D. Records maintained [20.2103(a), 20.2108, 35.2092]?
- E. Effluents:
 - 1. Release to sanitary sewer [20.2003]?
 - a. Material is readily soluble or readily dispersible [20.2003(a)(1)]?
 - b. Monthly average release concentrations do not exceed 10 CFR Part 20 App. B, Table 2 values?
 - c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003]?
 - d. Procedures to ensure representative sampling and analysis implemented [20.1501]?
 - 2. Release to septic tanks [20.2003]?
 - a. Within unrestricted limits [10 CFR Part 20 App. B, Table 2]?
 - 3. Waste incinerated?
 - a. License authorizes [20.2004(a)(3)]?
 - b. Directly monitor exhaust?
 - c. Airborne releases evaluated and controlled [20.1302, 20.1501]?
 - 4. Air effluents and ashes controlled [20.1101, 20.1201, 20.1301, 20.1501, 20.2001] (See also IP 87102, RG 8.37)

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- a. Air effluent less than 10 mrem constraint limit [20.1101]?
 - b. If no, reported appropriate information to NRC.
 - i. Corrective actions implemented and on schedule?
 - c. Description of effluent program:
 - i. Monitoring system hardware adequate?
 - ii. Equipment calibrated, as appropriate?
 - iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?
- F. Waste storage
1. Protection from elements and fire?
 2. Control of waste maintained [20.1801]?
 3. Containers properly labeled and area properly posted [20.1902, 20.1904]?
 4. Package integrity adequately maintained?
- G. Waste disposal:
1. Sources transferred to authorized individuals [20.2006, 20.2001, 30.41]?
 2. Name of organization: _____
- H. Records of surveys and material accountability are maintained [20.2103, 20.2108, 35.2092]?

Receipt And Transfer of Radioactive Material

- A. Describe how packages are received and by whom.
- B. Written package opening procedures established and followed [20.1906(e)]?
- C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [20.1906(b)(1)]?
- D. Incoming packages surveyed [20.1906(b)(2)]?
- E. Monitoring in (C) and (D) performed within time specified [20.1906(c)]?
- F. Transfer(s) performed per [30.41]?
- G. All sources surveyed before shipment and transfer [20.1501(a)]?
- H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51]?
- I. Package receipt/distribution activities evaluated for compliance with 20.1301?

Transportation (10 CFR 71.5(a) and 49 CFR 171-189)

- A. Shipments are:
 - 1. delivered to common carriers;
 - 2. transported in own private vehicle;
 - 3. both;
 - 4. no shipments since last audit.
- B. Return radiopharmacy doses or sealed sources?
 - 1. Licensee assumes shipping responsibility?
 - 2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:
- C. Packages:
 - 1. Authorized packages used?
 - 2. Performance test records on file?
 - a. DOT-7A packages
 - b. Special form sources
 - 3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class?
 - 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, “This End Up” (liquids), Name and Address of consignee)?
 - 5. Closed and sealed during transport?
- D. Shipping Papers:
 - 1. Prepared and used?
 - 2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper’s Name, Certification and Signature, Emergency Response Phone Number, “Limited Quantity” (if applicable), “Cargo Aircraft Only” (if applicable)?
 - 3. Readily accessible during transport?

Teletherapy and Gamma Stereotactic Radiosurgery Servicing

- A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [35.655(a)]?
- B. Needed service arranged for as identified during the inspection?
- C. Service performed by persons specifically authorized to do so [35.655(b)]?

Full Calibration-Therapeutic Medical Devices

- A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?
- B. Performed prior to first patient use [35.632(a)(1), 35.633(a)(1), 35.635(a)(1)]?
- C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders [35.632(a)(3)], 35.633(a)(3) and (4), 35.635(a)(3)]?
- D. Whenever spot-checks indicate output differs from expected by $\pm 5\%$ [35.632(a)(2)(i), 35.635(a)(2)(i)]?
- E. After source exchange, relocation, and major repair or modification [35.632(a)(2), 35.633(a)(2), 35.635(a)(2)]?
- F. Performed with properly calibrated instrument [35.632(c), 35.633(c), 35.635(c)]?
- G. Includes:
 - 1. For teletherapy:
 - a. Output measured within $\pm 3\%$ of expected for the range of field sizes, range of distances [35.632(b)(1)]?
 - b. Coincidence of radiation field and field light localizer [35.632(b)(2)]?
 - c. Uniformity of radiation field and beam angle dependence [35.632(b)(3)]?
 - d. Timer accuracy and linearity over the range of use [35.632(b)(4)]?
 - e. On-off error [35.632(b)(5)]?
 - f. Accuracy of all measuring and localization devices [35.632(b)(6)]?
 - 2. For remote afterloaders:
 - a. Output measured within $\pm 5\%$ of expected [35.633(b)(1)]?
 - b. Source positioning accuracy within ± 1 millimeter [35.633(b)(2)]?
 - c. Source retraction with backup battery upon power failure [35.633(b)(3)]?
 - d. Length of source transfer tubes [35.633(b)(4)]?
 - e. Timer accuracy and linearity over the typical range of use [35.633(b)(5)]?
 - f. Length of the applicators [35.633(b)(6)]?

- g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [35.633(b)(7)]?
 - h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [35.633(e)]?
3. For gamma stereotactic radiosurgery:
- a. Output measured within $\pm 3\%$ of expected [35.635(b)(1)]?
 - b. Helmet factors [35.635(b)(2)]?
 - c. Isocenter coincidence [35.635(b)(3)]?
 - d. Timer accuracy and linearity over the range of use [35.635(b)(4)]?
 - e. On-off error [35.635(b)(5)]?
 - f. Trunnion centricity [35.635(b)(6)]?
 - g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [35.635(b)(7)]?
 - h. Helmet microswitches [35.635(b)(8)]?
 - i. Emergency timing circuit [35.635(b)(9)]?
 - j. Stereotactic frames and localizing devices (trunnions) [35.635(b)(10)]?
- H. Output corrected mathematically for decay [35.632(e), 35.633(g), 35.635(e)]?
- I. Records maintained [35.2632]?

Periodic Spot Checks For Therapeutic Devices

- A. Performed at required frequency [35.642(a), 35.643(a), 35.645(a)]?
- B. Procedures established by authorized medical physicist [35.642(b), 35.643(b), 35.645(b)]?
- C. Procedures followed?
- D. Medical physicist reviews results within 15 days [35.642(c), 35.643(c), 35.645(b)]?
- E. Performed with properly calibrated instrument [35.642(a)(5), 35.645(c)(2)(i)]?
- F. Output and safety spot checks include:
 - 1. For teletherapy:
 - a. Timer accuracy and linearity over the range of use [35.642(a)(1)]?
 - b. On-off error [35.642(a)(2)]?
 - c. Coincidence of radiation field and field light localizer [35.642(a)(3)]?
 - d. Accuracy of all measuring and localization devices [35.642(a)(4)]?
 - e. The output for one typical set of operating conditions [35.642(a)(5)]?
 - f. Difference between measured and expected output [35.642(a)(6)]?

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- g. Interlock systems [35.642(d)(1)]?
 - h. Beam stops [35.642(d)(2)]?
 - i. Source exposure indicator lights [35.642(d)(3)]?
 - j. Viewing and intercom systems [35.642(d)(4)]?
 - k. Treatment room doors, inside and out [35.642(d)(5)]?
 - l. Electrical treatment doors with power shut off [35.642(d)(6)]?
2. For remote afterloaders:
- a. Interlock systems [35.643(d)(1)]?
 - b. Source exposure indicator lights [35.643(d)(2)]?
 - c. Viewing and intercom systems, except for LDR [35.643(d)(3)]?
 - d. Emergency response equipment [35.643(d)(4)]?
 - e. Radiation monitors used to indicate source position [35.643(d)(5)]?
 - f. Timer accuracy [35.643(d)(6)]?
 - g. Clock (date and time) in the unit's computer [35.643(d)(7)]?
 - h. Decayed source(s) activity in the unit's computer [35.643(d)(8)]?
3. For gamma stereotactic radiosurgery:
- a. Treatment table retraction mechanism [35.645(c)(1)(i)]?
 - b. Helmet microswitches [35.645(c)(1)(ii)]?
 - c. Emergency timing circuits [35.645(c)(1)(iii)]?
 - d. Stereotactic frames and localizing devices [35.645(c)(1)(iv)]?
 - e. The output for one typical set of operating conditions [35.645(c)(2)(i)]?
 - f. Difference between measured and expected output [35.645(c)(2)(ii)]?
 - g. Source output compared against computer calculation of output [35.645(c)(2)(iii)]?
 - h. Timer accuracy and linearity over the range of use [35.645(c)(2)(iv)]?
 - i. On-off error [35.645(c)(2)(v)]?
 - j. Trunnion centricity [35.645(c)(2)(vi)]?
 - k. Interlock systems [35.645(d)(1)]?
 - l. Source exposure indicator lights [35.645(d)(2)]?
 - m. Viewing and intercom systems [35.645(d)(3)]?
 - n. Timer termination [35.645(d)(4)]?

- o. Radiation monitors used to indicate room exposures [35.645(d)(5)]?
 - p. Emergency off buttons [35.645(d)(6)]?
- G. 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)]?
- H. Records maintained [35.2642, 35.2643, 35.2645]?

Installation, Maintenance, and Repair of Therapy Devices

- A. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [35.605, 35.655]? Name of organization/individual: _____
- B. Records maintained [35.2605, 35.2655]?

Operating Procedures For Therapy Devices

- A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [35.610(c)]?
- B. Copy of the entire procedures physically located at the device console [35.610(b)]?
- C. Procedures include:
1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [35.610(a)(4)]?
 2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [35.610(a)(4)]?
 3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally [35.610(a)(4)]?
- D. Radiation survey of patient is performed to ensure source is returned to shielded position [35.604(a)]?
- E. Records of radiation surveys maintained for 3 years [35.2404]?
- F. Authorized medical physicist and authorized user:
1. Physically present during initiation of patient treatment with remote afterloaders (*Note:* for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the authorized user) [35.615(f)(1) and (2)]?
 2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [35.615(f)(3)]?

Personnel Radiation Protection

- A. Exposure evaluation performed [20.1501]?
- B. ALARA program implemented [20.1101(b)]?
- C. External Dosimetry:
 - 1. Monitors workers per [20.1502(a)]?
 - 2. External exposures account for contributions from airborne activity [20.1203]?
 - 3. Supplier _____ Frequency _____
 - 4. Supplier is NVLAP-approved [20.1501(c)]?
 - 5. Dosimeters exchanged at required frequency?
- D. Internal Dosimetry
 - 1. Monitors workers per 20.1502?
 - 2. Briefly describe program for monitoring and controlling internal exposures [20.1701, 20.1702]?
 - 3. Monitoring/controlling program implemented (includes bioassays)?
 - 4. Respiratory protection equipment [20.1703]?
- E. Review of Records and Reports
 - 1. Reviewed by _____ Frequency _____
 - 2. Auditor reviewed personnel monitoring records for period _____ to _____
 - 3. Prior dose determined for individuals likely to receive doses [20.2104]?
 - 4. Maximum exposures TEDE _____ Other _____
 - 5. Maximum CDEs _____ Organs _____
 - 6. Maximum CEDE ____
 - 7. Internal and external summed [20.1202]?
 - 8. Were occupational limits met [20.1201]?
 - 9. NRC forms or equivalent [20.2104(d), 20.2106(c)]?
 - a. NRC-4 Complete:
 - b. NRC-5 Complete:
 - 10. If a worker declared her pregnancy during the audit period, then was the dose in compliance [20.1208] and were the records maintained [20.2106(e)]?
- F. Who performed any planned special exposures at this facility (number of people involved and doses received) [20.1206, 20.2104, 20.2105, 20.2204]?
- G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 20.2103, 20.2106]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events [criteria in 35.3045] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives 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]:
 - a. Submitted to Region within 15 days?

Notification and Reports

- A. In compliance with 19.13, 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?
- B. In compliance with 20.2201, 30.50 (theft or loss)?
- C. In compliance with 20.2202, 30.50 (incidents)?
- D. In compliance with 20.2203, 30.50 (overexposures and high radiation levels)?
- E. Aware of NRC Ops Center phone number?
- F. In compliance with 20.2203 (Constraint on air emissions)?

Posting and Labeling

- A. NRC Form 3, "Notice to Workers" is posted [19.11]?
- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6]?
- C. Other posting and labeling per 20.1902, 1904 and not exempted by 20.1903, 20.1905?

Recordkeeping for Decommissioning

- A. 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)]?
- B. Records include all information outlined in 10 CFR 30.35(g)?

Bulletins and Information Notices

- A. Bulletins, Information Notices, NMSS Newsletters, etc., received?
- B. Appropriate action in response to Bulletins, Generic Letters, etc.?

Special License Conditions or Issues

- A. Special license conditions or issues to be reviewed:
- B. Evaluation:

Audits and Findings

- A. Summary of findings:
- B. Corrective and preventive actions:

APPENDIX M

Model Procedures for an Occupational Dose Program

Model Procedures for an Occupational Dose Program

This model provides acceptable procedures for an external occupational dose program and references 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 10 CFR 20.1101 and Subparts C and F of 10 CFR Part 20. The model includes guidance as well as 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). 10 CFR 20.1201 provides the occupational dose limits for adults. 10 CFR 20.1502 provides in part that adults likely to receive in one year a dose in excess of 10 percent 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) and individuals must be informed on at least an annual basis of their doses (see 10 CFR 19.13(b)).

If an individual is likely to receive more than 10% of the annual dose limits, 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/her dose.

The As Low As Reasonably Achievable “ALARA” Program

10 CFR 20.1101 states 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 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 cm (1000

mg/cm²), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm²), and eye dose equivalent at 0.3 cm (300 mg/cm²). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

10 CFR 20.1502(a) requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent 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) shallow-dose equivalent to the skin
 - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of
 - 0.1 rem (1.0 mSv) DDE
 - 0.15 rem (1.5 mSv) eye dose equivalent
 - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
 - 0.5 rem (5 mSv) shallow-dose equivalent 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, 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:** Review 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 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 (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-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 non-uniform, 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.

10 CFR 20.2106 requires that the recording for individual monitoring be done on NRC Form 5 or equivalent. NRC 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.

In order to demonstrate compliance with occupational dose limits of 10 CFR 20.1201, 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, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers 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

NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in 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 or a group of workers' doses need 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 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 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 per year)	Investigational Level II (mrem per year)
whole body; head; trunk including male gonads; arms above the elbow; or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record on NRC Form 5, "Current Occupational External Radiation Exposures," 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 the 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 whose dose 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 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. A consideration of actions should be taken by the RSO 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.

- Re-establishment of Investigational Level II to a level above that listed in Table N.1.

Declared Pregnancy and Dose to Embryo/Fetus

10 CFR 20.1208 states that the licensee shall ensure that the dose to an embryo/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/fetus shall be taken as the sum of:

- The deep-dose equivalent to the declared pregnant woman; and
- The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

References:

- Methods for calculating the radiation dose to the embryo/fetus can be found in Regulatory Guide 8.36, "Radiation Dose To the Embryo/Fetus."
- NUREG/CR-5631, PNL-7445, Rev. 2, "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses" (1996).

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 1 year (10 CFR 20.1502). 10 CFR Part 20 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e., derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in $\mu\text{Ci/ml}$ that, if an occupational worker were to be continuously exposed to 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 10 CFR Part 20, Appendix B.

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 total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR Part 20 ALI and DAC numbers 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 non-stochastic 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:

- i. adequate equipment to perform bioassay measurements,
- ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,
- iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
- iv. the interval between bioassays,
- v. action levels, and
- vi. the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993, Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation

Doses, dated July 1992, and NUREG-1400, "Air Sampling in the Workplace," dated 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 Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to 10 CFR 20.1202, the external and internal doses must be summed if required to monitor both under 10 CFR 20.1502.

Two documents that contain helpful information regarding occupational doses are:

- NRC Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;" and
- NRC Regulatory Issue Summary 2002-10, "Revision of Skin Dose Unit in 10 CFR Part 20."

Copies of Regulatory Issue Summaries are available on the NRC web site in the Electronic Reading Room <<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/>>.

APPENDIX N

Model Emergency Procedures

Model Spill, Emergency Surgery, and Autopsy Procedures

Model Spill Procedures – Low and High Dose Unsealed Sources

This model provides acceptable procedures for responding to emergencies. Applicants may either adopt this model or develop alternative procedures to meet the requirements of 10 CFR 20.1101.

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a “caution radioactive material” labeled bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with “caution radioactive material” labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill 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 ALI, an alternative spill procedure may be restricted access pending complete decay.

Note: A report to NRC may be required pursuant to 10 CFR 30.50.

Use Table P.1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

Table N.1 Relative Hazards of Common Radionuclides

Radionuclide	Millicurie	Radionuclide	Millicurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- Disposable gloves and housekeeping 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;

- Pre-strung “Radioactive Material” labeling tags;
- Contamination wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear 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).
3. The Radiation Safety Staff will direct personnel in methods to keep doses ALARA during surgical procedures.
4. 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

The following procedures should be followed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. 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.
3. Protective eye wear 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 P-32 and Y-90.
4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord 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.

APPENDIX N

5. 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.

References: NCRP Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

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., RSO), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting 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, inform carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, inform 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 Division, Room _____. Unlock the door, place the package on top of the counter, 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 _____.

<u>Name</u>	<u>Home Telephone</u>
-------------	-----------------------

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 Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure 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 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 of 10 CFR Part 71 (e.g., 13.5 curies of Mo-99 [20 curies for domestic use], Cs-137, Ir-192; 54.1 curies of I-125; 541 curies of Xe-133, or 216 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it 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). NRC Regional Office and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i); and
- 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 notify the RSO or the designee of the RSO if the RSO is not present immediately.
3. Monitor the external surfaces of a labeled¹ 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.
4. Monitor the external surfaces of a labeled¹ 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 to 10 CFR Part 71.
5. 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.
6. Remove the packing slip.

¹Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

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7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.
9. 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.
10. 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. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample 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.
11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. 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 provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μ Ci) of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use 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.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- 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 should be within $\pm 5\%$ of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.

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- Calculate efficiency of the instrument.

For example,

$$Eff = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(activity \text{ of } std \text{ in } microcurie)}$$

where:

Eff = efficiency, in cpm / microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.
- The activity on the wipe sample is given by:

$$\frac{[(cpm \text{ from } wipe \text{ sample}) - (cpm \text{ from } bkg)]}{(Eff \text{ in } cpm/microcurie)}$$

= activity on wipe sample in microcurie

- Leak test records will be retained in accordance with 10 CFR 35.2067 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 microcurie;
 - A description of the method used to measure each test sample;
 - The date of the test; and
 - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005 μ Ci) or greater:
 - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67].
 - File a report within 5 days of the leak test in accordance with 10 CFR 35.3067.

APPENDIX R

Model Procedure for Area Surveys

Model Procedure for Area Surveys

This model provides acceptable procedures for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

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 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- 10 CFR 20.1301 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 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 assure that the requirements of 10 CFR 20.1301 are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour 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 dosage exceeding 30 μ Ci).
 - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μ Ci 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, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
 - Survey quarterly all sealed source and brachytherapy source storage areas.

- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example 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/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. Table K-1 entitled “Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples” in Appendix K 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 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 dpm/100 cm² for isotopes of iodine-131 in unrestricted areas). 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 (i.e., bone scan injections, Tc-99m heart agents, etc.), 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 (<200 microcuries 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 cpm) 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. Example 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 cm²)

Area, clothing	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	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	2000	20000

Table R.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm²)

Nuclide¹	Average^{2, 3, 6}	Maximum^{2, 4, 6}	Removable^{2, 5, 6}
I-125, 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 Sr-90 and others noted above.	5000	15000	1000

- ¹ Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.
- ² 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.
- ³ Measurements of average contaminant 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.
- ⁴ The maximum contamination level applies to an area of not more than 100 cm².
- ⁵ The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping 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.
- ⁶ The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

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 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 occupation doses ALARA;
- 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).

Alternate Survey Frequency

An example alternate survey frequency is described below. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table R.4 Grouping of Radioisotopes for Alternate Survey Frequency

Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 Tl-204
Group 3	C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb-175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 O-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table R.5 Classification of Laboratories for Alternate Survey Frequency

Group	Survey Frequency Category		
	Low	Medium	High
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Table R.6 Modifying Factors for Alternate Survey Frequency

Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

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. You may either adopt this model procedure or develop your own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This model does not restrict your 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 MBq (30 μ Ci), 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.

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 teletherapy 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, portal film verifications, and beam-modifying devices 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 done 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 written directive (as defined in 10 CFR 35.2), the licensee should develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 10 CFR 35.63, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in 10 CFR 35.40(b), including the patient or human research subject's name;
- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- 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; and
- 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 Microcurie of Sodium Iodide I-131

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. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the patient's or human research subject's identity 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 (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional 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 written directives for certain administrations of doses and to have procedures for administrations for which a written directive is required. Model procedures for meeting these requirements appear below.

- A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
- B. 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 non-radioactive 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).
- C. 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 one 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 arithmetic errors;
 - b. Appropriate transfer of data from the WD, treatment plan, tables and graphs;
 - c. Appropriate use of nomograms (when applicable); and
 - 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.

- D. After implantation but before completion of the procedure: record in the written directive 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 written directive may be maintained in the patient's chart.
- E. 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.
- F. 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); or
 - 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%.
- G. 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.
- H. 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: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except non-recastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- I. 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., arithmetic 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.

- J. 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, gamma stereotactic radiosurgery, 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, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

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 NRC Operations Center¹ 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 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. Also notify the referring physician and the patient as required by 10 CFR 35.3045.

¹The commercial telephone number of NRC Operations Center is (301) 951-0550. The Center will accept collect calls.

APPENDIX T

Model Procedures for Safe Use of Unsealed Licensed Material

Model Procedures for Safe Use of Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your 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 your 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 RSO. 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 with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with 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.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with 10 CFR 35.69 and 10 CFR 20.1904.

APPENDIX T

- 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 Part 20, 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 $\pm 20\%$ from the prescribed dosage, except as approved by an authorized user.
- When measuring the dosage, you 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, the patient's identity must be verified and the administration must be in accordance with the written directive (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 NRC license (or such individual's designee).

APPENDIX U

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

Section 35.75, “Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material,” of 10 CFR Part 35, “Medical Use of Byproduct Material,” permits 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 to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).”

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the “patient.”

Release Equation

The activities at which patients could be released were 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.”

NCRP Report No. 37 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
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
- Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
- Q_0 = Initial activity of the point source in millicuries, 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 centimeters
- 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, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).

- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- 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 (less than a few percent), relative to the external gamma dose (see “Internal Dose,” of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item U.1.1, “Release of Patients Based on Administered Activity.”

U.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements.

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 total effective dose equivalent of 5 millisieverts (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; and
- No shielding by tissue.

The total effective dose equivalent 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 breast-feeding an infant or child, as discussed in Item U.3.2, “Records of Instructions for Breast-Feeding 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, calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation U.2 or U.3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table U.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient’s breast milk. When the patient is breast-feeding 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 Items 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 breast-feeding infant or child in excess of 5 millisieverts (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

Licenseses 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 millisieverts (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 $\Gamma Q / 10,000 \text{ cm}^2$.

U.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licenseses 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 millisievert (0.5 rem), the patient may be released. Using this method, licenseses 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 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22

Table U.1 (continued)

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

† The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* 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 Item U.3.1, "Records of Release," for information on records.

** 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 millicurie values were calculated using Equations U.2 or U.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

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. You may either adopt these model instructions or develop your 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.¹ 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 breast-feeding an infant or child, additional instructions may be necessary (see Item U.2.2, “Additional Instructions for Release of Patients Who Could be Breast-Feeding 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 millisievert (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 millisievert (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 Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.¹ The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding 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 breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table U.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (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.

¹NRC does not intend to enforce patient compliance with the instructions nor is it the licensee’s responsibility to do so.

If a radiopharmaceutical not listed in Table U.3 is administered to a patient who could be breast-feeding, 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 by Stabin.

U.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, 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 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/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67***	1.7	47	0.04	4
I-123***	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111***	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6

Table U.2 (continued)

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201***	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** 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.

*** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

Notes: The values for activity were calculated using Equations U.2 or U.3 and the physical half-life. The values given in SI units (gigabecquerel values) were using conversion factors.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their state regulations before using these values.

Table U.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	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 Breast-Feeding
	(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	

Table U.3 (continued)

Radionuclide	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 Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
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 <i>In Vivo</i> Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	6000	150	
Tc-99m Sulphur 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 (continued)

Radionuclide	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 Breast-Feeding
	(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 breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

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."

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 breast-feeding.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee. Agreement State regulations may vary.

Agreement State licensees should check with 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:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding 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 breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in specifying the 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 _____.
- 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, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the 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 Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (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 breast-feeding.

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 breast-feeding 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 breast-feeding an infant or child	Administered activity	Administered activity \leq Column 1 of Table U.1	Yes, if administered activity $>$ Column 1 of Table U.2	No
	Retained activity	Retained activity \leq Column 1 of Table U.1	Yes, if retained activity $>$ Column 1 of Table U.2	Yes
	Measured dose rate	Measured dose rate \leq 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 breast-feeding an infant or child	All of the above bases for release		Additional instructions required if: Administered activity $>$ Column 1 of Table U.3 OR Licensee calculated dose from breast-feeding > 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 breast-feeding > 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 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.

References

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.

"Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Supplement A

Table U.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide ¹	Physical Half-Life (days) ²	Exposure Rate Constant ³ (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11 ⁴
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59 ⁴
P-32	14.29	N/A ⁶
Pd-103 implant	16.96	0.86 ⁵
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A ⁶
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A ⁶
Yb-169	32.01	1.83

¹ Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

² 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.

³ 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, pp. 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," U.S. NRC, February 1997.

- ⁴ R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. 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.
- ⁵ A.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.
- ⁶ 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 total effective dose equivalent to any individual would be no greater than 5 millisieverts (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:

$$D(t) = \frac{34.6 \Gamma Q_0 TE (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

- D(t) = Accumulated dose to time t, in rem;
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
- Γ = Exposure rate constant for a point source, R/mCi x hr 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 centimeters. This value is typically 100 cm; and
- t = Exposure time in days.

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-1)), 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; and
 - 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; and
 - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one 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 dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of iodine-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 ($t = \infty$) 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.

$$D(\infty) = \frac{34.6 (2.2 R \cdot cm^2/mCi \cdot hr)(60mCi)(8.04 d)(0.125)}{(100 cm)^2}$$

$$D(\infty) = 4.59 \text{ millisieverts (0.459 rem)}$$

Since the dose is less than 5 millisievert (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 as low as is reasonably achievable. 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 iodine-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 iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) 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 iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-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 iodine-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:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \text{ cm})^2} \left\{ E_1 T_p (0.8) (1 - e^{-0.693(0.33)/T_p}) \right. \\ \left. + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff} \right\}$$

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 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ 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 Item U.3.1 of this appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerel (150 millicurie) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-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: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) 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 Iodine-131 Treatments

Medical Condition	Extrathyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.20 ¹	0.32 ²	0.80 ¹	5.2 ¹
Post Thyroidectomy for Thyroid Cancer	0.95 ³	0.32 ²	0.05 ³	7.3 ²

¹ 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.

² International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 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.

³ 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:

$$D(\infty) = \frac{(34.6) (2.2) (150)}{(100 \text{ cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693 (0.33) / 8.04}) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.95) (0.32) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.05) (7.3) \}$$

$$D(\infty) = 3.40 \text{ mSv (0.340 rem)}$$

Therefore, thyroid cancer patients to whom 5550 megabecquerel (150 millicurie) of iodine-131 or less has been administered 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 dose is not greater than 5 millisieverts (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 dose to an individual exposed to a patient to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table U.5, and Table U.6, to account for the elimination of iodine-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:

$$D(\infty) = \frac{(34.6) (2.2) (55)}{(100 \text{ cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693 (0.33) / 8.04}) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.20) (0.32) \\ + e^{-0.693 (0.33) / 8.04} (0.25) (0.80) (5.2) \}$$

$$D(\infty) = 4.86 \text{ mSv (0.486 rem)}$$

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered 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 iodine-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 millicuries;

10^{-5} = Assumed fractional intake; and
 DCF = Dose conversion factor to convert an intake in millicurie to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

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 was developed in reference B-3 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 (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-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.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 megabecquerels (33 millicuries) of iodine-131 has 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/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.125 (see Example 1), the external dose is approximated as 2.5 millisieverts (0.25 rem). Thus, the internal dose is about 7% 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 incremental dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

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" (Ref. B-6). 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 Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) of iodine-131 has been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will again calculate the dose 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:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.80 \text{ mSv (0.08 rem)}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisievert (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 millisieverts (0.42 rem).

References for Supplement B

- B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, NUREG-1492, February 1997.
- B-2. 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.
- B-3. 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.
- B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.
- B-5. 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.

- B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

Regulatory Analysis

"Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at NRC's Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

APPENDIX V

Guidance for Mobile Medical Services

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of 10 CFR Part 35 as well as DOT regulations with regard to 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 Subpart H of 10 CFR Part 35.

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 use). A second type is transportation of byproduct material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. For the third type, which is limited to transportation and storage of the therapy device, the service provider 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 their possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with 10 CFR 35.80(a), which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of byproduct material at the client's address and will clearly delineate the authority and responsibility of each entity. 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. 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 location 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 job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. You should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital). As required by 10 CFR 30.33 and 10 CFR 35.12, you must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed facility should demonstrate that the building (or van) 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. 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, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with 10 CFR 20.1201, "Occupational dose limits for adults."

- You may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the byproduct material storage, provide for the following:
 - Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
 - Secured storage facilities available for storage of byproduct material and radioactive waste if the van is disabled; and
 - Byproduct material delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.
- If a base facility is located 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 facility in the event of contamination. Provisions for decontamination of the mobile medical service van, 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 2 mrem in any one hour nor 100 mrem per year.

Client Site

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) you should provide the following additional facility information:

- For therapy treatments with byproduct material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by 10 CFR 35.80(a), that location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that 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/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 you will provide transportable services to the client’s site for use within the client’s facility by the mobile medical service’s employees, you should provide the following client facility information and commitment:

- 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. You should 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, 10 CFR 35.643, and 10 CFR 35.647.

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, you must ensure the following:

- Each client is properly licensed for medical use of byproduct material. If applicable, you 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, transfer to the client's AUs 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, 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 you will instruct supervised individuals in your written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of byproduct material. Additionally, as required by 10 CFR 35.27, you will require the supervised individual to:

- Follow the instructions of the supervising authorized user for medical uses of byproduct material;

- Follow the instructions of the supervising authorized nuclear pharmacists or supervising authorized user for preparation of byproduct material for medical uses;
- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- 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, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by 10 CFR 35.80, you will check instruments for proper operation before use at each address of use. You will check dosage measurement instruments 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. Delivery of byproduct material to a van that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, you may pick up the byproduct material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with your radiation protection program required by 10 CFR 20.1101. You should indicate typical response times of the 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-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 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 and/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 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; and
- 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 AMP. 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, 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 phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170–189. 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; and
 - 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. You will 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.

Radioactive Waste Management

If waste will be stored in vans, the vans will be properly secured and posted as byproduct material storage locations. You will ensure that the van 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 8.28 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 sewerage system, in accordance with 10 CFR 20.2003. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system.

If restroom facilities are provided in the van 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, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-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 do not exceed 2 mrem/hour, 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, you will develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted 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.
- You must maintain records, as described in 10 CFR 35.2647 and 10 CFR 35.2643, showing the results of the above safety checks 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 a 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 Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

This model provides acceptable procedures for waste disposal. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Subpart K to 10 CFR Part 20, 10 CFR 20.1101, and 10 CFR 35.92.

Model Procedure for Decay-In-Storage

10 CFR 35.92 describes the requirements for decay-in-storage. 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 ALARA levels. Storage areas must be in a secure location.

- 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 disposed of 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 container may then be transferred to the decay-in-storage area.
- 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 detection survey meter for proper operation and current calibration status;
 - Monitor in a low-level radiation (<0.05 millirem per hour) 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.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and 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.

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 NRC 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.

APPENDICES X-BB

**Recordkeeping and Reporting Requirements;
DOT Rules for Shipping; References;
Public Comments on Drafts and NRC Responses**

APPENDIX X

Recordkeeping Requirements

Recordkeeping Requirements

Typical Records and Retention Times

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

APPENDIX X

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Radiation survey instrument calibrations	35.61	35.2061	3 years
Dosages of unsealed byproduct material for medical use	35.63	35.2063	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	35.67(b)	35.2067	3 years
Surveys for ambient radiation exposure rate	35.70	35.2070	3 years
Release of individuals containing unsealed byproduct material or implants containing byproduct material	35.75	35.2075	3 years
Mobile medical services	35.80(a)(1)	35.2080	3 years
Decay-in-storage	35.92	35.2092	3 years
Molybdenum-99 concentrations	35.204(b)	35.2204	3 years
Safety instruction	35.310; 35.410; 35.610	35.2310	3 years
Surveys after source implant and removal	35.404; 35.604	35.2404	3 years
Brachytherapy source accountability	35.406	35.2406	3 years
Calibration measurements of brachytherapy sources	35.432	35.2432	3 years
Decay of strontium-90 sources for ophthalmic treatments	35.433	35.2433	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.604	35.2605	3 years
Safety procedures	35.610(a)(4); 35.610(d)(2)	35.2610	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.630	35.2630	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	35.632; 35.633; 35.635	35.2632	3 years
Periodic spot-checks of teletherapy units	35.642	35.2642	3 years
Periodic spot-checks of remote afterloader units	35.643	35.6243	3 years

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Periodic spot-checks of gamma stereotactic radiosurgery units	35.645	35.6245	3 years
Additional technical requirements for mobile remote afterloader units	35.647	35.6247	3 years
Surveys of therapeutic treatment units	35.652	35.2652	duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

APPENDIX Y

Reporting Requirements

Reporting Requirements

Typical NRC Notifications And/Or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Reports to individual workers	none	annually	10 CFR 19.13(b)
Reports to former individual workers	none	upon request	10 CFR 19.13(c)
Notification of special circumstances to individuals	none	30 days	10 CFR 19.13(d)
Reports to worker terminating employment	none	upon request	10 CFR 19.13(e)
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i); 10 CFR 20.2203 (a)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii); 10 CFR 20.2203 (a)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i); 10 CFR 20.2203 (a)
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii); 10 CFR 20.2203(a)
Doses in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	none	30 days	10 CFR 20.2203(a)(3)
Planned special exposures	none	30 days	10 CFR 20.2204
Report to individuals of exceeding dose limits	none	30 days	10 CFR 20.2205
Report of individual monitoring	none	annually	10 CFR 20.2206
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)

APPENDIX Y

Event	Telephone Notification	Written Report	Regulatory Requirement
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)
Licensee permits individual to work as AU, ANP, or AMP	none	30 days	10 CFR 35.14(a)
AU, ANP, or AMP discontinues performance of duties under license or has a name change	none	30 days	10 CFR 35.14(b)(1)
Licensee's mailing address changes	none	30 days	10 CFR 35.14(b)(2)
Licensee's name changes without constituting a transfer of control	none	30 days	10 CFR 35.14(b)(3)
Licensee adds or changes areas of 35.100 or 35.200 use of byproduct material identified in application or license	none	30 days	10 CFR 35.14(b)(4)
Medical event	1 day	15 days	10 CFR 35.3045
Dose to embryo or nursing child	1 day	15 days	10 CFR 35.3047
Leaking source	none	5 days	10 CFR 35.3067

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

APPENDIX Z

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

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

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

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements

APPENDIX Z

for U.S. NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and

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

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

APPENDIX AA

List of Documents Considered in Development of this NUREG

List of Documents Considered in Development of this NUREG

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

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

Document Identification	Title	Date
RG 10.8, Revision 2	Guide for the Preparation of Applications for Medical Use Programs.	8/87
Appendix X to RG 10.8, Revision 2	Guidance on Complying With New Part 20 Requirements.	6/92
Draft RG DG-0009	Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs.	3/97
Draft RG FC 414-4	Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs.	12/85
P&GD FC 87-2	Standard Review Plan (SRP) for License Applications for the Medical Use of Byproduct Material.	12/87
Supplement 1 to P&GD FC 86-4; Revision 1	Mobile Remote Afterloading Brachytherapy Licensing Module.	5/97
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Addendum to Revision 1 to P&GD FC 86-4	Information Required for Licensing Remote Afterloading Devices – Increased Source Possession Limits.	7/95
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RG 8.39	Release of Patients Administered Radioactive Materials.	4/97
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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.
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APPENDIX BB

Summary of Public Comments on Drafts and NRC Responses

(This Appendix will be published as a separate document.)

Summary of Public Comments on Drafts and NRC Responses

The initial draft of NUREG-1556 Vol. 9 was published for public comment in August 1998. A revised draft was published in March 2002. Appendix Z of the March 2002 draft included a summary of comments on the 1998 draft and NRC responses. The NRC held two public workshops, on April 25 and April 30, 2002, to receive stakeholder comments on the March 2002 draft. The NRC also received written public comments during a 60-day comment period (April 5 to June 4, 2002). A summary and analysis of both sets of comments will be published as a separate document, Appendix BB to NUREG-1556 Vol. 9. This document will also be available on the NRC's web site <<http://www.nrc.gov>> in the Electronic Reading Room; interested parties may also check the NRC's web page on the Medical Use of Byproduct Material <<http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html>>.