

NUREG-1556
Vol. 9

Consolidated Guidance About Material Licenses

Program-Specific Guidance About Medical Use Licenses

Revised Draft Report for Comment

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Prepared by
P.A. Lanzisera, A.R. Jones, R.G. Gattone and R.D. Reid

**Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001**



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COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number draft NUREG-1556 Vol. 9, in your comments, and send them by the end of the 60 day comment period specified in the Federal Register notice announcing availability of this draft.

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ABSTRACT

The United States Nuclear Regulatory Commission (NRC) is issuing a draft of NUREG-1556, Volume 9, for public comment for a 60-day period. In addition to obtaining written comments, the staff will be conducting a public workshop on April 25, 2002, to obtain stakeholder comments on this volume, with emphasis on therapeutic applications of byproduct materials. A second public workshop will be held on April 30, 2002, to receive stakeholder input on guidance, with emphasis on diagnostic applications of byproduct materials. Both workshops will be held in the Auditorium at NRC Headquarters in Rockville, MD. Interested parties may contact Roger W. Broseus for details about attendance at either workshop. Dr. Broseus may be contacted via E-mail at RWB@nrc.gov or phone at 301-415-7608. Information about the workshops will also be posted at NRC's web site at <http://www.nrc.gov> — click on “Public Meeting Schedule.” A *Federal Register* Notice has also been published announcing the comment period and the meetings.

NRC staff is seeking input on the guidance contained in the draft NUREG, previously published for public comment in August 1998, in order to make the guidance as useful as possible to those who may seek NRC licensure under 10 CFR Part 35, “Medical Use of Byproduct Material.” Comments received after publication of the 1998 draft have been considered by staff; these comments and NRC responses appear in Appendix Z of the current draft. Comments about any of the guidance in Volume 9 are welcome; staff is especially interested in receiving comments on the following questions:

1. **Level of Detail and Format:** Is the format and level of detail in the guidance appropriate for first-time applicants? Should the guidance be more general in describing acceptable methods of meeting 10 CFR 35 requirements? If so, please provide suggestions for revisions. Discussion about the pros and cons of providing extensive detail about safety and other procedures would be especially helpful
2. **Model Procedures:** Are the model procedures, helpful as written? Should they be retained or rewritten? If so, please provide suggestions for revisions
3. **Licensing Guidance Specific to Diagnostic Nuclear Medicine:** The staff is considering development of a summary of the licensing requirements for diagnostic medical use of byproduct materials. Is such a document desirable? What should be provided in the guidance? How long should it be?
4. **Other Guidance:** Are there additional voluntary industry consensus standards or other publically available documents that should be considered for reference in NUREG-1556, Volume 9?

To facilitate NRC's handling of comments, we request that commenters relate their comments to specific sections and/or appendices in the NUREG. This will help place the comments in context and aid in understanding how they relate to the guidance.

ABSTRACT

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 allow for the implementation by licensees that may be specific to their needs while meeting the regulatory requirements. In the past, applicants have requested guidance from NRC staff on which procedures are acceptable, with the expectation that licensing process delays would thereby be avoided. Other have expressed the view that the provision of specific guidance results in the perception that the only way to receive a license is to adhere to the guidance. NRC staff seeks to meet the needs of applicants for licensure, while not suggesting that details in the guidance are prescriptive. Comments on Volume 9 will help NRC staff to provide guidance that is helpful.

Other guidance: Volume 9 of NUREG-1556 will provide guidance for licensure under revised Title 10, Part 35, "Medical Use of Byproduct Material." It will also be 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";
- 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 8.11, "Applications of Bioassay for Uranium";
- RG 8.20, "Applications of Bioassay for I-125 and I-131";
- RG 8.23, "Radiation Safety Surveys at Medical Institutions, Revision 1";
- RG 8.26, "Applications of Bioassay for Fission and Activation Products";
- RG 8.32, "Criteria for Establishing a Tritium Bioassay Program";
- RG 8.33, "Quality Management Program";
- RG 8.39, "Release of Patients Administered Radioactive Materials";
- 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";

ABSTRACT

- 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”;
- P&GD 3-15, “Standard Review Plan for Review of Quality Management Programs”; and
- RG 8.1, “Radiation Symbol.”

CONTENTS

ABSTRACT	iii
FOREWORD	xiii
ACKNOWLEDGMENTS	xvii
ABBREVIATIONS	xix
1 PURPOSE OF REPORT	1-1
1.1 LICENSES	1-3
1.1.1 GENERAL IN VITRO LICENSE	1-4
1.1.2 SPECIFIC LICENSE OF LIMITED SCOPE	1-5
1.1.3 SPECIFIC LICENSE OF BROAD SCOPE	1-5
1.2 THE 'AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)' CONCEPT	1-6
1.3 WRITTEN DIRECTIVE (WD) PROCEDURES	1-6
1.4 RESEARCH INVOLVING HUMAN SUBJECTS	1-6
2 AGREEMENT STATES	2-1
3 MANAGEMENT RESPONSIBILITY	3-1
4 APPLICABLE REGULATIONS	4-1
5 HOW TO FILE	5-1
5.1 PAPER APPLICATION	5-1
5.2 ELECTRONIC APPLICATION	5-2
6 WHERE TO FILE	6-1
7 LICENSE FEES	7-1
8 CONTENTS OF AN APPLICATION	8-1
8.1 ITEM 1: LICENSE ACTION TYPE	8-3
8.2 ITEM 2: APPLICANT'S NAME AND MAILING ADDRESS	8-3
8.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED ..	8-5
8.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION	8-6
8.5 ITEM 5: RADIOACTIVE MATERIAL	8-7
8.6 ITEM 5: FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING ..	8-10
8.7 ITEM 5: SEALED SOURCES AND DEVICES	8-12
8.8 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED	8-13
8.9 ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE	8-20
8.10 ITEM 7: RADIATION SAFETY OFFICER (RSO)	8-22
8.11 ITEM 7: AUTHORIZED USERS (AUs)	8-24
8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST	8-27
8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP)	8-28
8.14 ITEM 8: SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS	8-30
8.15 ITEM 9: FACILITIES AND EQUIPMENT	8-31
8.16 ITEM 9: FACILITY DIAGRAM	8-31

CONTENTS

8.17	ITEM 9: RADIATION MONITORING INSTRUMENTS	8-40
8.18	ITEM 9: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED BYPRODUCT MATERIAL	8-41
8.19	ITEM 9: DOSIMETRY EQUIPMENT – CALIBRATION AND USE	8-43
8.20	ITEM 9: OTHER EQUIPMENT AND FACILITIES	8-44
8.21	ITEM 10: RADIATION PROTECTION PROGRAM	8-48
8.22	ITEM 10: AUDIT PROGRAM	8-49
8.23	ITEM 10: OCCUPATIONAL DOSE	8-51
8.24	ITEM 10: PUBLIC DOSE	8-55
8.25	ITEM 10: MINIMIZATION OF CONTAMINATION	8-56
8.26	ITEM 10: OPERATING AND EMERGENCY PROCEDURES	8-57
8.27	ITEM 10: MATERIAL RECEIPT AND ACCOUNTABILITY	8-59
8.28	ITEM 10: ORDERING AND RECEIVING	8-60
8.29	ITEM 10: OPENING PACKAGES	8-61
8.30	ITEM 10: SEALED SOURCE INVENTORY	8-61
8.31	ITEM 10: USE RECORDS	8-62
8.32	ITEM 10: LEAK TESTS	8-63
8.33	ITEM 10: AREA SURVEYS	8-65
8.34	ITEM 10: PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE	8-69
8.35	ITEM 10: SAFE USE OF UNSEALED LICENSED MATERIAL	8-69
8.36	ITEM 10: INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES ..	8-71
8.37	ITEM 10: SPILL PROCEDURES	8-72
8.38	ITEM 10: EMERGENCY RESPONSE FOR SEALED SOURCES OR DEVICES CONTAINING SEALED SOURCES	8-73
8.39	ITEM 10: PATIENT OR HUMAN RESEARCH SUBJECT RELEASE	8-75
8.40	ITEM 10: SAFETY PROCEDURES FOR TREATMENTS WHERE PATIENTS ARE HOSPITALIZED	8-77
8.41	ITEM 10: PROCEDURES FOR DEVICE CALIBRATION, SAFETY CHECKS, OPERATION, AND INSPECTION	8-78
8.42	ITEM 10: MOBILE MEDICAL SERVICE	8-86
8.43	ITEM 10: TRANSPORTATION	8-88
8.44	ITEM 11: WASTE MANAGEMENT	8-90
8.45	ITEM 12: FEES	8-94
8.46	ITEM 13: CERTIFICATION	8-95
9	AMENDMENTS AND RENEWALS TO A LICENSE	9-1
10	TERMINATION OF ACTIVITIES	10-1

APPENDICES

A	List of Documents Considered in Development of this NUREG	A-1
B	NRC Form 313	B-1
C	License Application Checklist and Sample Licenses	C-1
D	Information Needed for Transfer of Control	D-1
E	Guidance on Financial Assurance Determination	E-1
F	Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority ..	F-1
G	NRC Forms 313A and 313B	G-1
H	Model Training Program	H-1
I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	I-1
J	Model Procedures for Dose Calibrator Calibration	J-1
K	Suggested Medical Licensee Audit	K-1
L	Model Procedures for an Occupational Dose Program	L-1
M	Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits	M-1
N	Emergency Procedures	N-1
O	Model Procedures for Ordering and Receiving Packages	O-1
P	Model Procedure for Safely Opening Packages Containing Radioactive Material	P-1
Q	Model Leak Test Program	Q-1
R	Model Procedure for Area Surveys	R-1
S	Procedures for Developing, Maintaining, and Implementing Written Directives	S-1
T	Model Procedures for Safe Use of Licensed Material	T-1
U	Release of Patients or Human Research Subjects Administered Radioactive Materials	U-1
V	Guidance for Mobile Services	V-1
W	Transportation	W-1
X	Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return	X-1
Y	NRC Form 314	Y-1
Z	Public Comments and NRC Responses on Draft	Z-1

CONTENTS

FIGURES

Figure 2.1 U.S. Map 2-2

Figure 8.1 Location of Use 8-6

Figure 8.2 Decommissioning Records 8-10

Figure 8.3 Financial Assurance Mechanisms 8-11

Figure 8.4 Gamma Stereotactic Radiosurgery Unit 8-17

Figure 8.5 Beta and/or Photon Radiation Catheter 8-19

Figure 8.6 Stent Implantation 8-19

Figure 8.7 RSO Responsibilities 8-23

Figure 8.8 Facility Diagram for Nuclear Medicine Suite 8-32

Figure 8.9 Iodine-131 NaI Administration for the Thyroid Carcinoma Patient 8-33

Figure 8.10 Overhead View of Manual Brachytherapy Patient Treatment Room 8-34

Figure 8.11 Teletherapy and HDR Treatment Room 8-35

Figure 8.12 Annual Occupational Dose Limits for Adults 8-52

Figure 8.13 Proper Security of Licensed Material 8-55

Figure 8.14 Material Receipt and Accountability 8-60

Figure 8.15 Leak Test Sample 8-64

Figure 8.16 Types of Surveys 8-66

Figure 8.17 Personnel Surveys 8-67

Figure M.1 Diagram of Office and HDR Facility M-3

TABLES

Table 2.1	Who Regulates the Activity?	2-1
Table 8.1	Sample Format for Byproduct Material	8-9
Table 8.2	Minimum Sealed Source Inventory Quantity Requiring Financial Assurance	8-11
Table 8.3	Radiopharmaceuticals Used in Therapy	8-15
Table C.1	Applicability Table	C-1
Table C.2	Items 5 and 6 on NRC Form 313: Radioactive Material And Use	C-4
Table C.3	Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal	C-7
Table E.1	Worksheet for Determining Need for Financial Assurance for Sealed Sources	E-1
Table I.1	Typical Survey Instruments	I-2
Table L.1	Investigational Levels	L-5
Table M.1	Information Known About the HDR Unit	M-3
Table M.2	Calculational Method, Part 1: Hourly and Annual Dose Received From the HDR Unit	M-4
Table M.3	Calculational Method, Part 2: Annual Dose Received From the HDR Unit	M-5
Table M.4	Calculational Method, Part 3: Summary of Information	M-6
Table M.5	Calculational Method, Part 3: Annual Dose Received from HDR	M-6
Table M.6	Calculational Method, Part 4: Summary of Information	M-7
Table M.7	Calculational Method, Part 4: Annual Dose Received from HDR	M-7
Table M.8	Combination Measurement – Calculational Method	M-10
Table N.1	Relative Hazards of Common Radionuclides	N-2
Table R.1	Ambient Dose Rate Trigger Levels	R-2
Table R.2	Surface Contamination Levels in Restricted Areas (dpm/100 cm ²)	R-3
Table R.3	Surface Contamination Levels in Unrestricted Areas (dpm/100 cm ²)	R-4
Table R.4	Grouping of Radioisotopes for Alternate Survey Frequency	R-5
Table R.5	Classification of Laboratories for Alternate Survey Frequency	R-5
Table R.6	Modifying Factors for Alternate Survey Frequency	R-6
Table U.1	Activities and Dose Rates for Authorizing Patient Release	U-5
Table U.2	Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release	U-8
Table U.3	Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child	U-10
Table U.4	Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained	U-15
Table U.5	Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine	U-17
Table U.6	Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments	U-24
Table Z.1	Comments Provided by the American College of Nuclear Physicians, California Chapter, Dated November 9 and December 2, 1998	Z-1

CONTENTS

Table Z.2	Comments Provided by the American College of Nuclear Physicians/Society of Nuclear Medicine, Dated December 16, 1998	Z-6
Table Z.3	Comments Provided by the Cleveland Clinic Foundation, Dated December 4, 1998	Z-9
Table Z.4	Comments Provided by the Kettering Medical Center, Dated September 15, November 11 and December 4, 1998	Z-10
Table Z.5	Comments Provided by the University of California, Los Angeles, Dated December 21, 1998	Z-13
Table Z.6	Comments Provided by the University of California, Dated November 10, 1998	Z-14
Table Z.7	Comments Provided by National Physics Consultants, Ltd., Dated November 12, 1998	Z-17
Table Z.8	Comments Provided by the University of Cincinnati, Dated November 10, 1998	Z-26
Table Z.9	Comments Provided by Allegheny University Hospitals, Dated November 1, 1998	Z-33
Table Z.10	Comments Provided by the American Society of Nuclear Cardiology, Dated November 12, 1998	Z-34
Table Z.11	Comments Provided by The Community Hospital, Undated	Z-35
Table Z.12	Comments Provided by Paul J. Early, Dated December 17, 1998	Z-36
Table Z.13	Comments Provided by Robert Forrest, CHP, Dated November 11, 1998	Z-37
Table Z.14	Comments Provided by the Health Physics Society, Dated December 14, 1998	Z-38
Table Z.15	Comments Provided by the Illinois Department of Nuclear Safety, Dated December 16, 1998	Z-39
Table Z.16	Comments Provided by Mallinckrodt, Inc., Dated December 16, 1998	Z-43
Table Z.17	Comments Provided by Mobile Testing, Dated October 10, 1998	Z-44
Table Z.18	Comments Provided by the Nuclear Energy Institute, Dated December 16, 1998	Z-45
Table Z.19	Comments from Public Meetings on 10 CFR Part 35	Z-46
Table Z.20	Comments Provided by the National Institutes of Health, Dated November and December, 1998	Z-51

FOREWORD

NRC is using Business Process Redesign (BPR) techniques to redesign its materials licensing process. This effort is described in NUREG-1539, "Methodology and Findings of NRC's Materials Licensing Process Redesign," dated April 1996. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. 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	Draft 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

FOREWORD

Vol. No.	Volume Title	Status
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

This document, NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated July 2001, is the ninth program-specific guidance document developed for the new process. It is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. It combines and updates the guidance for applicants and licensees previously found in RG 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs," dated August 1987, and the guidance for licensing staff previously found in P&GDs, draft RGs, and Standard Review Plans. In addition, this report also contains pertinent information found in Information Notices (INs), as listed in Appendix A.

Because this report takes a risk-informed, performance-based approach to medical use licensing, it reduces the amount of information needed from an applicant seeking to possess and use certain quantities of byproduct material. For instance, the regulations found in 10 CFR Part 35 and reflected in this report do not require the submission of detailed radiation monitoring equipment calibration procedures. Instead, confirmation of the development of procedures in accordance with the regulations is requested. The risk-informed, performance-based approach to the regulation of NRC licensed materials is also being emphasized in the inspection and enforcement arena.

FOREWORD

A team composed of NRC and state departments of health staff drafted this document, drawing on their collective experience in radiation safety in general and as specifically applied to medical use of byproduct material; input from external stakeholders was also considered during preparation of the guidance. A representative of NRC's Office of the General Counsel provided legal guidance.

NUREG-1556, Vol. 9, is not a substitute for NRC regulations. The approaches and methods described in this report are provided for information only.



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ABBREVIATIONS

AAPM	American Association of Physicists in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
AU	Authorized User
bkg	background
BPR	Business Process Redesign
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	centimeter cubed
cm ²	centimeter squared
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
ft	foot
GM	Geiger-Mueller
GPO	Government Printing Office
GSR	gamma stereotactic radiosurgery

ABBREVIATIONS

HDR	high dose-rate
I-125	iodine-125
I-131	iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low dose-rate
mCi	millicurie
ml	milliliter
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

ABBREVIATIONS

RG	Regulatory Guide
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)
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
μ Ci	microcurie
%	percent

1 PURPOSE OF REPORT

The term “patient” is used to represent “patient” or “human research subject” throughout this report. The term “applicant” is used when describing the application process and the term “licensee” is used when describing a regulatory requirement.

This report provides guidance to an applicant in preparing a medical use license application. It also provides guidance on NRC criteria for evaluating a medical use license application. It is not intended to address the commercial aspects of manufacturing, distribution, and service of sources in devices. Additionally, since this report gives guidance for applying for an application under 10 CFR Part 35, “Medical Use of Byproduct Material,” it does not specifically describe the possession and use of pacemakers, which are licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.”

Radionuclides are used for a variety of purposes in medicine. Typical uses are:

- Diagnostic studies with unsealed radionuclides;
- Therapeutic administrations with unsealed radionuclides;
- Diagnostic studies with sealed radionuclides;
- Manual brachytherapy with sealed sources; and
- Therapeutic administrations with sealed sources in devices (i.e., teletherapy, remote afterloaders, and gamma stereotactic radiosurgery (GSR) units).

This report describes the information needed to complete NRC Form 313 (Appendix B), “Application for Material License,” for medical use of radionuclides. This guidance volume (NUREG-1556, Vol. 9) may not directly address complete radiation safety and licensing guidance for uses specified in 10 CFR 35.1000. Therefore, NRC staff should be contacted with questions regarding licensing information for such uses. 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.

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;

PURPOSE OF REPORT

- **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.

The regulations require the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the regulations. The appendices describe model radiation protection procedures. Each applicant should read the regulations and model procedures carefully and then decide if the model procedure addresses specific radiation protection program needs at the applicant's facility. Applicants may adopt a model procedure or they may develop their own procedures to comply with the applicable regulation. 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. However, the applicant must state that applicable procedures have been developed, implemented, and maintained in accordance with the regulations.

NRC Form 313 does not have sufficient space for applicants to provide full responses to Items 5 through 11; as the form indicates, answers to those items must be provided on separate sheets of paper and submitted with the completed NRC Form 313.

Appendix C includes:

- Sample medical licenses with conditions most often found in these licenses (not all licenses will have all conditions);
- A checklist to assist the applicant in determining which sections of this document and required procedures apply to the type of medical license requested; and
- A checklist for providing application information.

Appendix C contains a sample license for pacemakers. However, as described above, this document provides guidance only on medical use of byproduct material, and does not specifically address the possession and use of pacemakers. Appendices D through Y contain additional information on various radiation protection topics.

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 terms are defined in 10 CFR Part 20. Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because 10 CFR Part 20 sets dose limits in terms of rem, not rad or

roentgen. Furthermore, the sources commonly used in therapy emit beta and photon radiation, and as 10 CFR Part 20 states, the quality factor of 1 is applied for high-energy beta emissions and photons, resulting in the following relation: 1 roentgen = 1 rad = 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).

Applicants and licensees should also be aware of an other document in this series that provides useful information for medical use licensees. 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.

1.1 LICENSES

NRC regulates the intentional internal or external administration of byproduct material, or the radiation from byproduct material, to patients or human research subjects for medical use. A specific license of either limited or broad scope is issued to authorize possession and use of licensed material. These licenses are issued pursuant to 10 CFR Parts 30, 33, and 35. NRC issues three types of licenses for the use of byproduct material in medical practices and facilities. These are the general *in vitro* license, the specific license of limited scope, and the specific license of broad scope.

NRC usually issues a single byproduct material license to cover an entire radionuclide program – except for nuclear-powered pacemakers. A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units. Although NRC may issue separate licenses to individual licensees for different medical uses, it does not usually issue separate licenses to different departments in a medical facility or to individuals employed by 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 Form 313. 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

PURPOSE OF REPORT

assurance that an adequate radiation protection program has been established. Additionally, guidance on use at multiple sites can be found in P&GD PG 1-23, "Guidance for Multi-Site Licenses."

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

1.1.1 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 microcurie 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 microcurie 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 millicurie. 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.

1.1.2 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.

1.1.3 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. 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 unspecified 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.

PURPOSE OF REPORT

1.2 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.

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," and RG 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be ALARA," provide NRC staff's position on this subject. Background information on the ALARA philosophy and its application in the medical environment is contained in NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions ALARA" and 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 WRITTEN DIRECTIVE (WD) PROCEDURES

10 CFR 35.41 requires 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, at a minimum, these procedures must address. Appendix S provides further information on developing these procedures.

1.4 RESEARCH INVOLVING HUMAN SUBJECTS

10 CFR 35.2 defines "medical use" to include the administration of byproduct material 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 conducted by limited specific medical use licensees and broad scope medical use licensees.

PURPOSE OF REPORT

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.

Licensees conducting human research using radioactive drugs, sealed sources, and/or devices are responsible for ensuring that, in addition to complying with 10 CFR 35.6, they comply with all other applicable NRC requirements and license conditions. Therefore, it is a licensee's responsibility to ensure that:

- It is authorized to possess the materials and devices needed to participate in the research studies;
- The materials and devices to be used in the research are included in the specific medical uses authorized in the license;
- The procedures in the research protocols do not conflict with NRC regulatory and license requirements; and
- It is in compliance with 10 CFR 35.6, its license, and any other NRC regulatory requirements.

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.

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

AGREEMENT STATES

Locations of NRC Offices and Agreement States

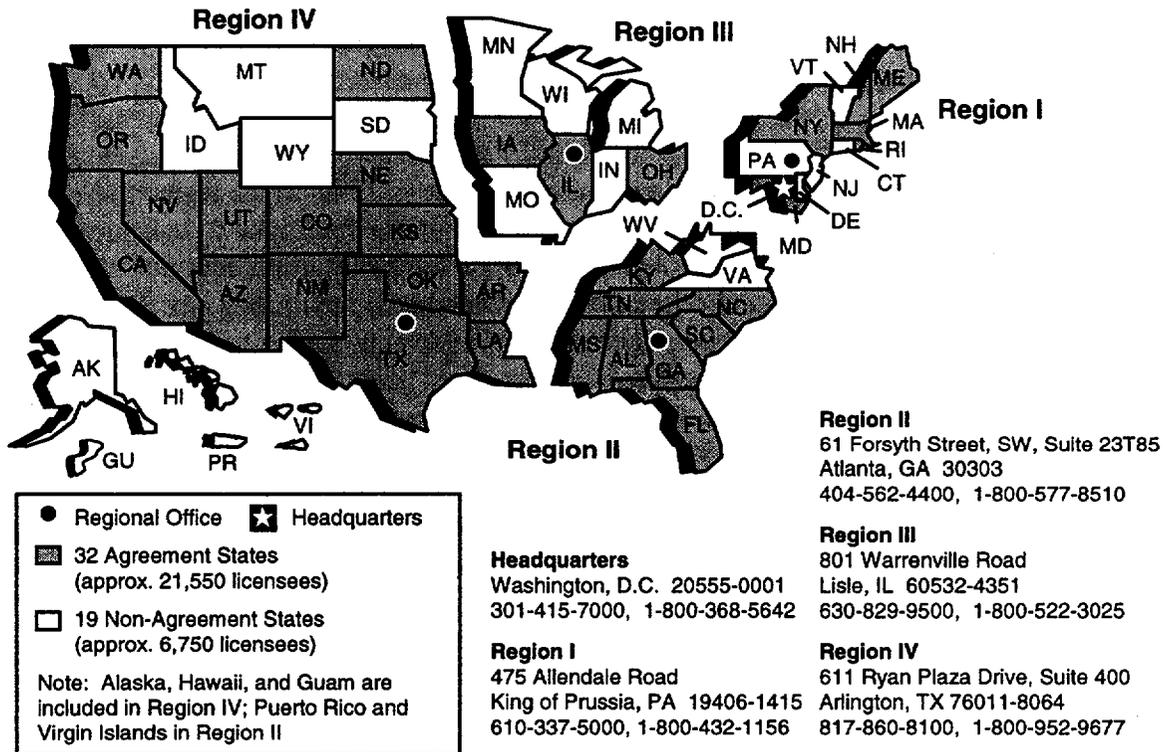


Figure 2.1 U.S. Map. Location of NRC Offices and Agreement States.

Reference: 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 (STP) 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 STP. STP 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).

“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.

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 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 “General Statement of Policy and Procedures for NRC Enforcement Actions,” NUREG-1600; NRC Inspection Manual, Chapter 2800 “Materials Inspection Program”; and Inspection Procedures in the 87100 series (e.g., 87115-Nuclear Medicine, 87116-Teletherapy, 87118-Brachytherapy, and 87119-Medical Broad Scope); 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>>, under “Nuclear Materials,” then “Enforcement,” “Guidance Documents,” or “Current Policy.”

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> in the "electronic reading room"; printed copies are available from the U.S. Government Printing Office.

- 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. For ordering information on the regulations, see the Notice of Availability on the inside front cover of this report.

- 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274"
- 10 CFR Part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 CFR Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC."

APPLICABLE REGULATIONS

In addition to the information provided in the Notice of Availability (on the inside front cover of this report), to request copies of the above documents, applicants 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 at <<http://www.nrc.gov>>, under "Reference Library," and then "Title 10 of The Code of Federal Regulations."

5 HOW TO FILE

5.1 PAPER 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 B) 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;
- 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 Appendix C, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application and one copy; and
- Retain one copy of the license application for future reference.

As required by 10 CFR 35.12(a), applications must be signed by the applicant's or licensee's management; see Section 8.46, Item 13, on "Certification."

Using the suggested wording of responses in this report will expedite NRC's review.

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

HOW TO FILE

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 are asked to follow these suggestions:

- 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 8.42 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.

In general, applicants that wish to possess or use licensed 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.

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 B) to the Office of the Chief Financial Officer (OCFO) at NRC Headquarters in Rockville, Maryland, (301) 415-7554. Information about fees may also be obtained by calling NRC toll-free at (800) 368-5642, extension 415-7554, 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 requested on NRC Form 313. Items 5 through 11 on the form request specific information about the 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.

Applicants must provide detailed information about the following:

- Proposed facilities and equipment;
- Training and experience of byproduct material users and the RSO;
- Delegation of authority to RSO;
- Financial assurance (if applicable);
- Mobile use of byproduct material (if applicable); and
- Procedures required by Subpart H, “Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units” (if applicable).

Additionally, in response to Items 9, 10, and 11, the applicant must provide a commitment to develop, implement, and maintain various procedures to meet the requirements of the applicable regulation. The language used in the Response from Applicant – “develop, implement, and maintain” – was chosen because this language is consistent with language used in 10 CFR 35.41 and 10 CFR 35.610. Responses linked to requirements in 10 CFR Part 20 also include the language “develop, implement, and maintain” even though the language in 10 CFR 20.1101 is “develop, document, and implement” and the language in 10 CFR 20.1906 is “establish, maintain, and retain.” To simplify the Response from Applicant and to avoid confusion, the language “develop, implement, and maintain” was chosen for all responses. A requirement or commitment to develop, implement, and maintain written procedures means the licensee will prepare written procedures, follow the procedures and keep them available for reference and review during NRC inspections. Procedures should provide for:

- Instruction of individuals in the procedures;
- Discussion of timeliness and frequency of conduct procedures;
- Periodic verification through observation, records review, or some other audit method, that individuals know the procedures and follow them; and
- Updating the procedures as necessary to accommodate changes in the license program, such as the introduction of new diagnosis or treatment methods.

CONTENTS OF AN APPLICATION

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. If a particular item requires the applicant to develop, implement, and maintain a procedure, the applicant may use the following wording in each response section on the application:

“We have developed and will implement and maintain written procedures for _____ that meet the requirements of 10 CFR _____.”

If a particular part of a section does not apply, simply note “NA” for “not applicable.” If a particular section applies, but a procedure does not have to be developed, simply note “N” for “no response required.” NA, 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 B), responses to Items 5 through 11 should be submitted on separate sheets of paper. Applicants may use Appendix C to assist with completion of the application. Applicants should note that using the suggested wording of responses will expedite NRC’s review.

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

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 renewal¹ 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.

Note: NRC must be notified before control of the license is transferred or whenever bankruptcy proceedings are initiated. See below 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.

¹ See "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.

CONTENTS OF AN APPLICATION

Timely Notification of Transfer of Control

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

Criteria: 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."

Discussion: 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 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 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.

Response from Applicant: No response is required for an applicant for a new license. Appendix D, excerpted from Appendix F of NUREG-1556, Vol. 15, identifies the information to be provided about transferring control.

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, <<http://www.nrc.gov>>, under "Reference Library," then "Information Notices" or "Technical Reports (NUREGS)."

Notification of Bankruptcy Proceedings

Regulation: 10 CFR 30.34(h).

Criteria: Immediately following filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the appropriate NRC Regional Administrator, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

Discussion: Even though a 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.

Response from Applicant: No response is required from an applicant at the time of application for a new license. Licensees must notify NRC immediately (i.e., within 24 hours) of the filing of a bankruptcy petition.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of Policy and Guidance Directive PG 8-11, "NMSS Procedures for Reviewing Declarations of Bankruptcy," dated August 8, 1996, and Inspection Procedure (IP) 87103, "Inspection of Material Licensee Involved in an Incident or Bankruptcy Filing."

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

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

Pursuant to 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 (see Figure 8.1). 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. Refer to P&GD PG 1-23, "Guidance for Multi-Site Licenses," for additional guidance on applying for use at multiple sites. If applying for a license for a mobile

CONTENTS OF AN APPLICATION

service as authorized pursuant to 10 CFR 35.18(b), the applicant should refer to Section 8.42 and Appendix V of this report for specific licensing guidance.

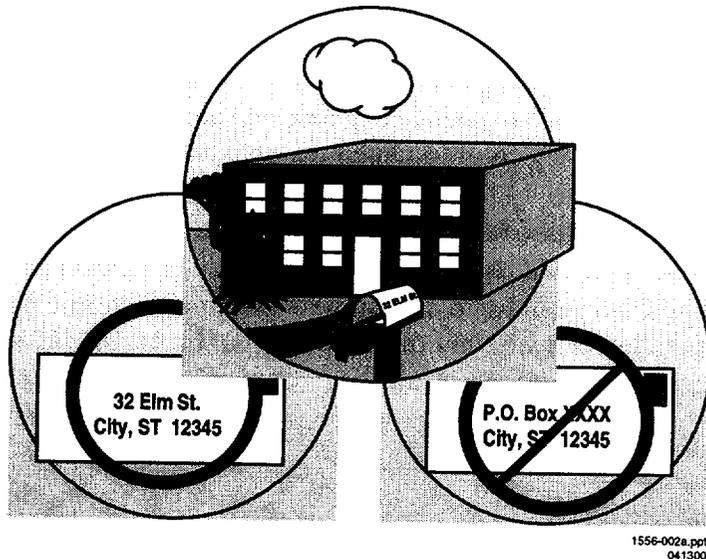


Figure 8.1 Location of Use.

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 “Financial Assurance and Recordkeeping for Decommissioning” below, 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

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). Any commitments the applicant makes should be signed by the individual named in Item 13 since only that individual is considered by NRC to have the authority to make commitments on behalf of the applicant. Therefore, NRC will not accept license amendments or renewals signed by the individual identified in Item 4 if this person differs from the one named in Item 13.

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 30.33; 10 CFR 30.34; 10 CFR 30.35; 10 CFR 32.210; 10 CFR 35.12; 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).

Discussion: Using the table formats below (see Table 8.1), the applicant should indicate the byproduct material requested. For 35.100, 35.200, and 35.300 material, the chemical/physical form may be "Any." In accordance with Item 5 on NRC Form 313, the maximum amount that will be possessed at any one time must be specified. For 35.100 and 35.200 material, the total amount requested may be "As Needed." For 35.300 material, the total amount requested must be specified. For 35.400, 35.500, 35.600, and 35.1000 material, the radionuclide, the chemical/physical form (e.g., sealed source and manufacturer's name and model number), the total amount in Becquerels (Bq), microcurie (μ Ci), millicurie (mCi), or curies (Ci), and maximum number of sources or activity possessed at any one time must be specified. For calibration, transmission, and reference sources covered under 10 CFR 35.65, the specific

CONTENTS OF AN APPLICATION

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.

For sealed sources used in devices, an applicant may wish to request two sources, one to be used in the device and one to be stored in its shipping container, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. Pursuant to 10 CFR 30.32 and 10 CFR 32.210, 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, it is permissible to 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 device source activity limit prior to installation in the device.

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. 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 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, depleted uranium for linear accelerator shielding, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). Sources that are authorized by 10 CFR 35.65, "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.

Table 8.1 Sample Format for Byproduct Material

Byproduct Material	Chemical/Physical Form	Maximum Amount
Any byproduct material included in 10 CFR 35.100	Any	As needed
Any byproduct material included in 10 CFR 35.200	Any	As needed
Any byproduct material included in 10 CFR 35.300	Any	300 millicurie
Cesium 137 (i.e., specific brachytherapy radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicurie per source and 1 curie total
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	Sealed source (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 (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 (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total
Depleted Uranium	Metal	99 kilograms
Any byproduct material identified in 10 CFR 31.11	Prepackaged kits	50 millicurie

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 shall submit the information as described above.

8.6 ITEM 5: FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

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

Criteria: 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.

Even if no financial assurance is required, licensees are required, under 10 CFR 30.35(g), to maintain records important to decommissioning in an identified location (see Figure 8.2). 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. 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), or to the appropriate NRC Regional Office before the license is terminated.

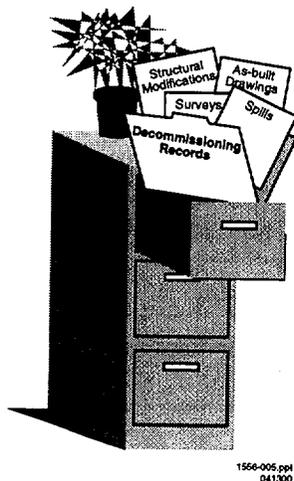


Figure 8.2 Decommissioning Records.

Discussion: The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most medical use applicants and licensees do not need to take any action to comply with the financial assurance requirements because either 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. See Appendix E for additional information.

Applicants and licensees that want to possess licensed materials exceeding the limits in 10 CFR 30.35 must submit evidence of financial assurance or a decommissioning funding plan (10 CFR 30.35 (b)). Figure 8.3 depicts acceptable methods of providing financial assurance. Regulatory Guide (RG) 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds, except for the Statement of Intent for Government licensees. See Appendix E for the recommended wording for a Statement of Intent.

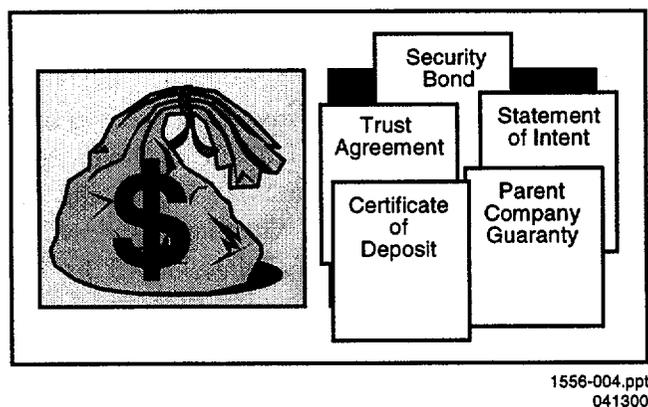


Figure 8.3 Financial Assurance Mechanisms.

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. Table 8.2 shows examples of the limits for select sealed sources.

Table 8.2 Minimum Sealed Source Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity in GBq	Activity in Ci
cesium-137 (Cs-137)	3.7×10^6	100,000
cobalt-60 (Co-60)	3.7×10^5	10,000
strontium-90 (Sr-90)	3.7×10^4	1,000

CONTENTS OF AN APPLICATION

Licenses 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.

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 RG 3.66.

Pursuant to 10 CFR 30.35(g), licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 10 CFR 30.34(b) or to the appropriate NRC Regional Office before the license is terminated.

Reference: See the Notice of Availability on the inside front cover of this report to obtain copies of Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, and Policy and Guidance Directive FC 90-2 (Rev. 1), "Standard Review Plan for Evaluating Compliance with Decommissioning Requirements," dated April 30, 1991.

8.7 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.

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 SDR 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 SDR Certificate or specifically approved on

a license. If such a review has not been conducted for the specific source/device model(s), licensees should request a copy of NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration," dated July 1998, 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 registration certificates, applicants may want to obtain copies of the certificates and review or discuss them with the manufacturer. A compilation of these registration certificates may be found at <<http://www.hsrdr.ornl.gov/nrc/ssdr/ssdrindx.html>>.

In addition, many sealed sources must have a National Institute of Standards and Technology (NIST) traceable calibration prior to use. Refer to Section 8.41 for additional information on calibration of therapy sealed sources.

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," dated July 1998.

Note: Information on SSD registration certificates is also available on the Internet at <<http://www.hsrdr.ornl.gov/nrc/ssdr/ssdrindx.html>> or by calling NRC's Registration Assistant toll-free at (800) 368-5642, extension 415-7217.

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

Regulations: 10 CFR 30.32(b); 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.

CONTENTS OF AN APPLICATION

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
10 CFR 35.600	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
10 CFR 35.600	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 (Emerging Technology)

Discussion: For 35.100, 35.200, and 35.300 material, 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 approved in 10 CFR 35.100).

The use of unsealed byproduct material in therapy (10 CFR 35.300) involves administering a radiopharmaceutical, either orally or by injection, to treat or palliate a particular disease. The most common form of radiopharmaceutical therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include 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. Table 8.3 contains a summary of several therapeutic radiopharmaceuticals and their uses.

If only requesting a specific radioisotope for therapy use under 10 CFR 35.300, the applicant should provide the information as described in the table below.

Table 8.3 Radiopharmaceuticals Used in Therapy

Agent	Form	Route of Administration	Therapeutic Use
I-131 sodium iodide	solution/ capsules	oral	hyperthyroidism thyroid carcinoma total body scan for thyroid metastasis (diagnostic)
phosphorus-32 (P-32) chromic phosphate	colloidal suspension	intraperitoneal or intrapleural cavity injection	peritoneal or pleural effusions
P-32 sodium phosphate	solution	oral or IV	polycythemia vera leukemia
strontium-89 chloride	solution	IV	skeletal metastasis
samarium-153 EDTMP	solution	IV	skeletal metastasis
rhenum-186 HEDP	solution	IV	skeletal metastasis
tin-117m DTPA	solution	IV	skeletal metastasis
dysprosium-165 FHMA	aggregate in solution	IV	rheumatoid arthritis
yttrium-90 FHMA	aggregate in solution	IV	rheumatoid arthritis

For 35.400 material, 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 correlate the sealed sources listed in Item 5 with the devices described in this item.

CONTENTS OF AN APPLICATION

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

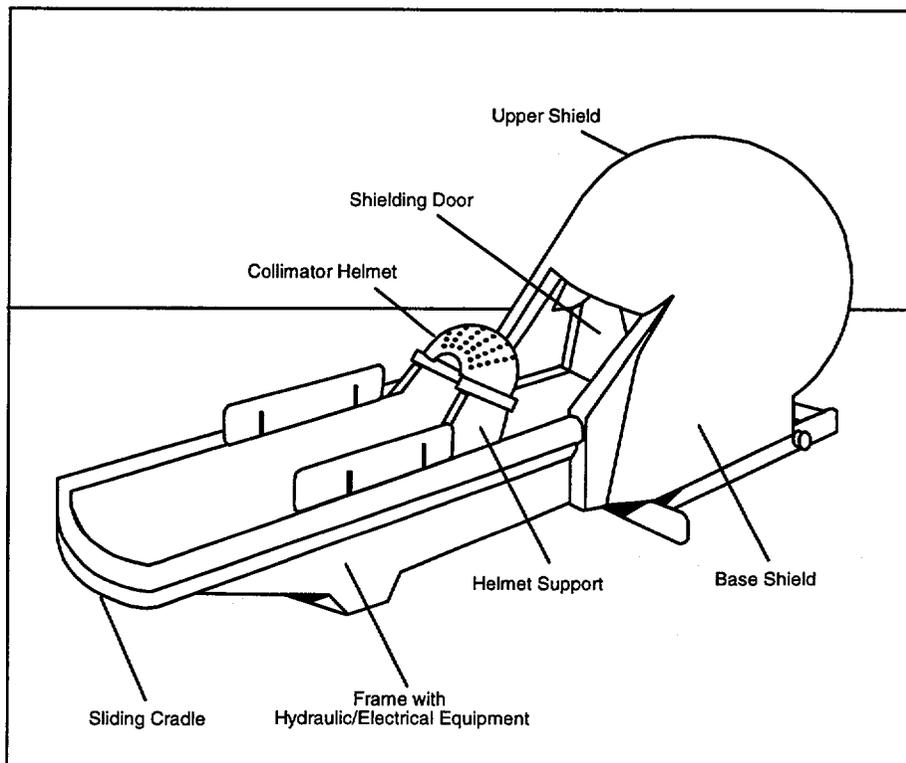
- **Interstitial Treatment of Cancer.** The following sources are routinely used:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells;
 - iridium-192 (Ir-192) as seeds encased in nylon ribbon; and
 - gold-198 (Au-198), iodine-125 (I-125), and palladium-103 (Pd-103) as a sealed source in seeds.
- **Eye Plaque Implants.** The eye plaque consists of a curved soft plastic insert that has a series of grooves molded into the rear convex surface that are designed to hold radioactive seeds. After the plastic insert is loaded with the seeds, a solid gold cover, matched in size to the insert, is placed over the convex surface of the insert and cemented in place to seal the seeds into a fixed array within the plaque. The insert is completely surrounded by the gold cover except for the concave surface that is placed against the eye. When used with I-125 and Pd-103 seeds, the gold cover provides considerable shielding of the normal tissues surrounding the eye and limits the external dose rates surrounding the patient. Although not implanted into the tumor, because the plaque is placed in the orbit of the eye over the tumor site and sutured to the sclera of the eye to stabilize its position on the tumor while in the orbit, 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. The following sources are routinely used for the intracavitary treatment of cancer:
 - Cs-137 and Co-60 as a sealed source in needles and applicator cells;
 - Ir-192 and Pd-103 seeds.
- **Topical (Surface) Applications.** The following sources are routinely used for topical applications:
 - Cs-137 and Co-60 as sealed sources in needles and applicator cells;
 - Sr-90 as a sealed source in an applicator for treatment of superficial eye conditions.

For 10 CFR 35.500 material, 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 following sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR:

- I-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis;
- I-125 as a sealed source in a portable imaging device.

For 10 CFR 35.600 material, 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). Figure 8.4 shows a schematic of a GSR unit. 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.



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Figure 8.4 Gamma Stereotactic Radiosurgery Unit.

CONTENTS OF AN APPLICATION

For 10 CFR 35.1000 material, the applicant should define the purpose of use and list the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item.

An example of an "emerging technology" (byproduct material approved for medical use not specifically addressed elsewhere in 10 CFR Part 35) is the use of byproduct material to prevent restenosis following angioplasty. Some research institutions have shown that post-operative radiation exposure reduces the probability of such restenosis. Radionuclides that are used in emerging technologies for restenosis include P-32, Sr-90, Ir-192, rhenium-186, rhenium-188, xenon-133, and hydrogen-3.

Emerging technologies for restenosis have been developed using radioactive catheters, pellets, and stents to treat coronary and peripheral vascular problems. These therapy devices contain ionizing radiation in the form of a gas, liquid, or solid that retards recoil and proliferation of smooth muscle cells in the affected vessel wall. The radiation can be ion implanted, plated, or encapsulated in a sealed source device attached to a guide wire used in the angioplasty procedure. The radioactive device can be permanently implanted, or it can be removed with the guide wire following treatment of the affected vessel wall.

Intracoronary radiation therapy is emerging as the primary discipline of the new technology. Several innovative types of intravascular radiation therapy devices for use after balloon angioplasty are being clinically investigated and include:

- Intracoronary Beta and/or Photon Radiation Catheter (Figure 8.5) – The catheter is not an implant and the radiation is delivered after a balloon angioplasty.
- Intracoronary Beta and/or Photon Radiation Stent (Figure 8.6) – The stent is a permanent implant and the radiation is delivered after balloon angioplasty.
- Intracoronary Beta and/or Photon Radiation Pellets – The pellets are a temporary implant and the radiation is delivered after balloon angioplasty.

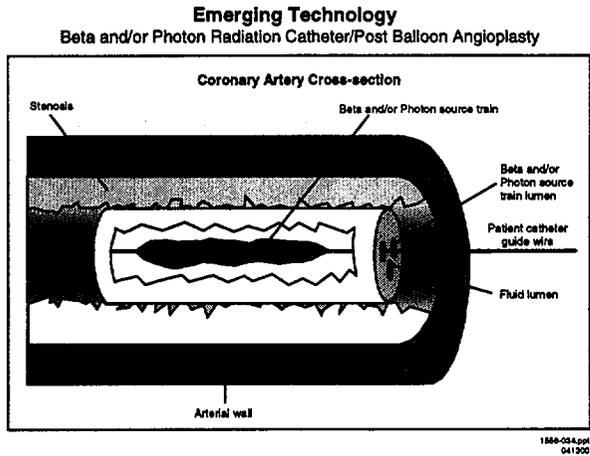


Figure 8.5 Beta and/or Photon Radiation Catheter.

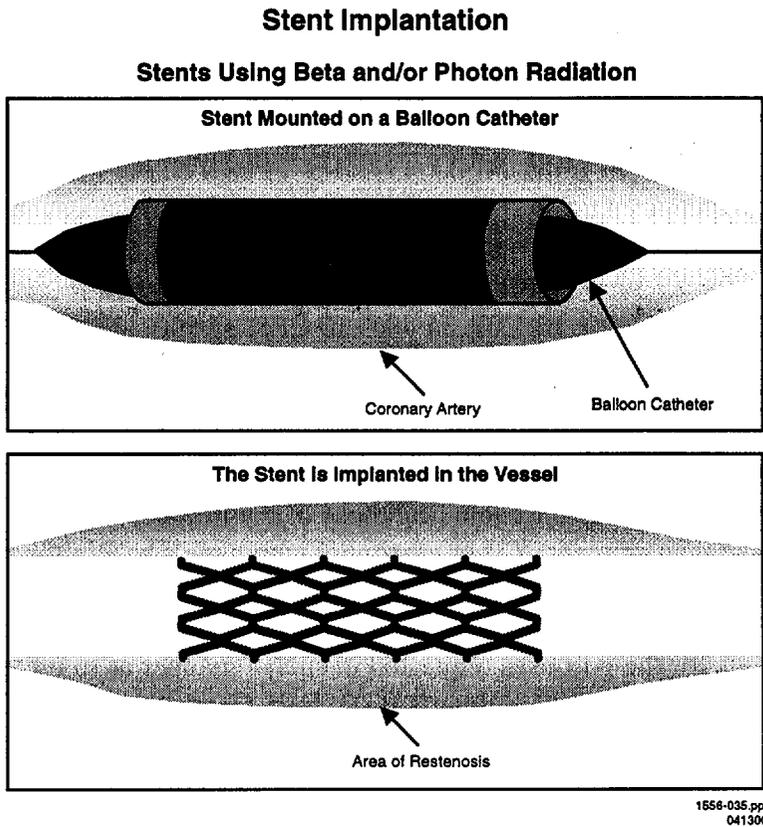


Figure 8.6 Stent Implantation.

CONTENTS OF AN APPLICATION

The United States Food and Drug Administration (FDA) has considered the use of radiation in the coronary and/or peripheral vasculature for the prevention of restenosis investigational with the potential for risk to patients. Legal and ethical considerations require U.S. patients be studied under an FDA "investigational device exemption" application. An "investigational device exemption" from the FDA does not preclude the necessity for an NRC license for the byproduct material. At the time of this writing, a couple of devices have been approved by the FDA for routine clinical use under the conditions of use as specified by the FDA. If the source is a sealed source, Section 8.7 describes the type of sealed source and device information that must be provided at the time of application. Additionally, broad scope licensees should refer to IN 99-024, "Broad-Scope Licensees' Responsibilities for Reviewing and Approving Unregistered Sealed Sources and Devices."

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.

Appendix C contains sample licenses that provide guidance on how to respond to Item 6.

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

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

Regulations: 10 CFR 30.33(a)(3); 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, members of the RSC (if required to establish), AMPs, and ANPs. 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 such a manner as to protect health and minimize danger to life or property. Subparts B, D, E, F, G, and J² of 10 CFR Part 35 give

² Subpart J of 10 CFR Part 35 will be deleted 2 years after the date of publication of the final revision of Part 35; applicants should check for possible revisions to Training and Experience requirements in Part 35.

specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

Applicants should note that a résumé or a curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience for NRC purposes because these documents often list publications rather than specific training required by NRC regulations.

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. In addition, 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, must establish an RSC to oversee all uses of byproduct material permitted by the license.

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)

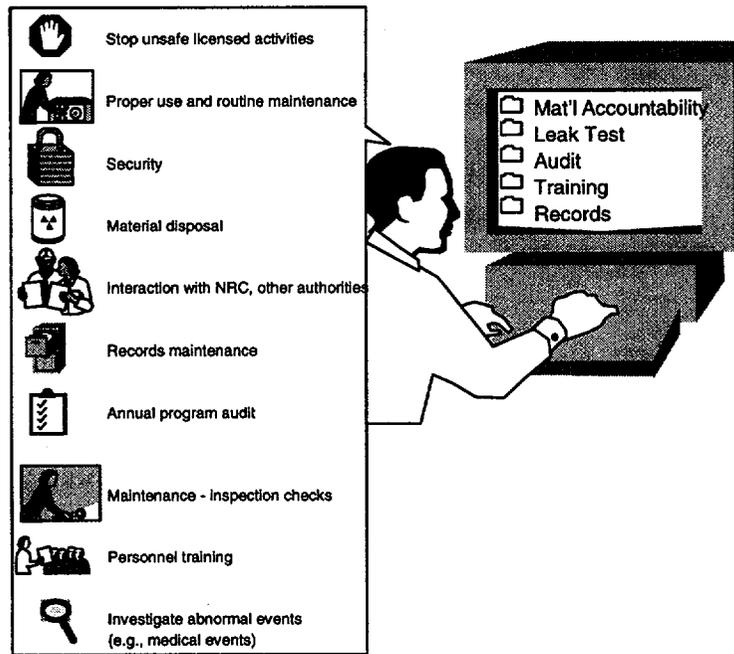
Regulations: 10 CFR 30.33(a)(3); 10 CFR 35.14; 10 CFR 35.24; 10 CFR 35.50; 10 CFR 35.57; 10 CFR 35.59; 10 CFR 35.2024.

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

- Certification by one of the professional boards recognized by NRC;
- Didactic training (200 hours) and 1 year of work experience 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; however, 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; however, the RSO must be available for meaningful, on-site, person-to-person interactions with licensee staff to satisfy requirements of 10 CFR 35.24. Typical RSO duties are illustrated in Figure 8.7 and described in Appendix F. Appendix F also contains a model RSO Delegation of Authority. Appendix G contains forms that can be used to document the RSO's training and experience.



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Figure 8.7 RSO Responsibilities. *Typical duties and responsibilities of RSOs.*

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

- Delegation of Authority and the written agreement of the RSO to be responsible for implementing the radiation protection program (see Appendix F).

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

CONTENTS OF AN APPLICATION

- 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 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. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

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.

Notes:

- 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 training and experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities 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 deleted 2 years after the publication of the final revision of 10 CFR Part 35. Until then, licensees may follow this provision of the rule to meet training and experience requirements, with the exception of 10 CFR 35.59, "Recentness of training."
- 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. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.11 ITEM 7: AUTHORIZED USERS (AUs)

Regulations: 10 CFR 30.33(a)(3); 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.

Criteria: Training and experience requirements for physician-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 Subpart J.

Discussion: An AU is defined in 10 CFR 35.2, "Definitions." Included in the responsibilities of AUs involved in medical use are 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 medical use of byproduct material;
- Preparation of WDs, if required.

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).

For *in vitro* studies, 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 the user's training and experience.

Applicants are reminded of recentness of training requirements described in 10 CFR 35.59. Specifically, physician-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, physician-AU 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.

CONTENTS OF AN APPLICATION

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 and as applicable to the use requested.

OR

- Description of the training and experience demonstrating that the proposed AU is qualified by training and experience for the use requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

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.

Notes:

- 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 deleted 2 years after the publication of the final revision of 10 CFR Part 35. Until then, licensees may follow this provision of the rule to meet training and experience requirements, with the exception of 10 CFR 35.59, "Recentness of training."
- 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. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.
- 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.

8.12 ITEM 7: AUTHORIZED NUCLEAR PHARMACIST (ANP)

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

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

Discussion: An ANP is defined in 10 CFR 35.2, "Definitions." 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).

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.

OR

- Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

AND

CONTENTS OF AN APPLICATION

- 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.

Notes:

- 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.
- Subpart J will be deleted 2 years after the publication of the final revision of 10 CFR Part 35. Until then, licensees may follow this provision of the rule to meet training and experience requirements, with the exception of 10 CFR 35.59, "Recentness of training."
- 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. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.13 ITEM 7: AUTHORIZED MEDICAL PHYSICIST (AMP)

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

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

Discussion: An AMP is defined in 10 CFR 35.2, "Definitions." 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.

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience for the units requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).

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.

Notes:

- 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 deleted 2 years after the publication of the final revision of 10 CFR Part 35. Until then, licensees may follow this provision of the rule to meet training and experience requirements, with the exception of 10 CFR 35.59, "Recentness of training."
- 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. Referrals to the ACMUI are normally limited to new types of medical use not previously described in the regulations or guidance.

8.14 ITEM 8: SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

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. Records of safety instruction provided must be maintained in accordance with 10 CFR 35.2310. 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 5.310, 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 must 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.

A model training program is provided in Appendix H.

Response from Applicant: No response is necessary.

8.15 ITEM 9: FACILITIES AND EQUIPMENT

Regulations: 10 CFR 30.33(a)(2).

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

Discussion: In 10 CFR 30.33(a)(2), NRC states that an application 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 8.16 through 8.20 for guidance.

8.16 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 30.32(b); 10 CFR 30.33(a)(2); 10 CFR 35.12; 10 CFR 35.14; 10 CFR 35.75; 10 CFR 35.315(a); 10 CFR 35.415; 10 CFR 35.615.

CONTENTS OF AN APPLICATION

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

Discussion: Applicants must describe the proposed facilities and equipment as required by 10 CFR 35.12 and must submit a facility diagram of the room or rooms (and adjacent areas) in which byproduct material will be received, prepared, used, administered, and stored. The diagram should be identified as Attachment 9.1. The areas to be represented in the diagram include rooms for patients hospitalized in accordance with 10 CFR 35.75; rooms used for preparing and administering radiopharmaceutical dosages or radiation doses; radioactive waste storage areas; and all byproduct material use areas, including those used for receipt and storage of the byproduct material. Pursuant to 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public," licensees must demonstrate compliance with 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," for unrestricted or controlled areas that are adjacent to rooms in which byproduct material will be received, used, administered, and stored. Figure 8.8 depicts a typical nuclear medicine suite.

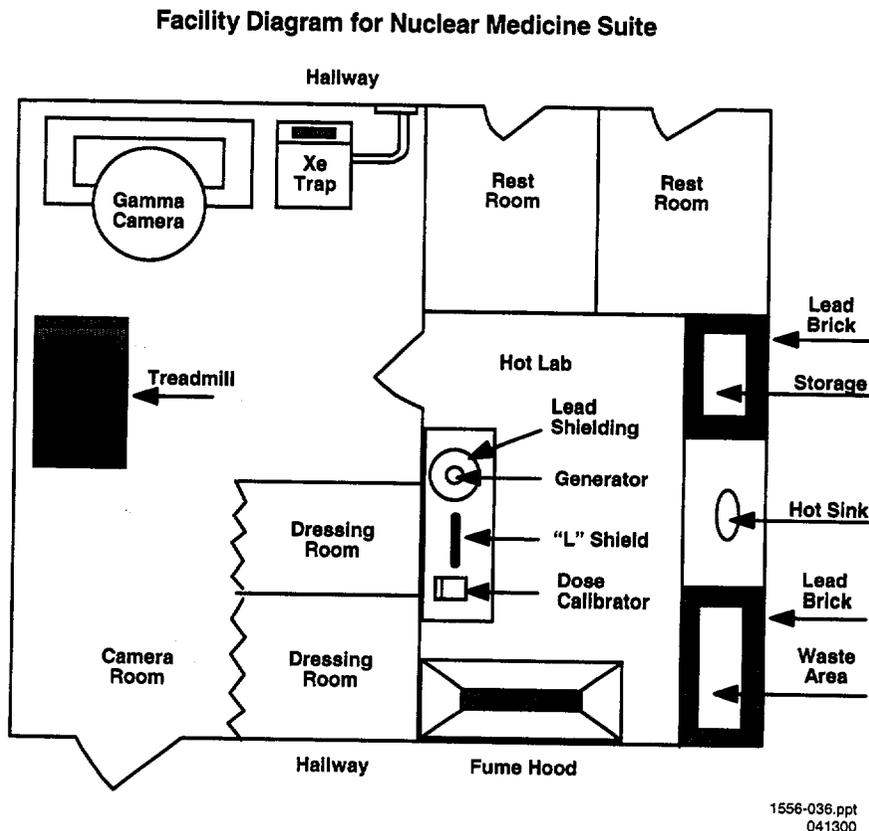


Figure 8.8 Facility Diagram for Nuclear Medicine Suite.

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. Use of byproduct material in a room that is not described in the license application requires prior NRC approval through a license amendment, except for areas of use where byproduct material is used in accordance with 10 CFR 35.100 and 10 CFR 35.200. Licensees must notify NRC, under 10 CFR 35.14, within 30 days following changes in areas of use for 10 CFR 35.100 and 10 CFR 35.200 byproduct material. Figure 8.9 presents a view of a radioiodine patient isolation room that contains some of the required elements discussed in the Response from Applicant section. Figure 8.10 presents an overhead view of a manual brachytherapy patient isolation room. Based on an evaluation of shielding and planned use of each area, the applicant must have determined whether each area adjacent to the treatment room will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations. For portable shields, the licensee should assure proper placement of the shield prior to each treatment. Applicants must also submit facility diagrams to illustrate areas above, beside, and below the facilities used for patient therapy treatments (e.g., other patient rooms, stairwells, nursing stations, and waiting areas). To assist in the review of these areas, the diagrams should be cross-sectional. The radiation dose levels associated with these areas must comply with 10 CFR 20.1302, "Compliance with dose limits for individual members of the public." In addition, if radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, submit additional room diagrams only if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided.

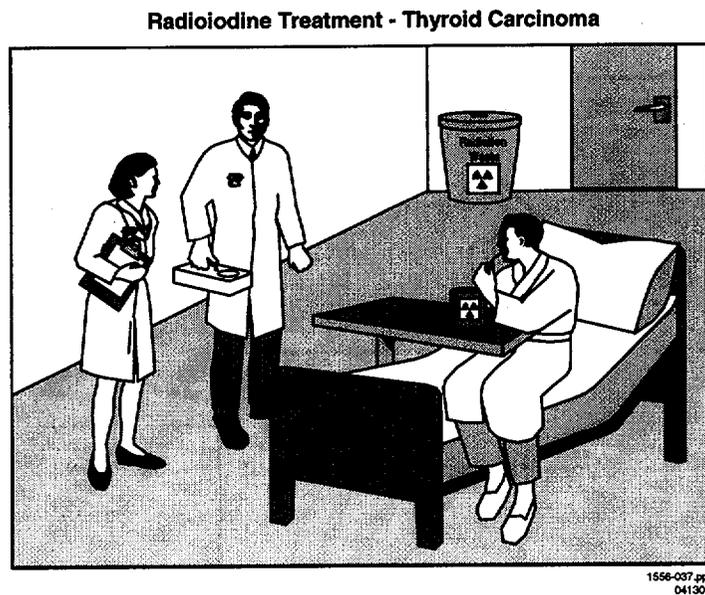
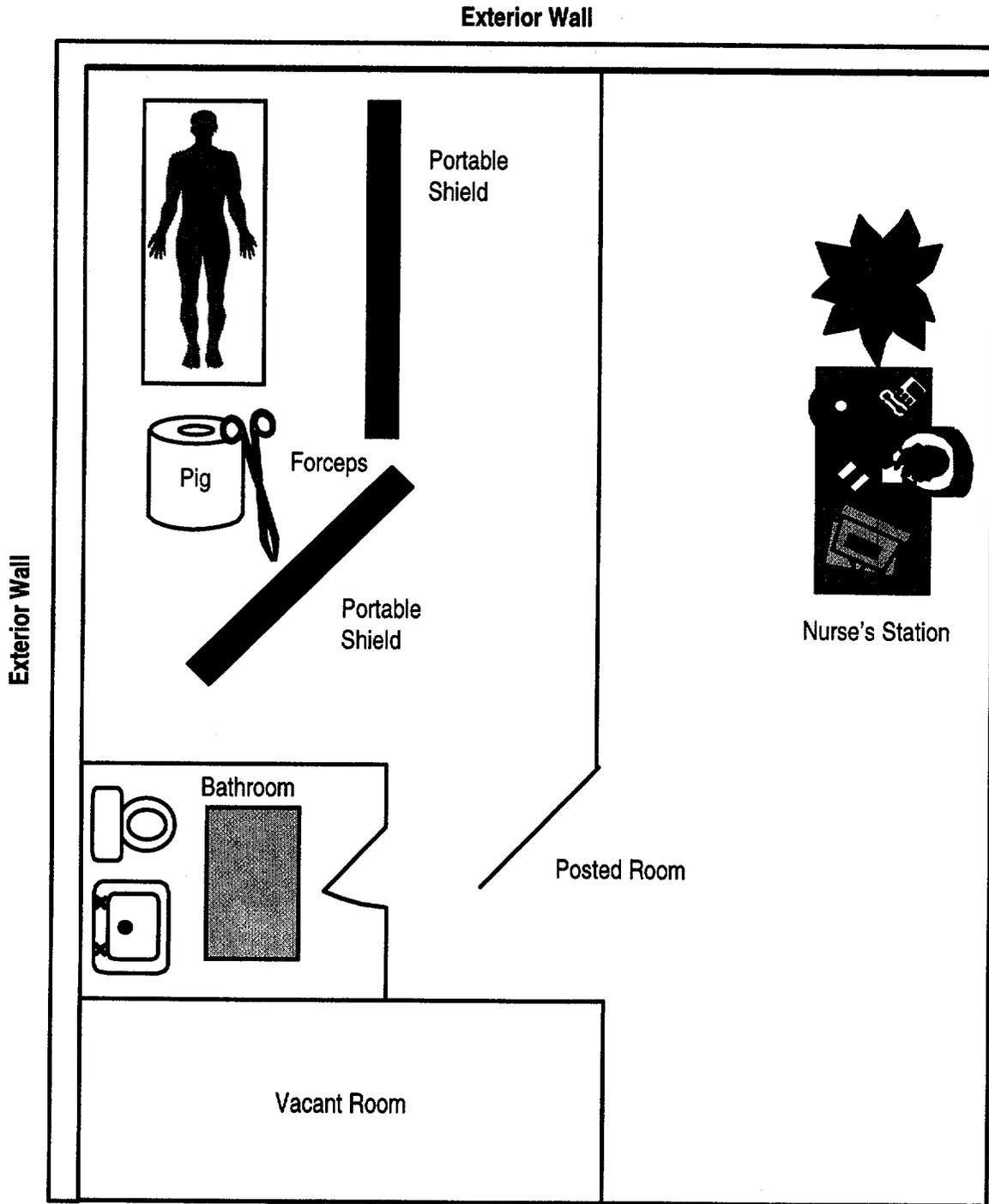


Figure 8.9 Iodine-131 NaI Administration for the Thyroid Carcinoma Patient. *The patient is required to be isolated in a private room (or with another radiopharmaceutical therapy patient) with a private bath.*



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Figure 8.10 Overhead View of Manual Brachytherapy Patient Treatment Room.

Figure 8.11 represents a combined HDR and teletherapy suite. Based on an evaluation of shielding and the planned use of each area, the applicant must determine if each area adjacent to the treatment room used for all therapies involving sealed sources will be maintained as a restricted or an unrestricted area, and must demonstrate compliance with NRC regulations.

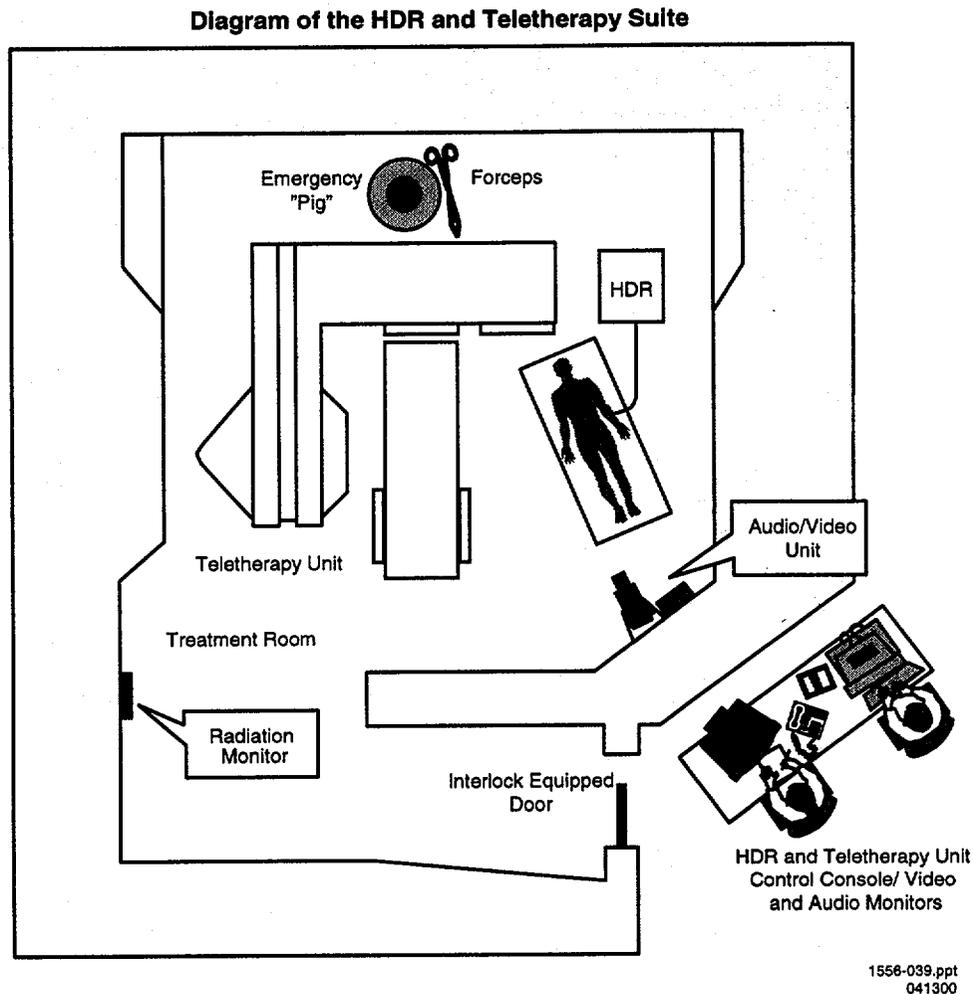


Figure 8.11 Teletherapy and HDR Treatment Room.

It may be necessary to restrict use of the teletherapy 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.

The teletherapy unit should be equipped with electrical or mechanical stops that limit use of the primary beam of radiation to ensure compliance with Subpart D of 10 CFR Part 20. Some

CONTENTS OF AN APPLICATION

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); the angle orientation convention described above applies:

- “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:

- Scale: use the same scale (preferably 1/4 inch = 1 foot) for all drawings;
- Direction of north;
- Location, room numbers, and principal use of each room or area where byproduct material is used or stored (e.g., patient therapy rooms, radioactive waste storage, nuclear medicine hot lab, manual brachytherapy source storage room);
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, as well as if the room is restricted or unrestricted as defined in 10 CFR 20.1003;
- Type, thickness, and density of any necessary shielding applicable to the quantities, form, and emissions of the radionuclide that will be used, 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.) (*Note:* beta emitters should be shielded using a material with a low atomic number to minimize the production of bremsstrahlung);
- Nature of and distances to all areas adjacent to therapy patient treatment rooms (including above, beside, and below), keeping in mind that plans are particularly helpful in showing the relationship of the patient treatment room to the rest of the building; and

CONTENTS OF AN APPLICATION

- Location of additional radiation safety equipment (e.g., fume hood, L-block, dose calibrator, fixed area monitors, remote handling tools, t-bars, Allen key) within the facility.

In addition to the above, for remote afterloader, teletherapy, and GSR facilities, applicants must provide information on the following:

- Type, thickness, and density of the shielding materials used on all sides of the treatment room, including the walls, floor, and ceiling;
- Location of doors, windows, conduits, and other penetrations and voids in the shielding materials;
- Nature of and distances to all areas adjacent to the treatment room (including above, beside, and below), with an indication of whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003, keeping in mind that plans and elevation drawings are particularly helpful in showing the relationships among the treatment room, the roof, and the rest of the building; and
- Location of the treatment unit and source(s) within the treatment room.

In addition to the above, for teletherapy and GSR facilities, applicants must provide the following information:

- Directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation;
- Height of earth against outside walls, as applicable.

When use of remote afterloader units is planned, provide detailed calculations of maximum radiation levels (and dose rates) that will exist in each area, restricted and unrestricted, adjacent to the room(s) where treatment is performed using a remote afterloader device, to demonstrate compliance with 10 CFR 20.1201 and 10 CFR 20.1301, respectively. (This includes areas above, beside, and below the treatment room.) The calculations should include the following:

- Expected radiation levels for each area adjacent to the room housing the device, taking into consideration the most adverse source orientations and maximum source activity to be used in the device. These calculations must be sufficient to demonstrate that the expected dose rates in restricted and unrestricted areas adjacent to the treatment room(s) meet the requirements of 10 CFR 20.1201 and 10 CFR 20.1301.
- Parameters (equations, constants, assumptions, etc.) used to perform the calculations described above. Include discussion of parameters such as distance to each area of concern, the type and thickness of material(s) used in barriers and shields, the transmission factor of the barriers or shields, and the maximum source strength. For HDR and pulsed dose-rate (PDR)

CONTENTS OF AN APPLICATION

remote afterloader devices, the use of portable shielding to meet the dose rate requirements of 10 CFR 20.1201 and 10 CFR 20.1301 is not permitted.

- The maximum anticipated workload data, such as device maximum "on time" per hour and per week, and occupancy factors used for all adjacent areas.
- Determination of the dose received by individuals present in unrestricted areas, with calculations reflecting continuous occupancy (i.e., occupancy factor of 1), unless the applicant can justify using a lower value.
- Demonstration 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.
 - Decreasing exposure times and/or limiting the number of patient treatments or increasing the size of the restricted area surrounding the treatment room.

In addition to the facility description for teletherapy and GSR units, applicants must provide:

- A copy of the manufacturer's calculation of source(s) intensity;
- Calculations of the maximum radiation levels expected in each adjacent area, including the following:
 - Maximum anticipated workload data (e.g., maximum number of patients treated per hour and per week, maximum dose and treatment time per patient, maximum on-time per hour and per week);
 - The value of each parameter used in the calculations. These parameters include such factors as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier;

CONTENTS OF AN APPLICATION

- Contributions from primary, leakage (with the source in the on position), and scattered radiation (including low-angle scatter that just misses the integral beam absorber for teletherapy);
 - Calculations for each area adjacent to the treatment room, including above, beside, and below the room, and a statement indicating if an area will be maintained as a restricted or unrestricted area. Calculations need not be provided for areas that have not been excavated;
 - Worst-case situations (e.g., use of maximum beam size; all patients treated in 1 hour using the critical orientation that produces high radiation levels in an adjacent area; if the teletherapy integral beam absorber is not used for all patient treatments, calculations based on use of the unattenuated primary beam where appropriate; situations within the capabilities of the teletherapy unit that are not prohibited by electrical or mechanical stops, regardless of the clinical usefulness of these orientations);
 - The dose received by individuals present in unrestricted areas with continuous occupancy (i.e., occupancy factor of 1), unless the licensee can make a compelling argument for using a lower value.
- For each unrestricted area, a statement of how the requirements of 10 CFR 20.1301(a)(1) and (2) will be met;
 - Describe the teletherapy unit's mechanical or electrical beam stops that restrict beam orientation, specify the direction in which the teletherapy head can be moved, and describe the maximum angle (from vertical) of the beam orientation in each direction. Identify the angle orientation convention (e.g., 0 degrees is vertical toward the floor, 90 degrees is horizontal toward the east wall, 180 degrees is vertical toward the ceiling, and 270 degrees is horizontal toward the west wall). If the teletherapy unit has an integral beam absorber (also called a beam catcher), provide similar information for those orientations in which: (1) the primary beam is directed toward the integral beam absorber; and (2) the primary beam is directed away from the integral beam absorber. Sketches may be used to describe how beam stops intercept the primary beam.

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.

8.17 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 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 must be available for use at all times when byproduct material is in use. The licensee must 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 specifically authorized by NRC or an Agreement State to perform calibrations. A licensee may use a calibration service if the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license. Applicants seeking authorization to perform survey meter calibrations must submit calibration facility diagrams in accordance with Section 8.16 of this document. Appendix I provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures.

Response from Applicant: Provide the following:

- The instrument type, sensitivity, and range for each type of radiation detected, and, if applicants possess only one survey instrument to meet the criteria established in 10 CFR

Part 35, a description of the procedures used when the survey instrument is being calibrated or repaired and either routine or emergency radiation surveys need to be performed.

AND

- A statement that: "Radiation monitoring instruments will be calibrated by a person authorized by NRC or an Agreement State 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 20.1101 and that meet the requirements of 10 CFR 35.61."

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.

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

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.

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, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees who receive unit dosages of byproduct material and do not split the dosages may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration. However, pursuant to 10 CFR 35.60, 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. Model procedures for calibration of dose calibrators are provided in Appendix J. Currently, no alpha-emitting nuclides are used in unsealed form in medicine. This document does not, therefore, provide guidance on the measurement of these radionuclides.

CONTENTS OF AN APPLICATION

Equipment used to measure dosages that emit gamma, alpha, or beta radiation 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, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

Dosage measuring equipment may be calibrated by persons authorized by NRC or an Agreement State to perform such services. For example, a licensee may use a calibration service if the service is licensed to perform these activities by NRC (or an equivalent Agreement State) license.

Response from Applicant: If applicable, provide the following:

- A statement that: "Equipment used to measure dosages of unsealed byproduct material will be calibrated by a person authorized by NRC or an Agreement State to perform dosage measuring equipment calibrations."

AND/OR

- A statement that: "We have developed and will implement and maintain written calibration procedures for equipment used to measure dosages of unsealed byproduct material in accordance with 10 CFR 35.41, and that meet the requirements in 10 CFR 35.60 and 10 CFR 35.63, as applicable."

AND

- Instrument type and, if only one dose calibrator is possessed, a description of procedures used when the dose calibrator is being calibrated or repaired and measurements of patient dosages are needed.

8.19 ITEM 9: DOSIMETRY EQUIPMENT – CALIBRATION AND USE

Regulations: 10 CFR 30.33(a)(2); 10 CFR 35.27; 10 CFR 35.41; 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.

Discussion: Except for brachytherapy 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, 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 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 accepted by nationally recognized bodies (e.g., ANSI). (Note: An AMP is not specified for brachytherapy 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). The calibration procedures described by AAPM Task Group No. 21 and Reports 41, 46, 51, 54, 59, 61, and 67 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.).
- A commitment to maintain a record of calibration measurements and associated calculations.

CONTENTS OF AN APPLICATION

Full calibrations, as described in greater detail in Section 8.41, must be performed before first medical use³, 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.

Response from Applicant: Provide the following:

- A statement that: "We will calibrate dosimetry equipment in accordance with the requirements in 10 CFR 35.630."

AND

- A statement that: "We have developed and will implement and maintain written therapy sealed source calibration and spot-check procedures in accordance with 10 CFR 35.41 that meet the requirements in 10 CFR 35.432, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645 (as applicable to the type of medical use requested)."

AND

- Identification of the instrument type, manufacturer, and model number.

References: Copies of 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," may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843 or by ordering electronically from <<http://www.aapm.org>>.

8.20 ITEM 9: OTHER EQUIPMENT AND FACILITIES

Regulations: 10 CFR 20.1101; 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.

³ For brachytherapy sources, "before first medical use" is defined as the first use following the effective date of the revised 10 CFR Part 35.

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

Discussion: The applicant must 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 (e.g., fume hoods, xenon traps, emergency response equipment, area monitors, remote handling tools, source transport containers, patient viewing and intercom systems, interlock systems). 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). If release limits in 10 CFR 35.75 might be exceeded, provide a room with a private bath as described in Section 8.16 of this document. Sources of patient contamination include airborne I-131 and radioactivity in the patient's urine, perspiration, and saliva.

To facilitate decontamination of the patient's room, floors, toilet areas, sink areas, counter tops, and other permeable surfaces, the licensee should consider covering areas with disposable materials having plastic on one side and an absorbent material on the other. In addition, items handled by the patient may be covered with plastic. If the radiopharmaceutical administered is secreted in perspiration or saliva, or may by some other means present as a source of surface contamination, then it may be helpful to place removable covers on telephone handsets, faucet and toilet handles, television remote controls, door handles, and nurse call buttons. P-32 is effectively shielded by a plastic syringe. After P-32 has been administered to a patient, there is no external radiation hazard; therefore, isolation of patients who have administrations of P-32 is not required. P-32 administered in colloidal form can contaminate bandages and dressings; therefore, waste containers labeled for disposal of radioactive wastes should be readily available.

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. 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 meets the requirements of 10 CFR 35.615(c). In addition, the beam-on monitors traditionally installed in therapy treatment rooms can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.

The applicant shall describe the system, required by 10 CFR 35.615(d), used to view and communicate with the patient continuously while the patient is in the treatment room. If a

CONTENTS OF AN APPLICATION

shielded viewing window will be used, the thickness, density, and type of material used shall 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 shall be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system must allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system is recommended to allow communication without requiring the patient to move to activate controls.

The applicant must also provide 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. Additionally, 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, it is necessary, under 10 CFR 20.1801, 10 CFR 30.33, 10 CFR 30.34, 10 CFR 35.41, and 10 CFR 35.615, to ensure 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;

CONTENTS OF AN APPLICATION

- 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.

For patient rooms where **low dose-rate (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: Provide a description of additional facilities and equipment required by the applicable section of 10 CFR Parts 30 and 35 (e.g., 10 CFR 20.1101, 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, and 10 CFR 35.657). For teletherapy, GSR, and remote afterloader facilities, include a description of the:

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

CONTENTS OF AN APPLICATION

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

8.21 ITEM 10: RADIATION PROTECTION PROGRAM

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 35.2024; 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, including when the revision does not require a license amendment (e.g., replacement of survey instruments with comparable survey instruments).

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. The table in Appendix C may be helpful in determining what information must be provided when requesting a license. The applicant/licensee should consider the following functional areas (as applicable to the type of medical program):

- Audit program;
- Occupational dose;
- Public dose;
- Minimization of contamination;
- Operating and emergency procedures;
- Material receipt and accountability:
 - Ordering and receiving,
 - Opening packages,

- Sealed source inventory, and
- Use records;
- Leak tests;
- Area surveys;
- Procedures for administrations requiring a written directive;
- Safe use of unsealed licensed material;
- Installation, maintenance, adjustment, repair, and inspection of therapy devices containing sealed sources;
- Spill procedures;
- Emergency response for sealed sources or devices containing sealed sources;
- Patient or human research subject release;
- Safety procedures for therapy treatments where patients are hospitalized;
- Procedures for device calibration, safety checks, operation, and inspection;
- Mobile medical service;
- Transportation; and
- Waste management.

Response From Applicant: Respond to subsequent sections of this document regarding Items 10 and 11 of the application.

8.22 ITEM 10: AUDIT PROGRAM

Regulations: 10 CFR 20.1101; 10 CFR 20.2102.

Criteria: Under 10 CFR 20.1101, 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;
- Occupational doses and doses to members of the public are ALARA (10 CFR 20.1101);
- Records of reviews and/or audits and other reviews of radiation protection program content are maintained for 3 years after the record is made.

CONTENTS OF AN APPLICATION

Discussion: The applicant should develop and implement procedures for the required review and/or audit of the radiation protection program's content and implementation. Appendix K contains model procedures. Some sections of Appendix K may not apply to every licensee and may not need to be addressed during each review and/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 and/or audit need not be reviewed at the next review and/or audit. Reviews and/or audits of the radiation protection program must be conducted at least annually.

NRC encourages licensee management to conduct performance-based audits by observing work in progress, interviewing staff about the radiation protection program, and spot-checking required records. As part of their review and/or audit 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. IN 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," dated May 1, 1996, provides guidance on this subject, and specifically describes a three-step corrective action process:

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

NRC will review the licensee's review and/or audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. Depending on the significance of the violation, if the violation is identified by the licensee and the three corrective steps are taken, NRC may exercise discretion and may elect not to cite a violation. NRC's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

For additional information on NRC's use of discretion on issuing a notice of violation, refer to NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

Under 10 CFR 20.2102, licensees must maintain records of audits and other reviews of radiation protection program content and implementation for 3 years from the date of the record. Audit records should contain audit findings, noted deficiencies, and corrective actions.

Response from Applicant: NRC does not require submission of a description of audit programs for review.

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 NRC's web site, <<http://www.nrc.gov>>, under "Nuclear Materials" and "Enforcement."

8.23 ITEM 10: OCCUPATIONAL DOSE

Regulations: 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; 10 CFR 35.27.

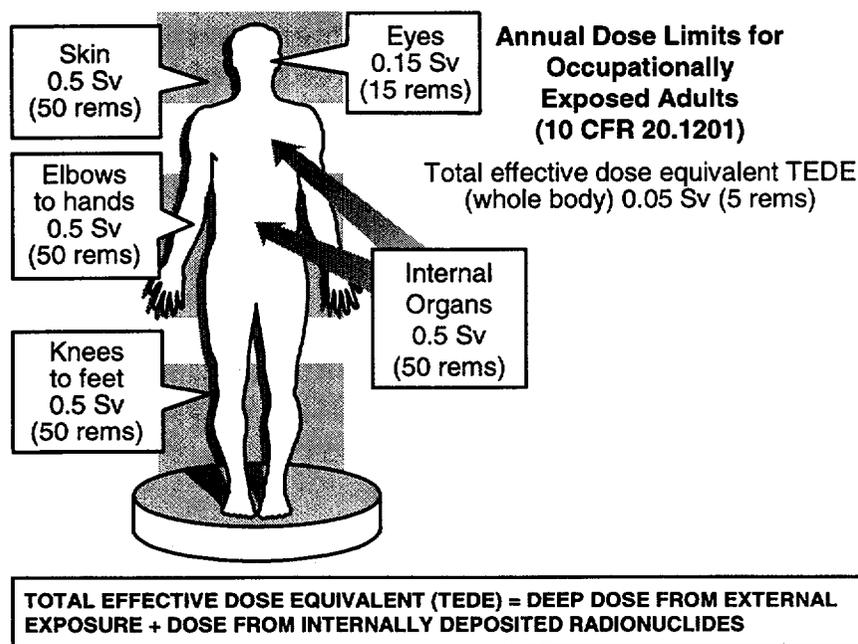
Criteria: Applicants must do either of the following:

- 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 8.12.

OR

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

CONTENTS OF AN APPLICATION



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Figure 8.12 Annual Occupational Dose Limits for Adults.

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.

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 L 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 rem) 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 and maintenance as required by 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). Film badges are usually exchanged monthly due to technical concerns about film fading. TLDs are usually exchanged quarterly. 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 monitoring is necessary, the applicant must measure the following:

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

For example, for individuals preparing or administering therapeutic dosages of I-131, licensees may need to assess thyroid burden measurements. For individuals who are occupationally exposed to lesser quantities of I-131, the frequency of bioassays for individuals should be based on quantities handled, type of compounds (volatile/non-volatile), and facilities used.

CONTENTS OF AN APPLICATION

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. Under 10 CFR 30.33(a)(2), the applicant must describe the equipment and facilities dedicated to the bioassay program required by 10 CFR 20.1501. If a commercial bioassay service will be used, the applicant must ensure that the service is licensed to perform these activities by an NRC (or an equivalent Agreement State) license.

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.

10 CFR 20.1202 describes the requirements for summing external and internal doses. Applicants must ensure that their occupational monitoring procedures include criteria for summing external and internal doses.

Response from Applicant: Provide the following:

- A description of facilities and equipment used for monitoring occupational exposure.

AND

- A statement that: "We have developed and will implement and maintain written procedures for monitoring occupational dose in accordance with 10 CFR 20.1101 that meet the requirements in Subparts C and F of 10 CFR Part 20."

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>>. See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG/CR-4884, "Interpretation of Bioassay Measurements" and RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program."

8.24 ITEM 10: PUBLIC DOSE

Regulations: 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.
- Control and maintain constant surveillance of licensed material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

Discussion: Members of the public include persons who are not radiation workers. This includes workers who 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 (see Figure 8.13). 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.

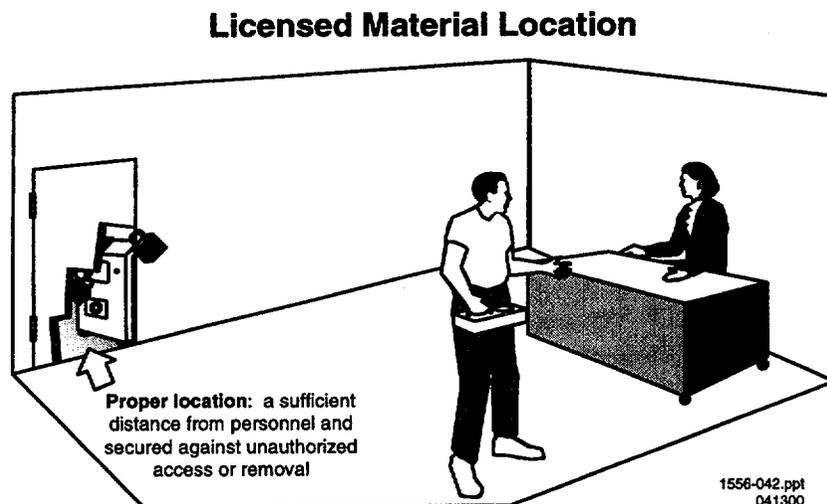


Figure 8.13 Proper Security of Licensed Material. *Licensed Material should be located away from occupied areas and secured to prevent unauthorized use or removal.*

CONTENTS OF AN APPLICATION

Public dose is also affected by the choice of storage and use locations and conditions. Licensed material may present a radiation field and must be located so that the public dose in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Licensees should use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time, increasing the distance, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to licensed material either by direct measurement, calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the manufacturer, the "inverse square" law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of licensed material. See Appendix M for an example demonstrating that individual members of the public will not receive doses exceeding the allowable public dose limits.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., the location of licensed material within a designated room, the type or frequency of licensed material use, or the occupancy of adjacent areas), the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

Response from Applicant: No response is required from the applicant in a license application except as provided in response to Section 8.16, but this matter will be examined during inspection. During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement, calculation, or both, 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. See Appendix M for examples of methods that demonstrate compliance with public dose limits.

8.25 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.

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 8.37, "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 SDDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SDDR 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. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: Provide a description of how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.

8.26 ITEM 10: 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 30.34(e); 10 CFR 30.50; 10 CFR 35.27; 10 CFR 35.41; 10 CFR 35.75; 10 CFR 35.310; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.406; 10 CFR 35.410; 10 CFR 35.415; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.3045; 10 CFR 35.3047; 10 CFR 35.3067.

Criteria: When using licensed material, licensees must do the following:

- Develop, implement, and maintain specific operating and emergency procedures containing the following elements:
 - Instructions for opening packages containing licensed material, 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;
 - Instructions for conducting area radiation level and contamination surveys;
 - Instructions for administering licensed material in accordance with the WD;
 - 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,

CONTENTS OF AN APPLICATION

(c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material;

- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s);
- Steps to ensure that patient release is in accordance with 10 CFR 35.75;
- Steps to take if a therapy patient undergoes emergency surgery or dies;
- Instructions for calibration of survey and dosage measuring instruments;
- Periodic spot checks of therapy device units, sources, and treatment facilities;
- Instructions for radioactive waste management.

AND

- 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. In addition, 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: Applicants shall develop, document, and implement specific procedures as part of a radiation protection program (e.g., operating and emergency procedures) based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. These procedures must be specific to the type and form of the licensed material used.

Sealed sources and radiopharmaceuticals 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. Therefore, operating procedures will also need to address access control. 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." Appendix N also provides model procedures for responding to emergency surgery or death of the therapy patient.

Applicants must 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 licensed material in excess of 10 times the quantity specified in Appendix C to Part 20 is lost or stolen. The RSO must be proactive in evaluating whether NRC notification is required for any incident involving licensed material. 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.

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

Reference: Copies of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," 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>>.

8.27 ITEM 10: MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 20.2201; 10 CFR 30.34(e); 10 CFR 30.35(g)(2); 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.27; 10 CFR 35.67.

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

- Secure licensed material;

CONTENTS OF AN APPLICATION

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

Discussion: As Figure 8.14 illustrates, 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. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed 6 months;
- Ordering and receiving licensed material;
- Package opening; and
- Use records.

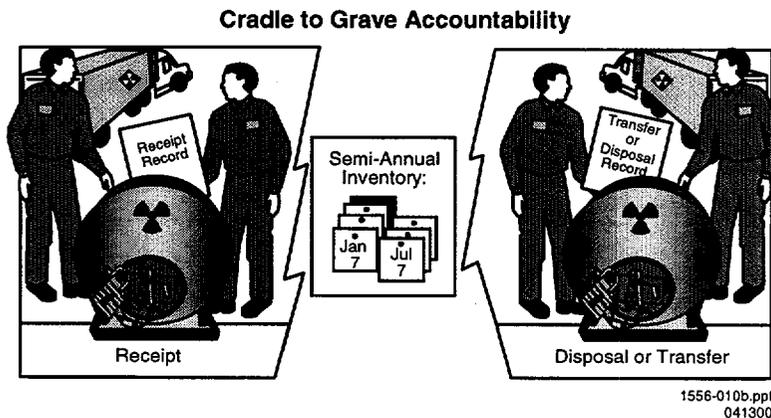


Figure 8.14 Material Receipt and Accountability. Licensees must maintain records of receipt, transfer, and disposal of licensed material and conduct semiannual physical inventories of sealed sources.

Response from Applicant: No response is necessary. Refer to the subsequent sections for guidance.

8.28 ITEM 10: ORDERING AND RECEIVING

Regulations: 10 CFR 20.1801; 10 CFR 20.1802; 10 CFR 20.1906; 10 CFR 30.34(e); 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.

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 for ordering and receiving licensed material.

Response from Applicant: No response is necessary.

8.29 ITEM 10: OPENING PACKAGES

Regulations: 10 CFR 20.1906; 10 CFR 20.2103; 10 CFR 35.27.

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

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

“We have developed and will implement and maintain written package opening procedures that meet the requirements of 10 CFR 20.1906.”

8.30 ITEM 10: 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.

CONTENTS OF AN APPLICATION

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. Inventory records must be maintained for 3 years.

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. The licensee shall retain each inventory record in accordance with 10 CFR 35.2067. In addition, 10 CFR 35.406 and 10 CFR 35.2406 require the licensee to make a record of brachytherapy source accountability when removing and returning brachytherapy sources from the storage location.

Response from Applicant: No response is necessary.

8.31 ITEM 10: USE RECORDS

Regulations: 10 CFR 30.51; 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 activity prior to medical use. The records must include:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned);
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 1.1 MBq (30 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 35.2204, records of molybdenum concentration must be made and must include:

- 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.

Additionally, to ensure accountability, the licensee should verify that the number of brachytherapy sources before and after the implant are equal. For permanent implants, this means that the total before the implant equals the number of sources implanted plus the number of sources returned or not used.

Response from Applicant: No response is necessary.

8.32 ITEM 10: 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. Records of test results must be maintained for 3 years.

CONTENTS OF AN APPLICATION

Discussion: Licensees must perform leak testing of any sealed source or brachytherapy source in accordance with 10 CFR 35.67. Appendix Q provides model leak testing procedures.

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 (see Figure 8.15).

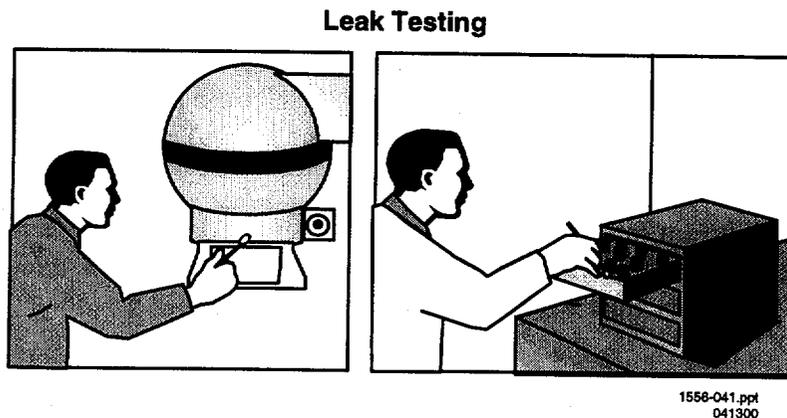


Figure 8.15 Leak Test Sample.

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; and
- 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.

8.33 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 35.27; 10 CFR 35.70; 10 CFR 35.2070.

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 members of the public will not receive more than 1 mSv (100 mrem) in 1 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.

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 (see Figure 8.16). 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.

CONTENTS OF AN APPLICATION

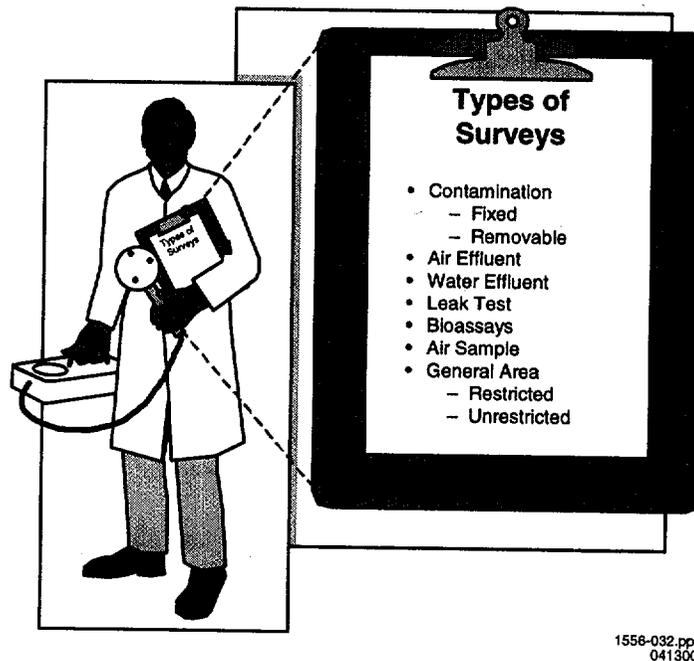


Figure 8.16 *Types of Surveys. There are many different types of surveys performed by licensees.*

Radiation surveys are used to detect and evaluate contamination of:

- Facilities (restricted and unrestricted areas);
- Equipment;
- Incoming and outgoing radioactive packages; and
- Personnel (during use, transfer, or disposal of licensed material) (See Figure 8.17).

Licensees also may use surveys to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

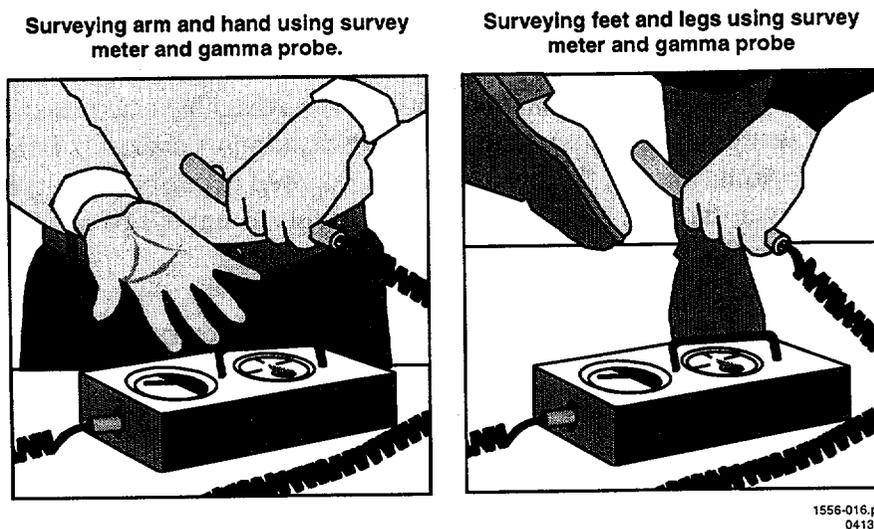


Figure 8.17 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted area.*

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. Licensees may need to perform many different types of surveys due to the particular use of licensed materials. The most important types of surveys are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas;
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe;
- Surveys of external radiation exposure levels in both restricted and unrestricted areas; 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

CONTENTS OF AN APPLICATION

with suggested survey frequencies for ambient radiation level and contamination surveys. For example, licensees are required to perform daily surveys in all areas where a WD is required for preparation and administration of radiopharmaceuticals (i.e., 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 if the patient is not released. However, the licensee should perform adequate surveys of patients' rooms after patient release and prior to release of the room for unrestricted use.

In addition, therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed. When developing area survey procedures, the licensee should consider surveys of:

- 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); and
- All trash exiting the patient's room.

The licensee must also perform surveys to ensure that radiation levels around a patient's room after source implantation are within the regulatory requirements [e.g., less than 0.02 mSv (2 mrem) in any 1 hour in any unrestricted area].

Not all instruments can measure a given type of radiation (e.g., alpha, beta, and gamma). The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. The energy of the radiation may not be high enough to penetrate some detector windows and be counted. The correct selection, calibration, and use of radiation detection instruments are important aspects of any radiation safety program. Additionally, applicants are reminded that probe movement speeds and surface-to-probe distances greatly affect ambient exposure rate survey results.

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.”

8.34 ITEM 10: PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

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: Provide the following statement:

“We have developed and will implement and maintain written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41.”

8.35 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.

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.

Users of licensed material must perform surveys required by 10 CFR 20.1302(a) (i.e., surveys of radiation levels and release of effluents to unrestricted and controlled areas). In addition, applicants must constrain doses from air emissions in accordance with 10 CFR 20.1101(d). Records of the results of the measurements are required by 10 CFR 20.2103(b)(4).

CONTENTS OF AN APPLICATION

Applicants must show how releases to the environment will be ALARA. The general guideline is 10% of the limit specified in 10 CFR 20.1301(a)(1). Licensees that possess sufficient quantities of volatile or potentially volatile licensed material to exceed 10 CFR Part 20 air emissions limits should demonstrate a basis for compliance with the applicable requirements. Such a basis could include one or more of the following:

- Measured concentrations of radionuclides in air effluents are below the concentrations specified in 10 CFR Part 20, Appendix B, Table 2 (and external dose <50 mrem/yr);
- Bounding calculations show that air effluents could not exceed the concentrations specified in 10 CFR Part 20, Appendix B, Table 2 (and external dose <50 mrem/yr);
- Dose modeling shows that the dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr.

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 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 licensed material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301, and 10 CFR 35.69.”

8.36 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.

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

CONTENTS OF AN APPLICATION

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 submit 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.

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).

8.37 ITEM 10: SPILL PROCEDURES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.1406; 10 CFR 20.2102; 10 CFR 20.2202; 10 CFR 20.2203; 10 CFR 30.34(e); 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.”

8.38 ITEM 10: EMERGENCY RESPONSE FOR SEALED SOURCES OR DEVICES CONTAINING SEALED SOURCES

Regulations: 10 CFR 19.11(a)(3); 10 CFR 20.1101; 10 CFR 20.2102; 10 CFR 20.2201-2203; 10 CFR 21.21; 10 CFR 21.51; 10 CFR 30.34(e); 10 CFR 30.50; 10 CFR 30.51; 10 CFR 35.27; 10 CFR 35.410; 10 CFR 35.610; 10 CFR 35.2310; 10 CFR 35.2610.

Criteria: Before handling sealed sources or using devices containing sealed sources, the applicant must develop, document, and implement written procedures for emergency response. For instance, 10 CFR 35.610 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures 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 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 incidents involving sealed sources or devices containing sealed sources. Appendix N contains model emergency response procedures for teletherapy units. Emergency procedures must address all types of licensed material and devices used and should be posted in restricted areas where sealed sources are used or stored. The instructions must 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 must contain procedures for evacuation

CONTENTS OF AN APPLICATION

and security of the involved area(s), source recovery, area reentry, and decontamination of facilities (if applicable). All equipment necessary for complying with emergency procedures shall be available near each treatment room; for example, these may include remote handling tools, t-bars, Allen keys, and shielded containers.

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a manual brachytherapy source becomes dislodged, 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 the following:

- A statement that: “We have developed and will implement and maintain written procedures for safe response to emergencies involving sealed sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12 that meet the requirements in 10 CFR 35.410 and 10 CFR 35.610, as applicable.”

AND

- Procedures developed in accordance with 10 CFR 35.610(a)(4).

8.39 ITEM 10: PATIENT OR HUMAN RESEARCH SUBJECT RELEASE

Regulations: 10 CFR 35.27; 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

CONTENTS OF AN APPLICATION

rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance. This implies that the licensee will confirm whether a patient is breast-feeding before releasing the patient.

In addition, 10 CFR 35.75(c) and 10 CFR 35.2075 require that the licensee maintain a record of the basis for authorizing the release of an individual for 3 years after the release date, if the TEDE is calculated by:

- Using the retained activity rather than the activity administered;
- Using an occupancy factor less than 0.25 at 1 meter;
- Using the biological or effective half-life; or
- Considering the shielding by tissue.

In 10 CFR 35.75(d) and 10 CFR 35.2075, the licensee is required to maintain a record for 3 years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 5 mSv (0.5 rem).

Appendix U provides guidance to the applicant for determining when:

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

Guidance on recordkeeping requirements in 10 CFR 35.75(c) and (d) and 35.2075 is contained in Section U.3 of Appendix U. The appendix 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: Provide the following statement:

“We have developed and will provide written instructions to patients or human research subjects (or their parent or guardian) released under 10 CFR 35.75 that meet the requirements in 10 CFR 35.75.”

8.40 ITEM 10: SAFETY PROCEDURES FOR TREATMENTS WHERE PATIENTS ARE HOSPITALIZED

Regulations: 10 CFR 20.1101; 10 CFR 20.1501; 10 CFR 20.1801; 10 CFR 20.2103; 10 CFR 35.315; 10 CFR 35.404; 10 CFR 35.604; 10 CFR 35.415; 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 ALARA.

Discussion: 10 CFR 35.315, 10 CFR 35.415, and 10 CFR 35.615 require the licensee to take certain safety precautions regarding radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients hospitalized in accordance with 10 CFR 35.75. This section does not include teletherapy or GSR outpatient treatments. The precautions are to 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. A record of the patient survey must be maintained for 3 years. 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:

- Provide a private 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 door 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

CONTENTS OF AN APPLICATION

the natural background radiation level or to confirm that they do not contain brachytherapy sources, 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. Therefore, licensees must ensure that access to rooms where patients are hospitalized, in accordance with 10 CFR 35.75, is limited to authorized personnel. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material 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.

8.41 ITEM 10: PROCEDURES FOR DEVICE CALIBRATION, SAFETY CHECKS, OPERATION, AND INSPECTION

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 10 CFR 20.1501; 10 CFR 20.2102; 10 CFR 20.2103; 10 CFR 20.2107; 10 CFR 30.34(e); 10 CFR 35.27; 10 CFR 35.604; 10 CFR 35.605; 10 CFR 35.610; 10 CFR 35.615; 10 CFR 35.632; 10 CFR 35.633; 10 CFR 35.635; 10 CFR 35.642; 10 CFR 35.643; 10 CFR 35.645; 10 CFR 35.652; 10 CFR 35.655; 10 CFR 35.657; 10 CFR 35.2310; 10 CFR 35.2404; 10 CFR 35.2605; 10 CFR 35.2610; 10 CFR 35.2632; 10 CFR 35.2642; 10 CFR 35.2643; 10 CFR 35.2645; 10 CFR 35.2652; 10 CFR 35.2655.

Criteria: Applicants must develop, maintain, and implement procedures for providing radiation safety for the use of sealed sources in devices. Applicants must also develop, maintain, and implement procedures to ensure that therapy sources and devices are calibrated and operating correctly.

Pertinent information in equipment manuals and other publications may be extracted and included in operating procedures, as applicable. Applicable AAPM documents may be referenced. A list of references is provided at the end of this section and may be helpful to applicants in providing responses in this area.

Discussion: Each functional area of medical use of sealed sources in devices is discussed separately below. The applicant should review the functional area(s) that apply to the type of medical use requested. Operating procedures shall be sufficient to ensure compliance with NRC regulations.

Diagnostic Sealed Sources and Devices

NRC regulations and good health physics practice require the licensee to provide personnel with clear and specific instructions on the medical use of sealed sources and devices. The SDDR for the specific source and device and the sealed source manufacturer's "device-specific" literature and instructions may help licensees develop the required instructions. These procedures may include, but are not limited to:

- Service and repair of the device;
- Routine proper use for sealed sources or devices containing sealed sources in accordance with NRC license and 10 CFR Parts 19, 20, and 35;
- Description of checks performed on the device to verify its proper operation after it has been moved and before it is used on patients, including the manufacturer's instruction for start-up, warm-up time, and phantom analysis for bone mineral analyzers; and
- Safety and security measures.

Teletherapy, Remote Afterloader, and GSR Sealed Sources and Devices

NRC regulations and good health physics practice require the licensee to provide personnel (e.g., medical physicists, technologists, and authorized users) with clear and specific instructions on the medical use of sealed sources and devices. Instructions should be tailored to the duties and responsibilities of the individual receiving instruction, whose duties may include safety device checks, instrument calibration, periodic spot checks, quality control checks, and leak tests. For example, housekeeping personnel who have access to therapy treatment rooms for cleaning would not follow the same instructions as therapy technologists operating therapy machines for patient treatment. Nursing personnel involved with remote afterloader treatments should receive specific instructions regarding a patient's care during the treatment process, especially if the treatment is to be conducted over a period of several hours and direct patient care is required.

CONTENTS OF AN APPLICATION

Applicants shall develop, maintain, 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 ALARA. The applicant must develop, maintain, and implement written procedures governing the operation of the therapy unit. The procedures must include:

- Use of the therapy unit, including security of the device, the console, and the console keys;
- Surveys of the therapy unit and remote afterloader patients;
- Computer system acceptance testing;
- Safety device checks;
- Periodic spot check measurements;
- Inspection and servicing;
- Full calibration measurements;
- Relocation of unit; and
- Recordkeeping.

The functional areas listed above are described in more detail below.

Use of the Therapy Unit

The operating procedures described in 10 CFR 35.610(d)(2) should specify who may operate the unit, how the unit may be used (i.e., in what orientations, for what purposes), typical treatment times and setups, how the unit is to be operated (i.e., the sequence of steps to be followed to begin treatment), and who must be present during the treatment. For example, the AU and AMP must be present for all GSR treatments. In addition, the licensee is reminded of the following requirements and may want to include descriptions of acceptable practice in the written procedures:

- Under 10 CFR 35.610(a)(2), a licensee must ensure that only individuals approved by the AU, RSO, or AMP are present (e.g., the patient) in the treatment room during treatment with the source(s).
- Under 10 CFR 35.615(e), if a source(s) is to be placed within the patient, a treatment procedure shall not be conducted if a decoupled or jammed source cannot be removed expeditiously from the patient.
- Under 10 CFR 35.642(e), 10 CFR 35.643(e), and 10 CFR 35.645(f), if the interlock system malfunctions, the device will be locked in the off position and not used, except as may be

necessary for repair, replacement, or check of the interlock system, until the interlock system is shown to be functioning properly.

- Under 10 CFR 35.642(e), 10 CFR 35.643(e), and 10 CFR 35.645(f), if a source exposure indicator light on the unit, control console, or facility is found to be either inoperable or intermittently inoperable, the device will be locked in the off position and not used, except as may be necessary for repair, replacement, or check of the indicator light until the indicator light is shown to be functioning properly.
- Under 10 CFR 35.610(a)(1), the licensee shall secure the unit, the console, the console keys, and the treatment room when not in use or unattended.

Surveys of the Therapy Unit

In accordance with 10 CFR 35.652, surveys following source replacement or repairs to the unit that could compromise the radiation safety of the unit or the source(s) in devices must be conducted. The survey program must include provisions for surveys defined in the SSDR to ensure that the maximum and average radiation levels from the surface of the device source safe do not exceed the levels stated in the SSDR with the source(s) in the shielded position. The licensee should develop procedures to address these surveys and any additional surveys that may be required by 10 CFR 20.1501 to assess potential radiological hazards (e.g., the device location changes significantly since the previous survey or as part of a response to a device alarm to ensure that the source(s) has been returned to the fully shielded position).

Safety Device Checks

Safety devices shall be checked periodically to ensure that they are operating properly. The frequency required by the regulations for each safety device varies. Such devices include timers, mechanical and electrical interlocks, warning lights and alarms, helmet position indicator microswitches, safety switches, door interlocks, beam collimators, and other devices that actively limit radiation exposure to patients and actively warn of, limit, or prevent radiation exposure to personnel. The results shall be recorded. The operating procedures shall contain instructions for making the checks, the frequency of such checks, prompt correction of any malfunctions or defects noted, and retention of appropriate records. A simple checklist may be used to complete the task and recordkeeping quickly and efficiently.

10 CFR 35.12(b)(2) requires an applicant to submit procedures required for therapy device spot checks developed in accordance with 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645.

When checks of safety devices indicate defects or malfunctions, there may be some delay before the defects or malfunctions can be corrected. The operating procedures should describe the steps

CONTENTS OF AN APPLICATION

that personnel will follow if a delay occurs. For example, using the therapy unit might be prohibited until the problem is corrected.

Documents such as ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," NCRP Report 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," NUREG/CR-6323, "Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices," NUREG/CR-6324, "Quality Assurance for Gamma Knives," and AAPM Report No. 54, "Stereotactic Radiosurgery," provide standards and recommendations for the frequency and procedures for making certain tests. If the standards or recommendations in these documents conflict with NRC regulations or license conditions, the minimum acceptable frequency is that specified in the regulation or license condition.

Relocation of Therapy Unit

10 CFR 35.13 requires that NRC approve a proposed location *before* a therapy unit is relocated (i.e., adds to or changes the areas of use identified in the application or on the license). The operating procedures should ensure that the necessary amendment to the NRC license is obtained before the therapy unit is relocated.

Inspection and Servicing of the Therapy Unit

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. This work, to assure proper functioning of the source exposure mechanism, must be done by a person or firm licensed to do so by NRC or an Agreement State. Preventive maintenance should also be addressed in the operating procedures to ensure that as systems deteriorate from use, they are identified and repaired. The operating procedures should include the following as related to the GSR: hydraulic system maintenance; collimator helmet supports, holes, plugs, bushings, and other helmet positioning equipment; and the systems related to the patient couch and the shielding door. Persons holding an Agreement State license are granted a general license to perform the same activities in non-Agreement States, pursuant to the requirements of 10 CFR 150.20. In addition, 10 CFR 35.605 limits device installation, maintenance, adjustment, and repair to certain designated personnel. The licensee should review the regulations in this section to ensure that compliance is achieved.

Computer System Acceptance Testing

10 CFR 35.657 requires that a licensee perform acceptance testing on the computerized treatment planning system that includes verification of the items listed in 10 CFR 35.657(a) through (e).

Such acceptance testing must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Periodic Spot Check Measurements of Teletherapy Units

10 CFR 35.642 specifies that output spot check tests must be performed once in each calendar month, and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system needed to make the output measurements. 10 CFR 35.642 also describes additional safety spot checks of each facility and the unit that must be performed monthly and at each source installation. The operating procedures must specify when and how the output spot check measurements will be made and should specify by whom the spot check tests will be made. The output measurements required shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the output spot check measurements; however, the AMP must review the results of each output spot check within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.642(c).

Teletherapy Full Calibration Measurements

10 CFR 35.632 requires that a licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy source before the first medical use of the unit and under the conditions listed in 10 CFR 35.632(a)(2) and (a)(3). The full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Periodic Spot Check Measurements of GSR Units

10 CFR 35.645 specifies that output spot check tests must be performed once in each calendar month, and 10 CFR 35.630 describes the characteristics of a properly calibrated dosimetry system needed to make the output measurements. 10 CFR 35.645 also describes additional safety spot checks of each facility and the unit that must be performed monthly, prior to first use on a given day, and after each source exchange. The operating procedures must specify when and how the spot check measurements will be made and should specify by whom the spot check tests will be made. The measurements shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot check measurements; however, the AMP must review the results of each spot check within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.645(b)(2).

CONTENTS OF AN APPLICATION

GSR Full Calibration Measurements

10 CFR 35.635 requires that a licensee authorized to use a GSR unit for medical use shall perform full calibration measurements on each GSR source before the first medical use of the unit and under the conditions listed in 10 CFR 35.635(a)(2) and (a)(3). Such full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Surveys of Remote Afterloader Patients

In accordance with 10 CFR 35.604, the licensee must perform surveys incident to use, including patient surveys performed after each treatment with a remote afterloader source. The patient must be surveyed with a portable radiation detection survey instrument to confirm that the source(s) has been removed and returned to the safe shielded position. The survey instrument should be capable of measuring dose rates of 1 - 1000 mrem per hour at a distance of 1 meter.

Periodic Spot Check Measurements of Remote Afterloader Units

10 CFR 35.643 specifies that spot check tests must be performed after each source installation and prior to the first use on a given day for all types of remote afterloaders, except low dose-rate remote afterloaders. Spot check tests on low dose-rate remote afterloaders must be performed after each source installation and before each patient treatment. The operating procedures must specify when and how the spot check measurements will be made and should specify by whom the spot check tests will be made. The measurements shall be performed in accordance with procedures established by an AMP. The AMP need not actually perform the spot check measurements; however, the AMP must review the results of each spot check measurement within 15 days and notify the licensee as soon as possible, in writing, of the results of each spot check, as required by 10 CFR 35.643(c).

Remote Afterloader Full Calibration Measurements

10 CFR 35.633 requires that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before the first medical use of the unit and under the conditions listed in 10 CFR 35.633(a)(2), (a)(3), and (a)(4). Such full calibration measurements must be performed in accordance with published protocols accepted by nationally recognized bodies (e.g., ANSI).

Recordkeeping

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. Examples of documents that must be maintained include:

- Copies of NRC licenses, license applications, and correspondence with NRC in support of a license request (10 CFR 19.11);
- Personnel dosimetry records (10 CFR 20.2103);
- Records of survey instrument calibrations (10 CFR 20.2103, 10 CFR 35.61, and 10 CFR 35.2061);
- Records of calibration of the dosimetry system used for full calibration measurements (10 CFR 35.630 and 10 CFR 35.2630);
- Records of calibration or intercomparison of the dosimetry system used for spot check measurements (10 CFR 35.630 and 10 CFR 35.2630);
- Results of full calibration measurements (10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635 and 10 CFR 35.2632);
- Results of spot check measurements (10 CFR 35.642, 10 CFR 35.643, 10 CFR 35.645, 10 CFR 35.2642, 10 CFR 35.2643, and 10 CFR 35.2645);
- Results of leak tests (10 CFR 35.67 and 10 CFR 35.2067);
- Records of instruction of new personnel and annual refresher training of personnel (10 CFR 35.610 and 10 CFR 35.2610);
- Records of instruction in emergency procedures (10 CFR 35.610 and 10 CFR 35.2610);
- Records of full inspection and servicing of the therapy unit (10 CFR 35.605, 10 CFR 35.655, 10 CFR 35.2605, and 10 CFR 35.2655);
- Records of receipt and disposal of radioactive material (10 CFR 30.51).

Response from Applicant: Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe medical use of sealed sources and devices and calibration of sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12 that meet the requirements of the applicable section(s) of 10 CFR Part 35, Subparts G and H."

AND

CONTENTS OF AN APPLICATION

- Procedures developed in accordance with 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, as applicable.

References: Copies of ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment," may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <<http://www.ansi.org>>. Copies of NCRP Report 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095, or ordered electronically from <<http://www.ncrp.com>>. See the Notice of Availability on the inside front cover of this report to obtain copies of NUREG/CR-6323, "Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices," NUREG/CR-6276, "Quality Management in Remote Afterloading Brachytherapy," and NUREG/CR-6324, "Quality Assurance for Gamma Knives." Copies of AAPM Report No. 54, "Stereotactic Radiosurgery," may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740-3843, or ordered electronically from <<http://www.aapm.org>>.

8.42 ITEM 10: MOBILE MEDICAL SERVICE

Regulations: 10 CFR 20.1101; 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.2; 10 CFR 35.18; 10 CFR 35.80; 10 CFR 35.647; 10 CFR 35.2080; 10 CFR 35.2647; 10 CFR 71.5; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; Subpart H of 10 CFR Part 71; 10 CFR 150.20; 49 CFR Parts 171-178.

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

Discussion: Appendix V describes specific licensing items pertaining to mobile services. "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. Additionally, in-van imaging services may not be considered an NRC-licensed activity if services are limited to patient imaging (i.e., byproduct material is not administered), and byproduct material is not possessed or used.

CONTENTS OF AN APPLICATION

Self-contained mobile service involves a mobile treatment or administration facility that provides ready-to-deliver mobile services on arrival at a client's site. The facility is entirely self-contained with a shielded treatment or administration area, remote afterloader device (if applicable), and safety equipment (e.g., dose calibrators, patient viewing systems, intercom, etc.).

Transportable mobile service involves transport of the byproduct material for use in a pre-existing shielded treatment or administration facility at the client site. The mobile service licensee may provide the byproduct material, associated equipment, and trained personnel, or the client may choose to provide the trained personnel to use the byproduct material. Before using a remote afterloader for this type of service, the device must be installed in an appropriately shielded treatment room. Other support equipment, such as viewing systems, area monitors, and intercoms must have been separately installed and available for use in the treatment room before treatment of patients commences.

To facilitate the licensing of mobile medical services, the types of services provided are broken down into the following 3 classes:

- Class 1 mobile service providers (byproduct material, trained personnel, and facility) are authorized to provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. Class 1 mobile service providers are responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).
- Class 2 mobile service providers (byproduct material and trained personnel) are authorized to provide the transportation to and use of the byproduct material within the client's facility. Class 2 mobile service providers are also responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).
- Class 3 mobile service providers (byproduct material only) are authorized to provide the byproduct material to a client site so that the client can perform treatments (or administrations). Under this class of service, the mobile service provider authorization is limited to the possession, limited servicing, and transport of the byproduct material and associated equipment. The client will need a separate authorization (license) to perform patient treatments (or administrations) with the byproduct material and the client will be responsible for all aspects of byproduct material use and patient treatment(s) (or administrations), as applicable, including, but not limited to, dose calibrator measurements, sealed source calibration, remote afterloader device function checks, and all safety system checks.

A mobile service provider may apply for one or multiple classes of service. However, a single client site may be authorized only for a single class of service. This restriction on client sites is intended to eliminate possible confusion that may arise over responsibilities for use and control of byproduct materials at client sites authorized for multiple classes of service.

CONTENTS OF AN APPLICATION

Class 1 and Class 2 mobile medical service licensees must ensure that patients treated meet the release criteria in 10 CFR 35.75.

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 service license should contact all states where they plan to conduct mobile services, to clarify requirements associated with an authorization to practice medicine within the state's jurisdiction.

Response from Applicant: Refer to Appendix V for the type of additional information to provide.

8.43 ITEM 10: 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.

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 exempted 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 at temporary job sites (e.g., the licensee's facilities);
- Actually takes possession of the licensed material under its license.

Additionally, for Type B package shipments, the licensee should verify and the manufacturer (or service licensee) must:

- Use an approved Type B package;
- Register with NRC as a user of the Type B package;
- Possess an NRC-approved QA plan.

CONTENTS OF AN APPLICATION

For each shipment, it must be clear who possesses the licensed material and who is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

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 W 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. 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, and Revision 1 of RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated June 1986.

8.44 ITEM 11: WASTE MANAGEMENT

Regulations: 10 CFR 20.1101; 10 CFR 20.1301; 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 35.27; 10 CFR 35.92; 10 CFR 35.2092; 10 CFR 61.3; 10 CFR 71.5.

Criteria: Licensed materials must be disposed of in accordance with NRC requirements by:

- Transfer to an authorized recipient;
- 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.

Appropriate records must be maintained.

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 X contains model procedures for decay-in-storage and generator or other licensed material return. 10 CFR 20.2001 requires that licensees dispose of licensed material only by means specified therein. In 10 CFR 20.2006, NRC requires that for licensed material transferred to a land disposal facility, the licensee must comply with the specific requirements in 10 CFR 20.2006 and Appendix G to 10 CFR Part 20, i.e., manifest, certification, and control and tracking. 10 CFR 35.92 specifies the requirements for handling of waste by decay-in-storage. In accordance with 10 CFR 71.5, NRC requires that licensees who transport licensed material outside the site of usage, or where transport is on public highways, or who deliver it for transport, comply with the applicable regulations of DOT in 49 CFR Parts 170 through 189. 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. Long-term storage should be designed to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers). Containers should have 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)). Make a record of the disposal in accordance with 10 CFR 20.2108.
 - 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

CONTENTS OF AN APPLICATION

restricted area. Make a record of the release in accordance with 10 CFR 20.2103 and 10 CFR 20.2107.

- 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)). Make a record of the disposal in accordance with 10 CFR 20.2108.
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must receive specific approval from NRC. Contact the appropriate NRC Regional Office for guidance on treatment or disposal of material by incineration in accordance with 10 CFR 20.2004.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) must 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 uncompacted waste, and examining containers for defects.

General Guidance for Waste Disposal

- Under 10 CFR 20.1904 and 10 CFR 35.92, all radioactivity labels must be removed or obliterated from empty or adequately decayed containers and packages prior to disposal in in-house (non-radioactive) waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed. If waste is decayed biomedical waste, labels may not need to be defaced. In accordance with 10 CFR 35.92(a)(2), radiation labels do not require removal or obliteration if the label is on materials that are within containers that will be managed as biomedical waste after they have been released from the licensee.

- Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the impact of various available disposal routes, including occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

Decay-In-Storage

For radionuclides of byproduct material with a half-life of less than 120 days, licensees may dispose of waste in ordinary trash as long as the following criteria are followed:

- Hold byproduct material for decay until the waste cannot be distinguished from background level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;
- Remove or obliterate all radiation labels, except as noted above; and
- Maintain proper records.

Returning Sources

Because of the nature of the material contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in 10 CFR 20.2001(a)(1). Authorized recipients are the original manufacturer of the sealed source, a commercial firm licensed by NRC or an Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., their license specifically authorizes possession of the same radionuclide, form, and use).

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 implanted with a pacemaker dies. If the pacemaker was not originally implanted by your facility, you should contact the hospital where the pacemaker was implanted to arrange for explantation and notify NRC. The licensee (e.g., the implanting hospital) 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.

CONTENTS OF AN APPLICATION

Before transferring radioactive material, a licensee must verify that the recipient is authorized to receive the material using one of the methods described in 10 CFR 30.41. Additionally, 10 CFR 71.5 requires that licensees who transport licensed material outside the site of usage, or where transport is on public highways, or who deliver it to a carrier for transport, comply with the regulations of DOT in 49 CFR Parts 170 through 189. Records of the transfer must be maintained as required by 10 CFR 30.51.

Licensees should promptly dispose of unused sealed sources to minimize potential problems such as access by unauthorized individuals, use for inappropriate purposes, and improper disposal.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Licensees are cautioned that, on several occasions, incinerator and sanitary landfill operators have returned waste shipments that have triggered their portal monitors. Information Notice 99-33, "Management of Wastes Contaminated with Radioactive Materials," describes this issue in greater detail. In many cases, the waste is from patients who have been released under 10 CFR 35.75. Licensees should review state and local ordinances for disposal of waste at these facilities to ensure that their waste is acceptable.

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."

The next two items on NRC Form 313 are to be completed on the form itself.

8.45 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.

8.46 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. NRC will return all unsigned applications for proper signature.

Notes:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, they become part of the licensing conditions and regulatory requirements.

9 AMENDMENTS AND RENEWALS TO A LICENSE

Regulations: 10 CFR 2.109; 10 CFR 30.34; 10 CFR 30.36(a); 10 CFR 30.38; 10 CFR 35.13; 10 CFR 35.14.

It is the licensee's obligation to keep the license current. 10 CFR 30.34 describes the terms and conditions of licenses. If any of the information provided in the original application is to be modified or changed by the licensee, the licensee may submit an application for a license amendment, as described in 10 CFR 30.38 and 10 CFR 35.13, to reflect the proposed change. Because 10 CFR 30.34 requires that the licensee follow the terms and conditions of the license, the licensee must receive authorization for the change before the change takes place, except for those items outlined in 10 CFR 35.14. Also, 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)).

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);
- Changing the RSO;
- Receiving byproduct material in excess of the amount, or receiving radionuclides or forms different than currently authorized on the NRC license; and
- 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.

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.

AMENDMENTS AND RENEWALS TO A LICENSE

In addition for license renewals, describe clearly the exact nature of the changes, additions, and deletions. Provide a complete and up-to-date application if either:

- There are many outdated documents are referenced, or
- There have been significant changes in regulatory requirements, NRC's guidance, the licensee's organization, or the radiation protection program

Note: Using the wording of responses suggested in this report will expedite NRC's review.

10 TERMINATION OF ACTIVITIES

Regulation: 10 CFR 20.1401-1405; 10 CFR 30.6; 10 CFR 30.34(b); 10 CFR 30.35(g); 10 CFR 30.36; 10 CFR 30.51.

Criteria: The licensee must do the following:

- Notify NRC, in writing, within 60 days, when its license has expired or a decision has been made to permanently cease licensed activities at the entire site, regardless of contamination levels;
- Notify NRC, in writing, within 60 days, when principal activities have not been conducted for 24 months or a decision has been made to permanently cease licensed activities in any separate building or outdoor area, if those areas contain residual radioactivity making them unsuitable for release according to NRC requirements;
- Certify the disposition of licensed materials by submitting NRC Form 314, "Certificate of Disposition of Materials," or equivalent information;
- Before a license is terminated, send the records important to decommissioning (as required by 10 CFR 30.35(g)) to the appropriate NRC Regional Office, or if licensed activities are transferred or assigned according to 10 CFR 30.34(b), transfer records important to decommissioning to the new licensee.

Discussion: Subpart E to 10 CFR Part 20 describes the radiological criteria for license termination. A licensee's determination that a facility is not contaminated is subject to verification by NRC inspection.

Licensees may maintain information on surveys and leak tests on an ongoing basis and as a 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.

NRC Form 314 found in Appendix Y may be used by licensee's for documenting the disposition of their licensed material.

For additional guidance on the disposition of licensed material, see Section 8.44, "Waste Management." For guidance on decommissioning records, see Section 8.6, "Financial Assurance and Recordkeeping for Decommissioning."

Licensees should promptly dispose of unused licensed material to minimize potential problems, such as access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

TERMINATION OF ACTIVITIES

Response from Applicant: The applicant is not required to submit a response to NRC during the initial application. However, when the license expires or at the time the licensee ceases operations, then the applicant must perform decommissioning activities and submit NRC Form 314 or equivalent information.

Reference: Copies of NRC Form 314, "Certificate of Disposition of Materials," are available upon request from NRC Regional or Field Offices; see Appendix Y.

Appendix A

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."

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

APPENDIX A

Document Identification	Title	Date
P&GD 3-17 (previously 16)	Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants.	
RG 8.23	Radiation Safety Surveys at Medical Institutions, Revision 1.	1/81

The additional references listed below were used.

References

Title 10, Code of Federal Regulations

1. Part 2 – Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders.
2. Part 19 – Notices, Instructions, and Reports to Workers; Inspections and Investigations.
3. Part 20 – Standards for Protection Against Radiation.
4. Part 21 – Reporting of Defects and Noncompliance.
5. Part 30 – Rules of General Applicability to Domestic Licensing of Byproduct Material.
6. Part 31 – General Domestic Licenses for Byproduct Material.
7. Part 32 – Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material.
8. Part 33 – Specific Domestic Licenses of Broad Scope for Byproduct Material.
9. Part 35 – Medical Use of Byproduct Material.
10. Part 40 – Domestic Licensing of Source Material.
11. Part 70 – Domestic Licensing of Special Nuclear Material.
12. Part 71 – Packaging and Transportation of Radioactive Material.
13. Part 150 – Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274.
14. Part 170 – Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended.
15. Part 171 – Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC.

Title 49, Code of Federal Regulations

1. Part 172 – Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, and Training Requirements.
2. Part 173 – Shippers – General Requirements for Shipments and Packagings.
3. Part 177 – Carriage by Public Highway.
4. Part 178 – Specifications for Packagings.

NRC Regulatory Guides (RG)

1. RG 1.86 – Termination of Operating Licenses for Nuclear Reactors, June 1974.
2. RG 3.66 – Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72, June 1990.
3. RG 7.10, Revision 1 – Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material, June 1986.
4. RG 8.4 – Direct-Reading and Indirect-Reading Pocket Dosimeters, February 1973.
5. RG 8.7 – Instructions for Recording and Reporting Occupational Radiation Exposure Data, Revision 1, June 1992.
6. RG 8.9 – Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program, Revision 1, June 1993.
7. RG 8.10 – Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable, Revision 1-B, September 1975.
8. RG 8.13 (Draft) – Instruction Concerning Prenatal Radiation Exposure, October 1994.
9. RG 8.18 – Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable, Revision 1, October 1982.
10. RG 8.21 – Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants.
11. RG 8.25 – Air Sampling in the Workplace, Revision 1, June 1992.
12. RG 8.29 – Instruction Concerning Risks from Occupational Radiation Exposure, Revision 1, February 1996.

APPENDIX A

13. RG 8.34 – Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, July 1992.
14. RG 8.36 – Radiation Dose to the Embryo/Fetus, July 1992.
15. RG 10.2 – Guidance to Academic Institutions Applying for Specific Byproduct Material Licenses of Limited Scope, Revision 1, December 1976.
16. RG 10.5 (Draft) – Applications for Type A Licenses of Broad Scope, October 1994.
17. RG 10.8 – Revision (Draft NUREG-1569 - never published), Program-Specific Guidance for Medical Use Licensees, 1997.
18. RG FC 412-4 (Draft) – Guide for the Preparation of Applications for the Use of Radioactive Materials in Leak-Testing Services, June 1985.
19. RG FC 413-4 (Draft) – Guide for the Preparation of Applications for Licenses for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments, June 1985.

NRC Information Notices (IN)

1. IN 89-25, Revision 1 – Unauthorized Transfer of Ownership or Control of Licensed Activities.
2. IN 94-70 – Issues Associated with Use of Strontium-89 and Other Beta Emitting Radiopharmaceuticals.
3. IN 96-28 – Suggested Guidance Relating to Development and Implementation of Corrective Action.
4. IN 97-30 – Control of Licensed Material During Reorganizations, Employee-Management Disagreements, and Financial Crises.
5. IN 99-33 – Management of Wastes Contaminated with Radioactive Materials.

NRC Policy and Guidance Directives (P&GD)

1. P&GD FC 90-2, Revision 1 – Standard Review Plan for Evaluating Compliance with Decommissioning Requirements, April 1991.
2. P&GD PG 1-23 – Guidance for Multi-Site Licenses, April 1996.

3. P&GD PG 8-11 – NMSS Procedures for Reviewing Declarations of Bankruptcy, August 1996.
4. P&GD FC 92-01 – Information Required for Licensing Mobile Nuclear Medicine Services, April 1992.

NRC NUREGs

1. NUREG-0267, Revision 1 – Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable, October 1982.
2. NUREG-1134 – Radiation Protection Training for Personnel Employed in Medical Facilities, May 1985.
3. NUREG-1400–Air Sampling in the Workplace, September, 1993.
4. NUREG-1492 – Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, February 1997.
5. NUREG-1539 – Methodology and Findings of the NRC’s Materials Licensing Process Redesign, April 1996.
6. NUREG-1541 (Draft) – Process and Design for Consolidating and Updating Materials Licensing Guidance, April 1996.
7. NUREG-1556, Volume 3 (July 1998) – Consolidated Guidance about Materials Licensees: Applications for Sealed Source and Device Evaluation and Registration, September 1997.
12. NUREG-1556, Volume 11 - Program-Specific Guidance About Licenses of Broad Scope.
9. NUREG-1556, Volume 18 – Program Specific Guidance about Service Provider Licenses, November 2000.
10. NUREG-1556, Volume 20 – Guidance about Administrative Licensing Procedures, December 2000.
11. NUREG-1600 – General Statement of Policy and Procedures for NRC Enforcement Actions, June 1995 and Compilation of NRC Enforcement Policy as of September 10, 1997.
12. NUREG/CR-4444 – Radiation Safety Issues Related to Radiolabeled Antibodies, 1991.
13. NUREG/CR-4884 – Interpretation of Bioassay Measurement, July 1987.
14. NUREG/CR-6323 – Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices: A Preliminary Application, September 1995.

APPENDIX A

15. NUREG/CR-6324 – Quality Assurance for Gamma Knives, September 1995.
16. NUREG-CR-6276 – Quality Management in Remote Afteloading Brachytherapy, October 1994.
17. NUREG-1736 – Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation, 1995.

National Council on Radiation Protection and Measurements (NCRP) Publications

1. NCRP Report No. 30 – Safe Handling of Radioactive Materials, 1964.
2. NCRP Report No. 37 – Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides, 1970.
3. NCRP Report No. 40 – Protection Against Radiation from Brachytherapy Sources, 1972.
4. NCRP Report No. 49 – Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV, 1976.
5. NCRP Report No. 57 – Instrumentation and Monitoring Methods for Radiation Protection, 1978.
6. NCRP Report No. 58 – A Handbook of Radioactivity Measurement Procedures, Second Edition, 1985.
7. NCRP Report No. 69 – Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV, 1981.
8. NCRP Report No. 71 – Operational Radiation Safety – Training, 1983.
9. NCRP Report No. 87 – Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, February 1987.
10. NCRP Report No. 102 – Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use), 1989.
11. NCRP Report No. 105 – Radiation Protection for Medical and Allied Health Personnel, 1989.
12. NCRP Report No. 107 – Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel, 1990.
13. NCRP Commentary No. 11 – Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, February 1995.

International Commission on Radiological Protection (ICRP) Publications

1. ICRP Report No. 26 – Recommendations of the International Commission on Radiological Protection, 1977.
2. ICRP Report No. 30 – Limits for Intakes of Radionuclides by Workers, 1978.
3. ICRP Report No. 35 – General Principles of Monitoring for Radiation Protection of Workers, 1982.
4. ICRP Publication No. 53 – Radiation Dose to Patients from Radiopharmaceuticals, 1987.
5. ICRP Publication 54 – Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation, 1987.

ANSI Standards

1. ANSI N13.4-1971 (R1983) – Specification of Portable X- or Gamma Radiation Survey Instruments.
2. ANSI N13.5-1972 (R1989) – Performance and Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation.
3. ANSI N13.6-1966 (R1989) – Practice for Occupational Radiation Exposure Records Systems.
4. ANSI N14.5-1987 – Leakage Tests on Packages for Shipment of Radioactive Materials.
5. ANSI N42.12-1994 – Calibration and Usage of Thallium-Activated Sodium Iodide Detector Systems for Assay of Radionuclides.
6. ANSI N42.13-1986 (R1993) – Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides.
7. ANSI N42.15-1990 – Performance Verification of Liquid Scintillation Counting Systems.
8. ANSI N42.17A-1989 – Performance Specifications for Health Physics Instrumentation-Portable Instrumentation for Use in Normal Environmental Conditions.
9. ANSI N322 – Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters.
10. ANSI N323A-1997 – Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments.
11. ANSI N449.1-1978 (R1984) – Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment.

APPENDIX A

American Association of Physicists in Medicine (AAPM) Reports

1. AAPM Task Group No. 21 – A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams, 1984.
2. AAPM Report No. 41 – Remote Afterloading Technology (Remote Afterloading Technology Task Group No. 41), 1993.
3. AAPM Report No. 46 – Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40), 1994.
4. AAPM Report No. 51, Dosimetry of Interstitial Brachytherapy Sources, (Radiation Therapy Committee Task Group No. 43), 1995.
5. AAPM Report No. 54 – Stereotactic Radiosurgery, (Radiation Therapy Committee Task Group No. 42), 1995.
6. AAPM Report No. 59 – Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56), 1997.
7. AAPM Report No. 61 – High Dose Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59) 1998.
8. AAPM Report No. 67 – Protocol for Clinical Dosimetry of High Energy Photon and Electron Beams, Medical Physics 26(9), pp. 1847-1870, (Radiation Therapy Committee Task Group No. 51) September, 1999.

Other Technical Publications

1. International Commission on Radiation Units and Measurements (ICRU), "Certification of Standardized Radioactive Sources," Report No. 12, 1968.
2. U.S. Department of Health, Education, and Welfare, "Radiological Health Handbook," 1970.
3. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.
4. International Atomic Energy Agency (IAEA), "Monitoring of Radioactive Contamination on Surfaces," Technical Report Series No. 120, 1970.
5. IAEA, "Handbook on Calibration of Radiation Protection Monitoring Instruments," Technical Report Series No. 133, 1971.

6. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine-131," *American Journal of Public Health*, Volume 68, Number 3, 1978.
7. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10⁻⁶ a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.
8. Bureau of Radiological Health, "Radiation Safety in Nuclear Medicine: A Practical Guide," Department of Health and Human Services (HHS) Publication FDA 82-8180, November 1981.
9. Center for Devices and Radiological Health, "Recommendations for Quality Assurance Programs in Nuclear Medicine Facilities," HHS Publication FDA 85-8227, October 1984.
10. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable over Ten Years Post Intake," *Radiation Protection Dosimetry*, Volume 11, No. 1, 1985.
11. "Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine*, 1987.
12. J. R. Johnson and D. W. Dunford, "GENMOD – A Program for Internal Dosimetry Calculations," AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987.
13. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, 1988.
14. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal*, Volume 55, No. 6, 1988.
15. A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990.
16. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990.
17. M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991.
18. P. Early, D. B. Sodee, "Principles and Practice of Nuclear Medicine," 2nd ed., 1995.

Appendix B

NRC Form 313

<p>NRC FORM 313 (5-1989) 10 CFR 30, 32, 33 34, 35, 36, 39 and 40</p>	<p>U. S. NUCLEAR REGULATORY COMMISSION</p>	<p>APPROVED BY OMB: NO. 3150-0120</p>	<p>EXPIRES:08/31/2002</p>		
<p>APPLICATION FOR MATERIAL LICENSE</p>		<p>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.</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: 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>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 601 WARRENVILLE RD. LISLE, IL 60532-4351</p>			
<p>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</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: NUCLEAR MATERIALS LICENSING SECTION U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TX 78011-8084</p>			
<p>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, S.W., SUITE 23765 ATLANTA, GEORGIA 30303-8931</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 (Check appropriate item) <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>		<p>2. NAME AND MAILING ADDRESS OF APPLICANT (include Zip code)</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 TELEPHONE NUMBER</p>			
<p>SUBMIT ITEMS 5 THROUGH 11 ON 6-1/2 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 (See 10 CFR 170 and Section 170.31) FEE CATEGORY AMOUNT ENCLOSED \$</p>			
<p>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.</p>					
<p>CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE</p>		<p>SIGNATURE</p>	<p>DATE</p>		
<p>FOR NRC USE ONLY</p>					
<p>TYPE OF FEE</p>	<p>FEE LOG</p>	<p>FEE CATEGORY</p>	<p>AMOUNT RECEIVED \$</p>	<p>CHECK NUMBER</p>	<p>COMMENTS</p>
<p>APPROVED BY</p>				<p>DATE</p>	

Appendix C

License Application Checklist and Sample Licenses

License Application Checklist and Sample Licenses

The instructions in Table C.1, Applicability Table, may be followed to determine if the information must be provided or if “NA” 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. If any “Y” beside an item is highlighted, you must provide detailed information in response to the item. If the letters “NA” (not applicable) are highlighted, you may respond “NA” on your application. If any “N” beside an item is highlighted, no information in response is required, however, NRC regulations that apply to the given category apply to your type of license. If any “P” beside an item is highlighted, you must provide a commitment to develop, implement, and maintain a procedure in response to the item. Note that some modules have additional item numbers that may need to be addressed. “APP” indicates the applicable appendices found in this document.

In addition, sample licenses are included that may provide guidance on the particular type of medical use you are requesting.

Table C.1 Applicability Table

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
N/A	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
N/A	Unsealed Byproduct Material – Written Directive Required		Y					
N/A	Manual Brachytherapy			Y				
N/A	Sealed Sources for Diagnosis				Y			
N/A	Teletherapy Units					Y		
N/A	Remote Afterloader Units					Y		
N/A	Gamma Stereotactic Radiosurgery Units					Y		
N/A	Other Medical Uses (e.g., Emerging Technologies)						Y	
8.6	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	E
8.7	Sealed Source Registry	N	N	Y	Y	Y	Y	
8.10	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	F, G

APPENDIX C

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.11	Authorized User(s)	Y	Y	Y	Y	Y	Y	G
8.12	Authorized Nuclear Pharmacist(s)	Y	Y	N/A	N/A	N/A	Y	G
8.13	Authorized Medical Physicist(s)	N/A	N/A	Y	N/A	Y	Y	G
8.14	Training Program	N	N	N	N	N	N	H
8.16	Facility Diagram and Equipment	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instrument Calibration	P	P	P	N	P	P	I
8.18	Dose Calibrator Calibration	P	P	N/A	N/A	N/A	P	J
8.19	Dosimetry Equipment and Therapy Sealed Source Calibration	N/A	N/A	P	N/A	P	P	
8.20	Other Equipment and Facilities	Y	Y	Y	Y	Y	Y	
8.22	Audit Program	N	N	N	N	N	N	K
8.23	Occupational Dose	P	P	P	P	P	P	L
8.24	Public Dose	N	N	N	N	N	N	M
8.25	Minimization of Contamination	Y	Y	Y	Y	Y	Y	
8.28	Ordering and Receiving	N	N	N	N	N	N	O
8.29	Opening Packages	P	P	P	P	P	P	P
8.30	Sealed Source Inventory	N	N	N	N	N	N	
8.31	Use Records	N	N	N	N	N	N	
8.32	Leak Tests	N	N	N	N	N	N	Q
8.33	Area Surveys	P	P	P	P	P	P	R
8.34	Written Directive Procedures	N/A	P	P	N/A	P	P	S
8.35	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.36	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.37	Spill Procedures	P	P	N/A	N/A	N/A	P	N
8.38	Emergency Response for Sealed Sources or Devices	N/A	N/A	P	P	Y	Y	N

APPENDIX C

Item #	Topic	35.100/200	35.300	35.400	35.500	35.600	35.1000	APP
8.39	Patient or Human Research Subject Release	P	P	P	N/A	P	P	U
8.40	Safety Procedures for Therapy Treatments where Patients are Hospitalized	N/A	N	N	N/A	N*	N	
8.41	Safety Checks, Device Calibration, Operation, and Inspection Procedures	N/A	N/A	N/A	P	Y	Y	
8.42	Mobile Medical Service	Y	Y	Y	Y	Y	Y	V
8.43	Transportation	N	N	N	N	N	N	W
8.44	Waste Management	P	P	P	P	P	P	X

* N/A for teletherapy and gamma stereotactic radiosurgery

Tables C.2 and C.3 are provided to assist in responding to items 5 through 11 on NRC Form 313.

APPENDIX C

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

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material identified in 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study approved in 10 CFR 35.100.
	Any byproduct material identified in 10 CFR 35.200	Check all that apply: <input type="checkbox"/> Unit dosages only; <input type="checkbox"/> Any except generators; <input type="checkbox"/> Any	As needed	Any imaging and localization study approved in 10 CFR 35.200.
	Any byproduct material identified in 10 CFR 35.300	Check all that apply: <input type="checkbox"/> Unit dosages only; <input type="checkbox"/> Any	___ millicurie	Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300. Check Box <input type="checkbox"/> if patients will be hospitalized <i>until</i> they can be released pursuant to 10 CFR 35.75.
	Iodine-131	Any	___ millicurie	Check all that apply: <input type="checkbox"/> Diagnosis and treatment of hyperthyroidism; <input type="checkbox"/> Treatment of cardiac dysfunction; <input type="checkbox"/> Thyroid carcinoma. Check Box <input type="checkbox"/> if use will include activities greater than 33 millicurie per administration.

APPENDIX C

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Byproduct material identified in 10 CFR 35.400 Check all that apply: <input type="checkbox"/> Ir-192; <input type="checkbox"/> Cs-137; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe	Sealed sources (Manufacturer _____, Model No. _____)	___ millicurie	Any brachytherapy procedure approved in 10 CFR 35.400. Check Box <input type="checkbox"/> if patients will be hospitalized <i>until</i> they can be released pursuant to 10 CFR 35.75.
	Strontium-90	Sealed sources (Manufacturer _____, Model No. _____)	___ millicurie	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and approved in 10 CFR 35.400.
	Byproduct material identified in 10 CFR 35.500 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe	Sealed sources (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources as approved in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
	Iridium-192	Sealed sources (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	One source for medical use described in 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 sources (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	One source for medical use described in 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.

APPENDIX C

Yes	Radioisotope	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Cobalt-60	Sealed sources (Manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	For medical use described in 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 identified in 10 CFR 31.11	Prepackaged kits	___ millicurie	<i>In vitro</i> studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Cesium-137	Sealed sources (Manufacturer _____, Model No. _____)	___ millicurie	Non-human use. For use in a Manufacturer _____ Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed sources (Manufacturer _____, Model No. _____)	___ millicurie per source and ___ millicurie total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicurie 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. _____	___ millicurie	Purpose of use _____.

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

Item Number and Title	Suggested Response	Yes
<p>Item 7: Radiation Safety Officer Name: _____</p>	<p>Attached Delegation of Authority and RSO agreement to be responsible for implementing the radiation protection program (see Appendix F).</p> <p>Attached written certification, signed by a preceptor RSO, that the training and experience have 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>Attached 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>Attached copy of the certification(s) for the board(s) recognized by NRC as applicable to the types of use for which he or she has RSO responsibilities.</p> <p>Attached description of the training and experience 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. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).</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>

APPENDIX C

Item Number and Title	Suggested Response	Yes
<p>Item 7: Authorized Users Names and Requested Uses for Each Individual</p> <hr/> <hr/>	<p>Attached written certification, signed by a preceptor AU physician, that the training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.</p> <p style="text-align: center;">AND</p> <p>Attached 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>Attached copy of the certification(s) for the board(s) recognized by NRC as applicable to the use requested.</p> <p style="text-align: center;">OR</p> <p>Attached description of the training and experience demonstrating that the proposed AU is qualified by training and experience for the use requested. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Item Number and Title	Suggested Response	Yes
<p>Item 7: Authorized Nuclear Pharmacists</p> <p>Names: _____</p>	<p>Attached written certification, signed by a preceptor ANP, that the training and experience have been satisfactorily completed and that the individual has achieved a level of competency sufficient to function independently as an ANP.</p> <p style="text-align: center;">AND</p> <p>Attached 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 ANP.</p> <p style="text-align: center;">OR</p> <p>Attached copy of the certification(s) for the radiopharmacy board(s) recognized by NRC.</p> <p style="text-align: center;">OR</p> <p>Attached description of the training and experience demonstrating that the proposed ANP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).</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 Medical Physicists</p> <p>Names: _____</p>	<p>Attached written certification, signed by a preceptor AMP, that the training and experience have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP for the uses requested has been achieved.</p> <p style="text-align: center;">AND</p> <p>Attached 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 uses requested.</p> <p style="text-align: center;">OR</p> <p>Attached copy of the certification(s) for the board(s) recognized by NRC.</p> <p style="text-align: center;">OR</p> <p>Attached description of the training and experience demonstrating that the proposed AMP is qualified by training and experience. NRC Forms 313A and 313B may be used for this purpose (see Appendix G).</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

Item Number and Title	Suggested Response	Yes
<p>Item 9: Radiation Monitoring Instruments</p>	<p>The instrument types possessed, including the sensitivity and range for each type of radiation detected, are _____.</p> <p style="text-align: center;">AND</p> <p>If we possess only one survey instrument, we will obtain a backup survey instrument of comparable sensitivity and range when our survey instrument is being calibrated or repaired.</p> <p style="text-align: center;">AND</p> <p>Radiation monitoring instruments will be calibrated by a person authorized by NRC or an Agreement State to perform survey meter calibrations.</p> <p style="text-align: center;">AND/OR</p> <p>We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1101, that also meet the requirements of 10 CFR 35.61.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Dose Calibrator and Other Dosage Measuring Equipment</p>	<p>The instrument type possessed is _____.</p> <p style="text-align: center;">AND</p> <p>If we possess only one dose calibrator, we will obtain a backup dose calibrator when our dose calibrator is being calibrated or repaired and patient dosages are required to be measured.</p> <p style="text-align: center;">AND</p> <p>Dosage measuring equipment will be calibrated by a person authorized by NRC or an Agreement State to perform dosage measuring equipment calibrations.</p> <p style="text-align: center;">AND/OR</p> <p>We have developed and will implement and maintain written dosage measuring equipment calibration procedures in accordance with 10 CFR 35.41, that also meet the requirements in 10 CFR 35.60 and 10 CFR 35.63, as applicable.</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>

APPENDIX C

Item Number and Title	Suggested Response	Yes
<p>Item 9: Dosimetry Equipment – Calibration and Use</p>	<p>The instrument type, manufacturer, and model number is _____</p> <p style="text-align: center;">AND</p> <p>We will calibrate dosimetry equipment in accordance with the requirements in 10 CFR 35.630.</p> <p style="text-align: center;">AND</p> <p>We have developed and will implement and maintain written therapy sealed source calibration and spot check procedures in accordance with 10 CFR 35.41, that also meet the requirements in 10 CFR 35.432, 10 CFR 35.632, 10 CFR 35.633, 10 CFR 35.635, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645 (as applicable to the type of medical use requested).</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Item 9: Other Equipment and Facilities</p>	<p>Attached is a description of additional facilities and equipment. These include:</p> <ul style="list-style-type: none"> • Fume hoods; • Xenon traps; • Emergency response equipment; • Area radiation monitor; • Remote handling tools; • Source transport container; • Patient viewing and intercom systems; • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Private rooms used for unsealed source therapy treatments; • Methods for controlling occupancy for each restricted area; • Mechanisms for ensuring that no two therapy units can be operated simultaneously if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is located in the treatment room; • Mechanisms for ensuring that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons. 	<p><input type="checkbox"/></p>

Item Number and Title	Suggested Response	Yes
Item 10: Audit Program	The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections and should not be submitted in the license application.	N/A
Item 10: Occupational Dose	The facilities, if applicable, and equipment used for monitoring occupational exposure are _____	<input type="checkbox"/>
	<p>AND</p> We have developed and will implement and maintain written procedures for monitoring occupational dose in accordance with 10 CFR 20.1101, that also meet the requirements in Subparts C and F of 10 CFR Part 20.	<input type="checkbox"/>
Item 10: Public Dose	The applicant's program for controlling doses to individual members of the public will be examined during inspection and should not be submitted in the license application except as provided in response to Item 9.	N/A
Item 10: Minimization of Contamination	Attached is a description of how the facility design and the procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.	<input type="checkbox"/>
Item 10: Ordering and Receiving	The applicant's program for ordering and receiving licensed material will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Opening Packages	We have developed and will implement and maintain written package-opening procedures that meet the requirements of 10 CFR 20.1906.	<input type="checkbox"/>
Item 10: Sealed Source Inventory	The applicant's program for inventorying sealed sources will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Use Records	The applicant's program for recording the use of licensed material will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Leak Tests	The applicant's program for leak testing sealed sources will be examined during inspection and should not be submitted in the license application.	N/A

APPENDIX C

Item Number and Title	Suggested Response	Yes
Item 10: Area Surveys	We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101, that also meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.	<input type="checkbox"/>
Item 10: Procedures for Administrations Requiring a Written Directive	We have developed and will implement and maintain written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41.	<input type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	We have developed and will implement and maintain procedures for safe use of unsealed licensed material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1301 and 10 CFR 35.69.	<input type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	We will contract with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair, and inspect all therapy devices.	<input type="checkbox"/>
	OR	
	Name of the proposed employee and types of activities requested:	<input type="checkbox"/>
	AND	
	Attached description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the types of activities requested.	<input type="checkbox"/>
	AND	
	Attached copy of the manufacturer's training certification and an outline of the training.	<input type="checkbox"/>
Item 10: Spill Procedures	We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10CFR 20.1101.	<input type="checkbox"/>
Item 10: Emergency Response for Sealed Sources or Devices Containing Sealed Sources	We have developed and will implement and maintain written procedures for safe response to emergencies involving sealed sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12, that also meet the requirements of 10 CFR 35.410 and 10 CFR 35.610 (as applicable).	<input type="checkbox"/>
	AND	
	Attached procedures developed in accordance with 10 CFR 35.610(a)(4)	<input type="checkbox"/>

Item Number and Title	Suggested Response	Yes
Item 10: Patient or Human Research Subject Release	We have developed and will provide written instructions to patients or human research subjects (or their parent or guardian), released pursuant to 10 CFR 35.75, that also meet the requirements in 10 CFR 35.75.	<input type="checkbox"/>
Item 10: Safety Procedures for Treatments Where Patients are Hospitalized	The applicant's responses to "Other Equipment and Facilities" and "Occupational Dose" will be considered in response to this item.	<input type="checkbox"/>
Item 10: Procedures for Device Calibration, Safety Checks, Operation, and Inspection	We have developed and will implement and maintain written procedures for safe medical use of sealed sources and devices and calibration of sources in accordance with 10 CFR 20.1101 and 10 CFR 35.12, that also meet the requirements of the applicable section(s) of 10 CFR Part 35, Subparts G and H.	<input type="checkbox"/>
	AND Attached procedures developed in accordance with 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, as applicable.	<input type="checkbox"/>
Item 10: Mobile Medical Service	Attached is the information requested in Appendix V to NUREG-1556, Volume 9.	<input type="checkbox"/>
Item 10: Transportation	The applicant's program for transportation will be examined during inspection and should not be submitted in the license application.	N/A
Item 10: Waste Management	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"/>

Following are several examples of medical licenses. The license conditions are not necessarily the most current conditions placed on NRC licenses and may change over time based on the most recent version of NUREG-1556, Vol. 20, "Guidance About Administrative Licensing Procedures."

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 style="text-align: center;">Licensee</p> <p>1. Sample Gamma Knife</p> <p>2. 100 Main Street King of Prussia, Pennsylvania</p>	<p>3. License Number 99-12345-01</p> <p>4. Expiration Date May 31, 2002</p> <p>5. Docket No. 030-54321 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cobalt 60</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed Sources (Manufacturer _____ Model No. _____)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. _____ curies per source and _____ curies total</p>
--	---	--

9. Authorized Use

A. For medical use described in 10 CFR 35.600, in a _____ Stereotactic Radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located at 100 Main Street, King of Prussia, Pennsylvania.
- 11. A. License material listed in item 6 above is only authorized for use by, or under the supervision of, John Smith, M.D. and Jessica Water, M.D.
- B. The Medical Physicists for this license are Kimberly Therapy, Ph.D. and Ronald Stereo, M.S.
- 12. The Radiation Safety Officer for this license is Kimberly Therapy, Ph.D.
- 13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

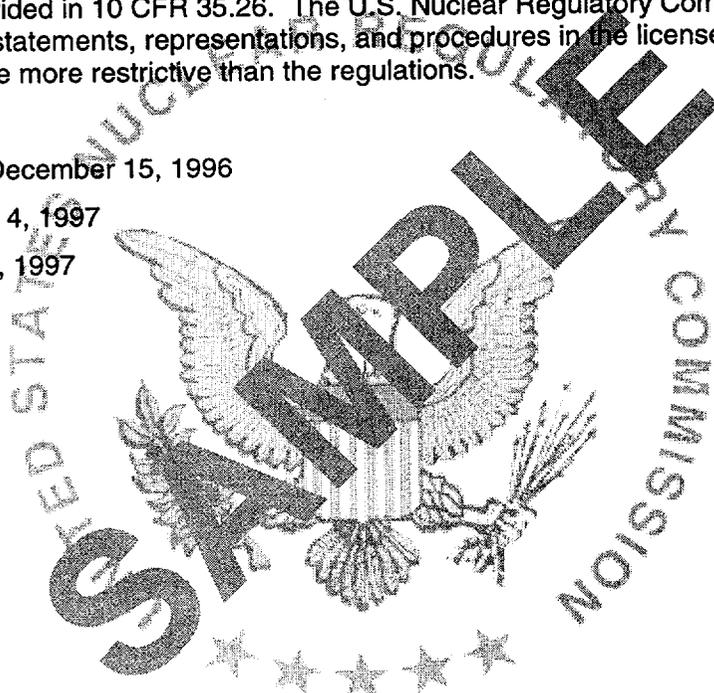
99-12345-01

Docket or Reference Number

030-54321

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, except for minor changes in the medical use radiation safety procedures as provided 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, 1996
- B. Letter dated March 4, 1997
- C. Letter dated May 8, 1997



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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	3. License Number 99-02120-01
2. 1234 Main Street	4. Expiration Date March 31, 2009
Anytown, Pennsylvania 02120	5. Docket No. 030-02120
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 identified in 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any, except generators	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any	C. 300 millicuries
D. Cesium 137	D. Sealed sources (Manufacturer xxx, Model No. yyy)	D. 500 millicuries
E. Gadolinium 153	E. Sealed sources (Manufacturer xxx, Model No. yyy)	E. 0.5 curies per source and 1 curie total
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged Kits	F. 50 millicuries
G. Cesium-137	G. Sealed source (Manufacturer aaa, Model No. bbb)	G. 200 millicuries
H. Americium-241	H. Sealed sources (Manufacturer zzz, Model No. ccc)	H. _____ millicuries per source and _____ millicuries total
I. Depleted Uranium	I. Metal	I. 99 kilograms

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

99-02120-01

Docket or Reference Number

030-02120

J. Iridium-192

J. Sealed Sources
(Manufacturer xxx, Model
No. xxx)

J. 10 curies per source and
20 curies total

Note: Insert total possession limit in items 8.C, D, F and G. Insert manufacturer and model number of sealed sources in parenthesis in items 7.D, E, G, H, and J. Insert activity per source and total activity for sealed sources in items 8.E, H, and J. Depleted uranium should not exceed 999 kilograms in item 8.I. At 1,000 kilograms, a licensee is required to file a statement annually regarding foreign origin source material; see 40.64(b).

Note: Insert manufacturer and model number of device in items 9.G and J. Americium-241 in item 6.H is not necessarily covered by 10 CFR 35.67 (Calibration and Reference Sources), therefore it needs to be listed.

9. Authorized Use

- A. Any uptake, dilution and excretion study approved in 10 CFR 35.100.
B. Any imaging and localization study approved in 10 CFR 35.200.
C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.

Note: Insert "for which the patient can be released under the provisions of 10 CFR 35.75" if the licensee is performing outpatient therapy procedures only.

- D. Any brachytherapy procedure approved in 10 CFR 35.400.

Note: Insert "for which the patient can be released under the provisions of 10 CFR 35.75" if the licensee is performing outpatient therapy procedures only.

- E. Diagnostic medical use of sealed sources approved in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
F. *In vitro* studies.
G. Non-human use. For use in a _____ Model _____ for calibration and checking of licensee's survey instruments.
H. Use as an anatomical marker.
I. Shielding in a linear accelerator.
J. One source for medical use described in 10 CFR 35.600, in a _____ High Dose Rate Remote Afterloading Brachytherapy Device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

99-02120-01

Docket or Reference Number

030-02120

CONDITIONS

10. Licensed material may be used 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. The Medical Physicist for this license is Cecil Source, Ph.D.

Note: There must be at least one authorized user listed in Condition 13 who is authorized for each of the materials and uses listed in item 6. For example: If John Therapy, M.D. left the institution and no authorized user who qualified for his material and use authorizations was added to the license, 35.400 materials, the remote afterloader, and DU would need to be removed from the license. If Thomas Group, D.O. left, however, no changes to the licensees' materials use authorization would be needed.

13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

Jane Diagnostic, M.D.

35.100; 35.200; 35.300; 35.500; *In vitro* studies; Cesium-137; Americium-241

Thomas Group, D.O.

35.100; 35.200; Strontium-89 for uses identified in 35.300

Gilbert Lawrence, M.D.

35.100; 35.200; 35.500; Iodine-131 for treatment of hyperthyroidism and cardiac dysfunction

John Therapy, M.D.

35.400; Iridium-192 for uses in a High Dose Rate Remote Afterloading Brachytherapy Device; Depleted Uranium

James Pathology, Ph.D.

In vitro studies

14. 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), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.

Note: The Cesium-137 sealed source, listed in Item 6.G and the Americium source in Item 6.H, are not covered by 10 CFR Part 35 (35.65, 35.400, 35.500 and 35.600) and require that license conditions 15-18 regarding uses of sealed sources be listed on the license. Sealed source conditions need not be listed on a medical license unless the license authorizes a sealed source not covered by Part 35.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02120-01

Docket or Reference Number
030-02120

15. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. 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.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

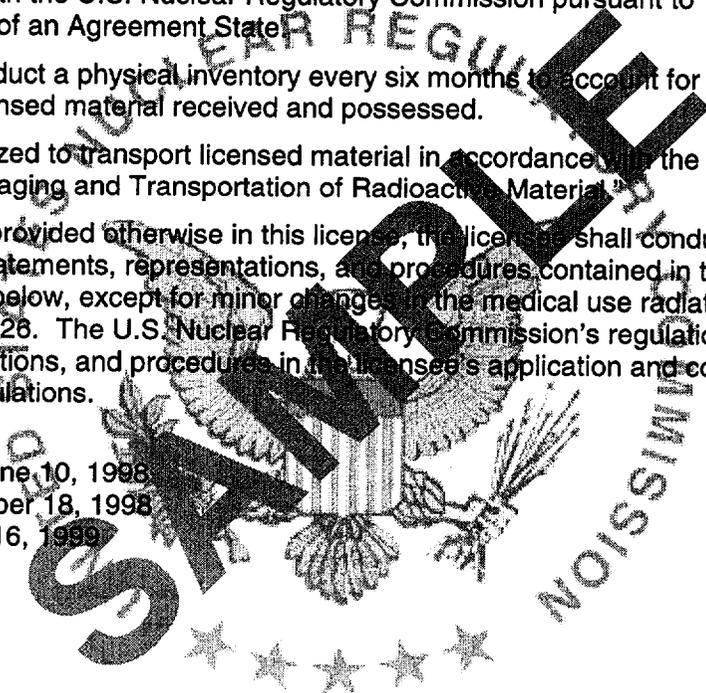
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02120-01

Docket or Reference Number
030-02120

16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
17. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
18. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed.
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, except for minor changes in the medical use radiation safety procedures as provided 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, 1998
- B Letter dated November 18, 1998
- C Letter dated March 16, 1999



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: March 20, 1999

By: Original signed by _____

Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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 style="text-align: center;">Licensee</p> <p>1. Sample Pacemaker License</p> <p>2. 100 Medical Center Drive King of Prussia, Pennsylvania 19406</p>	<p>In accordance with the application dated September 30, 1994</p> <p>3. License Number SNM-22160 is amended in its entirety to read as follows:</p> <p>4. Expiration Date October 31, 1999</p> <p>5. Docket No. 070-22160 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Plutonium (principal radionuclide Pu-238)</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed source (Manufacturer xxx, Model No. yyy)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. _____ milligrams per source and _____ grams total</p>
<p>9. Authorized Use</p> <p>A. As a component of _____ nuclear-powered pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explanation, recovery, disposal and implantation.</p>		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 100 Medical Center Drive, King of Prussia, Pennsylvania.
11. The Radiation Safety Officer for this license is Chief Radiologist, M.D.
12. The physicians responsible for implantation, follow-up, explanation, 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.
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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

SNM-22160

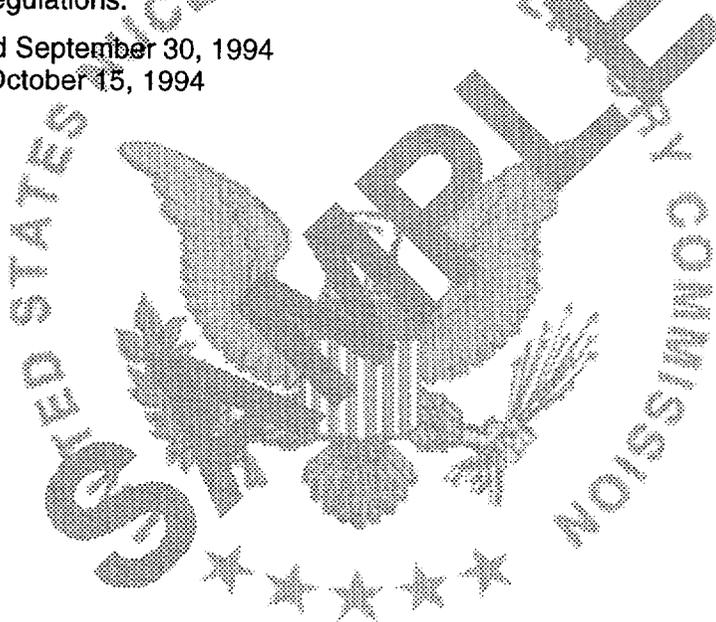
Docket or Reference Number

070-22160

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 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, 1994

B Letter received October 15, 1994



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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 02300	4. Expiration Date October 31, 2004
	5. Docket No. 99-02110 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 number 1 through 83	A. Any	A. 200 millicuries per radionuclide and 15 curies total
B. Any byproduct material with atomic number 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 (Manufacturer xxx, Model No. yyy)	J. 12 curies per source and 24 curies total

9. Authorized Use

Note: Insert the sealed source manufacturer and model number in 7.J parenthesis above. Insert HDR afterloading unit manufacturer and model number in blank in 9.J below.

MATERIALS LICENSE**SUPPLEMENTARY SHEET**

License Number

99-02110-01

Docket or Reference Number

030-02110

- A. through I. Medical diagnosis, therapy and research in humans. Research and development as defined 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 _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 300 Main Street, Anytown, Pennsylvania.
- 11 A. Licensed material shall be used by, or under the supervision of, individuals designated in writing by the Radiation Safety Committee, Albert Einstein, M.D., Ph.D., Chairperson.
- B. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in 10 CFR 35.2.
- C. Individuals designated in writing to work as authorized users or authorized nuclear pharmacists, as defined in 10 CFR 35.2, shall meet the training and experience criteria established in 10 CFR Part 35, Subparts B, and D through H, and shall be designated by the licensee's Radiation Safety Committee.
- D. The Radiation Safety Officer for this license is Patty Melt, Ph.D.
- E. The Medical Physicist for this license is Melba Toast, M.S.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
13. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

99-02110-01

Docket or Reference Number

030-02110

14. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed 3 years.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. 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.
- E. Sealed sources and detector cells need not be leak tested if:
- (i) they contain only hydrogen-3; or
 - (ii) they contain only a radioactive gas; or
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U. S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source or detector cell involved, the test results, and corrective action taken.
- G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

99-02110-01

Docket or Reference Number

030-02110

15. 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 which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
16. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
17. The licensee is authorized to hold radioactive material with a physical half-life of less than 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 ten 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.
18. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific conditions of this license.
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."

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 5 OF 5 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

99-02110-01

Docket or Reference Number

030-02110

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, except for minor changes in the medical use radiation safety procedures as provided 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 23, 1994
- B. Letter dated June 8, 1994
- C. Letter dated July 26, 1994
- D. Letter dated August 8, 1994
- E. Letter dated October 4, 1994



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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	4. Expiration Date October 31, 2004
King of Prussia, Pennsylvania 02300	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	A. Sealed sources (Manufacturer yyy, Model No. xxx)	A. 5,500 curies per source and 11,000 curies total
B. Depleted Uranium	B. Metal	B. _____ kilograms

9. Authorized Use

Note: Insert teletherapy sealed source manufacturer and model number in 7.A parenthesis above. Depleted uranium possession limit in 8.B above may not exceed 999 kilograms. Insert teletherapy unit/device manufacturer and model number in blank 9.A below.

A. One source for medical use described in 10 CFR 35.600, in a _____ 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 only at the licensee's facilities located at 200 Cobalt Street, King of Prussia, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Sarah Smith, M.S.
- 12. The Medical Physicist for this license is Sarah Smith, M.S.
- 13. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

David Jones, M.D.

Material and Use

Cobalt-60 for uses in a Teletherapy Unit;
Depleted uranium

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

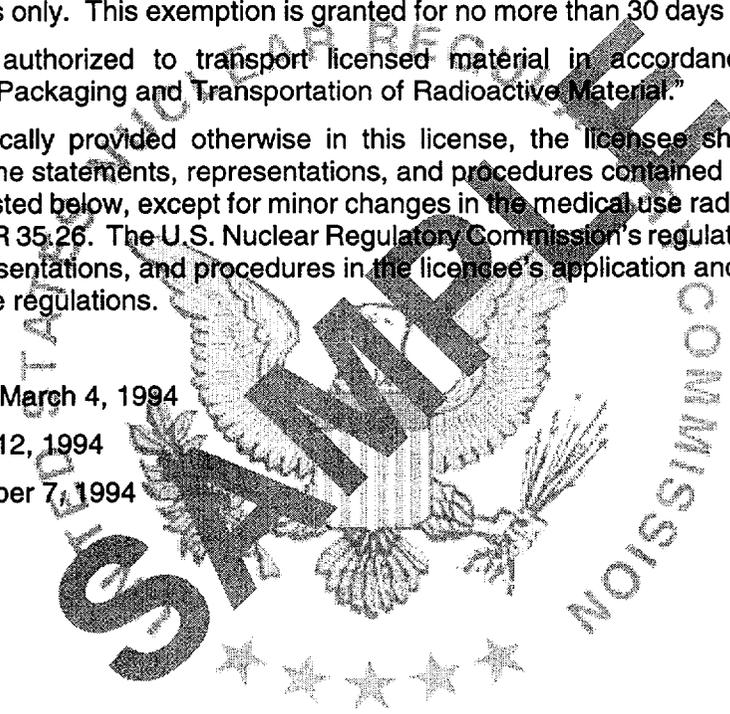
License Number

99-02300-01

Docket or Reference Number

030-02300

- 14. The licensee is exempted 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.
- 15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 16. 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, except for minor changes in the medical use radiation safety procedures as provided 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 4, 1994
 - B. Letter dated May 12, 1994
 - C. Letter dated October 7, 1994



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____

By: Original Signed by _____

Nuclear Materials Safety Branch 1
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406

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>In accordance with the application dated July 17, 1994</p>
<p>1. Sample <i>In Vitro</i> Testing Laboratory</p>	<p>3. License Number 99-02410-01 is amended in its entirety to read as follows:</p>
<p>2. 1234 Clinical Way Petri, Delaware 02410</p>	<p>4. Expiration Date September 30, 2004</p>
	<p>5. Docket No. 030-02410 Reference No.</p>
<p>6. Byproduct, source, and/or special nuclear material</p>	<p>7. Chemical and/or physical form</p>
<p>A. Hydrogen-3 B. Carbon-14 C. Phosphorus-32 D. Iron-59 E. Iodine-125</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 5 millicuries B. 5 millicuries C. 5 millicuries D. 2 millicuries E. 10 millicuries</p>
<p>9. Authorized Use</p> <p>A. through E. <i>In vitro</i> laboratory studies.</p>	

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located at 1234 Clinical Way, Petri, Delaware.
- 11. A. Licensed material shall be used by, or under the supervision of, Maria Kitt, Ray D. O'Tracer or Otto Radiograph.
B. The Radiation Safety Officer for this license is Maria Kitt.
- 12. Licensed material shall not be used in or on human beings.
- 13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 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 ten 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
99-02410-01

Docket or Reference Number
030-02410

Amendment No. 01

- 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.
- 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. The 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 17, 1994
 - B. Letter dated September 8, 1994



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: _____ By: _____

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Appendix D

Information Needed for Transfer of Control

Information Needed for Transfer of Control

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 E

Guidance on Financial Assurance Determination

Guidance on Financial Assurance Determination

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 E.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 E.1 and must be used to determine the need for financial assurance for both sealed and unsealed byproduct material.

Table E.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 gigabecquerels.

As 10 CFR 30.35 describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit financial assurance. RG 3.66¹, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990, provides sample documents for financial mechanisms. Because a Statement of Intent for government licensees is not described in RG 3.66, the recommended wording for this statement is shown below.

¹ See the Notice of Availability (inside front cover of this report) to obtain copies of RG 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72," dated June 1990.

APPENDIX E

Suggested Wording for a Statement of Intent for a Government Licensee

[DATE]

TO: U. S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 [or appropriate regional address]

STATEMENT OF INTENT

As [TITLE] of [LICENSEE NAME], I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by U. S. Nuclear Regulatory Commission Material License No. _____. This authority is established by [NAME OF DOCUMENT(S) GOVERNING CONTROL OF FUNDS]. Within this authority, I intend to have funds made available when necessary, in an amount up to [DOLLAR AMOUNT] to decommission [DESCRIPTION OF FACILITIES]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [NAME OF DOCUMENTS] is attached as evidence that I am authorized to represent [LICENSEE NAME] in this transaction.

[SIGNATURE]
[NAME]
[TITLE]

Attachment: As stated

Appendix F

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 (see Figure 8.7). 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:

- Activities involving licensed material that the RSO considers unsafe are stopped;
- 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 SSDL 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 F

- 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 anytime. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

I accept the above responsibilities,

Signature of Radiation Safety Officer

cc: Affected department heads

Appendix G

NRC Forms 313A and 313B

Documentation of Training and Experience

General Guidance

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. Complete retraining is neither practical nor necessary in most cases. 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 emergency procedures relative to the therapy unit to be used by the applicant.

The simplest and most straightforward method of demonstrating acceptable training and experience is through certification by a professional board recognized by NRC. Equally straightforward evidence is that the applicant is listed as a user on an NRC or Agreement State license or permit issued by a medical broad scope or master materials licensee, provided that the applicant is authorized for the same types of use(s) requested in the application under review, and that the applicant meets the recentness of training criteria described in 10 CFR 35.59. For users who have been previously authorized under a medical broad scope or master materials license, the applicant should submit either verification of previous authorization(s) granted by the broad scope or master materials licensee or evidence of acceptable training and experience.

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) 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

APPENDIX G

preceptor forms, NRC Forms 313A and 313B 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.

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. The Technical Assistance Request response dated June 15, 1995, "Interpretation of the Requirements for Physicians who Interpret Diagnostic Imaging Scans," provides additional guidance on this issue.

NRC Form 313A is under development.

APPENDIX G

NRC Form 313B is under development.

Appendix H

Model Training Program

Model Training Program

Model procedures for describing training programs appear below. 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) will 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 (10 CFR 19.12);
- Basic radiation protection to include concepts of time, distance, and shielding (10 CFR 19.12);
- Concept of maintaining exposure ALARA (10 CFR 19.12, 10 CFR 20.1101);
- Risk estimates, including comparison with other health risks (10 CFR 19.12);
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable) (10 CFR 20.1201);
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used (10 CFR 19.12);
- 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);

APPENDIX H

- 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, 10 CFR 35.27);
- Appropriate surveys to be conducted, including surveys of all material leaving radioactive material areas (10 CFR 20.1501);
- Proper use of required survey instruments (10 CFR 20.1501);
- Emergency procedures (10 CFR 19.12);
- 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 will 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 35.610);
- 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 (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610); 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 be sure to address the sections of 10 CFR 35 listed in 10 CFR 35.51(b)(1). Note, for example, that additional training requirements apply to 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 required for treatment planning and quality control system, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in 10 CFR 35.390 and Subparts F and H of 10 CFR 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 will include the following:

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);
- Health protection problems 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).