



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

APPLICATION GUIDE 3.1
November 1, 2018

APPLICATION GUIDE FOR MEDICAL USE OF RADIOACTIVE MATERIAL

RADIATION CONTROL PROGRAM MC 2835
P. O. Box 149347 Austin, Texas 78714-9347

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AGENCY CONTACTS

For questions on the application and any related correspondence, please contact

Phone: (512) 834-6661

Email: RAMlicensing@dshs.texas.gov

The rules and forms referenced in this guide, as well as this and other guides are available on the [agency's website](#).

Suggestions for improvements in guides are encouraged. Letters containing comments and suggestions should be sent to the Department of State Health Services, Attn.: Manager, Radioactive Materials Licensing-MC 2835, P.O. Box 149347, Austin, Texas 78714-9347.

Texas is divided into health service regions and, in general, inspectors are assigned to specific regions. Once a license is issued, an agency inspector will periodically visit the licensee to conduct a risk-informed, performance based inspection. The inspection will cover requirements in rule as well as implementation of procedures identified in the content of your application. For more information on inspections, visit the agency website.

Abbreviations

AAPM	American Association of Physicists in Medicine
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
Bq	becquerel
CEDE	committed effective dose equivalent
CFR	<i>Code of Federal Regulations</i>
Ci	curie
cc	cubic centimeter
cm	centimeter
cm ²	square centimeter
DAC	derived air concentration
DDE	deep-dose equivalent
DOT	U.S. Department of Transportation
dpm	disintegrations per minute
FDA	U.S. Food and Drug Administration
GBq	gigabecquerel
GSR	gamma stereotactic radiosurgery
HDR	high-dose rate
I-125	iodine-125
I-131	iodine-131
ICRP	International Commission on Radiological Protection
IN	Information Notice
kBq	kilobecquerel
L/C	License Condition
LDR	low-dose rate

MBq	megabecquerels
MDR	medium-dose rate
MML	Master Materials License
mCi	millicurie
mg	milligram
Mo-99	molybdenum-99
mR	milliroentgen
mrad	millirad
mrem	millirem
mSv	millisievert
NaI	sodium iodide
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
NSTS	National Source Tracking System
NVLAP	National Voluntary Laboratory Accreditation Program
PET	Positron Emission Tomography
PDR	pulsed dose-rate
QA	quality assurance
R	roentgen
Ra-226	radium-226
Rb-82	rubidium-82
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	shallow-dose equivalent
SLN	sentinel lymph node
Sr-82	strontium-82
Sr-85	strontium-85

Sr-90	strontium-90
SSD	sealed source and device
Sv	Sievert
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	Transport Index
TLD	thermoluminescent dosimeters
U-235	uranium-235
WD	written directive
Y-90	yttrium-90
μCi	microcurie
%	percent

I. OVERVIEW

SCOPE AND PURPOSE

The Department of State Health Services (the agency) regulates the use of radioactive material as identified in Chapter 401 of the Texas Health and Safety Code. Medical and veterinary use of radioactive material requires the issuance of a specific radioactive material license. This report provides guidance to an applicant applying for medical or veterinary use of radioactive material and also provides agency staff with the criteria for evaluating such applications.

This application guide is NOT a substitute for the rules in Title 25 Texas Administrative Code (25 TAC) Chapter 289 and compliance with it is not required. Methods for compliance with rules different from those set out in this guide will be acceptable if they are considered by the agency to provide for public health and safety and demonstrate compliance with rules. Once the agency receives satisfactory information from an applicant, a license to receive, possess, use, transfer or acquire radioactive material will be issued.

This report outlines agency criteria for evaluating a medical use license application for the following types of medical or veterinary uses:

- Use of unsealed radioactive material for uptake, dilution and excretion studies that do not require a written directive under 25 TAC Section (§) 289.256(ff)
- Use of unsealed radioactive material for imaging and localization studies that do not require a written directive under 25 TAC §289.256(hh)
- Use of unsealed radioactive material that requires a written directive under 25 TAC §289.256(kk)
- Use of sealed sources for manual brachytherapy under 25 TAC §289.256(rr)
- Use of sealed sources for diagnosis under 25 TAC §289.256(bbb)
- Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit under 25 TAC §289.256(ddd)
- Other medical and veterinary uses under 25 TAC §289.256(q)

The agency also regulates the use of machines that produce radiation. A separate application will need to be filed regarding uses of such machines. Information regarding application for that use is beyond the scope of this guidance document.

For more information, visit the agency's radiation control website at <https://www.dshs.texas.gov/radiation/>.

To assist applicants, the bullets in the table below indicate that applicants for that type of use should review the guidance section.

Section of this Guide that Applicants for a Particular Type of Use Should Review								
	Item	Type of §289.256 Use						
		(ff)	(hh)	(kk)	(rr)	(bbb)	(ddd)	(q)
1	License Action Type	•	•	•	•	•	•	•
2	Legal Business Name and Mailing Address	•	•	•	•	•	•	•
3a	Address(es) of Radioactive Material Use and/or Storage	•	•	•	•	•	•	•
3b	Address Where Records will be Maintained	•	•	•	•	•	•	•
4	Radiation Safety Officer Name and Contact Information	•	•	•	•	•	•	•
5	Radioactive Material Requested	•	•	•	•	•	•	•
6	Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience	•	•	•	•	•	•	•
6.1	Radiation Safety Officer	•	•	•	•	•	•	•
6.2	Authorized Users	•	•	•	•	•	•	•
6.3	Authorized Nuclear Pharmacists	•	•	•				•
6.4	Authorized Medical Physicists				•		•	•
7	Training for Individuals Working in or Frequenting Restricted Areas	•	•	•	•	•	•	•
8	Facilities and Equipment	•	•	•	•	•	•	•
8.1	Facility Diagram	•	•	•	•	•	•	•
8.2	Radiation Monitoring Instruments	•	•	•	•	•	•	•
8.3	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed RAM	•	•	•				•
8.4	Therapy Unit – Calibration and Use				•		•	•
8.5	Other Equipment and Facilities	•	•	•	•	•	•	•
9	Radiation Protection Program	•	•	•	•	•	•	•
9.1	Audit Program	•	•	•	•	•	•	•
9.2	Occupational Dose	•	•	•	•	•	•	•
9.3	Public Dose	•	•	•	•	•	•	•
9.4	Operating, Safety, and Emergency Procedures	•	•	•	•	•	•	•
9.5	Spill/Contamination Procedures	•	•	•	•	•	•	•

Section of this Guide that Applicants for a Particular Type of Use Should Review								
	Item	Type of §289.256 Use						
		(ff)	(hh)	(kk)	(rr)	(bbb)	(ddd)	(q)
9.6	Emergency Procedures for Therapy Devices Containing Sealed Sources						•	•
9.7	Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources						•	•
9.8	Ordering and Receiving	•	•	•	•	•	•	•
9.9	Opening Packages	•	•	•	•	•	•	•
9.10	Material Receipt and Accountability	•	•	•	•	•	•	•
9.11	Leak Tests	•	•	•	•	•	•	•
9.12	Area Surveys	•	•	•	•	•	•	•
9.13	Procedures for Administrations When a Written Directive is Required			•	•		•	•
9.14	Safe Use of Unsealed RAM	•	•	•				•
9.15	Safety Procedures for Treatment When Patients Are Hospitalized			•	•		•	•
9.16	Mobile Nuclear Medicine Service	•	•	•	•	•	•	•
9.17	Release of Patients or Human Research Subjects			•	•			•
9.18	Minimization of Contamination	•	•	•	•	•	•	•
9.19	Records of Dosages and Use of Brachytherapy Sources	•	•	•	•			•
9.20	Recordkeeping	•	•	•	•	•	•	•
9.21	Reporting	•	•	•	•	•	•	•
9.22	Transportation	•	•	•	•	•	•	•
9.23	Security Program for Category 1 and Category 2 RAM				•		•	•
10	Waste Management/Disposal	•	•	•	•	•	•	•
11	Financial Qualification and Financial Assurance	•	•	•	•	•	•	•
12	Certification	•	•	•	•	•	•	•

TYPES OF LICENSES

Licenses for radioactive material are of two types: general and specific. General licenses are provided in 25 TAC §289.251 and may be effective without the filing of an application with the agency or the issuance of license documents. The general license is subject to other applicable portions of the rules and any limitations of the general license. A specific license requires the submission of an application to the agency and the issuance of a licensing document.

Specific Medical Use License

The agency defines the following, under 25 TAC §289.256(c) "Definitions":

- "medical use" as "the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user."
- "patient" as a human or animal under medical care and treatment.
- "Authorized user" (AU) for human use as "a physician licensed by the Texas Medical Board; or a dentist licensed by the Texas State Board of Dental Examiners; or a podiatrist licensed by the Texas State Board of Podiatric Medicine," who meets the training and experience requirements specified in the applicable subsections of 25 TAC §289.256 or who is identified as an AU (i) on an agency, U. S. Nuclear Regulatory Commission (NRC) or Agreement State license, (ii) on a permit issued by an NRC master material license or an NRC master material broad scope permittee that is authorized to permit the medical use of radioactive material, or (iii) on a permit issued by an NRC or Agreement State broad scope licensee authorized to permit the medical use of radioactive material.
- "Authorized user" for veterinary use as "an individual who is a veterinarian licensed by the Texas State Board of Veterinary Medical Examiners" and who is certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine; or has received training in accordance with the applicable subsections of 25 TAC §289.256; or who is identified as an AU on (i) an agency, NRC or Agreement State license that authorizes the veterinary use of radioactive material, (ii) on a permit issued by an NRC master material license or an NRC master material broad scope permittee that is authorized to permit the medical or veterinary use of radioactive material, or (iii) on a permit issued by an NRC or Agreement State broad scope licensee authorized to permit the medical or veterinary use of radioactive material.
- "Veterinary use" as "the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients under the supervision of an authorized user."

The agency issues two types of specific licenses for the medical use of radioactive material in medical practices and facilities: the specific license of limited scope and the specific license of broad scope. Specific licenses of broad scope are beyond the scope of this guide.

Although the agency usually issues a single radioactive materials license to cover an entire radiation safety program, the agency may issue separate licenses to individual licensees for different medical uses. The agency does not usually issue separate licenses to different departments in a medical facility or to individuals employed by a medical facility or with whom the medical facility has contracted.

Research Involving Human Subjects

The definition of “medical use” includes the administration of radioactive material or radiation therefrom to human research subjects. 25 TAC §289.256(d), “Provisions for research involving human subjects,” addresses the protection of the rights of human subjects involved in research by medical use licensees. For these licensees, prior agency 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 25 TAC §289.256(d)(1), research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

General In Vitro License

In 25 TAC §289.251(f)(4)(G), “General license for the use of radioactive material for certain *in vitro* clinical or laboratory testing not to include research and development,” the agency establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain radioactive material for *in vitro* clinical or laboratory tests not involving “medical use” (i.e., not involving administration to humans). The general license in 25 TAC §289.251(f)(4)(G) explains the requirements for using the materials listed. The agency enacted an exemption exempting users from the registration requirement in 25 TAC §289.251(f)(4)(G)(iv).

The agency limits possession to a total of 200 microcuries (μCi) of photon-emitting materials listed in 25 TAC §289.251(f)(4)(G) at any one time, at any one location of storage or use. An applicant needing more than 200 μCi of these materials must apply for a specific license.

APPLICABLE RULES

It is the applicant's or licensee's responsibility to obtain and have available up-to-date copies of applicable rules, to read and understand the requirements of each of these rules, and to comply with each applicable rule. The following Sections of 25 TAC, Chapter 289 are applicable to licensing medical use of radioactive materials:

201 "General Provisions for Radioactive Material"

202 "Standards for Protection Against Radiation from Radioactive Materials"

203 "Notices, Instructions, and Reports to Workers; Inspections"

204 "Fees for Certificates of Registration, Radioactive Material Licenses,
Emergency Planning and Implementation, and Other Regulatory Services"

205 "Hearing and Enforcement Procedures"

251 "Exemptions, General Licenses, and General License Acknowledgments"

252 "Licensing of Radioactive Material"

256 "Medical and Veterinary Use of Radioactive Material"

257 "Packaging and Transportation of Radioactive Material"

FORMAT OF THIS GUIDE

The format for each item of technical information in this guide is as follows

Rules – references the rules applicable to the item;

Criteria – outlines the criteria used to evaluate the applicant's response;

Discussion – provides additional information on the topic; and

Response from Applicant – provides suggested response(s) or indicates that no response is needed on that topic during the initial licensing process.

Notes and references are self-explanatory and may not be found for each item on RC Form 252-2.

Some sections of the guidance include references to other documents or resources that may be useful to the applicant. If reference or resource documents include information conflicting with current rules, the rules in 25 TAC §289 apply. For example, some references or resources may include alternate limits for occupational and public dose; however, licensees should note that the limits in 25 TAC §289.202 are applicable. Many of the documents may be accessed online at the NRC Library.

PURPOSE OF APPENDICES AND NOTE ON PROCEDURES

Attached to this application guide are appendices that may be submitted as an applicant's procedures. Appendix A is a checklist which identifies documents that an applicant should submit. Subsequent appendices serve as model procedures.

The applicant should carefully consider each procedure provided to the agency in the licensing process. After a license is issued, the licensee must conduct its program in accordance with statements, representations, and procedures contained in the application and in correspondence with the agency, when incorporated into a license by reference.

THE "AS-LOW-AS-REASONABLY-ACHIEVABLE" (ALARA) CONCEPT

In 25 TAC §289.202(e), "Radiation protection programs," rules state that "each licensee shall develop, document, and implement a radiation protection program sufficient to ensure compliance..." with 25 TAC §289.202 and "the licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are...ALARA." This section also requires that licensees review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

References and Resources: Applicants should consider the ALARA philosophy detailed in the following reports when developing plans to work with licensed radioactive materials. The following documents and resources contain information, methods, and references useful to those who are establishing radiation protection programs to maintain radiation exposures at ALARA levels in medical facilities:

- NRC Regulatory Guide (RG) 8.10, "Operating Philosophy for Maintaining Occupational and Public Radiation Exposures ALARA," August 2016.
- NRC RG 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," February 1996.
- NRC RG 8.18, "Information Relevant to Ensuring that Occupational Radiation Exposures at Medical Institutions Will Be ALARA," April 2011.
- NRC NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation."
- National Council on Radiation Protection and Measurements (NCRP) Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," December 31, 1990.
- NCRP Report No. 127, "Operational Radiation Safety Program," 1998.

II. HOW TO FILE AN APPLICATION

APPLICATION PREPARATION

Applicants for a radioactive materials license should do the following:

- Use the most recent guidance in preparing an application.
- Complete RC Form 252-2 "Application for Radioactive Material License," Items 1 through 4, and 12 on the form itself.
- Complete RC Form 252-2 "Application for Radioactive Material License," Items 5 through 10, on supplementary pages.
- Complete RC Form 252-1 "Business Information Form".
- Complete the appropriate RC Form 256 series of forms to document training and experience.
- Provide sufficient detail for the agency to determine that equipment, facilities, training, experience, and the radiation protection program are adequate to protect health and safety and minimize danger to life and property.
- For each supplementary page submitted with the application, identify and cross-reference submitted information to the item number on the application or the topic to which it refers. Use standard 8.5 by 11-inch paper. Ensure that print is clear and sharp.
- Submit the required fee. The review of a new radioactive materials license application will not begin until the appropriate application fee has been paid. Refer to 25 TAC §289.204 to determine the amount of the fee or contact 512-231-5627 or RadiationFeesandRecords@dshs.texas.gov.
- Avoid submitting proprietary or personally identifiable information unless specifically requested by the agency. Personally identifiable information includes social security numbers, home telephone number, dates of birth and radiation dose information. If such information must be submitted, it should be separated from the rest of the application paperwork and marked to meet the appropriate exemption from public disclosure rule as described by 25 TAC §289.201(m).
- Ensure the protection of Security-Related Sensitive Information. Applicants who will possess category 1 or category 2 quantities of radioactive material, as defined in 25 TAC §289.201(b), must ensure protection of certain types of information such as the quantities and locations of radioactive material at licensed facilities, and associated security measures. A cover letter should clearly state that the attached documents contain security-related sensitive

information and the top of every page of a document that contains such information should be clearly marked: "Official Use Only – Security Related Information" For the pages having security-related sensitive information, an additional marking should be included (e.g., an editorial note box) adjacent to that material. For further information, see the NRC's Regulatory Issue Summary (RIS) 2005-31, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Material," December 22, 2005.

WHERE TO FILE

New license applications must be submitted as paper applications to the address noted in the table below, as applicable.

Renewal applications may be submitted electronically to: RAMLicensing@dshs.texas.gov. Please include your license number in the subject line.

NEW License Application and Fee	Radiation Control Program MC 2003 Texas Department of State Health Services P.O. Box 149347 Austin, TX 78714-9347
Regular correspondence, license renewal or amendment request	Radiation Control Program MC 2835 Texas Department of State Health Services P.O. Box 149347 Austin, TX 78714-9347
Special service deliveries such as Fed EX, UPS or hand delivery	Radiation Control Program MC 2835 Texas Department of State Health Services 8407 Wall Street Austin, TX 78754

III. MANAGEMENT RESPONSIBILITY

COMMITMENTS AND RESPONSIBILITIES

The agency defines management as the chief executive officer or other individual delegated the authority to manage, direct or administer the licensee's activities. A representative of management is expected to sign a license application as stated in 25 TAC §289.252(d)(2).

The signature on an application acknowledges the applicant's commitments and responsibility for the following:

- Maintain doses to workers and the general public ALARA and assign a radiation safety officer to oversee the program.
- Perform an annual review of the radiation safety program to follow ALARA considerations.
- Consider changes to procedures and equipment that may reduce radiation doses.
- Maintain complete and accurate records of the radiation protection program.
- Comply with agency and U. S. Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures and agency license commitments.
- Maintain security and control of radioactive materials.
- Provide financial and other resources (space, equipment, personnel, etc.) necessary to ensure patients, workers and the general public are protected from radiation hazards.
- Approve only qualified individuals to handle and use radioactive materials.

SAFETY CULTURE

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees and applicants for a license subject to agency authority. The agency has adopted the Nuclear Regulatory Commission's Safety Culture Policy.

"Nuclear safety culture" is defined in the U.S. Nuclear Regulatory Commission (NRC) Safety Culture Policy Statement (76 FR 34773; June 14, 2011) as "the core values and behaviors resulting from a collective commitment by leaders and individuals to

emphasize safety over competing goals to ensure protection of people and the environment.” Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal-conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). Refer to the table below for the traits of a positive safety culture from the NRC’s Safety Culture Policy Statement.

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

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

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

Traits of a Positive Safety Culture

Leadership Safety Values and Actions	Problem Identification and Resolution	Personal Accountability
Leaders demonstrate a commitment to safety in their decisions and behaviors.	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	All individuals take personal responsibility for safety.
Work Processes	Continuous Learning	Environment for Raising Concerns
The process of planning and controlling work activities is implemented so that safety is maintained.	Opportunities to learn about ways to ensure safety are sought out and implemented.	A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.
Effective Safety Communications	Respectful Work Environment	Questioning Attitude
Communications maintain a focus on safety.	Trust and respect permeate the organization.	Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

IV. CONTENTS OF AN APPLICATION

INTRODUCTION

This section explains, item by item, the information that medical use applicants must provide for each item in RC Form 252-2. Incomplete or incorrect information may cause unnecessary delay for the agency and applicant in processing the application.

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

ITEM 1: LICENSE ACTION TYPE

Rules: 25 TAC §289.252(d)(1), 25 TAC §289.252(z)(1)

Criteria: A new license application must be filed in a manner prescribed by the agency according to 25 TAC §289.252(d)(1). A renewal application must be filed according to 25 TAC §289.252(z)(1).

Discussion: For new license applications, a pre-licensing visit may be conducted prior to issuance of the license.

Response from Applicant: Identify whether your application is for a new license or renewal of an existing license by checking the appropriate box. If you hold a current or prior license issued by the agency, the NRC or another Agreement State, provide the license number(s)/name(s) where noted.

ITEM 2: LEGAL BUSINESS NAME AND MAILING ADDRESS OF APPLICANT/LICENSEE

Rules: 25 TAC §289.252(d)(1)

Criteria: The name provided must be the legal business name of the company with direct control over the proposed uses of radioactive material.

Discussion: A division or department within the business should not be identified as the primary business name.

The mailing address must be in Texas. A PO Box is an acceptable mailing address. The applicant should be prepared to receive correspondence at the proposed mailing address as the agency may begin corresponding immediately to the business mailing address provided by the applicant.

Response from Applicant: Provide the legal business name and assumed name or dba, if applicable, and the mailing address to receive agency correspondence.

Note: Once licensed, the applicant must notify the agency within 15 calendar days regarding a change in the business name or change in mailing address as described in 25 TAC §289.252(x)(5)(B).

ITEM 3A: ADDRESS(ES) OF RADIOACTIVE MATERIAL USE AND/OR STORAGE

Rules: 25 TAC §289.252(e)(8), 25 TAC §289.256(f)(4)

Criteria: The applicant's permanent facility must be located in Texas as required by 25 TAC §289.252(e)(8) and 25 TAC §289.256(f)(4). Any proposed permanent facility must be within the State of Texas boundaries and not under exclusive federal jurisdiction.

Discussion: If radioactive material is to be used or stored at more than one location under the license, the specific address must be provided for each facility. The descriptive address should be sufficient to allow an agency inspector to find the facility location. A post office box address is not acceptable.

"Temporary job site" means a location, other than the specific location(s) of use authorized on the license, where mobile medical services are conducted for limited periods of time.

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

Response from Applicant: Provide each address where radioactive material will be used or stored including the street address, suite number (if applicable), city, state and zip code. Indicate whether radioactive material will be used at temporary job sites.

ITEM 3B: ADDRESS WHERE RECORDS WILL BE MAINTAINED

Rules: 25 TAC §289.202(l)(5), 25 TAC §289.256(dd)(1)(C)

Criteria: Each applicant must designate a main records site and must make and retain records at that site, and each authorized use site, in accordance with 25 TAC §289.202(l)(5) and as specified in license conditions.

Mobile nuclear medicine providers must have at least one fixed facility where records may be maintained as described by 25 TAC §289.256(dd)(1)(C).

Discussion: Records pertinent to operations at each authorized site must be maintained at that site and copies of all records must be maintained at the main site. The main records address will be designated as a site on the license.

Response from Applicant: Provide the street address, suite number (if applicable), city, state and zip code of the main records site.

ITEM 4: RADIATION SAFETY OFFICER

Rules: 25 TAC §289.252(f), 25 TAC §289.256(g).

Criteria: Each applicant must designate a Radiation Safety Officer (RSO) in accordance with 25 TAC §289.252(f)(1).

Discussion: An RSO must be designated for each license issued by the agency. The RSO serves as the primary contact with the agency and is responsible for establishing and overseeing the radiation protection program.

Response from Applicant: Provide the proposed radiation safety officer's name and contact information including email address. Failure to provide appropriate contact information may delay processing the application.

ITEM 5: RADIOACTIVE MATERIAL REQUESTED

Rules: 25 TAC §289.252(d)(9), 25 TAC §289.256(y), 25 TAC §289.256(ff), 25 TAC §289.256(hh), 25 TAC §289.256(kk), 25 TAC §289.256(rr), 25 TAC §289.256(bbb), 25 TAC §289.256(ddd), 25 TAC §289.256(q), 25 TAC §289.256(y)

Criteria: Radioactive material for medical or veterinary use is divided into seven types of use: 25 TAC §289.256(ff), (hh), (kk), (rr), (bbb), (ddd) and (q). Depleted uranium is used in shielding and collimation in medical devices.

Discussion: The applicant must indicate the radioactive material requested. Specifically, RC Form 252-2 requests element and mass number, chemical and/or physical form, the maximum amount that will be possessed at any one time, and the purpose(s) for which radioactive material will be used. The applicant should refer to Checklist A-1 of Appendix A of this guide for an acceptable format for describing the radioactive material. The amount and type of information necessary will vary according to the type of use and material requested.

§289.256(ff) and §289.256(hh) Use: The chemical/physical form may be "Any radiopharmaceutical except gas" permitted by 25 TAC §289.256(ff) or 25 TAC §289.256(hh), as appropriate. The total amount requested may be "As needed." The applicant should define the purpose of use by stating the applicable section of 25 TAC §289.256 and the description of the applicable modality. Applicants using generators should refer to Checklist A-1 of Appendix A of this guide for an acceptable format for requesting this use.

Applicants requesting use of Tc-99m for Sentinel Lymph Node (SLN) Biopsy Procedures should review and consider necessary licensing requirements outlined in the NRC's Regulatory Issue Summary 2008-31 "Licensing Requirements for Sentinel Lymph Node Biopsy," including that SLN tissue may be transferred to a nonlicensed

facility for pathology analysis as long as the tissue does not contain more than 100 microcuries of technetium-99m (Tc-99m), which is based on the exemption criteria in 25 TAC §289.251(e)(2), "Exempt Quantities."

§289.256(kk) Use: The chemical/physical form may be "Any radiopharmaceutical except gas". The total amount requested may be "As needed." The applicant should define the purpose of use by stating "Any use of unsealed material that requires a written directive permitted by 25 TAC §289.256(kk)."

25 TAC §289.256(rr) Use: The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use in order to minimize the need for license amendments if they change model or vendor.

The applicant should define the purpose of use by stating "Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr)."

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

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

25 TAC §289.256(bbb) Use: The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use in order to minimize the need for license amendments if they change model or vendor. The applicant should define the purpose of use by stating that the applicable use is 25 TAC §289.256(bbb), and, if applicable, confirm that the sources requested and the associated devices are compatible.

For therapy devices, the applicant must consider the shipped, installed, and medical use limitations on activity. Limitations are described in the Sealed Source and Device

(SSD) registration certificates and U.S. Food and Drug Administration (FDA) 510k certificates.

Gamma stereotactic radiosurgery (GSR) and teletherapy sources are usually at or above Category 1 quantities, and co-located high dose-rate (HDR) brachytherapy sources are usually at or above Category 2 quantities. The applicant should refer to Item 9.24 for additional requirements.

25 TAC §289.256(ddd) Use: The radionuclide; the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number); the activity per source and the total activity in microcuries (μCi), millicuries (mCi), or curies (Ci), including replacement sources; and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible alternate source models they might use in order to minimize the need for license amendments if they change model or vendor.

The applicant should define the purpose of use by stating the applicable section of §289.256(ddd) (e.g., teletherapy, remote afterloader, GSR) and include the manufacturer's name(s) and model number(s) of the device(s) containing a sealed source(s) [e.g., for use in a (Manufacturer's Name and Unit Type, Model) radiation therapy unit for the treatment of humans]. An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible and conform to the SSD registry designations registered with the Agency, the NRC or an Agreement State. If applicable, the applicant should specify that authorization is being requested for an additional source to be stored in its shipping container, incident to source replacement.

§289.256(q) Use: The radionuclide, the chemical/physical form, and the total amount must be specified. The applicant must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under 25 TAC §289.256(q) when the type of use is not covered under 25 TAC §289.256(ff) – (ddd). Applicants should refer to the NRC's Medical Uses Licensee Toolkit and consult with the agency to discuss the contents of the application.

Veterinary use of radioactive material: Applicants should clearly specify if radioactive material will be used in animals by veterinarians for diagnostic and therapeutic purposes. Applicants should also state whether the studies will be limited to small animals (e.g., rats, mice) or may also include larger animals (e.g., dogs, pigs, horses). Similarly, the veterinary use should specify whether the material will be used in pets (e.g., cats, dogs) or in farm animals (e.g., cattle, horses, pigs). Appendix Q of this guide provides guidance for developing radiation safety procedures for these studies and describes additional information to be submitted with the application.

Calibration, Transmission, and Reference Sources: For calibration, transmission, and reference sources covered under 25 TAC §289.256(y), the specific sources do not need to be listed on the license as long as the licensee is authorized by 25

TAC §289.256(n), (o), (p), or (q) for the medical use of radioactive material. However, if the quantities specified in 25 TAC §289.256(y), are exceeded, the specific sources need to be listed on the license.

Sealed Sources and Devices: In accordance with 25 TAC §289.252(d)(9), applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 25 TAC §289.256(y)). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by the Agency, the NRC or an Agreement State or when information required in 25 TAC §289.252(d)(11) is provided.

Shielding Material/Depleted Uranium Use: An applicant using depleted uranium as shielding constituting part of any shipping container is exempt from licensure if the container meets the requirements of 25 TAC §289.251(d)(3)(F). Applicants using depleted uranium in products or devices for the purpose of providing shielding, including beam shaping and collimation do so under the general license issued by 25 TAC §289.251(f)(3)(D).

Other material: The applicant should make a separate entry for other required items (e.g., unsealed Ra-226 not previously described; more radioactive material for in vitro testing than is allowed under 25 TAC §289.251(f)(4)(G); radiation survey meter calibration source; dosimetry system constancy check source; material for in vitro, animal, or human research studies).

Response from Applicant: The applicant should submit the information as described above. Applicants may complete and submit Checklist A-1 of Appendix A of this guide or submit an equivalent.

ITEM 6: INDIVIDUAL(S) RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Rules: 25 TAC §289.252(e)(1), 25 TAC §289.256(c), 25 TAC §289.256(f)(3)(C), 25 TAC §289.256(g), 25 TAC §289.256(h), 25 TAC §289.256(i), 25 TAC §289.256(l), 25 TAC §289.256(m), 25 TAC §289.256(gg), 25 TAC §289.256(jj), 25 TAC §289.256(nn), 25 TAC §289.256(oo), 25 TAC §289.256(pp), 25 TAC §289.256(qq), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), 25 TAC §289.256(ccc), 25 TAC §289.256(ttt)

Criteria: Under 25 TAC §289.252(e)(1), the agency requires that an applicant and all personnel who will be handling radioactive material to be qualified by training and experience to use radioactive materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. The RSO, Authorized Users (AU), Authorized Medical Physicists (AMP), and Authorized Nuclear Pharmacists (ANP) must have adequate training and experience and applicants must submit qualifications as per 25 TAC §289.256(f)(3)(C).

Discussion: The authority and responsibilities of the RSO including establishing and overseeing operating, radiation safety, emergency, and ALARA procedures are specified in 25 TAC §289.256(g). Other personnel who have a role in the radiation protection program are AUs, AMPs, ANPs, and members of the Radiation Safety Committee (RSC), if the licensee is required to establish an RSC. The AU, AMP, ANP, and RSO are defined in 25 TAC §289.256(c), "Definitions."

Applicants should ensure that they submit the specific training information required by 25 TAC §289.256(gg), 25 TAC §289.256(jj), 25 TAC §289.256(nn), 25 TAC §289.256(oo), 25 TAC §289.256(pp), 25 TAC §289.256(qq), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), 25 TAC §289.256(ccc), 25 TAC §289.256(ttt), as applicable. The RC Form 256 series of forms provides a convenient format for submitting this information. Forms can be found on the agency website. A résumé or a curriculum vitae is not generally appropriate, because such documents usually contain personally identifiable information and the document usually does not supply all the information needed to evaluate an individual's training and experience for agency review.

Applicants are reminded of recentness of training requirements described in 25 TAC §289.256(m). Specifically, RSO, AU, AMP, and ANP applicants must have successfully completed the applicable training and experience described in 25 TAC §289.256 within 7 years preceding the date of the application. Alternatively, RSO, AU, AMP, or ANP applicants must submit documentation for related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other pathways to meeting requirements for training and experience.

Additionally, 25 TAC §289.256(l) "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist," provides that experienced

individuals who are named on a license or permit are not required to comply with the training requirements to continue performing those medical uses for which they were authorized before the effective date of changes to the rules in 25 TAC §289.256(l).

Licensees that are authorized for two or more different types of uses of radioactive material under 25 TAC §289.256(kk), (rr), including sealed sources for manual brachytherapy authorized under 25 TAC §289.252(q), and (ddd), or two or more types of units under subsection (ddd), including remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units authorized under 25 TAC §289.256(q) are required under 25 TAC §289.256(i), to establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. Membership in the committee must include an AU for each type of use permitted by the license, the RSO, a representative of the nursing service, if applicable, and a representative of management who is neither an AU nor the RSO. The committee may include other members the licensee considers appropriate.

Applicants requesting non-medical uses of radioactive material an individual (e.g. survey instrument calibration) must provide documentation of the individual's training and experience to use radioactive materials, 25 TAC §289.252(e)(1).

Response from Applicant: Refer to Item 6.1 – 6.4 for each type of individual responsible for the radiation protection program.

- Provide an organizational chart or description that identifies the individuals responsible for the Radiation Protection Program, including the reporting structure through upper management.

For applicants required to establish a Radiation Safety Committee in accordance with 25 TAC §289.256(i):

- Describe the committee membership, by title only;
- Describe the duties and responsibilities of the committee, to include at least those listed in 25 TAC §289.256(i)(3).

6.1 RADIATION SAFETY OFFICER

Rules: 25 TAC §289.252(e)(1), 25 TAC §289.252(x)(5), 25 TAC §289.256(c), 25 TAC §289.256(f)(2), 25 TAC §289.256(h), 25 TAC §289.256(l), 25 TAC §289.256(m), 25 TAC §289.256(r).

Criteria: The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by 25 TAC §289.256(g). The RSO must have adequate training and experience. The training and experience requirements for the RSO are described in 25 TAC §289.256(h), "Training for Radiation Safety Officer," and allow for the following training pathways:

- certification as provided in 25 TAC §289.256(h)(1) by a specialty board whose certification process has been recognized by the agency, the NRC or an Agreement State, plus a written attestation signed by a preceptor RSO as provided in 25 TAC §289.256(h)(5) and training as specified in 25 TAC §289.256(h)(6)
- completion of classroom and laboratory training (200 hours) and 1 year of full-time radiation safety experience as described in 25 TAC §289.256(h)(2), plus a written attestation signed by a preceptor RSO as provided in 25 TAC §289.256(h)(5) and training as specified in 25 TAC §289.256(h)(6)
- certification as provided in 25 TAC §289.256(h)(3) as a medical physicist under §289.256(j)(1), plus a written attestation signed by a preceptor RSO as provided in 25 TAC §289.256(h)(5) and training as specified in 25 TAC §289.256(h)(6)
- identification as provided in 25 TAC §289.256(h)(4) on the licensee's license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities, plus a written attestation signed by a preceptor RSO as provided in 25 TAC §289.256(h)(5) and training as specified in 25 TAC §289.256(h)(6)

Discussion: The person responsible for the radiation protection program is the RSO. The RSO is key to overseeing and ensuring safe operation of the licensee's radiation protection program. The RSO must have adequate training to understand the hazards associated with radioactive material and be familiar with all applicable regulatory requirements. In accordance with 25 TAC §289.256(g)(1), the licensee must establish in writing the authority, duties, and responsibilities of the RSO and ensure that the RSO is provided sufficient authority, organizational freedom, time, and resources to perform his or her duties. Appendix C of this guide lists the duties of the RSO.

The agency requires the name of the RSO to be listed on the license to ensure that licensee management always has a responsible, qualified person identified and that the named individual knows of his or her designation as RSO. Appendix C also provides a model Delegation of Authority, which should be used to further emphasize the agreement on duties and responsibilities of the RSO by management and the designated RSO.

The agency has authorized individuals who are not employed full-time by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to ensure that the duties and responsibilities are performed, the RSO must be onsite periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 25 TAC §289.256(g)(3). The RSO, or staff designated by the RSO, must be capable of physically arriving at the licensee's authorized use site(s) within a reasonable time of being notified of an emergency or unsafe condition, in accordance with 25 TAC §289.256(g)(4)

Response from Applicant: Provide the following:

Documentation of the proposed RSO's training and experience in accordance with 25 TAC §289.256(h) by submitting one of the following:

- The license number of the license designating the individual as an RSO, if issued by the agency OR a copy of the license, if issued by the NRC or another Agreement State
- RC Form 256-1a (Accepted Specialty Board Certification)
- RC Form 256-1b (Classroom and laboratory training and 1-year experience)
- RC Form 256-1c (AU on the licensee's license) OR
- Equivalent documentation
- If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

If the RSO is not based at the main site on the license or if there are multiple sites on the license, address the following in the application or amendment, to demonstrate how the requirements of 289.256(g)(3) and (g)(4) will be met:

- Identify other commitments of the RSO for other agency, NRC or Agreement State licensed facilities, along with a description of how the RSO will allocate time to permit performance of the duties of the RSO as described in the rules. State the RSO's minimum amount of onsite time (hours per week).
- Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
- Describe the overall availability of the RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements.
- Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his or her presence.

Notes:

- For up to 60 days each calendar year, a licensee may permit an AU or an individual qualified to be an RSO to function as a temporary RSO, as authorized by 25 TAC §289.256(g)(5). Licensees must maintain certain records, including qualifications and dates of service, as specified by 25 TAC §289.256(g)(5).

- The licensee must notify the agency in writing within 15 calendar days if an RSO permanently discontinues his or her duties under the license, as required by 25 TAC §289.252(x)(5).

6.2 AUTHORIZED USERS

Rules: 25 TAC §289.252(e)(1), 25 TAC §289.256(c), 25 TAC §289.256(h), 25 TAC §289.256(l), 25 TAC §289.256(m), 25 TAC §289.256(s), 25 TAC §289.256(gg), 25 TAC §289.256(jj), 25 TAC §289.256(nn), 25 TAC §289.256(oo), 25 TAC §289.256(pp), 25 TAC §289.256(qq), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), 25 TAC §289.256(bbb), 25 TAC §289.256(ccc), 25 TAC §289.256(ttt)

Criteria: Training and experience requirements for Authorized Users (AU) for medical use are described in 25 TAC §289.256(gg), 25 TAC §289.256(jj), 25 TAC §289.256(nn), 25 TAC §289.256(oo), 25 TAC §289.256(pp), 25 TAC §289.256(qq), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), 25 TAC §289.256(bbb), 25 TAC §289.256(ccc), 25 TAC §289.256(ttt).

Discussion: AU for medical use is defined in 25 TAC §289.256(c). Although the agency does not define “AU” for nonmedical uses, for purposes of this discussion the term AU will also be used to mean individuals authorized for the nonmedical uses described below.

An authorized user for human use must be licensed by the Texas Medical Board, Texas State Board of Dental Examiners or by the Texas State Board of Podiatric Medicine according to 25 TAC §289.256(c)(5)(A). An authorized user for veterinary use must be licensed by the Texas State Board of Veterinary Medical Examiners. Practitioners not in good standing (e.g. license canceled, expired, or suspended) may not be allowed to serve as an authorized user for a radioactive material license while under such a status by their respective board. The agency does not authorize visiting AUs (locum tenens). All AUs must be approved by the agency prior to using and/or directing the medical use of radioactive material.

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

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

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision in accordance with 25 TAC §289.256(s), "Supervision".

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

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

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

Response from Applicant:

AU for Medical Uses: Provide the following:

1. Names of proposed authorized users and the uses requested. For each proposed authorized user, confirm he or she has an active registration the Texas Medical Board, Texas State Board of Dental Examiners, the Texas State Board of Podiatric Medicine, or the Texas State Board of Veterinary Medical Examiners, as applicable;
2. Documentation of the proposed AU's training and experience in accordance with 25 TAC §289.256 by submitting one of the following:
 - The license number of the license designating the individual as an AU for the use(s) requested, if issued by the agency OR a copy of the license, if issued by the NRC or another Agreement State
 - RC Form 256-4a, RC Form 256-5a, and/or RC Form 256-6a (Accepted Specialty Board Certification), as applicable
 - RC Form 256-4b, RC Form 256-5b, and/or RC Form 256-6b (Hours of Training and Experience), as applicable OR
 - Equivalent documentation

- If applicable, recently received related training and experience, if the original training and experience was received greater than 7 years ago

AU for Nonmedical Uses: Provide the following:

1. Name of the proposed nonmedical use AU
2. Description of types, quantities, and proposed nonmedical uses for which the individual is responsible
3. Description of each individual's educational and radiation safety training and experience with the types of materials and uses requested; this may include
 - a copy of the NRC or Agreement State license listing the individual as an AU for the same types, quantities, and uses requested
 - a permit issued by an MML licensee or broad scope licensee or broad scope permittee identifying the individual as an AU for the types, quantities, and uses requested
4. Detailed radiation training and experience applicable to the use requested

6.3 AUTHORIZED NUCLEAR PHARMACISTS

Rules: 25 TAC §289.252(e)(1), 25 TAC §289.252(r), 25 TAC §289.256(c), 25 TAC §289.256(s), 25 TAC §289.256(k), 25 TAC §289.256(l), 25 TAC §289.256(m)

Criteria: Training and experience requirements for ANPs are described in 25 TAC §289.256(k).

Discussion: At many licensed medical facilities, an ANP is directly involved with the preparation of radiopharmaceuticals under the provisions of 25 TAC §289.256(ff)(2), 25 TAC §289.256(hh)(2), or 25 TAC §289.256(ff)(2).

Technologists, or other personnel, may prepare radioactive material for medical use under an ANP's supervision in accordance with 25 TAC §289.252(r)(3)(A) and 25 TAC §289.256(s), "Supervision," and in compliance with applicable FDA and other Federal and State requirements. Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an AU.

Response from Applicant: Provide the following:

1. Names of proposed Authorized Nuclear Pharmacists;
2. Documentation of the proposed ANP's training and experience in accordance with 25 TAC §289.256 by submitting one of the following:

- The license number of the license designating the individual as an ANP for, if issued by the agency OR a copy of the license, if issued by the NRC or another Agreement State
- RC Form 256-3a (Accepted Specialty Board Certification)
- RC Form 256-3b (Hours of Training and Experience) OR
- Equivalent documentation
- If applicable, recently received related training and experience, if the original training and experience was received greater than 7 years ago

6.4 AUTHORIZED MEDICAL PHYSICISTS

Rules: 25 TAC §289.252(e)(1), 25 TAC §289.256(c), 25 TAC §289.256(j), 25 TAC §289.256(l), 25 TAC §289.256(m)

Criteria: Training and experience requirements for AMPs are described in 25 TAC §289.256(j).

Discussion: At licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and other tasks associated with the administration of the radiation dose.

Response from Applicant: Provide the following:

1. Names of proposed Authorized Medical Physicists and the uses requested;
2. Documentation of the proposed AU's training and experience in accordance with 25 TAC §289.256 by submitting one of the following:
 - The license number of the license designating the individual as an AU for the use(s) requested, if issued by the agency OR a copy of the license, if issued by the NRC or another Agreement State
 - RC Form 256-4a (Accepted Specialty Board Certification)
 - RC Form 256-4b (Hours of Training and Experience) OR
 - Equivalent documentation
 - If applicable, recently received related training and experience, if the original training and experience was received greater than 7 years ago

ITEM 7: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Rules: 25 TAC §289.203(c), 25 TAC §289.252(e)(1), 25 TAC §289.256(s), 25 TAC §289.256(II), 25 TAC §289.256(uu), 25 TAC §289.256(ggg), 25 TAC §289.257(e)(1)(F)

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instructions as required by 25 TAC §289.203 and §289.256. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 100 millirem [1 millisievert (mSv)], the licensee must provide safety instructions as required by 25 TAC §289.203(c), "Instruction to workers." Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 25 TAC §289.256(II), 25 TAC §289.256(uu), and 25 TAC §289.256(ggg). Under 25 TAC §289.256(s), the licensee's AUs and ANPs are required to provide safety instruction to all personnel using radioactive material under their supervision.

All individuals who handle radioactive material be qualified by training and experience in order to minimize danger to occupational workers and members of the public, as required by 25 TAC §289.252(e)(1).

Discussion: AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 100 mrem [1 mSv] in a year. Licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instructions commensurate with their assigned duties, and if it is likely that they could receive doses over 100 mrem [1 mSv] in a year, they must receive instructions as specified by 25 TAC §289.203(c). For example, a licensee might determine that housekeeping staff, while not likely to receive doses over 100 mrem [1 mSv], 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 non-radiation workers (e.g., housekeeping, security) may assist in controlling abnormal events, such as loss of radioactive material. In addition, licensees should ensure that contractor staff receives safety instructions.

Individuals, such as nuclear medicine technologists, who will be authorized to handle and administer radioactive material must be qualified through training and experience. The agency considers certification by the Nuclear Medicine Technologist Certification Board (CNMT) or certification in nuclear medicine by the American Registry of Radiologic Technologists [ARRT(N)] to be evidence of qualification. Additionally, nuclear medicine technologists must be certified as a general certificate medical radiologic technologist (MRT) under Texas Occupations Code Chapter 601, Medical Radiologic Technologists.

Licensees who intend to permit individuals not certified in nuclear medicine technology to handle or administer radioactive material, such as x-ray technologists and/or

Registered Nurses, must ensure that these individuals are qualified to use radioactive material through training and experience. Appendix D of this guide provides a training program acceptable to the agency for training these individuals.

In addition to safety instructions required by 25 TAC §289.203(c), and in accordance with 25 TAC §289.256(ll), 25 TAC §289.256(uu), and 25 TAC §289.256(ggg), the licensee must provide radiation safety instructions to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 25 TAC §289.256(cc). This safety instruction should be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the AU, if the patient has a medical emergency or dies.

In accordance with 25 TAC §289.256(s)(1), individuals working with licensed material under the supervision of an AU must receive instructions on the licensee's written operating, safety, and emergency procedures, written directive procedures, agency rules, and agency license conditions with respect to the use of radioactive material.

In accordance with 25 TAC §289.256(s)(2), a licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an ANP or an AU, shall instruct supervised individuals in the preparation of radioactive material for medical use and require the individuals to follow their instructions, the licensee's written operating, safety, and emergency procedures, the license conditions, and agency rules. A licensee that permits supervised activities, under 25 TAC §289.256(s) paragraphs (1) and (2), is responsible for the acts and omissions of the supervised individuals.

A licensee must ensure that individuals who prepare a package containing radioactive material for shipment or transport are trained in accordance with Agency and U.S. DOT regulations.

Appendix D of this guide provides a model training program that provides one way to satisfy the requirements referenced above. In addition, the NRC's Medical Uses Licensee Toolkit provides guidance for training suggested for emerging technologies [e.g., yttrium-90 (Y-90) microsphere brachytherapy], regulated under 25 TAC §289.256(q).

Response from Applicant: Provide the following:

- the statement: "Nuclear medicine technologists will be certified as a general certificate medical radiologic technologist (MRT) under Texas Occupations Code Chapter 601, Medical Radiologic Technologists";
- a description of the minimum training and experience you will require for individuals (i.e. nuclear medicine technologists, registered nurses, x-ray technologists) who will handle or use radioactive material under supervision of an AU; and

- a description of the training and instructions to be provided to individuals working under supervision of an AU and individuals working with or around radioactive materials. See Appendix D for a model program;
- a description of the training provided to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 25 TAC §289.256(cc)

Note: Alternative methods for demonstrating compliance with the referenced rules will be evaluated against the previously listed criteria.

ITEM 8: FACILITIES AND EQUIPMENT

Rules: 25 TAC §289.252(e)(2)

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

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in 25 TAC §289.252(e)(2). Applications will be approved if, among other things, “the applicant’s proposed equipment and facilities are adequate to protect health and minimize danger to life or property.” Facility and equipment requirements depend on the scope of the applicant’s operations (e.g., planned use of the material, types of radioactive emissions, quantity and form of radioactive materials possessed). Applicants should focus particularly on preparation steps involving liquids, gases, and volatile radioactive materials; and the use high-energy photon-emitters.

Response from Applicant: Refer to Items 8.1 through 8.4 for guidance.

8.1: FACILITY DIAGRAM

Rules: 25 TAC §289.201(b) and (m), 25 TAC §289.202(e)(2), 25 TAC §289.202(f), 25 TAC §289.202(n), 25 TAC §289.202(y), 25 TAC §289.252(d)(7), 25 TAC §289.252(e)(2) and (e)(9), 25 TAC §289.256(cc), 25 TAC §289.256(mm), 25 TAC §289.256(vv), 25 TAC §289.256(hhh)

Criteria: In order to issue a license, the agency must find that facilities and equipment are adequate to protect health and minimize danger to life or property as required under 25 TAC §289.252(e)(2). In accordance with 25 TAC §289.202(e)(2), the licensee must design facilities to achieve occupational doses and doses to members of the public ALARA.

Discussion: Applicants must describe the proposed facilities and equipment. The facility diagram should include the room or rooms where radioactive material is prepared, used, administered, and stored, at a level of detail that is sufficient to demonstrate that: the facilities and equipment are adequate to protect health and

minimize danger to life or property; access will be controlled in accordance with 25 TAC §289.202(y); and that use of radioactive material will not result in an exceedance of the occupational or public dose limits stated 25 TAC §289.202(f) and 25 TAC §289.202(n), respectively. The applicant should identify the restricted area, defined as any area where access is limited by the licensee to protect individuals from undue risk against sources of radiation, according to 25 TAC §289.201(b).

If an applicant submits documents that give the exact location of use and storage for any amount of radioactive material, the applicant should clearly mark these documents "Official Use Only – Security Related Information".

If facility drawings were prepared by a professional engineer or engineering firm, the drawings must be final and signed, sealed, and dated in accordance with Title 22 of the Texas Administrative Code, Chapter 131.

Response from Applicant: All medical use applicants are required to provide facility diagrams. The applicant should determine if the response includes security-related sensitive information and needs to be marked accordingly. See Section II of this guide, "How to File an Application" for more information.

Provide the following:

- A brief description of scope and magnitude of use of radioactive material at each proposed facility
- A facility diagram that identifies:
 - the room number and principal use of each room of radioactive material use and/or storage, including patient treatment rooms;
 - principal use of each adjacent room; and
 - the restricted area.
- A diagram of each room of use or storage that identifies the location(s) of:
 - receipt and preparation areas;
 - storage areas, including waste storage;
 - imaging equipment
 - treadmills used for stress testing,
 - radiation delivery devices (e.g. xenon delivery/traps, aerosol units)
- For radiopharmaceutical and sealed source therapies, provide a description of areas surrounding the treatment rooms, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 25 TAC §289.201(b).
- For remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units, provide shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent

verification of shielding calculations. The calculations should include the workload assumptions used.

- For teletherapy facilities, applicants should provide the directions of primary beam use for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.
- For 25 TAC §289.256(q) uses (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the NRC's Medical Uses Licensee Toolkit.
- Licensees or applicants that intend to administer radioactive material to patients in temporary use areas, such as in hospital patient rooms, or special procedures room, must indicate their intention to do so. It is not necessary to provide diagrams of these areas.

References and Resources:

- NCRP Report No. 40, "Protection against Radiation from Brachytherapy Sources," 1972.
- NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV," 1976.
- NCRP Report No. 102, "Medical X-Ray, Electron Beam and Gamma-Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)," 1989.
- NCRP Report No. 151 "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," 2005.
- AAPM Task Group 108, "PET and PET/CT Shielding Requirements," 2006.

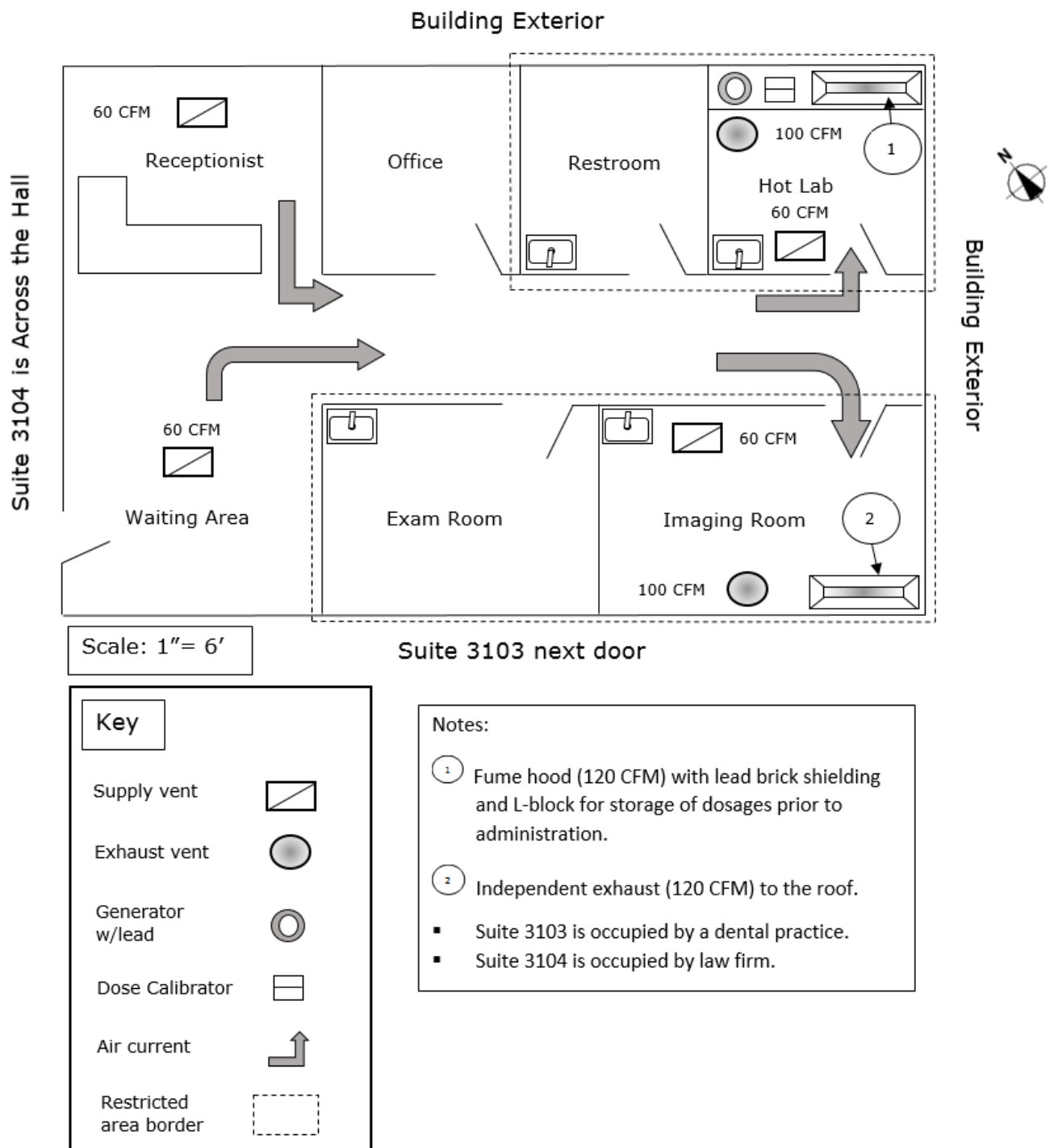


FIGURE 1. EXAMPLE FACILITY LAYOUT

8.2: RADIATION MONITORING INSTRUMENTS

Rules: 25 TAC §289.202(e), 25 TAC §289.202(o), 25 TAC §289.202(p), 25 TAC §289.252(e)(1), 25 TAC §289.256(w)

Criteria: All licensees must possess calibrated radiation detection and measuring instruments that will be used for radiation protection and to ensure compliance with surveys required by 25 TAC §289.202(o) and 25 TAC §289.202(p), including survey and monitoring instruments and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containment and contamination control.

Any instrument used to make quantitative radiation measurements shall be operable and calibrated at intervals not to exceed 12 months by persons, including licensed personnel, who are qualified and authorized to perform calibrations in accordance with an agency, the NRC, or an Agreement State license, as required by 25 TAC §289.202(p)(3). The licensee shall ensure calibration of survey instruments as described by 25 TAC §289.256(w) and retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made in accordance with 25 TAC §289.256(www).

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 25 TAC §289.202(e) must include provisions for survey instrument calibration. Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low-energy or low-activity seeds [e.g., iodine-125 (I-125), palladium-103] if they become dislodged in the operating room or patient's room (e.g., NaI instruments), or the contamination limits specified in 25 TAC §289.202(ggg)(6) and §289.202(eee).

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

- portable or stationary count rate meters
- portable or stationary dose rate or exposure rate meters
- area monitors
- single or multichannel analyzers
- liquid scintillation counters

- gamma counters
- proportional counters
- solid state detectors
- hand- and foot-contamination monitors

An applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Rule Guide 6.11 Survey Instrument Calibration provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures if the licensee requests to perform in-house calibration of their own radiation survey meters to meet the requirements detailed in 25 TAC §289.256(w), "Calibration of survey instruments."

Response from Applicant: Provide the following:

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

OR

A statement that: "We will perform in-house calibration of our radiation survey meters." Submit a copy of the calibration procedures in accordance with in accordance with the requirements in 25 TAC §289.202(p)(3) and that meet the requirements in 25 TAC §289.256(w).

AND

- The manufacturer and model number of all instruments and detectors (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.
- Applicants or licensees intending to use a portable survey meter or an imaging camera to analyze contamination wipes identify the instrument and detector to be used and submit the following additional information:
 - minimum detectable activity (MDA) calculation to demonstrate that the system (instrument and detector) can detect, at a minimum, the acceptable surface contamination levels in 25 TAC §289.202(ggg)(6) and

- procedure for analyzing wipes, including how a consistent geometry will be maintained.

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

8.3: DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED RADIOACTIVE MATERIAL

Rules: 25 TAC §289.252(e)(2), 25 TAC §289.256(f)(3)(A)(ii), 25 TAC §289.256(v), 25 TAC §289.256(x).

Criteria: The requirements for possession, use, and calibration of dose calibrators used to measure the activity of patient dosages are described in 25 TAC §289.256(v).

The licensee must determine the activity of each dosage of unsealed radioactive, in accordance with 25 TAC §289.256(x). An applicant must describe the methodology for measurement of doses administered to humans and research subjects as required by 25 TAC §289.256(f)(3)(A)(ii).

Discussion: If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 25 TAC §289.252(r), "Specific licenses for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive materials," or a PET radioactive drug producer authorized under 25 TAC §289.252(kk), and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.

A licensee restricted to only unit doses prepared in accordance with 25 TAC §289.252(r) does not need to determine the activity of each dose, unless the administration time of the unit dose deviates from the nuclear pharmacy's pre-calibrated time by 15 minutes or more, in accordance with 25 TAC §289.256(x)(5).

If the licensee performs direct measurements of dosages in accordance with 25 TAC §289.256(x) (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.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards [e.g., American National Standards Institute (ANSI)] or the manufacturer's instructions. The measurement equipment may be a well-type ionization chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately for the type and energy of radiation emitted and is both accurate and reliable. A model procedure for performing calibration tests of a dose calibrator are described in Appendix F.

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

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

For applicants who will use rubidium-82 (Rb-82)/strontium-82 (Sr-82) generators, it is not possible to meet agency requirements for calibration of dose calibrators and determination of dosage prior to medical use. There are currently neither nationally recognized standards nor specific calibration procedures by the manufacturer for calibrating the radiation detector used to measure the Rb-82 dosage in a dynamic mode. Until such standards or procedures are developed, compliance with 25 TAC §289.256(v) is not possible. Due to the 76 second half-life of Rb-82 the manufacturer has designed the equipment to directly infuse doses into

a patient therefore a licensee would be unable to determine a dosage prior to medical use in accordance with 25 TAC §289.256(x). Applicants who will use Rb-82 generators must provide procedures and commitments to ensure that equipment is tested and personnel are trained in the use of the equipment.

Response from Applicant: Provide the following:

Applicants intending to use a dose calibrator:

- Your procedures for calibrating dose calibrators in accordance with 25 TAC §289.256(v). You may use the model procedure in Appendix F or develop and submit your own procedure.

AND

- A description of the equipment used to measure the dosages.

OR

Applicants who will not use a dose calibrator:

- Confirm that you will use only unit doses prepared by a manufacturer or preparer licensed in accordance with 25 TAC §289.252(r) or an equivalent NRC or Agreement State license

Applicants who will use Rb-82 generators must also provide the following:

- Confirm that you will maintain documentation of the infusion cart maintenance performed every 12 months by the manufacturer to document the completion and results of the infusion pump flow rate and radiation detector test.
- Confirm that the radiation safety officer, all authorized users, and individuals working under supervision of authorized users will successfully complete training specific to the manufacturer and model of generator and infusion cart being used. This training requirement will be met by satisfactory completion of a training program, which addresses all of these required topics, provided by the manufacturer. You must maintain documentation that all AUs using Rb-82 and the RSO have satisfactorily completed such training, to include:
 - (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 activity and the Sr-82 and Sr-85 breakthrough levels;
 - (2) dose calibrator calibration procedures; and
 - (3) safety procedures for the clinical use of Rb-82 chloride.

Until the generator manufacturer develops static or dynamic calibration procedures for calibrating the radiation detector in the infusion cart, the quality control procedures must include:

- (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator;
 - (2) how to adjust the infusion cart readout setting; and
 - (3) when these tests are required by the manufacturer.
- Confirm that you will record the activity of each dosage administered, as provided by the infusion cart.

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

8.4: THERAPY UNIT – CALIBRATION AND USE

Rules: 25 TAC §289.252(e)(2), 25 TAC §289.256(p)(10) and (11), 25 TAC §289.256(ww), 25 TAC §289.256(xx), 25 TAC §289.256(iii), 25 TAC §289.256(jjj), 25 TAC §289.256(kkk), 25 TAC §289.256(III), 25 TAC §289.256(mmm), 25 TAC §289.256(nnn), 25 TAC §289.256(ooo), 25 TAC §289.256(qqq)

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

Discussion: Except for manual brachytherapy sources and LDR remote afterloader sources, where the source output or activity is determined by the manufacturer, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. In accordance with 25 TAC §289.256(ww), if the manual brachytherapy source output or activity is not determined by the manufacturer, the licensee must perform a calibration prior to medical use. Dosimetry systems and sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to 25 TAC §289.256(iii), "Dosimetry equipment." The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, American College of Radiology, ANSI). Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of Sr-90 sources. In accordance with 25 TAC §289.256(xx), the licensee's AMP must calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments.

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy, in accordance with written procedures established by the AMP [25 TAC §289.256(mmm), 25 TAC §289.256(nnn), and 25 TAC §289.256(ooo)]. These procedures must be submitted in accordance with 25 TAC §289.256(p)(11). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. See Appendix G of this guide for model procedures for performing spot-checks of remote afterloader devices.

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

Licensees must perform full calibrations before first medical use, whenever spot-check measurements (if required) indicate that the output differs by more than 5 percent (%) from the output obtained at the last full calibration corrected mathematically for decay, following replacement of the sources or reinstallation of the unit in a new location not previously described in the license, following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and at intervals as defined in 25 TAC §289.256(jjj), 25 TAC §289.256(kkk), and 25 TAC §289.256(lll). Manual brachytherapy sources must be calibrated only initially, prior to use.

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

In accordance with 25 TAC §289.256(qqq), licensees must perform surveys around therapy devices to ensure that the maximum radiation levels and the average radiation levels from the surface of the main source safe with the sources in the shielded position do not exceed the levels stated in the SSD registry.

Response from Applicant: Provide the following:

- Procedures for performing and documenting the periodic spot checks required by 25 TAC §289.256(mmm), 25 TAC §289.256(nnn), and/or 25 TAC §289.256(ooo), as applicable to the license application.

References and Resources:

- AAPM Task Group No. 21, "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams," 1984.
- AAPM Report No. 46, "Comprehensive QA for Radiation Oncology, (Radiation Therapy Committee Task Group No. 40)," 1994.
- AAPM Report No. 54, "Stereotactic Radiosurgery," 1995.
- AAPM Report No. 59, "Code of Practice for Brachytherapy Physics, (Radiation Therapy Committee Task Group No. 56)," 1997.
- AAPM Report No. 61, "High Dose Rate Brachytherapy Treatment Delivery, (Radiation Therapy Committee Task Group No. 59)," 1998.
- AAPM Report No. 67, "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams, Medical Physics 26(9), pp. 1847-1870, (Radiation Therapy Committee Task Group No. 51)," September, 1999.
- AAPM Report No. 68, "Permanent Prostate Seed Implant Brachytherapy, (AAPM Task Group No. 64)," October 1999.
- AAPM Report No. 84, "Update of AAPM Task Group No. 43 Report: A Revised AAPM Protocol for Brachytherapy Dose Calculations," March 2004.
- Erratum: "Supplement to the 2004 update of the AAPM Task Group No.43 Report," December 2004.
- AAPM Report No. 84S, "Supplement to the 2004 Update of the AAPM Task Group No. 43 Report," June 2007.
- NCRP Report No. 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV," 1981.

8.5: OTHER EQUIPMENT AND FACILITIES

Rules: 25 TAC §289.202(z), 25 TAC §289.202(aa), 25 TAC §289.252(e)(2) and (e)(9), 25 TAC §289.256(vv), 25 TAC §289.256(hhh)

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

As required by 25 TAC §289.252(e)(9), applicants must provide a written statement from the owner of the property, or the owner's agent, acknowledging that the owner is aware that radioactive material will be stored and used on the property. This requirement does not apply to property owned or held by a government entity or to a property on which radioactive material is used under an authorization for temporary job site use.

Discussion: The applicant should describe any other proposed equipment and facilities available for safe use and storage of radioactive material listed in Item 5 of this application. In accordance with 25 TAC §289.202(z) and 25 TAC §289.202(aa), the applicant should ensure that the facilities include the appropriate caution signs and postings. For uses authorized by 25 TAC §289.256(rr), 25 TAC §289.256(ddd), and 25 TAC §289.256(q), as applicable, applicants are required to provide a description of emergency response equipment. In addition, the items below describe other necessary radiation safety equipment.

For radiopharmaceutical therapy: The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations described in Item 8.1 (e.g., private room with private bath). The most widely used source of radiopharmaceutical therapy is I-131 sodium iodide. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g., a fume hood). Also note there are hazards associated with volatile iodine in capsule form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium iodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

For manual brachytherapy: The applicant should describe emergency response equipment in accordance with 25 TAC §289.256(vv).

For teletherapy, GSR, and HDR facilities: The applicant should focus on facilities and equipment required by 25 TAC §289.256(hhh):

- Appropriate radiation monitors to be used by any individual entering the treatment room to ensure that radiation levels have returned to ambient levels. One method of meeting this requirement is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source.
- A system for continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system) will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to

suspending all treatments until the electronic system is repaired and functioning again.

- A system for communication with the patient in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.
- An electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the on-off control for the source(s) is reset at the console.

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

- The PDR device control console is *not* accessible to unauthorized personnel during treatment.
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected.
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position.
 - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted or radiation present" or the appropriate internal error condition(s) exists.
 - The "source safe and radiation present" signal should also be self-testing. If a "source not safe" input is received without a corresponding "radiation

present” signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment.

- The audible alarm should be sufficiently loud to be clearly heard by the facility’s responsible device/patient monitoring staff at all times.
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

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

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

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

Response from Applicant:

- Identify the owner of the property.
- If the property is owned by another company, provide a written statement from the owner or owner’s agent acknowledging the owner is aware that radioactive material is used and stored on the property.
- Describe the handling devices, shielding, and storage containers used when handling and storing radioactive material to maintain doses ALARA.

For radiopharmaceutical therapy: describe the additional equipment for this use, such as portable shields (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).

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

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

- warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
- area radiation monitoring equipment
- viewing and intercom systems (except for LDR units)
- steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
- methods to ensure that whenever the device is not in use or is unattended, the unit, the console and the console keys will be secured when unattended
- emergency response equipment

Reference:

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

ITEM 9: RADIATION PROTECTION PROGRAM

Rules: 25 TAC §289.202(e), 25 TAC §289.252(e), 25 TAC §289.252(w)(2), 25 TAC §289.256(r), 25 TAC §289.256(s)(3)

Criteria: Applicants must develop, document, and implement a radiation safety program sufficient to ensure compliance with 25 TAC §289.202 rules and submit that program to assist in the agency's review of the application, in accordance with 25 TAC §289.252(e). The program may be incorporated in the licensee's operating, safety and emergency procedures. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. Under 25 TAC §289.252(w)(2), the agency may incorporate into radioactive material licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to minimize danger to occupational and public health and safety and the environment; to require reports and recordkeeping and to prevent loss or theft of radioactive material. Rule 25 TAC §289.256(r) requires that licensees without broad-scope authorization must apply for and receive a license amendment prior to changing operating, safety and emergency procedures.

Discussion: Applicants/licensees must abide by all applicable rules; develop, implement, and maintain procedures when required; and provide requested

information about the proposed radiation safety program during the licensing process. Appendix A of this guide may be helpful in determining what information should be provided when requesting a license.

Response from Applicant: Respond to subsequent sections of this document regarding Item 9 of the application.

Reference:

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

9.1 AUDIT PROGRAM

Rules: 25 TAC §289.202(e), 25 TAC §289.202(mm), 25 TAC §289.256(g)(1)(M)

Criteria: Licensees must review the content and implementation of their radiation protection program at intervals not to exceed 12 months, in accordance with 25 TAC §289.202(e), to ensure:

- the radiation protection program is current and complies with agency and U.S. DOT rules, as applicable and the terms and conditions of the license;
- occupational doses and doses to members of the public are ALARA;
- if a licensee has determined personnel monitoring is not required in accordance with 25 TAC §289.202(q)(1) and (3), the assessment made to determine that monitoring is not required must be reevaluated for the licensee's current operating conditions; and

Records of audits and other reviews of program content are maintained for at least 3 years.

Under 25 TAC §289.256(g)(1)(M), RSOs must ensure that personnel are complying with agency rules, the conditions of the license and the licensee's operating, safety and emergency procedures.

Discussion: Appendix H of this guide contains a suggested annual audit program that is specific to medical licensees and is acceptable to the agency. Since all areas indicated in Appendix H may not be applicable to every licensee and all items may not need to be addressed during each audit, licensees may wish to develop a program-specific audit checklist. Reviews or audits of the content and implementation of the radiation protection program must be conducted at an interval not to exceed 12 months.

The agency considers performance-based reviews, by observing work in progress, interviewing staff, and spot-checking required records, to be one way to ensure personnel are following radiation safety procedures. As part of the review or audit programs, licensees should consider including unannounced audits of authorized and supervised users. It is essential that once problems are identified, comprehensive corrective actions are taken in a timely manner.

With regard to audit records, 25 TAC §289.202(mm), requires that licensees maintain records of audits and other reviews of program content and implementation for 3 years after the record is made. The agency has found audit records that contain the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow up.

Response from Applicant: Provide the following:

- the statement: "An audit of the radiation protection program will be performed at an interval not to exceed 12 months"
- a description of the program for ensuring personnel are complying with agency rules, conditions of the license and the licensee's operating, safety and emergency procedures; and
- the document(s) used to perform audits and other reviews of the program.

Reference:

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

9.2 OCCUPATIONAL DOSE

Rules: 25 TAC §289.201(b), 25 TAC §289.202(f), 25 TAC §289.202(g), 25 TAC §289.202(h), 25 TAC §289.202(i), 25 TAC §289.202(l), 25 TAC §289.202(m), 25 TAC §289.202(p), 25 TAC §289.202(q), 25 TAC §289.202(x), 25 TAC §289.202(j), 25 TAC §289.202(rr), 25 TAC §289.202(ggg)(2), 25 TAC §289.203(d)

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

The use of individual monitoring devices for external dose is required, pursuant to 25 TAC §289.202(q), for:

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

- 5 rems [50 mSv] shallow-dose equivalent to the skin
- 5 rems [50 mSv] shallow-dose equivalent to any extremity
- minors who are likely to receive an annual dose in excess of any of the following (each evaluated separately)
 - 0.1 rem [1.0 mSv] deep-dose equivalent
 - 0.15 rems [1.5 mSv] lens (of the eye) dose equivalent
 - 0.5 rem [5 mSv] shallow-dose equivalent to the skin
 - 0.5 rem [5 mSv] shallow-dose equivalent to any extremity
- declared pregnant women who are likely to receive a dose from radiation sources external to the body during the entire pregnancy in excess of 0.1 rem [1.0 mSv] deep-dose equivalent
- individuals entering a high or very high radiation area

Internal exposure monitoring is required, pursuant to 25 TAC §289.202(q)(3), for the following:

- adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit on intake for ingestion and inhalation
- minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem [1.0 mSv] and declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem [1.0 mSv]

The licensee must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person, in accordance with 25 TAC §289.202(f)(7).

Licensees who use radioactive volatile liquids, gasses or aerosols that may cause an intake by an occupational worker are required to monitor if the annual exposure exceeds 10% of the annual limit according to 25 TAC §289.202(q)(3)(A). Development of a bioassay program is one acceptable way to monitor internal doses. Bioassay is defined in 25 TAC §289.201(b) as "The determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body." Texas Regulatory Guide 5.9 provides criteria acceptable to the Agency for the development and implementation of a bioassay program for any licensee handling or processing I-125 or I-131 to comply with 25 TAC §289.202(i). U.S. Nuclear Regulatory Commission

Regulatory Guide 8.9 describes acceptable methodologies for developing and implementing a bioassay program generally for any radionuclide contaminant.

Discussion: Applicants should review the use of all radioactive materials and when determining, for agency requirements, who is an occupationally exposed individual. The definitions in 25 TAC §289.201(b) define occupational dose, a minor, a declared pregnant woman, and the embryo/fetus of a declared pregnant woman.

The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with 25 TAC §289.202(q). If an adult radiation worker is likely to receive in 1 year a dose greater than 10 percent of any applicable limit, monitoring for occupational exposure is required. Monitoring is required for minors and declared pregnant females as shown in the criteria section. The licensee should perform an evaluation of the dose the individual is likely to receive prior to allowing the individual to receive the dose. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If this prospective evaluation shows that an adult individual's dose is not likely to exceed 10 percent of any applicable limit, there are no recordkeeping or reporting requirements in regard to the individual's exposure. However, the evaluation must be documented. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in this prospective evaluation. Only dose that could be received at the facility performing the evaluation need be considered when determining the need for monitoring, and therefore, recordkeeping and reporting requirements. If it was determined that monitoring was not required and a subsequent evaluation shows that the 10 percent threshold has or will be exceeded, the dose received when monitoring was not provided should be estimated, recorded, and reported. These estimates can be based on any combination of work location radiation monitoring or survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. The licensees must also consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure and must have a program in place to sum those exposures in accordance with 25 TAC §289.202(g).

Licensees should use RC Form 202-2, "Cumulative Occupational Dose History," and RC Form 202-3, "Occupational Dose Record for a Monitoring Period," to record individual dose. If monitoring is not required to demonstrate compliance with all limits but is required relative to one or more specific limits, the licensee should enter "N/A" for "not applicable" in the blocks on RC Form 202-2, "Cumulative Occupational Dose History," and RC Form 202-3, "Occupational Dose Record for a Monitoring Period," to indicate the areas for which monitoring was not required (e.g., extremity or skin doses). Where monitoring was provided but not measurable, the licensee should enter "ND" for "not detectable."

If the prospective evaluation shows that the individual adult is likely to exceed 10 percent of an applicable limit, then monitoring and reporting of the results of monitoring performed, regardless of the actual dose received, is required. Licensees must provide individual radiation exposure data to each worker as required by 25 TAC §289.203(d).

Licensees should also perform prospective evaluations of the doses that may be received by occupationally exposed minors and declared pregnant women. As with individual adult workers, licensees must supply and require the use of individual monitoring devices to monitor external exposures and monitor the occupational intake of radioactive material when the results of prospective dose evaluations exceed the doses specified in 25 TAC §289.202(q).

When evaluating an external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within 25 TAC §289.202 limits.

When evaluating doses from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within 25 TAC §289.202 limits.

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

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See ANSI N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters," for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration [25 TAC §289.202(p)(3)].

When personnel dosimeters that require processing to determine the radiation dose are used to comply with the individual monitoring requirement for external doses in 25 TAC §289.202(q)(1), licensees must use dosimeters supplied by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor. The

exchange frequency for dosimeters is typically monthly or quarterly. Applicants should consult with their NVLAP approved processor for its recommendations for exchange frequency and proper use of the dosimeter. The National Institute of Standards and Technology (NIST) maintains a directory of laboratories that are NVLAP-approved.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 25 TAC §289.202(i) and §289.202(q). If internal dose assessment is necessary, the applicant shall measure the following:

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

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

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

Response from Applicant: Provide one of the following:

- Documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 25 TAC §289.202(q)

OR

- Procedures for monitoring external occupational exposure and, if applicable, internal occupational exposure.

References and Resources:

- NRC's RG 8.7, Revision 2 "Instructions for Recording and Reporting Occupational Radiation Exposure Data"
- NRC's RG 8.9, Revision 1 "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"

- NRC's RG 8.20, Revision 2 "Applications of Bioassay for Radioiodine"
- NRC's RG 8.25, Revision 1 "Air Sampling in the Workplace"
- NRC's RG 8.34 "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"
- NRC's RG 8.36 "Radiation Dose to the Embryo/Fetus"
- ANSI N13.30-2011 "Performance Criteria for Radiobioassay"
- NRC's IN 2000-10 "Recent Events Resulting in Extremity Exposures Exceeding Regulatory Limits"

9.3 PUBLIC DOSE

Rules: 25 TAC §289.202(e)(4), 25 TAC §289.202(n), 25 TAC §289.202(o), 25 TAC §289.202(y)

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

Discussion: Public dose is defined in 25 TAC §289.201(b) as "the dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) where the individual is when he or she receives the dose. Applicants should note that the limit of 2 mrem in any one hour applies as if the individual was continuously present.

25 TAC §289.202(o) describes how compliance may be achieved for public dose limits. Public dose is controlled, in part, by ensuring that licensed material is secure

(e.g., located in a locked area) to prevent unauthorized access or use by individuals coming into the area. Some medical use devices containing licensed material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only AUs and personnel using radioactive material under their supervision should have access to these keys. Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security. For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD), are often used to show compliance

The definition of “public dose” does not include doses received due to exposure to patients released in accordance with 25 TAC §289.256(cc). If a patient is released pursuant to 25 TAC §289.256(cc), licensees are not required to limit the radiation dose to members of the public (e.g., visitors in a waiting room or individuals near a PET “quiet room”) from a patient to 2 mrem [2 mSv] in any one hour. Patient waiting rooms and “quiet rooms” need only be controlled for those patients not meeting the release criteria in 25 TAC §289.256(cc).

The regulations in 25 TAC §289.202(n)(6) allow licensees to permit visitors to a patient who cannot be released under 25 TAC §289.256(cc) to receive a dose greater than 0.1 rem [1 mSv], provided the dose does not exceed 0.5 rem [5 mSv], and the AU has determined before the visit that it is appropriate. The NRC’s RIS 2005-24, “Control of Radiation Dose to Visitors of Hospital Patients,” November 23, 2005, discusses some of the measures that may be used to maintain control and minimize doses to visitors. RIS 2006-18, “Requesting Exemption from the Public Dose Limits for Certain Caregivers of Hospital Patients,” August 31, 2006, describes dose limits for members of the public that are designated as caregivers. Caregiver dose limits may be established on a case-by-case basis by the licensee. The justification for incurring the exposure is that it is beneficial, or possibly essential, to the wellbeing of the patient, and may, therefore, be considered an extension of the patient’s medical treatment.

In assessing the adequacy of facilities to control public dose, licensees should consider the design factors discussed under “Facility Diagram” in Item 8.

The licensee must control emissions to air of all radioactive material such that the individual member of the public likely to receive the highest total effective dose equivalent does not exceed the constraint level in 25 TAC §289.202(e)(4) “Radiation Protection Programs,” of 10 millirem/year [0.10 mSv/year] from those emissions. If exceeded, the licensee must report this as described in Item 9.22 and take prompt actions to ensure against recurrence.

Response from Applicant: Provide your procedure for performing an assessment of dose to demonstrate that any member of the public will not exceed a radiation dose of 100 mrem [1 mSv] in a year and the dose in any unrestricted area will not exceed 2 mrem [0.02 mSv] in any one hour. Licensees may refer to the agency's Rule Guide 6.4, "Demonstrating Compliance with Public Dose Limits," for guidance on preparing a written evaluation or may develop their own procedures.

9.4 OPERATING, SAFETY, AND EMERGENCY PROCEDURES

Rules: 25 TAC §289.202(e)(1), 25 TAC §289.202(mm), 25 TAC §289.202(bbb), 25 TAC §289.252(e)(7), 25 TAC §289.252(mm), 25 TAC §289.256(f)(3)(A), 25 TAC §289.256(www)

Criteria: This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document. In addition, these procedures must be posted in accordance with 25 TAC §289.203(b)(1)(C).

The licensee must develop, implement, and maintain specific operating and emergency procedures sufficient to ensure compliance with 25 TAC §289.202(e) and applicable sections in 25 TAC §289.256. Operating, radiation safety and emergency procedures must be submitted as part of the application in accordance with 25 TAC §289.202(e)(1), 25 TAC §289.252(e)(7), and 25 TAC §289.256(f)(3)(A). According to 25 TAC §289.256(f)(3)(A) the applicant must establish operating, safety and emergency procedures for:

1. radiation safety precautions and instructions;
2. methodology for measurement of dosages or doses to be administered to patients or human or animal research subjects;
3. calibration, maintenance, and repair of instruments and equipment necessary for radiation safety;
4. waste disposal procedures; and
5. other information required by rule, which may include:
 - Instructions for opening packages containing licensed material (see Item 9.9, "Opening Packages").
 - Instructions for using licensed material and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements.
 - Maintaining accountability of radioactive material (see Item 9.10, "Material Receipt and Accountability")

- Testing sealed sources for leakage or contamination (See Item 9.11 "Leak Tests")
- Instructions for conducting area radiation level and contamination surveys (see Item 9.12, "Area Surveys")
- Instructions for administering licensed material in accordance with the WD (see Item 9.13, "Procedures for Administrations when a Written Directive Is Required")
- Instructions for the safe use of unsealed radioactive material (see Item 9.14)
- Steps to ensure that patient release is in accordance with 25 TAC §289.256(cc) (see Item 9.17, "Release of Patients or Human Research Subjects")
- Instructions for calibration of survey and dosage measuring instruments (see Item 8.2, "Radiation Monitoring Instruments," and 8.3, "Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material.").
- Periodic spot-checks of therapy device units, sources, and treatment facilities (see Item 8.4, "Therapy Unit – Calibration and Use").
- Making, maintaining and retaining records, including records of dosages (See Item 9.19 "Records of Dosages" and Item 9.15 "Recordkeeping")
- Instructions for radioactive waste management (see Item 10, "Waste Management/Waste Disposal")
- Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred:
 - (a) leaking or damaged source,
 - (b) device malfunction and/or damage,
 - (c) licensed material spills,
 - (d) theft or loss of licensed material, or
 - (e) any other incidents involving licensed material (see Appendix J "Model Emergency Procedures" and Appendix R "Reporting Requirements").

- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Item 9.6, "Emergency Procedures for Therapy Devices Containing Sealed Sources").
- Steps to take if a therapy patient undergoes emergency surgery or dies.

The licensee must:

- Make operating procedures, including emergency procedures, available to all users (e.g., post the procedures or the location of procedure storage).
- Maintain a current copy of the procedures at each location of use, or, if this is not practicable, post a notice describing the procedures and state where they may be examined.
- Use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA, in accordance with 25 TAC §289.202(e)(2).
- Secure or control radioactive material at all times.

Discussion: Sealed sources and unsealed radioactive material used for therapy can deliver significant doses in a short time. The same may be true for high-activity PET radiopharmaceuticals, if not shielded. The security of licensed material is described in 25 TAC §289.202(y). Access control to high- and very-high-radiation areas and the security of licensed material are described in 25 TAC §289.202(s), "Control of access to high radiation areas;" 25 TAC §289.202(t), "Control of access to very high radiation areas;" and 25 TAC §289.202(y), "Security and control of licensed sources of radiation." Unauthorized access to licensed material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

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

Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking sources, medical events, interlock failures, stuck sources). After its occurrence becomes known to the licensee, the agency must be

notified when an incident involving licensed material occurs. Refer to the rules [25 TAC §289.202(ww) – (yy), 25 TAC §289.202(bbb), 25 TAC §289.256(uuu), 25 TAC §289.256(vvv)] for a description of when notifications are required.

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

Response from Applicant: Provide a copy of your procedure for responding to emergencies.

Applicants requesting use of radioactive seeds for localization: Review and respond to the information described in the NRC's Licensing Guidance "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes."

Applicants requesting Xe-133: Submit the following information:

1. Specify the average and maximum activity (mCi) of Xe-133 to be used for any one study, and to be used in any one week.
2. Provide a sketch of the room where the Xe-133 will be used, showing all air supply, recirculation, inlet and exhaust vents, with arrows to indicate the airflow patterns. Provide a sketch of the Xe-133 storage facility, if bulk xenon is used, and describe ventilation for that area.
3. Describe the method of exhausting air from the facility during times Xe-133 is used. Describe the method used to prevent recirculation of air to the rest of the facility during times Xe-133 is used. Specify airflow rates into and out of the room. Specify how far the point of exhaust is from any unrestricted area or fresh air intake.
4. Describe the method used for administering the dose to the patient and the method used for trapping, or exhausting the exhaled Xe-133. Describe the procedure for testing the xenon trap (if used) to assure that it is properly trapping the xenon or confirm that management requirements will be adhered to.
5. Provide emergency procedures in place to cope with large accidental releases of Xe-133, such as loss of an entire patient dose or spill of bulk quantity.
6. Demonstrate the exposure of facility personnel and the general public to Xe-133 is within limits of 25 TAC §289.202(ggg)(2).

NOTE: When performing calculations for room concentrations and room evacuation periods after an accidental release, use the worksheet provided in Appendix E.

7. Confirm all associated ventilation systems will be tested annually, to verify system integrity and effectiveness. Bear in mind, any change(s) in use or exhaust air flow will affect all calculations.

9.5 SPILL/CONTAMINATION PROCEDURES

Rules: 25 TAC §289.202(e)

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 25 TAC §289.202(e) must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Appendix J of this guide contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, State and local authorities, and the agency, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, and containment of spills and other releases, as well as appropriate methods for reentering and decontaminating facilities (when necessary).

Response from Applicant: Provide a copy of your procedures for responding to spills of licensed material.

9.6 EMERGENCY PROCEDURES FOR THERAPY DEVICES CONTAINING SEALED SOURCES

Rules: 25 TAC §289.256(p)(10) and (11), 25 TAC §289.256(ggg), 25 TAC §289.256(hhh)

Criteria: Before using materials under 25 TAC §289.256(ddd), "Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit," the applicant must develop, document, implement, and submit written emergency procedures in accordance with 25 TAC §289.256(p)(10) and (11). Regulations in 25 TAC §289.256(ggg), "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a GSR unit. The procedures needed to meet 25 TAC §289.256(ggg) must include

- instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
- the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure

- the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally

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

Regulations in 25 TAC §289.256(hhh), "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," require the physical presence of certain individuals for therapy units to ensure that safety precautions are appropriately implemented. The following documents provide useful information regarding physical presence requirements:

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

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

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

- Location of emergency source recovery equipment, specifying what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Radiation safety priorities, such as giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).
- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Response from Applicant: Provide:

- Emergency procedures that will be physically posted at the unit console, to include the following:
 - instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
 - the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
 - the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally
- A description of the training in the operating and emergency procedures for the unit, including drills of the emergency procedures. Training must be provided initially and at least annually, to all individuals who will operate the unit.

9.7 INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Rules: 25 TAC §289.202(e), 25 TAC §289.252(e), 25 TAC §289.256(fff), 25 TAC §289.256(rrr)

Criteria: Applicants requesting authorization to install, maintain, adjust, repair, and inspect their own therapy devices containing sealed sources must develop, document, submit, and implement those procedures in accordance with 25 TAC §289.202(e) and 25 TAC §289.252(e). In accordance with 25 TAC §289.256(fff), "Installation, maintenance, adjustment, and repair," and 25 TAC §289.256(rrr), "Five-year inspection for teletherapy and gamma stereotactic radiosurgery units,"

licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturers' written recommendations and instructions and according to the SSD registry. In addition, 25 TAC §289.256(rrr) requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

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

The agency requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by the agency, the NRC or an Agreement State to perform such services. Most licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review 25 TAC §289.256(fff) before responding to this item. Requirements in 25 TAC §289.256(fff) allow for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant:

- Confirm that installation, maintenance, adjustment, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source shielding, the sealed source driving unit, or other electronic or mechanical component that could expose the sealed source, reduce the shielding around the sealed source, or compromise the radiation safety of the unit or the sealed source will be performed by a person specifically licensed by the agency, the NRC, or an agreement state

OR

Applicants who will perform installations, maintenance, adjustments or repairs:

Provide sufficient information to allow the agency to evaluate and approve such authorization in accordance with 25 TAC §289.256(fff) and 25 TAC §289.256(rrr). This should include the following:

— name of the proposed employee and types of activities requested

AND

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

AND

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

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

9.8 ORDERING AND RECEIVING

Rules: 25 TAC §289.202(y), 25 TAC §289.202(ee),

Criteria: The requirements for receiving packages containing licensed material are found in 25 TAC §289.202(ee), "Procedures for Receiving and Opening Packages." Additionally, the security of licensed material, required by 25 TAC §289.202(y), must be considered for all receiving areas.

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

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

In regard to mobile nuclear medicine services, radioactive material shall not be delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

Response from Applicant: Provide your procedure for ordering and receiving licensed material.

9.9 OPENING PACKAGES

Rules: 25 TAC §289.202(ee)

Criteria: Licensees must ensure that packages are opened safely and that the requirements of 25 TAC §289.202(ee) are met.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 25 TAC §289.202(ee) are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

Rule Guide 6.1 "Opening Packages Containing Radioactive Material" contains model procedures that represent one method for safely opening packages containing radioactive materials. Applicants are reminded that 25 TAC §289.202(ee)(3) 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 your procedure for safely opening packages containing radioactive material.

9.10 MATERIAL RECEIPT AND ACCOUNTABILITY

Material Receipt and Accountability

Rules: 25 TAC §289.202(y), 25 TAC §289.201(d), 25 TAC §289.201(g), 25 TAC §289.202(tt), 25 TAC §289.202(ww), 25 TAC §289.202(hhh), 25 TAC §289.252(cc), 25 TAC §289.256(z), 25 TAC §289.256(tt)

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

- Secure licensed material. [25 TAC §289.202(y)]
- Maintain records of receipt, transfer, and disposal of licensed material. [25 TAC §289.201(d), 25 TAC §289.202(tt)]
- Ensure that material received does not exceed license possession limits.
- Conduct physical inventories at semi-annual intervals (not to exceed 6 months) to account for all sealed sources containing radioactive material. [25 TAC §289.256(z)]
- Update transactions in the National Source Tracking System (NSTS), including annual inventory reconciliation [25 TAC §289.202(hhh)], if applicable
- Maintain accountability for brachytherapy sources in storage or use [25 TAC §289.256(tt)]

Discussion: Licensed materials must be tracked from "cradle to grave," from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal in order to ensure accountability; to identify that licensed material is missing and document the last confirmed possession of the material when it is lost, stolen [25 TAC §289.202(ww)], or misplaced; and to ensure that possession limits listed on the license are not exceeded.

Licensees are required under 25 TAC §289.202(y) to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

Receipt, inventory, transfer, and disposal records must be maintained for the times specified in 25 TAC §289.256(www). Typically, these records contain the following types of information:

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

If the licensee uses manual brachytherapy sources, the following records of use must be kept in accordance with 25 TAC §289.256(tt)(3):

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

Response from Applicant: Provide the following:

- A description of how radioactive material will be secured from unauthorized removal or access.
- The statement: "A physical inventory of all sealed sources will be performed at intervals not to exceed six months. Records will be maintained for three years and will include the model and serial number of each source, the radionuclide, activity and location of each source, the date of the inventory and identification of the individual who performed the inventory."

For applicants who will possess nationally tracked sources:

- Procedures for updating transactions in the National Source Tracking System, including performing annual inventory reconciliation

For applicants who will possess brachytherapy sealed sources:

- Procedures for maintaining accountability at all times for all brachytherapy sources in storage or in use including returning sources to a secure storage area promptly after use and maintaining records of removing and returning sources to storage in accordance with §289.256(tt)(3).

9.11 LEAK TESTS

Rules: 25 TAC §289.201(g), 25 TAC §289.202(bbb), 25 TAC §289.256(z)

Criteria: The agency requires testing to determine if there is any radioactive leakage from sealed sources. Analysis of tests for leakage or contamination must be performed by persons specifically authorized by the agency, the NRC or another Agreement State to perform this service, or in accordance with procedures submitted by the applicant and approved by the agency. Leak test records shall be retained for 3 years after they are made.

Discussion: Licensees must perform leak testing of sealed sources possessed under 25 TAC §289.256 (e.g., calibration, transmission, reference, or brachytherapy sources), in accordance with 25 TAC §289.256(z), "Requirements for possession of sealed sources and brachytherapy sources" and §289.201(g) "Tests for Leakage and/or Contamination of Sealed Sources."

Under §289.201(g), licensees are required to perform leak tests at 6-month intervals or at other intervals approved by the agency, the NRC or an Agreement State and specified in the SSD registration certificate and before first use, unless accompanied by a certificate indicating that the test was performed within the past 6 months. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. If the test reveals the presence of 0.005 microcuries [185 Bq] or more of removable contamination, a licensee must immediately withdraw the source from use and take

action to prevent the spread of contamination. A report must be filed with the agency in accordance with 25 TAC §289.202(bbb).

The licensee does not need to leak test sources if:

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

Applicants who intend perform in-house analysis of leak test sample must submit a request to the agency for approval. Rule Guide 6.2 "Analyzing Tests for Leakage or Contamination" provides model procedures are one way to perform leak testing for sealed sources.

Response from Applicant: Provide the following:

If leak test analysis will be performed by a licensed company, please provide the following statement:

"Leak tests will be performed at intervals as specified in rule or in the Sealed Source and Device registration certificate. Leak tests will be analyzed by an organization licensed by the agency, the NRC or another Agreement State. Records of leak test results will be maintained."

OR

If leak test analysis will be performed in-house, provide:

- The manufacturer and model of the instrument that will be used to analyze leak test samples; and
- A copy of your procedures for performing leak test sample analysis.

9.12 AREA SURVEYS

Rules: 25 TAC §289.201(b), 25 TAC §289.202(e), 25 TAC §289.202(f), 25 TAC §289.202(n), 25 TAC §289.202(p), 25 TAC §289.202(mm), 25 TAC §289.202(nn) 25 TAC §289.202(eee), 25 TAC §289.202(ggg)(6), 25 TAC §289.256(bb), 25 TAC

§289.256(mm), 25 TAC §289.256(ss), 25 TAC §289.256(eee), 25 TAC §289.256(www).

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

- Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 100 mrem/yr [1 mSv/yr] and that the dose in any unrestricted area will not exceed 2 mrem [0.02 mSv] in any one hour from licensed operations, in accordance with 25 TAC §289.202(n).
- 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 25 TAC §289.202(f).
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.
- Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 25 TAC §289.202(e).
- Ensure that contamination of surfaces or facilities or equipment in unrestricted areas does not exceed the limits as specified in 25 TAC §289.202(eee) and 25 TAC §289.202(ggg)(6).

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 25 TAC §289.202(e) must include provisions for area surveys. Surveys, as defined in 25 TAC §289.201(b) are evaluations of radiological conditions and potential hazards. These evaluations, as required by 25 TAC §289.202(p), may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions.

There are many different kinds of surveys that are performed by licensees: fixed contamination, removable contamination, air effluent, water effluent, leak test, bioassay, air sample, external radiation exposure levels, restricted area, unrestricted area and personnel.

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 rules, including:

- surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment.
- measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where licensed material is or could be released to unrestricted areas (Refer to the NRC's Regulatory Guide 8.25, "Air Sampling in the Workplace," June 1992, and NUREG-1400, "Air Sampling in the Workplace," September 1993, for further guidance on air sampling.)
- bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe.
- surveys of external radiation exposure levels in both restricted and unrestricted areas
- surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier)

The frequency of routine surveys depends on the type of survey, 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.

Similarly, the location of routine surveys will depend on many factors. Applicants should select locations to survey based on how likely it is that contamination would be present in that location. Example locations include doorknobs, sinks (and traps if disposing material to the sanitary sewer), countertops, floors, injection areas, hallways, and restrooms. An example survey diagram is included in Figure 2.

In accordance with 25 TAC §289.256(bb), medical use licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a WD is required (diagnostic activities exceeding 30 μCi (1.1 MBq) of I-131 and all therapy treatments); when the licensee administers radiopharmaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey of the patient's room. Licensees should perform surveys after the patient's release, in accordance with 25 TAC §289.256(mm). Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate that public dose limits are not exceeded.

As therapy sealed sources (including applicators, catheters, and therapy sources used for diagnostic purposes) may become dislodged during implantation or after

surgery, and inadvertently lost or removed, the licensee must perform surveys in accordance with 25 TAC §289.256(ss):

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

In addition, the licensee should also consider the following:

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

In accordance with 25 TAC §289.256(eee), the licensee must survey patients and the remote afterloader unit to confirm that the source has been removed from the patient and returned to the safe shielded position.

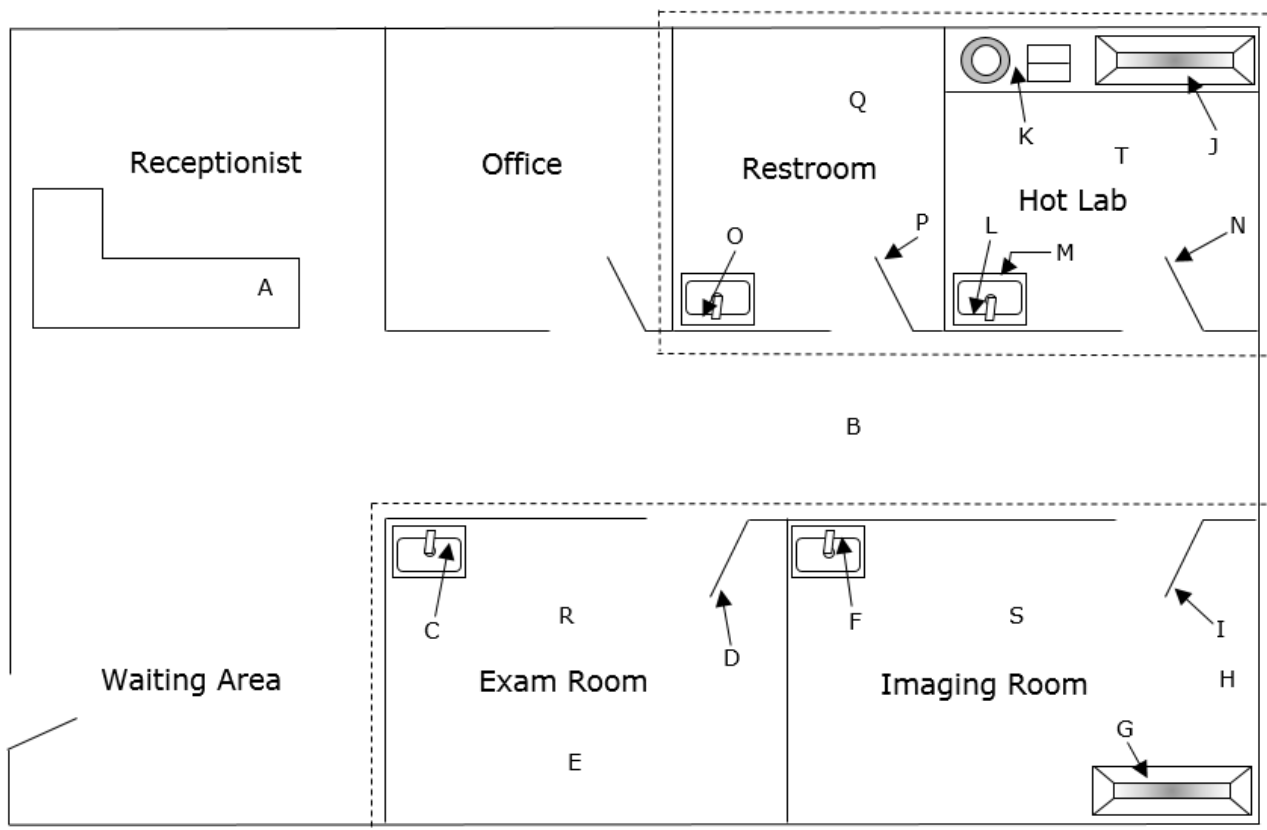
Licensee must maintain records of surveys in accordance with 25 TAC §289.202(mm), 25 TAC §289.202(nn), and 25 TAC §289.256(www).

Appendix L contains model procedures that represent one acceptable method of establishing survey frequencies for medical use, ambient radiation levels, and contamination surveys.

Response from Applicant: Provide your written procedures for performing surveys. Applicants may choose to adopt and submit the model procedure in Appendix L or develop their own procedure.

References and Resources:

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



Scale: 1" = 5'

Key

Generator w/lead



Dose calibrator



Restricted area border



Notes:

Samples A-B are judgmental locations in unrestricted areas based on personnel or patient paths leading out of the restricted areas.

Samples C-Q are judgmental locations in restricted areas based on personnel or patient uses of equipment of facilities.

Samples R-T are random locations in the restricted areas.

FIGURE 2. EXAMPLE SURVEY DIAGRAM

9.13 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

Rules: 25 TAC §289.256(t), 25 TAC §289.256(yy), 25 TAC §289.256(sss)

Criteria: The requirements for written directives are set forth in 25 TAC §289.256(t) "Written directives." Under 25 TAC §289.256(t)(4), "Procedures for administrations requiring a written directive," medical use licensees are required to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by AUs.

Discussion: A medical use licensee preparing written directives must develop, implement, and maintain written procedures to provide high confidence that, among other things, each administration is in accordance with the WD and the patient's identity is verified. Therefore, licensees should have checks in place to ensure that the correct patient is treated and each component of the WD is met. For purposes of determining whether medical event reporting is required, licensees should also provide definitive criteria for evaluating the adequacy of the dose delivered to the intended treatment site, compared to the prescribed dose, and the acceptability of the dose delivered to any other organ or tissue, compared to the dose expected from the administration defined in the written directive.

Additionally, under 25 TAC §289.256(yy), the licensee must perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

Appendix M of this guide provides guidance on developing the procedures.

Response from Applicant: Provide procedures for ensuring each administration is in accordance with the written directive.

9.14 SAFE USE OF UNSEALED RADIOACTIVE MATERIAL

Rules: 25 TAC §289.202(e), 25 TAC §289.256(f)(3)(A)

Criteria: Before using licensed material, the licensee must develop and implement operating, safety, and emergency procedures that includes specific information on radiation safety precautions and instructions, to satisfy the requirements of 25 TAC §289.256(f)(3)(A).

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 25 TAC §289.202(e) must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and disposed of. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

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

- use of syringe shields and/or vial shields, specific to the energy emitted (e.g., PET shields should be used when handling high-energy fluorine-18)
- wearing laboratory coats and gloves when handling unsealed radioactive material
- monitoring hands after handling unsealed radioactive material
- designing equipment and facilities to protect health and minimize danger to life or property in accordance with 25 TAC §289.252(e)(2)

Appendix N of this guide contains model procedures that provide one method for the safe use of unsealed radioactive material.

Response from Applicant: Provide your procedures for the safe use of unsealed radioactive material.

9.15 SAFETY PROCEDURES FOR TREATMENT WHEN PATIENTS ARE HOSPITALIZED

Rules: 25 TAC §289.202(f), 25 TAC §289.202(n), 25 TAC §289.202(p), 25 TAC §289.202(y), 25 TAC §289.256(mm), 25 TAC §289.256(ss)(2), 25 TAC §289.256(vv), 25 TAC §289.256(eee)(1), 25 TAC §289.256(hhh), 25 TAC §289.256(q)

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

Discussion: Under 25 TAC §289.256(mm), 25 TAC §289.256(vv), 25 TAC §289.256(hhh), and 25 TAC §289.256(q), licensees are required to take certain safety precautions for uses of radioactive material involving radiopharmaceutical therapy, manual brachytherapy, remote afterloader brachytherapy, or emerging technologies involving patients who cannot be released in accordance with 25 TAC §289.256(cc). The precautions described below are provided to help ensure compliance with the exposure limits in 25 TAC §289.202.

Under 25 TAC §289.256(ss)(2) and 25 TAC §289.256(eee)(1), licensees are required to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. When sources are placed within the patient's body, 25 TAC §289.256(hhh)(5) requires that licensed activities be limited

to treatments that allow for expeditious removal of a decoupled or jammed source. In addition, applicants must take the following steps for patients who cannot be released under 25 TAC §289.256(cc):

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage. (**Note:** 25 TAC §289.256(mm)(2) allows for a room shared with another radiopharmaceutical therapy patient.)
- Provide a private room for patients implanted with brachytherapy sources.
- Visibly post a "Radioactive Materials" sign on the patient's room and a note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room [25 TAC §289.256(mm) and 25 TAC §289.256(vv)].
- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation survey meter set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or handle them as radioactive waste [25 TAC §289.256(mm) and 25 TAC §289.202(p)].
- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies [25 TAC §289.256(mm), 25 TAC §289.256(vv), and 25 TAC §289.256(hhh)].

Licensees are required to perform adequate surveys to evaluate the extent of radiation levels in accordance with 25 TAC §289.202(p). Therefore, licensees must evaluate the exposure rates around patients who cannot be released under the requirements of 25 TAC §289.256(cc) and are hospitalized following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

Licensees are required to secure licensed material in storage from unauthorized access or removal in accordance with 25 TAC §289.202(y). Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material temporarily stored in the patient's room and unnecessary personnel exposures.

In order to control exposures to individuals, in accordance with 25 TAC §289.202(f) and 25 TAC §289.202(n), 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: Provide the following:

- A floor plan identifying the room where patients who cannot be released in accordance with 25 TAC §289.256(cc) will be housed
- Procedures to ensure (a) posting of a “Radioactive Materials” sign on the patient’s room and a note on the door or in the patient’s chart indicating where and how long visitors may stay in the patient’s room; (b) the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies; and (c) for patients administered radioactive drugs, that material and items removed from a patient’s room will be surveyed to ensure their radioactivity cannot be distinguished from the natural background radiation level or that material/items will be handled as radioactive waste and for patients with implanted sealed sources, that emergency response equipment will be available near each treatment room.

9.16 MOBILE NUCLEAR MEDICINE SERVICE

Rules: 25 TAC §289.256(dd), 25 TAC §289.256(ppp), 25 TAC §289.257, 49 CFR Parts 171-178

Criteria: In addition to the requirements in 25 TAC §289.256(dd) and 25 TAC §289.256(ppp), mobile nuclear medicine service licensees must comply with all other applicable rules.

Discussion: A mobile nuclear medicine service means the transportation of radioactive material to and its medical use at the client’s address. “Temporary jobsite” means a location, other than the specific location(s) of use authorized on the license, where mobile medical services are conducted for limited periods of time. Mobile nuclear medicine service licensees may transport licensed material and equipment into a client’s building or may bring patients into the transport (e.g., van). In either case, the van should be located on the client’s property that is under the client’s control. Mobile PET service licensees must consider a “quiet room” as an area of use if the patients in the “quiet room” cannot be released under the provisions of 25 TAC §289.256(cc).

A self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client’s site. Companies providing transportation only will not be licensed for medical use under 25 TAC §289.256. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

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

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

Mobile nuclear medicine service licensees must ensure that the criteria in 25 TAC §289.256(cc) are met before releasing patients treated in their facilities.

Refer to Appendix O for additional guidance on information to provide in applications and Rule Guide 6.5 "Summary of Transportation Requirements" for information on transportation requirements (25 TAC §289.257 and 49 CFR Parts 171-178).

The applicant must have at least one fixed facility where records may be maintained and radioactive material may be delivered by manufacturers or distributors.

Response from Applicant: Provide the following:

- Identify the type of mobile medical service to be offered
- Provide a copy of your procedures specific to mobile nuclear medicine service providers

9.17 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

Rules: 25 TAC §289.256(cc)

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 0.5 rem [5 mSv]. Patients treated with temporary eye plaques may be released from the hospital provided that the procedures ensure that the exposure rate from the patient is less than 5 millirem [0.05 mSv] per hour at a distance of 1 meter from the eye plaque location.

Licensees must provide radiation safety instructions to patients released (or to their parent or guardian) in accordance with 25 TAC §289.256(cc)(2).

Discussion: Under 25 TAC §289.256(cc)(2), the licensee is required to provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 0.1 rem [1 mSv]. If the dose to a breastfeeding infant or a child could exceed 0.1 rem [1 mSv], assuming there was no interruption of breastfeeding, the instructions also shall include:

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

Appendix P provides guidance to the applicant for determining when

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (See Section P.1 in Appendix P).
- Instructions to the patient are required by 25 TAC §289.256(cc)(2) (See Section P.2 of Appendix P).

Under 25 TAC §289.256(cc)(3), a licensee must maintain a record of each patient released in accordance with 25 TAC §289.256. The record must include the basis for authorizing the release of an individual and, if applicable, the instructions 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 0.5 rem [5 mSv].

Appendix P 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 25 TAC §289.256(cc).

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

Response from Applicant: Provide the following:

- Procedures for determining the release of a patient who has been administered radioactive drugs or implants containing radioactive material to ensure the dose to any other individual from exposure to the released patient is not likely to exceed 0.5 rem (5 mSv)

- Procedures for determining if instructions to a patient are required

9.18 MINIMIZATION OF CONTAMINATION

Rules: 25 TAC §289.202(ddd)(6) and 25 TAC §289.256(y)

Criteria: Applicants must describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste in accordance with 25 TAC §289.202(ddd)(6).

Discussion: Applicants should consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed radioactive material. As described in Appendix J, cleanup procedures should be implemented for contamination events.

Sealed sources and devices that are approved by the agency, NRC or another Agreement State and located and used according to their SSD registration certificates usually pose little risk of contamination. Leak tests performed as specified in the SSD registration certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of in accordance with 25 TAC §289.201(g). These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant: A response from applicants is not required under the following condition: The agency will consider that the above criteria have been met if the information provided in the applicant's responses satisfy the criteria in Items 8, 8.1, 9, 9.11, 10, on the following topics: facility and equipment, facility diagram, radiation protection program, and waste management.

9.19 RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCES

Rules: 25 TAC §289.201(d), 25 TAC §289.256(x), 25 TAC §289.256(ii), 25 TAC §289.256(ww)

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

Discussion: Licensees are required to make and maintain records of each dosage and administration prior to medical use, in accordance with 25 TAC §289.256(x). 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 30 μCi [1.1 MBq]
- date and time of dosage determination
- name of the individual who determined the dosage

Licensees may choose to develop a list of standard procedures, i.e. standing orders, which specifies the radiopharmaceutical to be used and the activity to be administered, or a prescribed dose range, as appropriate. This list should be dated, signed by an authorized user listed on the licensee's radioactive material license, should be routinely updated, and a copy available to individuals working under supervision of an authorized user.

Dosage determination for unit dosages may be made either by direct measurement or by a decay correction based on the activity determined by the manufacturer or preparer licensed under 25 TAC §289.252(r), a PET radioactive drug producer licensed under §289.252(kk) or equivalent NRC or Agreement State requirements. A licensee restricted to only unit doses prepared by a manufacturer or preparer does not need to perform a dosage determination unless the administration time of the unit dose deviates from the manufacturer or preparer's pre-calibrated time by 15 minutes or more.

A licensee who uses molybdenum-99/technetium-99m generator must measure and record the molybdenum-99 concentration of the first eluate after receipt of a generator, in accordance with 25 TAC §289.256(ii). Records of Mo-99 concentration must include:

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

A licensee who uses a strontium-82/rubidium-82 generator must measure and record the concentration of strontium-82 and strontium-85 before the first patient use of the day, in accordance with 25 TAC §289.256(ii). Records must include:

- ratio of the measurements expressed as μCi of Sr-82 per mCi of Rb-82 chloride (kBq of Sr-82 per MBq of Rb-82)
- ratio of the measurements expressed as μCi of Sr-85 per mCi of Rb-82 chloride (kBq of Sr-85 per MBq of Rb-82)

- date and time of the measurement
- name of the individual who made the measurement

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

Licensees using brachytherapy sealed sources must determine the sealed source output or activity and the positioning accuracy within applicators prior to the first medical use, as required by 25 TAC §289.256(ww). Licensees can use a dosimetry system that meets the requirements of 25 TAC §289.256(iii) using published protocols accepted by nationally recognized bodies or may use measurements provided by the source manufacturer or an accredited calibration laboratory.

Response from Applicant: Provide the following:

- a description of how you will determine and record the activity of each dosage

Applicants who will use molybdenum-99/technetium-99m and/or strontium-82/rubidium-82 generators must also provide:

- confirmation that the molybdenum-99 concentration and/or strontium-82 and strontium-85 concentration, as applicable, will be measured and a record maintained.

Applicants who will use brachytherapy sealed sources must also:

- Describe how you will determine the sealed source output or activity and the sealed source positioning within applicators.

9.20 RECORDKEEPING

Rules: 25 TAC §289.201(d); 25 TAC §289.202(ggg)(5); 25 TAC §289.202(II) – (vv); 25 TAC §289.252(gg)(7); 25 TAC §289.256(www).

Criteria: The general provision for records is identified in 25 TAC §289.202(II).

Licensees must maintain records as provided in 25 TAC §289.201(d); 25 TAC §289.202(ggg)(5); 25 TAC §289.202(II) – (vv); and 25 TAC §289.256(www).

Each licensee must make, maintain and retain records at each authorized use site in accordance with 25 TAC §289.202(mm); 25 TAC §289.252(mm) and 25 TAC §289.256(www).

Discussion: The licensee must maintain certain records to comply with agency rules, the conditions of the license, and commitments made in the license application and correspondence with the agency. Licensees are required to maintain, in an identified location, decommissioning records related to records of spills or unusual

occurrences involving the spread of contamination, leaking sources and to structures and equipment in restricted areas where radioactive materials are used and/or stored, in accordance with 25 TAC §289.252(gg)(7).

Operating procedures should identify which individuals in the organization are responsible for maintaining which records.

Response from Applicant: No response is necessary.

9.21 REPORTING

Rules: 25 TAC §289.202(ww) – (bbb); 25 TAC §289.202(hhh)(1); 25 TAC §289.256(uuu) and (vvv).

Criteria: Licensees are required to report to the agency via telephone, written report, or both, in the event that the safety or security of radioactive material may be compromised. The specific events that require reporting are explained in 25 TAC §289.256(uuu) and (vvv); 25 TAC §289.202(ww) – (bbb); and in 25 TAC §289.202(hhh)(1). The timing and type of report are specified within these parts.

Discussion: The agency requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, 25 TAC §289.202, and §289.256 include provisions that describe reporting requirements associated with the medical use of radioactive material. A table of reporting requirements appears in Appendix R of this guide.

Response from Applicant: No response is necessary.

9.22 TRANSPORTATION

Rules: 25 TAC §289.252(cc); 25 TAC §289.257(e); 25 TAC §289.257(g); 25 TAC §289.257(i); Subpart H; 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 agency and DOT regulations.

Discussion: Most packages of licensed material for medical use contain quantities of radioactive material that require the use of Type A packages. Many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the “Limited Quantity” criteria described in 49 CFR 173.421, “Excepted Packages for Limited Quantities of Class 7 (Radioactive) Materials,” and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.005 mSv/h [0.5 mrem/h]).

The general license in 25 TAC §289.251(f)(4)(F) "General license for intrastate transportation of radioactive material," provides the authorization used by most licensees to transport, or to deliver to a common or contract carrier for transport, radioactive material in a package, provided the transportation is in accordance with applicable DOT requirements appropriate to the mode of transport. The requirements for transportation of licensed material are set forth in 25 TAC §289.257, "Packaging and Transportation of Radioactive Material." The rules in 25 TAC §289.257(g) exempt any physician, licensed by a State to dispense drugs in the practice of medicine and who is also licensed under 25 TAC §289.256 or the equivalent NRC or Agreement State regulations, from the requirements for transportation. This exemption applies to transport by the physician of radioactive material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or GSR) may need to ship licensed material in Type B packages. The Type B package requirements for transporting or delivering the package to a carrier for transport are set forth in 25 TAC §289.257. These include registration as a user of the package and the requirement to have an NRC-approved quality assurance (QA) plan. See 25 TAC §289.257(i)(1)(C)(iii) for registration information and 25 TAC §289.257(s) for QA plan information. For information about these QA programs, see the NRC's RG 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," March 2005. For further information about registering as a user of a package or submitting a QA program for review, contact NRC's Division of Spent Fuel Management by calling NRC toll-free at 800-368-5642, extension 415-9956.

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

- is authorized to possess the licensed material (see 25 TAC §289.252(cc))
- actually takes possession of the licensed material under its license

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

Rule Guide 6.3 "Packaging Radioactive Material for Transport or Delivery" provides a model program.

Rule Guide 6.5 lists major DOT regulations that apply to medical use licensees.

Medical use licensees are reminded of the following:

- The licensee must properly block and brace the transportation case when transporting radioactive material to ensure that the material does not shift during transport.
- The licensee must have emergency response information, including current emergency response telephone numbers that meet the requirements of Subpart G, "Emergency Response Information," of 49 CFR Part 172, "Hazardous Materials Table, Special Provisions, Hazardous Materials Communications, Emergency Response Information, Training Requirements, and Security Plans."
- Initial and recurrent training must be given to all employees who package or transport radioactive material per the requirements of Subpart H, "Training," of 49 CFR Part 172. Individuals who prepare shipping papers are also classified as hazmat employees subject to the training requirements.
- The licensee shall maintain transportation shipping records in accordance with the requirements of Subpart C, "Shipping Papers," of 49 CFR Part 172, including the proper shipping name, hazard class (Class 7), United Nations identification number, the name of the shipper, and the name and activity of each radionuclide.

Response from Applicant: Provide your procedures for packaging radioactive material for transport or delivery to a common or contract carrier.

Note: Licensees who will transport radioactive material on public highways will need to submit additional procedures.

9.23 SECURITY PROGRAM FOR CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIAL

Rules: 25 TAC §289.201(b), 25 TAC §289.202(hhh), 25 TAC §289.252(ii), 25 TAC §289.252(jj)(9)

Criteria: Licensees must ensure the security of Category 1 and Category 2 radioactive material. The requirements of 25 TAC §289.252(ii) apply to licensees that possess an aggregated Category 1 or Category 2 quantity of radioactive material. These terms are defined in 25 TAC §289.201(b), and the radionuclides referenced in these 25 TAC §289.201(b) definitions are listed in 25 TAC §289.252(jj)(9). The applicant should refer to 25 TAC §289.252(jj)(9) to determine whether its proposed activities would be subject to the 25 TAC §289.252(ii) requirements. Gamma stereotactic radiosurgery (GSR) and teletherapy sources are usually at or above Category 1 quantities, and co-located high dose-rate (HDR) brachytherapy sources are usually at or above Category 2 quantities.

As required by 25 TAC §289.252(ii)(3)(B)(ii), licensees must name one or more Reviewing Officials to make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

Discussion: In accordance with 25 TAC §289.252(ii), "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material", any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material must, among other things:

- establish, implement, and maintain an access authorization program and a security program to ensure physical protection of the radioactive material.
- before giving individuals unescorted access to Category 1 or Category 2 quantities of radioactive material, conduct background investigations of these individuals, to determine that they are trustworthy and reliable, in accordance with 25 TAC §289.252(ii)(4).
- establish a security program designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.
- implement a training program for those individuals implementing the security program.
- provide for physical protection of Category 1 or Category 2 quantities of radioactive materials in transit. These requirements apply to licensees delivering such material to a carrier for transport, as well as cases in which licensees are transporting such material. Please note that the requirements applicable to the transport of Category 1 quantities of radioactive material are more stringent than those applicable to Category 2 quantities.
- implement the 25 TAC §289.252(ii) security requirements before they take possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

Any licensee that has not previously been made subject to the provisions of 25 TAC §289.252(ii), shall notify the agency in writing at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category threshold. Pursuant to 25 TAC §289.252(ii)(10)(B) as part of the security program, the licensee must develop and maintain written procedures that document how the requirements will be met.

After completing the background investigation on an RO, the licensee must provide a certification, under oath or affirmation, that the RO has been deemed trustworthy and reliable by the licensee. The oath or affirmation requirement may be satisfied by using a notary public to authenticate oaths or affirmations and to certify that the

information provided is correct and true. An alternate method for complying with the oath or affirmation requirement is presented in the United States Code, Title 28, Section 1746 (28 U.S.C. § 1746). This method allows use of the following unsworn declaration to satisfy the oath or affirmation requirement:

I declare [or certify, verify, state] under penalty of perjury that the foregoing is true and correct.

Executed on [date] [Signature].

For additional guidance on implementing 25 TAC §289.252(ii) requirements, see the NRC's NUREG-2155, "Implementation Guidance for 10 CFR Part 37, "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material."" Additional information regarding best practices for protection of risk-significant radioactive material is available in NUREG-2166, "Physical Security Best Practices for the Protection of Risk-Significant Radioactive Material."

Additionally, Category 1 and Category 2 sealed sources must be tracked in the NSTS in accordance with 25 TAC §289.202(hhh). The rules in 25 TAC §289.202(hhh) require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report (NSTTR) to the NRC. The NSTTRs are maintained in the NSTS, a secure computer system that tracks Category 1 and Category 2 nationally tracked sources from the time they are manufactured or imported through the time of their disposal or export, or until the source activity decays to below Category 2.

Response from Applicant:

Applicants for a license: Provide a certification, under oath or affirmation, that the RO has been deemed trustworthy and reliable by the licensee.

License renewal: Indicate if there has been a change to the designated Reviewing Official. If so, provide a certification, under oath or affirmation, that the RO has been deemed trustworthy and reliable by the licensee and a letter designating the Reviewing Official (RO).

Please note, under 25 TAC §289.252(ii), security plans are not submitted to the agency, but are subject to review during agency inspections.

ITEM 10: WASTE MANAGEMENT/WASTE DISPOSAL

Rules: 25 TAC §289.201(d)(1), 25 TAC §289.202(n), 25 TAC §289.202(ff) – (kk), 25 TAC §289.202(fff), Table II of 25 TAC §289.202(ggg)(2), Table III of 25 TAC §289.202(ggg)(2)(F), 25 TAC §289.252(x)(11), 25 TAC §289.252(cc), 25 TAC §289.256(ee).

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

- transfer to an authorized recipient [25 TAC §289.202(ff)(1)(E), 25 TAC §289.202(jj), 25 TAC §289.252(cc)]
- decay-in-storage [25 TAC §289.256(ee)]
- release in effluents within the limits in 25 TAC §289.202(n)
- as authorized under 25 TAC §289.202(hh) and 25 TAC §289.202(fff)

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 25 TAC §289.202(e) must include provisions for waste disposal of licensed material. Appendix S contains model procedures that represent one way to provide for decay-in-storage and generator or other licensed material return. Applicants are reminded to take into account the following information when they develop procedures (as applicable):

- Prior to transferring licensed material to an authorized recipient, licensees must ensure that the recipient is authorized to receive the material. Records of transfer and disposal must be maintained until the license is terminated.
- Licensees transferring licensed material to a licensed low-level radioactive waste disposal facility in accordance with 25 TAC §289.202(jj) must make and maintain records required by 25 TAC §289.257(ff).
- Licensees are authorized to transfer residual radiopharmaceutical waste for decay in storage to the individuals who manufactured, compounded and supplied the radiopharmaceuticals, in accordance with 25 TAC §289.202(ff)(1)(E).
- When setting up a program for decay-in-storage, consider short-term and long-term storage and designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location and appropriately posted in accordance with 25 TAC §289.202(aa). In addition, all storage containers must be appropriately labeled in accordance with 25 TAC §289.202(cc). The decay time should be based on the radionuclide(s), half-life, and the activity present when the waste was placed into storage. Such waste may be disposed of as in-house trash if radiation surveys of the waste indicate that radiation levels are indistinguishable from background. The surveys should be performed with an appropriate radiation detection meter set on its most sensitive scale in a low background area and without any interposed shielding. All radiation labels must be defaced or removed from containers and packages prior to disposal as ordinary trash, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released.

- Check and calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153) may not be held for decay-in-storage and must be disposed of in accordance with 25 TAC §289.202. In accordance with 25 TAC §289.251(e)(2)(E), radioactive materials not originally distributed as exempt, may not be considered exempt even if they decay below the exempt quantities.
- In accordance with 25 TAC §289.202(o), 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 25 TAC §289.202(n), "Dose Limits for Individual Members of the Public," and 25 TAC §289.202(gg), "Disposal by Release into Sanitary Sewerage," respectively.
 - Rules for disposal in the sanitary sewer appear in 25 TAC §289.202(gg). Material must be readily soluble or dispersible in water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations. See 25 TAC §289.202(gg)(2).)
 - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table III of 25 TAC §289.202(ggg)(2). These limits apply at the boundary of the restricted area.

Licensees proposing to dispose of licensed material in accordance with 25 TAC §289.202(hh) "Treatment by Incineration", 25 TAC §289.202(ii) "Discharge by Release in to Septic Tanks", or paragraph 4 of 25 TAC §289.202(fff) "Exemption of Specific Wastes" must apply for and receive approval from the agency. Please contact the agency for additional guidance.

As required by 25 TAC §289.252(x)(11), licensees cannot not hold sources, devices, or radioactive waste not authorized for disposal by decay in storage for longer than 24 months following the last principal activity of use. Licensees may be excluded from the 24-month time limit by submitting to the agency for approval a written plan for future use of the sources or devices. If a licensee storing waste cannot meet the 24-month time limit, the licensee can submit to the agency for approval a written plan for an alternative disposal timeframe.

Response from Applicant: Provide your waste disposal procedures for licensed material. Applicants may adopt the model procedures in Appendix S or develop their own procedure. Applicants proposing to dispose of licensed material using methods not addressed by Appendix S must submit additional procedures.

ITEM 11: FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE

Rules: 25 TAC §289.252(d)(5), 25 TAC §289.252(d)(6), 25 TAC §289.252(e)(11), 25 TAC §289.252(gg), 25 TAC §289.252(jj)(2), 25 TAC §289.252(jj)(8).

Criteria: As required by 25 TAC §289.252(d)(5), each applicant must submit a completed RC Form 252-1, "Business Information Form". The applicant must be authorized to conduct business in the State by the Texas Secretary of State unless otherwise exempt, as described in 25 TAC §289.252(e)(11). All applicants using an assumed name or "doing business as" (dba) name in their application must file an assumed name certificate with the Secretary of State and/or office of the county clerk, as required by 25 TAC §289.252(e)(11).

In accordance with 25 TAC §289.252(d)(6), each applicant must demonstrate to the agency that it is financially qualified to conduct the activity requested for licensure, including any required decontamination and disposal of radioactive material. Methods for demonstrating financial qualification are specified in 25 TAC §289.252(jj)(8). An applicant can attest to financial qualification by checking the appropriate box on page 1 of RC Form 252-1, "Business Information Form".

Licensees possessing certain radioactive material in excess of the limits specified in 25 TAC §289.252(gg), "Financial assurance and recordkeeping for decommissioning," must provide evidence of financial assurance for decommissioning. Quantities of specific radionuclide activities that mandate certain levels of financial assurance are listed in 25 TAC §289.252(jj)(2).

Discussion: The requirement for demonstration of financial qualification is separate from the requirement specified in subsection 25 TAC §289.252(gg) for certain applicants or licensees to provide financial assurance.

Once licensed, the applicant must notify the agency in writing immediately after any kind of bankruptcy filing as identified in 25 TAC §289.252(x)(6)-(8).

Most applicants and licensees for a medical use license do not need to comply with the financial assurance requirements because most radioactive materials requested or authorized on the license will have a half-life less than 120 days. The thresholds for sealed sources are such that a licensee would need to possess hundreds of sealed sources before the financial assurance requirements would apply.

The requirements for financial assurance and record keeping for decommissioning are described in 25 TAC §289.252(gg).

Response from Applicant: Provide the following:

- A completed Business Information Form, RC 252-1.
- For Corporations, Limited Liability Companies (LLC), Limited Partnerships (LP), or Professional Associations (PA): Attach a copy of your "certificate of status" issued by the Texas Secretary of State. If using a dba, also submit your "certificate of filing."
- For Government entities, Sole Proprietorships or General Partnerships: Attach a copy of your Employer Identification Number (EIN) certificate or other documentation confirming your EIN. If using a dba, also submit your "certificate of filing" issued by the Secretary of State.
- For applicants required to provide financial assurance, a completed RC Form 252-1 ADD Financial Assurance Addendum.

ITEM 12: CERTIFICATION

The chief executive officer or other individual delegated the authority to manage, direct or administer the licensee's activities must sign RC Form 252-2, as required by 25 TAC §289.252(d)(2). The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant/licensee. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment to and responsibility for the radiation protection program. The agency will return all unsigned applications for proper signature.

The RSO, if not a member of company management, may sign an initial application if the applicant also provides a signed "Delegation of Authority". Appendix C includes a model document that applicants may use for this purpose.

Note: When the application includes licensing commitments, those items become binding and are part of the license conditions and regulatory requirements.

V. LICENSE AMENDMENTS

TIMELY SUBMITTAL OF AMENDMENTS

Rules: 25 TAC §289.252(w)(2), 25 TAC §289.252(aa), 25 TAC §289.256(r).

Criteria: It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit a request for a license amendment before the change takes place. The change is not in effect until the amendment has been issued. License amendment requests must be filed in accordance with 25 TAC §289.252(aa).

25 TAC §289.256(r) describes amendment of medical use, specific licenses at request of licensee.

Discussion: Under 25 TAC §289.256(r), a licensee is required to apply for and receive a license amendment before several activities can occur, including:

- receiving or using radioactive material for a type of use that is authorized in accordance with 25 TAC §289.256, but is not authorized on the licensee's current license;
- permitting anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license;
- changing RSOs, except as provided in 25 TAC §289.256(g)(5)
- receiving radioactive material in excess of the amount or in a different form, or receiving a different radionuclide than is authorized on the license;
- adding or changing the areas in which radioactive material is used or stored and are identified in the application or on the license;
- changing the address(es) of use identified in the application or on the license; and
- changing operating, safety, and emergency procedures.

Response from licensee: No response is required from an applicant for a new license.

Requests for a license amendment must:

- be signed by management or the RSO;
- include the license number;

- specify the respects in which the license should be amended and the grounds for the amendment.

TIMELY NOTIFICATION OF TRANSFER OF CONTROL

Transfer of Control

Rule: 25 TAC §289.252(x)(2)

Criteria: In accordance with 25 TAC §289.252(x)(2), transfer of licenses to other persons is prohibited unless the agency, after securing full information, finds that the transfer is in accordance with agency rules and orders and gives its consent *in writing*. The agency must be contacted at least 30 days prior to a licensee relinquishing control of a site.

Discussion: Transferring control may be the result of a sale, merger, reorganization or transfer of certain operations or assets of a corporation, partnership, or sole proprietorship. The agency identifies a licensed legal entity based on the unique file or charter number generated by the Texas Secretary of State. If transfer of control does not affect the file or charter number, such as a change in company name or organizational changes in officers or registered agent, then an amendment may be required. However, if transfer of control results in the issuance of a new file or charter number, the new entity must apply for a new radioactive material license.

Response from Applicant: No response is required from an applicant for a new license. However, current licensees should refer to Regulatory Guide 8.1, "Guide for Submitting Applications or Amendment Requests due to Changes in Licensed Legal Entity" for more information.

NOTIFICATION OF BANKRUPTCY PROCEEDINGS

Rule: 25 TAC §289.252(x)(6) – (8)

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

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains subject to all applicable agency regulatory requirements. The agency must be notified when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility).

Response from Applicant: No response is required from an applicant for a new license. Licensees must immediately notify the agency, in writing, following the filing of a voluntary or involuntary petition for bankruptcy by or against the licensee.

OTHER

Licensees are required to notify the agency of program changes as noted below:

- decommissioning activities in accordance with 25 TAC §289.252(y)(4), including permanently ceasing principal activities at a site or under the license
- change in mailing address in accordance with 25 TAC §289.252(x)(5)(B)
- name change that does not constitute a transfer of control in accordance with 25 TAC §289.252(x)(5)(A)
- the intent to vacate premises, prior to vacating and relinquishing possession or control in accordance with 25 TAC §289.202(ccc)
- waste, sources or devices not authorized for disposal by decay in storage and that are not in use for longer than 24 months in accordance with 25 TAC §289.252(x)(11)

VI. LICENSE RENEWALS

Rules: 25 TAC §289.252(d), 25 TAC §289.252(e), 25 TAC §289.252(z)

Criteria: 25 TAC §289.252(z) requires that renewal of specific licenses be filed in accordance 25 TAC §289.252(d) and 25 TAC §289.252(e), which describe filing an application for a specific license and the requirements for the issuance of specific licenses, respectively.

Discussion: Licensees are responsible for filing renewal documentation which consists of all the information required for initial licensure. The timeline for submitting a renewal application in proper form is not less than 30 days prior to the license expiration date. If an application is submitted in proper form not more than 90 days after the expiration date, then the agency may reinstate the license. A licensee may be cited for a violation if the licensee is in possession of radioactive material with an expired license during the 90-day period.

Training documentation for individuals already authorized on the license may be omitted from renewal applications for that specific license.

Response from licensee: Not less than 30 days prior to the license expiration date, submit a complete and up-to-date application, including all required program elements outlined in Appendix A of this guide.

APPENDIX A LICENSE APPLICATION CHECKLIST

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

Items 1-4 and 12 should be completed on RC Form 252-2. Checklist A-1 may be used to describe Item 5 (Radioactive Material), and Checklist A-2 may be used to describe Items 6 and 7 (Training and Experience), Item 8 (Facilities and Equipment), Item 9 (Radiation Protection Program), and Item 10 (Waste Management). Please note that the procedures provided are not all-inclusive. Finally, Appendix R is not a model procedure; however, it is included in Checklist A-2 to remind licensees of reporting requirements.

Checklist A-1 outlines the detailed responses that may be made to Item 5 of the application for the type of radioactive material requested and purposes for which it will be used. An applicant may copy the checklist and include it in the license application.

Checklist A-2 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. An applicant may copy the checklist and include it in the license application.

Checklist A-1: Item 5 on RC Form 252-2: Radioactive Material Requested
(Check all applicable rows, fill in details, and attach copy of the checklist to the application or provide information separately.)

Radionuclide		Form or Make/ Model No.	Max Quantity	Purpose Of Use
<input type="checkbox"/>	Any radioactive material permitted by 25 TAC §289.256(ff)	Any radiopharmaceutical form, except gas and aerosol	As needed	Any uptake, dilution and excretion study permitted by 25 TAC §289.256(ff)
<input type="checkbox"/>	Any radioactive material permitted by 25 TAC §289.256(hh)	Any radiopharmaceutical form, except gas and aerosol	As needed	Any uptake, dilution and excretion study permitted by 25 TAC §289.256(hh)
<input type="checkbox"/>	Xenon-133	Any radiopharmaceutical	____ millicuries	Any imaging and localization study permitted by Title 25 TAC §289.256(hh)
<input type="checkbox"/>	Molybdenum-99/ Technetium-99m	Solid or liquid	____ generators, no single generator to exceed ____ millicuries	Elution of generator systems for preparation of radiopharmaceuticals.
<input type="checkbox"/>	Strontium-82/Rubidium-82	Solid or liquid	____ generators, no single generator to exceed ____ millicuries	Elution of radiopharmaceuticals for patient imaging.
<input type="checkbox"/>	Germanium-68/Gallium-68	Solid or liquid	____ generators, no single generator to exceed ____ millicuries	For use of the Eckert and Ziegler GalliaPharm™ generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies.
<input type="checkbox"/>	Fluorine-18	Liquid	____ millicuries	Instrument calibration and reference

Checklist A-1: Item 5 on RC Form 252-2: Radioactive Material Requested
(Check all applicable rows, fill in details, and attach copy of the checklist to the application or provide information separately.)

Radionuclide		Form or Manufacturer/ Model No.	Max Quantity	Purpose Of Use
<input type="checkbox"/>	Gadolinium-153	Sealed source (Manufacturer _____ Model No. _____)	____ curies per source and ____ curies total	Instrument calibration and reference in a (Manufacturer _____ Model No. _____) device.
<input type="checkbox"/>	Any radioactive material permitted by 25 TAC §289.256(kk)	Any radiopharmaceutical form, except gas and aerosol	As needed	Any use of unsealed material that requires a written directive permitted by 25 TAC §289.256(kk).
<input type="checkbox"/>	Iodine-125	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Radioactive seed localization permitted by 25 TAC §289.256(q)
<input type="checkbox"/>	Palladium-103	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Radioactive seed localization permitted by 25 TAC §289.256(q)
<input type="checkbox"/>	Cesium-131	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).
<input type="checkbox"/>	Cesium-137	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).

Checklist A-1: Item 5 on RC Form 252-2: Radioactive Material Requested
(Check all applicable rows, fill in details, and attach copy of the checklist to the application or provide information separately.)

Radionuclide		Form or Manufacturer/ Model No.	Max Quantity	Purpose Of Use
<input type="checkbox"/>	Iodine-125	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).
<input type="checkbox"/>	Iridium-192	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).
<input type="checkbox"/>	Palladium-103	Sealed source (Manufacturer _____ Model No. _____)	____ millicuries	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).
<input type="checkbox"/>	Strontium-90	Sealed source (Manufacturer _____ Model No. _____)	____ curies per source and ____ curies total	Any use of sealed sources for manual brachytherapy permitted by 25 TAC §289.256(rr).
<input type="checkbox"/>	Yttrium-90	Sealed source (SIR-Spheres Y-90 microspheres)	____ millicuries/vial and ____ curies total	Medical use permitted by 25 TAC §289.256(q) using SIR-Spheres Y-90 microspheres and delivery system.
<input type="checkbox"/>	Yttrium-90	Sealed source (TheraSphere Y-90 microspheres)	____ millicuries/vial and ____ curies total	Medical use permitted by 25 TAC §289.256(q) using TheraSphere Y-90 microspheres and delivery system.
<input type="checkbox"/>	Iridium-192	Sealed source (Manufacturer _____)	____ curies per source and	Medical use permitted by 25 TAC

Checklist A-1: Item 5 on RC Form 252-2: Radioactive Material Requested
(Check all applicable rows, fill in details, and attach copy of the checklist to the application or provide information separately.)

Radionuclide		Form or Manufacturer/ Model No.	Max Quantity	Purpose Of Use
		<div>_____</div> <div>Model No. _____)</div> <div>Device (Manufacturer</div> <div>_____</div> <div>Model No. _____)</div>	____ curies total	§289.256(ddd), in a high dose rate remote afterloader unit. Replacement source in its shipping container.
<input type="checkbox"/>	Cobalt-60	<div>Sealed source (Manufacturer</div> <div>_____</div> <div>Model No. _____)</div> <div>Device (Manufacturer</div> <div>_____</div> <div>Model No. _____)</div>	<div>____ curies per source and</div> <div>____ curies total</div>	Medical use permitted by 25 TAC §289.256(q) in a gamma stereotactic radiosurgery unit. Sources in approved shipping containers during periods of source exchange.
<input type="checkbox"/>	Any radioactive material listed in 25 TAC §289.251(f)(4) (G)	Prepackaged kits	____ millicuries	<i>In vitro</i> studies.
<input type="checkbox"/>	Other List radionuclide: _____	Form or Manufacturer/ Model No. _____	____ millicuries	Purpose of use _____

Checklist A-2: Items 6 through 10 on RC Form 252-2: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

ITEM 6: Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience

- ☐ Provide an organizational chart or description that identifies the individuals responsible for the Radiation Protection Program, including the reporting structure through upper management.
- ☐ For applicants required to establish a Radiation Safety Committee in accordance with 25 TAC §289.256(i):
 - Describe the committee membership, by title only;
 - Describe the duties and responsibilities of the committee, to include at least those list in 25 TAC §289.256(i)(3).

Item 6.1: Radiation Safety Officer (RSO)

- ☐ Provide the agency license number_____ OR a copy of the license or a permit issued by the NRC or an Agreement State broad scope on which the individual was named as the RSO within the last 7 years [For a license of the same types of use]

OR

- ☐ Provide documentation of training and experience and preceptor attestation using RC Form 256 series, as appropriate to the requested use(s), or equivalent documentation and

If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

AND, if applicable

- ☐ For consultant-RSO, contractor, or RSO not based at the main site, provide all of the following:
 - Commitments of the consultant-RSO for other agency, NRC or Agreement State licensed facility, along with a description of how the consultant-RSO will allocate time to permit performance of the duties of the RSO as described in the rule. The statement should include the consultant-RSO's minimum amount of onsite time (hours per week)
 - Identification of an in-house representative who will serve as the point of contact during the RSO's absence

- A description of the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of the radiation safety program and related regulatory requirements
- Specification of the maximum amount of time it will take the consultant-RSO to arrive at the facility in the event of an emergency that requires his or her presence

Item 6.2: Authorized Users

(Provide for each authorized user. Attach additional sheets, if necessary)

- ☐ Provide the agency license number_____ OR a copy of the license or a permit issued by the NRC or an Agreement State broad on which the individual was named as the AU within the last 7 years
- OR
- ☐ Provide documentation of training and experience and preceptor attestation using RC Form 256-4a or 256-4b, as appropriate, or equivalent documentation and

If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

Item 6.3: Authorized Nuclear Pharmacists

(Provide for each authorized user. Attach additional sheets, if necessary)

- ☐ Provide the agency license number_____ OR a copy of the license or a permit issued by the NRC or an Agreement State broad on which the individual was named as the ANP within the last 7 years
- OR
- ☐ Provide documentation of training and experience and preceptor attestation using RC Form 256-3a or 256-3b, as appropriate, or equivalent documentation and

If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

Item 6.4: Authorized Medical Physicists

(Provide for each authorized user. Attach additional sheets, if necessary)

- ☐ Provide the agency license number_____ OR a copy of the license or a permit issued by the NRC or an Agreement State broad on which the individual was named as the AMP within the last 7 years
- OR

- ☐ Provide documentation of training and experience and preceptor attestation using RC Form 256-2a or 256-2b, as appropriate, or equivalent documentation and

If applicable, recently received related training, if the original training and experience was received greater than 7 years ago

Item 7: Training for Individuals Working in or Frequenting Restricted Areas

- ☐ The statement: "Nuclear medicine technologists will be certified as a general certificate medical radiologic technologist (MRT) under Texas Occupations Code Chapter 601, Medical Radiologic Technologists

AND

- ☐ A description of the minimum training and experience you will require for individuals (i.e. nuclear medicine technologists, registered nurses, x-ray technologists) who will handle or use radioactive material under supervision of an AU

AND

- ☐ A description of the training and instructions to be provided to individuals working under supervision of an AU and individuals working with or around radioactive materials

AND, if applicable

- ☐ A description of the training provided to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with 25 TAC §289.256(cc)

Table A-2: Items 6 through 10 on RC Form 252-2: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

Item 8: Facilities and Equipment

Item 8.1: Facility Diagram

- ☐ A brief description of scope and magnitude of use of radioactive material at each proposed facility
- ☐ A facility diagram that identifies:
 - the room number and principal use of each room of radioactive material use and/or storage, including patient treatment rooms;
 - principal use of each adjacent room; and

- the restricted area
- ☐ A diagram of each room of use or storage that identifies the location(s) of:
- receipt and preparation areas;
 - storage areas, including waste storage;
 - imaging equipment
 - treadmills used for stress testing,
 - radiation delivery devices (e.g. xenon delivery/traps, aerosol units)
- ☐ For radiopharmaceutical and sealed source therapies, provide a description of areas surrounding the treatment rooms, including the occupancy factors, and indicate whether the areas are restricted or unrestricted
- ☐ For remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units, provide shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The calculations should include the workload assumptions used.
- ☐ For teletherapy facilities, applicants should provide the directions of primary beam use for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.
- ☐ For 25 TAC §289.256(q) uses (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the NRC's Medical Uses Licensee Toolkit.
- ☐ Licensees or applicants that intend to administer radioactive material to patients in temporary use areas, such as in hospital patient rooms, or special procedures room, must indicate their intention to do so. It is not necessary to provide diagrams of these areas.

Item 8.2: Radiation Monitoring Instruments

- ☐ A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the agency, NRC or an Agreement State to perform instrument calibrations."
- AND
- ☐ The manufacturer and model number of all instruments and detectors that will be used to perform required surveys.

OR

A statement that: "We will perform in-house calibration of our radiation survey meters." Submit a copy of the calibration procedures in accordance with in accordance with the requirements in 25 TAC §289.202(p)(3) and that meet the requirements in 25 TAC §289.256(w).

AND

- ☐ The manufacturer and model number of all instruments and detectors (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys.

AND, if applicable

- ☐ Applicants intending to use a portable survey meter or an imaging camera to analyze contamination wipes must identify the instrument and detector to be used submit the following additional information:
 - Minimum detectable activity (MDA) calculation to demonstrate that the system (instrument and detector) can detect, at a minimum, the acceptable surface contamination levels in 25 TAC §289.202(ggg)(6);
 - procedure for analyzing wipes, including how a consistent geometry will be maintained

Item 8.3: Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material

Applicants intending to use a dose calibrator:

- ☐ Your procedures for calibrating dose calibrators in accordance with 25 TAC §289.256(v). You may use the model procedure in Appendix F or develop and submit your own procedure.

AND

- ☐ A description of the equipment used to measure the dosages

OR

Applicants who will not use a dose calibrator:

- ☐ Confirm that you will use only unit doses prepared by a manufacturer or preparer licensed in accordance with 25 TAC §289.252(r) or an equivalent NRC or Agreement State license.

Applicants who will use Rb-82 generators must also provide:

- ☐ Confirm that you will maintain documentation of the infusion cart maintenance performed every 12 months by the manufacturer to document the completion and results of the infusion pump flow rate and radiation detector test.

AND

- ☐ Confirm that the radiation safety officer, all authorized users, and individuals working under supervision of authorized users will successfully complete training provided by the manufacturer and specific to the manufacturer and model of generator and infusion cart being used. Records of training will be maintained. Such training must include: (1) elution and quality control procedures needed to determine Rb-82 activity and the Sr-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedures for the clinical use of Rb-82 chloride. The quality control procedures must include: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer.

AND

- ☐ Confirm that you will record the activity of each dosage administered, as provided by the infusion cart.

Item 8.4: Therapy Unit – Calibration and Use

- ☐ Procedures for performing and documenting the periodic spot checks required by 25 TAC §289.256(mmm), 25 TAC §289.256(nnn), and/or 25 TAC §289.256(ooo), as applicable to the license application.

Item 8.5: Other Equipment and Facilities

- ☐ Identify the owner of each property where radioactive material will be used or stored.

AND

- ☐ If a property is owned by another company, provide a written statement from the owner or owner's agent acknowledging he or she is aware that radioactive material is used and stored on the property.
- ☐ Describe the handling devices, shielding and storage containers used when handling and storing radioactive materials to maintain doses ALARA.
- ☐ For radiopharmaceutical therapy: describe the additional equipment for this use, such as portable shields (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).
- ☐ For manual brachytherapy: provide a description of the emergency response equipment.

- ☐ For teletherapy, GSR, and remote afterloader facilities: provide a description of the following:
- warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room
 - area radiation monitoring equipment
 - viewing and intercom systems (except for LDR units)
 - steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room
 - methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons
 - emergency response equipment

Item 9: Radiation Protection Program

Item 9.1: Audit Program

- ☐ the statement: "An audit of the radiation protection program will be performed at an interval not to exceed 12 months"
- AND
- ☐ a description of the program for ensuring personnel are complying with agency rules, conditions of the license and the licensee's operating, safety and emergency procedures;
- AND
- ☐ the document(s) used to perform audits and other reviews of the program

Item 9.2: Occupational Dose

- ☐ Documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 25 TAC §289.202(q)
- OR
- ☐ Procedures for monitoring external occupational exposure and, if applicable, internal occupational exposure.

Item 9.3: Public Dose

- ☐ Provide your procedure for performing an assessment of dose to demonstrate that any member of the public will not exceed a radiation dose of 100 mrem [1 mSv] in a year and the dose in any unrestricted area will not exceed 2 mrem [0.02 mSv] in any one hour.

Item 9.4: Operating, Safety, and Emergency Procedures

- ☐ Provide a copy of your procedure for responding to emergencies.
- ☐ Applicants requesting use of radioactive seeds for localization purposes should review and respond to the information described in the U.S. NRC's Licensing Guidance "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes."

Applicants requesting Xe-133 must also provide the following:

- ☐ Specify the average and maximum activity (mCi) of Xe-133 to be used for any one study, and to be used in any one week.
- ☐ Provide a sketch of the room where the Xe-133 will be used, showing all air supply, recirculation, inlet and exhaust vents, with arrows to indicate the airflow patterns. Provide a sketch of the Xe-133 storage facility, if bulk xenon is used, and describe ventilation for that area.
- ☐ Describe the method of exhausting air from the facility during times Xe-133 is used. Describe the method used to prevent recirculation of air to the rest of the facility during times Xe-133 is used. Specify airflow rates into and out of the room. Specify how far the point of exhaust is from any unrestricted area or fresh air intake.
- ☐ Describe the method used for administering the dose to the patient and the method used for trapping, or exhausting the exhaled Xe-133. Describe the procedure for testing the xenon trap (if used) to assure that it is properly trapping the xenon or confirm that management requirements will be adhered to.
- ☐ Provide emergency procedures in place to cope with large accidental releases of Xe-133, such as loss of an entire patient dose or spill of bulk quantity.
- ☐ Demonstrate the exposure of facility personnel and the general public to Xe-133 is within limits of 25 TAC §289.202(ggg)(2).
- ☐ Confirm all associated ventilation systems will be tested annually, to verify system integrity and effectiveness.

Item 9.5: Spill/Contamination Procedures

- ☐ Provide a copy of your procedures for responding to spills of licensed material.

Item 9.5: Ordering and Receiving

- ☐ Provide your procedure for ordering and receiving licensed material.

Item 9.6: Emergency Procedures for Therapy Devices Containing Sealed Sources

- ☐ Provide a copy of the emergency procedures that will be physically posted at the unit console, to include the following:
 - instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions
 - the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure
 - the names and telephone numbers of AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally
- ☐ A description of the training in the operating and emergency procedures for the unit, including drills of the emergency procedures. Training must be provided initially and at least annually, to all individuals who will operate the unit.

Item 9.7 Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

- ☐ Confirm that installation, maintenance, adjustment, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the sealed source shielding, the sealed source driving unit, or other electronic or mechanical component that could expose the sealed source, reduce the shielding around the sealed source, or compromise the radiation safety of the unit or the sealed source will be performed by a person specifically licensed by the agency, the NRC, or an agreement state

OR

Provide sufficient information to allow the NRC to evaluate and approve such authorization in accordance with 25 TAC §289.256(fff) and 25 TAC §289.256(rrr). This should include the following:

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

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

Item 9.8: Ordering and Receiving

- ☐ Provide your procedure for ordering and receiving licensed material.

Item 9.9: Opening Packages

- ☐ Provide your procedure for safely opening packages containing radioactive material.

Item 9.10: Material Receipt and Accountability

- ☐ A description of how radioactive material will be secured from unauthorized removal or access.
- ☐ The statement: "A physical inventory of all sealed sources will be performed at intervals not to exceed six months. Records will be maintained for three years and will include the model and serial number of each source, the radionuclide, activity and location of each source, the date of the inventory and identification of the individual who performed the inventory."

For applicants who will possess nationally tracked sources:

- ☐ Procedures for updating transactions in the National Source Tracking System, including performing annual inventory reconciliation.

For applicants who will possess brachytherapy sealed sources:

- ☐ Procedures for maintaining accountability at all times for all brachytherapy sources in storage or in use including returning sources to a secure storage area promptly after use and maintaining records of removing and returning sources to storage in accordance with §289.256(tt)(3).

Item 9.11: Leak Tests

- ☐ If leak test analysis will be performed by a licensed company, please provide the following statement:

"Leak tests will be performed at intervals as specified in rule or in the Sealed Source and Device registration certificate. Leak tests will be analyzed by an organization licensed by the agency, the NRC or another Agreement State. Records of leak test results will be maintained."

- ☐ If leak test analysis will be performed in-house, provide:

- The manufacturer and model of the instrument that will be used to analyze leak test samples; and
- A copy of your procedures for performing leak test sample analysis.

Item 9.12: Area Surveys

- ☐ Provide your procedures for performing surveys.

Item 9.13: Procedures for Administrations When a Written Directive is Required

- ☐ Provide procedures for ensuring each administration is in accordance with the written directive.

Item 9.14: Safe Use of Unsealed Radioactive Material

- ☐ Provide your procedures for the safe use of unsealed radioactive material.

Item 9.15: Safety Procedures for Treatment When Patients are Hospitalized

- ☐ Provide:
 - A floor plan identifying the room where patients who cannot be released in accordance with 25 TAC §289.256(cc) will be housed
 - Procedures to ensure (a) posting of a "Radioactive Materials" sign on the patient's room and a note on the door or in the patient's chart indicating where and how long visitors may stay in the patient's room; (b) the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies; and (c) for patients administered radioactive drugs, that material and items removed from a patient's room will be surveyed to ensure their radioactivity cannot be distinguished from the natural background radiation level or that material/items will be handled as radioactive waste and for patients with implanted sealed sources, that emergency response equipment will be available near each treatment room.

Item 9.16: Mobile Medical Service

- ☐ Identify the type of mobile medical service to be offered
- ☐ Provide your procedures specific to mobile nuclear medicine service providers

Item 9.17 Release of Patients or Human Research Subjects

- ☐ Provide:
- Procedures for determining the release of a patient who has been administered radioactive drugs or implants containing radioactive material to ensure the dose to any other individual from exposure to the released patient is not likely to exceed 0.5 rem (5 mSv)
 - Procedures for determining if instructions to a patient are required

Item 9.18: Minimization of Contamination

A response from applicants is not required under the following condition: The agency will consider that the above criteria have been met if the information provided in the applicant's responses satisfy the criteria in Items 8, 8.1, 9, 9.11, 10, on the following topics: facility and equipment, facility diagram, radiation protection program, and waste management.

Item 9.19: Records of Dosages and Use of Brachytherapy Sources

- ☐ A description of how you will determine and record the activity of each dosage

Applicants requesting possession of molybdenum-99/technetium-99m and/or strontium-82/rubidium-82 generators:

- ☐ • Provide your procedure for measuring the molybdenum-99 concentration and/or strontium-82 and strontium-85 concentration, as applicable, in accordance with 25 TAC §289.256(ii)

Applicants who will use brachytherapy sealed sources must also:

- ☐ Describe how you will determine the sealed source output or activity and the sealed source positioning within applicators.

Item 9.20: Recordkeeping

No response is necessary.

Item 9.21: Reporting

No response is necessary.

Item 9.22: Transportation

- ☐ Provide your procedures for packaging radioactive material for transport or delivery to a common or contract carrier

Item 9.23: Security Program for Category 1 and Category 2 Radioactive Material

- ☐ Applicants for a license: Provide a certification, under oath or affirmation, that the RO has been deemed trustworthy and reliable by the licensee. a letter designating the Reviewing Official (RO).
- ☐ License renewal: Indicate if there has been a change to the designated Reviewing Official. If so, provide a certification, under oath or affirmation, that the RO has been deemed trustworthy and reliable by the licensee. a letter designating the Reviewing Official (RO).

Security plans are subject to review during agency inspections and should not be submitted to the agency

Item 10: Waste Management/Waste Disposal

- ☐ Provide your procedures for disposal of licensed material.

Item 11: Financial Qualification and Financial Assurance

- ☐ A completed Business Information Form, RC 252-1 with the appropriate box under "Certification of Financial Qualification," on page 1
- ☐ For applicants using an assumed or doing business as (DBA) name in their application provide a copy of the assumed name certificate
- ☐ If financial assurance is required, submit evidence of financial assurance.

APPENDIX B SAFETY CULTURE POLICY STATEMENT

The purpose of this Statement of Policy is to set forth the agency's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees and applicants for a license, subject to agency authority.

Nuclear Safety Culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The performance of individuals and organizations can be monitored and trended and, therefore, may be used to determine compliance with requirements and commitments and may serve as an indicator of possible problem areas in an organization's safety culture. The agency will not monitor or trend values. These will be the organization's responsibility as part of its safety culture program.

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

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort versus safety. It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the agency's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

1. *Leadership Safety Values and Actions* – Leaders demonstrate a commitment to safety in their decisions and behaviors;
2. *Problem Identification and Resolution* – Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
3. *Personal Accountability* – All individuals take personal responsibility for safety;

4. *Work Processes* – The process of planning and controlling work activities is implemented so that safety is maintained;
5. *Continuous Learning* – Opportunities to learn about ways to ensure safety are sought out and implemented;
6. *Environment for Raising Concerns* – A safety-conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
7. *Effective Safety Communication* – Communication maintains a focus on safety;
8. *Respectful Work Environment* – Trust and respect permeate the organization; and
9. *Questioning Attitude* – Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should be noted that these traits were not developed to be used for inspection purposes.

It is the agency's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The agency recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The agency will take this into consideration as the regulated community addresses the Statement of Policy.

APPENDIX C RSO RESPONSIBILITIES

Every licensee, as required by §289.256(g), must establish in writing the authority, duties and responsibilities of the Radiation Safety Officer and ensure that the RSO is provided sufficient authority, organizational freedom, time, resources, and management prerogative to perform the following duties:

- (1) establish and oversee operating, safety, emergency, and as low as reasonably achievable (ALARA) procedures, and to review them at least annually to ensure that the procedures are current and conform with 25 TAC 289;
- (2) ensure that required radiation surveys and leak tests are performed and documented in accordance with 25 TAC 289, including any corrective measures when levels of radiation exceed established limits;
- (3) ensure that individual monitoring devices are used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made in accordance with §289.203 of this title;
- (4) investigate and cause a report to be submitted to the agency for each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by 25 TAC 289 and each theft or loss of source(s) of radiation, to determine the cause(s), and to take steps to prevent a recurrence;
- (5) investigate and cause a report to be submitted to the agency for each known or suspected case of release of radioactive material to the environment in excess of limits established by 25 TAC 289;
- (6) have a thorough knowledge of management policies and administrative procedures of the licensee;
- (7) identify radiation safety problems;
- (8) assume control and initiate, recommend, or provide corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;
- (9) verify implementation of corrective actions;
- (10) ensure that records are maintained as required by 25 TAC §289;
- (11) ensure the proper storing, labeling, transport, use, and disposal of sources of radiation, storage, and/or transport containers;

- (12) ensure that inventories are performed in accordance with the activities for which the license application is submitted;
- (13) ensure that personnel are complying with 25 TAC 289, the conditions of the license, and the operating, safety, and emergency procedures of the licensee;
and
- (14) serve as the primary contact with the agency.

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 rules. You are hereby delegated the authority necessary to meet the responsibilities of Title 25 Texas Administrative Code Section 289.256(g), including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations when justified to maintain radiation safety.

You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Texas Department of State Health Services at any time.

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

Signature of Management Representative

Date

I accept the above responsibilities.

Signature of Radiation Safety Officer

Date

cc: Affected department heads

APPENDIX D MODEL TRAINING PROGRAM

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and background knowledge of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet agency requirements.

Model Training Program for Medical and Non-Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, rules, terms of the license, or type of radioactive material or therapy device used.

Training will be conducted by the RSO or the RSO's designee.

Records of worker training will be maintained for 3 years. The training records will include the date of the instruction or training, a brief outline of subjects covered, and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Medical Use of Radioactive Material

Individuals who receive, possess, use, transfer, or prepare radioactive material for medical use under the supervision of an AU will receive instructions in the preparation of radioactive material for medical use and instructions on the licensee's written operating, safety and emergency procedures, written directive procedures, Agency rules, and license conditions.

Training for professional staff [e.g., AU, AMP, authorized nuclear pharmacist, radiation safety officer (RSO), nurse, dosimetrist, technologist, therapist] may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues).
- Basic radiation protection to include concepts of time, distance, and shielding.
- Concept of maintaining exposure as low as is reasonably achievable. [25 TAC §289.202(e)]

- Risk estimates, including comparison with other health risks.
- Posting requirements. [25 TAC §289.202(aa)]
- Proper use of personnel dosimetry (when applicable).
- Access control procedures. [25 TAC §289.202(y)]
- Proper use of radiation shielding, if used.
- Patient release procedures [25 TAC §289.202(cc)]
- 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. [25 TAC §289.203(c), 25 TAC §289.256(ll), 25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- Occupational dose limits and their significance. [25 TAC §289.202(f)]
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy. [25 TAC §289.202(m)]
- Worker's right to be informed of occupational radiation exposure. [25 TAC §289.203(d)]
- Each individual's obligation to report unsafe conditions to the RSO. [25 TAC §289.203(c)]
- Applicable rules, license conditions, information notices, bulletins, etc. [25 TAC §289.203(c)]
- Where copies of the applicable rules, the license, and its application are posted or made available for examination. [25 TAC §289.203(b)]
- Proper recordkeeping required by agency rules. [25 TAC §289.202(ll)]
- Radiation survey instrumentation and survey techniques
- Appropriate surveys to be conducted. [25 TAC §289.202(p)]
- Proper calibration of required survey instruments. [25 TAC §289.202(p)]
- Emergency procedures.

- Minimization of contamination.
- Discussion of internal exposure pathways.
- Decontamination and release of facilities and equipment. [25 TAC §289.202(ddd)(6), 25 TAC §289.252(y)]
- Dose to individual members of the public. [25 TAC §289.202(n)]
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing). [25 TAC §289.256(s)]
- Hazardous Materials (HAZMAT) training for preparing shipments of radioactive material (25 §289.257(e) and Title 49 CFR Part 172)

Training for individuals who prepare packages containing radioactive material for shipment or transport

Individuals who prepare packages containing radioactive material for shipment or transport will complete hazardous materials training within 90 days after employment or a change in job function and every three years thereafter, in accordance with Title 49, CFR, Part 172: Subpart H.

A record of training will be retained for each employee and will include: the hazmat employee's name; the most recent training completion date of the hazmat employee's training; a description, copy, or the location of the training materials used to meet the requirements in paragraph (a) of this section; the name and address of the person providing the training; and certification that the hazmat employee has been trained and tested, as required by this subpart.

Training for Individuals Involved in Nonmedical Use of Radioactive Material

Training for staff working with radioactive material for nonmedical uses or animals containing radioactive material may include, as appropriate, the elements that are listed above for medical uses. All training should be commensurate with the individual's duties.

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Radioactive Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), commensurate with their duties:

- leak testing of sealed sources [25 TAC §289.201(g)]

- emergency procedures (including emergency response drills) [25 TAC §289.256(II), 25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- operating instructions [25 TAC §289.256(s), 25 TAC §289.256(ggg)]
- computerized treatment planning system [25 TAC §289.256(sss)]
- dosimetry protocol [25 TAC §289.256(iii)]
- detailed pretreatment quality assurance checks [25 TAC §289.256(s), 25 TAC §289.256(ggg)]
- 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 [25 TAC §289.256(II), 25 TAC §289.256(uu)]
- patient control procedures [25 TAC §289.256(II), 25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) [25 TAC §289.256(II), 25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for gamma stereotactic radiosurgery (GSR), correct positioning of the helmet) [25 TAC §289.256(t)]
- 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) [25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- size and appearance of different types of sources and applicators [25 TAC §289.256(uu), 25 TAC §289.256(ggg)]
- previous incidents, events, and/or accidents
- for remote afterloaders, teletherapy units, and GSR units, initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes
 - design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms

- hands-on training in actual operation of the device under the direct supervision of an experienced user, including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures
- a method, such as practical examinations, to determine each trainee’s competency to use the device for each type of proposed use

Additional Training for Authorized Medical Physicists

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 25 TAC §289.256(j)(2). Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of strontium-90 sources used for ophthalmic treatments [25 TAC §289.256(xx)]. Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 25 TAC §289.256(j)(3).

Additional Training for Authorized Users for Medical Uses of Radioactive Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 25 TAC §289.256(nn), 25 TAC §289.256(pp), 25 TAC §289.256(qq), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), and 25 TAC §289.256(ttt), attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in §289.256(nn), 25 TAC §289.256(zz), 25 TAC §289.256(aaa), and 25 TAC §289.256(ttt)

Training for Non-Radiation Workers

For the purposes of this section, non-radiation workers include personnel engaged in janitorial and/or housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 100 millirem [1 millisievert] in a year will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel.

Topics of instruction may include the following:

- storage, transfer, or use of radiation and/or radioactive material [25 TAC §289.203(c)]

- potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) [25 TAC §289.203(c)]
- the applicable provisions of agency rules and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) [25 TAC §289.203(c)]
- responsibility to report promptly to the licensee any condition that may lead to or cause a violation of agency rules and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) [25 TAC §289.203(c)]
- appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material [25 TAC §289.203(c)]
- radiation exposure reports that workers may request, as per 25 TAC §289.203(d), "Notifications and reports to individuals" [25 TAC §289.203(c)].

References and Resources:

- NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel," 1989.
- NCRP Report No. 134, "Operational Radiation Safety Training," October 2000.
- ICRP Report No. 75, "General Principles for the Radiation Protection of Workers," 1997.

APPENDIX E SUPPLEMENTAL INFORMATION FOR USE OF Xe-133

I. Facility Design

In general, no Xe-133 should be released into any room where it is used, nor exhausted to the environment. Thus, for radiation safety, the ideal facility should use a leak proof xenon trap to capture, hold and shield exhausted Xe-133 until it decays to background.

In practice, however, Xe-133 leaks occur and xenon traps do not capture all Xe-133. Xenon traps can actually pass a large percentage of Xe-133 when saturated with moisture or other contaminants. Releases also occur because of xenon trap malfunctions or accidents. Therefore, a facility should be designed to quickly exhaust any Xe-133 that may be released in the room, without excessive exposure to the involved health care providers, the patient(s), and/or members of the public located outside the facility or immediate area.

To reduce possible Xe-133 leakage, the use facility should have a closed room with an exhaust system that directs air outside the facility during periods Xe-133 is administered. The room exhaust should be at a rate that creates negative pressure, with respect to adjacent rooms. Sum the total airflow for the supply air and sum the total airflow for the exhaust vents. Compare the total supply to the total exhaust. If the rate of total supply airflow exceeds the total airflow of exhaust air flow, adjustments to the air supply must be made. Total air flow exhaust rate must exceed total air supply flow rates in order for negative pressure to be present.

In addition, there should be no recirculation of air to the remainder of the facility when Xe-133 is administered. Exhausted air should be released outside the facility at a point that is not normally accessible to personnel and not near any other air intake involved with the facility's ventilation system.

Once appropriate dilution is achieved, the exhaust to the outside may be shut off and the room may be returned to normal air circulation.

II. Collection and/Disposal of Xe-133

Patients should be required to exhale into a face mask or mouth piece connected by a flexible hose that exhausts to a xenon trap or directly outside of the facility.

If exhaled Xe-133 is exhausted directly outside, **into an unrestricted location**, the exhaust rate must comply with 25 TAC §289.202(o), for the total amount of Xe-133 used (i.e., the average concentration of Xe-133 in the unrestricted area, closest to the point of discharge, must not exceed 5×10^{-7} microcuries per milliliter of air on an annual basis or 1.25×10^{-4} in any one hour).

If a xenon trap is used, the exhaust rate must be sufficient for just the Xe-133 that leaks during administration. A conservative estimate would be 25% of the total

amount used. If Xe-133 is trapped, the room exhaust air flow rate can be 25% of the flow rate necessary to exhaust the Xe-133 directly outside the facility.

Personnel exposure to Xe-133, that leaks in the room where it is used, may not exceed concentration limits specified in 25 TAC §289.202(f) (i.e. an average 40 hour, weekly concentration for Xe-133 must not exceed 1×10^{-4} microcuries per milliliter of air). Since xenon may not be released directly into the room, the release limits to the unrestricted area will generally be the limiting factor.

III. Exhaust Flow Rate

Applicants should submit calculations that demonstrate air concentrations of Xe-133 do not exceed personnel exposure limits of 25 TAC §289.202(f), and that all Xe-133 releases meet the limits of 25 TAC §289.202(o).

In lieu of the calculations for weekly room concentrations, the Agency will approve the use of the Xe-133 for use in negative pressured rooms that have an outside exhaust rate as indicated below for the workload and system used (*calculations assume continuous exhaust, 168 hours/week*):

Weekly Workload (mCi/wk)	Outside Exhaust Rate Using a Xenon Trap (cfm)	Outside Exhaust Rate Without a Xenon Trap (cfm)
10	* 50	70
25	* 50	175
50	90	350
100	175	700
250	450	1750

A minimum exhaust flow rate of **50 cfm is considered necessary to maintain sufficient negative pressure in the room.*

NOTE: If the room exhaust is carried through a conduit to the roof or released at some point inaccessible and removed from the general public, the additional dilution and dispersion of Xe-133 in air may be such that these flow rates may be substantially reduced.

IV. Safety Considerations

- A. If a major accidental release of Xe-133 occurs during a procedure, the room must be evacuated and air exhausted from the room until Xe-133 concentration is below 1×10^{-4} microcuries per milliliter (100 microcuries per cubic meter).
- B. If a xenon trap is used, the air exhausted from trap filters should be periodically collected and counted to determine whether Xe-133 is leaking through the filters. When trap filters no longer trap Xe-133 efficiently, they must be

replaced or made effective, as prescribed by the manufacturer. An automatic monitoring and alarm system is therefore more convenient for the user.

- C. The equation used to demonstrate room concentration(s), after any accidental release, is:

$$C = C_0 e^{- (F/V) t}$$

C = Room concentration

C₀ = Initial room concentration (assume total mixing)

F = Exhaust flow rate in cubic feet per minute (cfm)

V = Room volume in cubic feet

t = Minutes

The resulting time should be calculated and posted in the Xe-133 use room, with appropriate emergency instructions.

XENON-133 WORKSHEET

RAML NO.: _____

PREPARER: _____

LICENSEE: _____

DATE: _____

ROOM #: _____

Legend: A = Activity
f = Fraction
V = Volume of Air Exhausted

XENON CONCENTRATION FORMULA $C = \frac{A}{V} \times f$ REGULATORY LIMIT $1 \times 10^{-4} \mu\text{Ci/ml}$

FORMULA SIMPLIFIED $C = \frac{\mu\text{Ci/wk} \times .25}{\text{cfm} \times (1.699 \times 10^6 \text{ ml/cf/hr}) \times 40 \text{ hrs}} = \frac{\text{ } \times 10^{-4}}{\text{ }} \mu\text{Ci/ml}$

* cfm = A continuous exhaust rate. Do not calculate or include an exhaust fan that runs only a few hours a week.

XENON EXPONENTIAL DILUTION FORMULA (The evacuation time following a single release)

Legend} C = Maximum Allowed Room Concentration C_0 = Initial Room Concentration
F = Flow rate (cfm)
V = Room Volume (cubic feet)
t = Time (min.)
 $C = C_0 e^{-F/V \times t}$

REGULATORY LIMIT FOR RESTRICTED AREA $1 \times 10^{-4} \mu\text{Ci/ml}$ [or $2.832 \mu\text{Ci/cf}$]

FORMULA SIMPLIFIED $t_{(\text{min})} = (\text{cf} / \text{cfm}) \times \ln_0 [\text{cf} \times 2.832 / \mu\text{Ci}]$
 $t = (\text{cf} / \text{cfm}) \times \ln_0 [\text{cf} \times 2.832 / \mu\text{Ci}] = \text{ } \text{minutes}$

ROOM #:

XENON CONCENTRATION $C = \frac{\mu\text{Ci/wk} \times .25}{\text{cfm} \times (1.699 \times 10^6) \times 40 \text{ hrs}} = \frac{\text{ } \times 10^{-4}}{\text{ }} \mu\text{Ci/ml}$

XENON EXPONENTIAL DILUTION FORMULA (The evacuation time following a single release)

$t = (\text{cf} / \text{cfm}) \times \ln_0 [\text{cf} \times 2.832 / \mu\text{Ci}] = \text{ } \text{minutes}$

YES = Adherence	NO = Response required; address and justify	YES / NO
* Negative pressure will be established, set, and checked annually:		___ / ___
* Established ventilation rates will be verified annually, as a minimum:		___ / ___
* Discharge Remote [greater than (>) 25 ft] to all air intakes:		___ / ___
* Re-circulating air in the use room is prevented during use:		___ / ___
* Closed, self-shielded delivery system is used:		___ / ___
* Frequency and efficiency testing protocols of xenon/charcoal trap is consistent with manufacturer=s specifications (must maintain records):		___ / ___
* Doors are closed and exhaust fans are on during, and for 30 minutes following the use of xenon (i.e., Xe-133):		___ / ___

RSO's Signature

APPENDIX F MODEL PROCEDURES FOR CALIBRATION OF DOSE CALIBRATORS

The model procedures provide acceptable methods for dose calibrator testing when measuring photon-emitting radionuclides. Applicants may either adopt this procedure or develop an alternative procedure in accordance with manufacturer's instructions or a national recognized standard.

The tests should be performed at the indicated frequency:

- Constancy, at least once per day prior to assay of patient dosages (+/- 10%)
- Linearity, at installation and at least annually thereafter (+/- 10%)
- Geometry dependence, at installation (+/- 10%)
- Accuracy, at installation and at least annually thereafter (+/- 10%)

The dose calibrator will be repaired, replaced, or corrected arithmetically if the dose calibrator falls outside the suggested tolerances. For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 30 microcuries (1.11 megabecquerels) if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use.

Constancy means reproducibility in measuring a constant source over a long period of time. At least one relatively long-lived source such as cesium-137, cobalt-60, cobalt-57, or radium-226 will be assayed using a reproducible geometry each day before using the calibrator. Two or more sources with different photon energies and activities will also be used.

1. Assay each reference source using the appropriate dose calibrator setting (e.g., use the cesium-137 setting to assay cesium-137).
2. Measure background at the same setting and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
3. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.
4. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Record (e.g., plot, log) the results.
5. Notify the radiation safety officer (RSO) or the authorized user if the test results fall outside +/- 10% of the expected results.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 30 microcuries. This test will be performed using a vial or syringe of technetium-99m whose activity is at least as large as the maximum activity normally assayed for administration.

Time Decay Method

1. Assay the technetium-99m syringe or vial in the dose calibrator and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.
2. Repeat the assay at approximately 4-hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
3. Convert the time and date information you recorded to hours elapsed since the first assay.
4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.
5. Notify the RSO, if the deviation is more than +/- 10%.

Shield Method

"Sleeves" of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

1. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within six minutes (i.e. approximately 1 percent of decay of Tc-99m).
2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4. Continue for all sleeves.
5. Complete the decay method linearity test Steps 2 through 5 above.
6. From the data recorded in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.
7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step 3.
8. Continue for all sleeves.
9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

1. Assay the technetium-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity. Record the net activity.
2. Steps 3 through 5 below must be completed within 6 minutes.
3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
5. Continue for all sleeves.
6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.
7. Notify the RSO, if the worst deviation is more than $\pm 10\%$.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and construction normally used for injections or administrations, and a vial similar in size, shape and construction to the generator and radiopharmaceutical kits normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and

your predetermined safety margin is $\pm 10\%$. If 5 cc syringes 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

Note: If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

1. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 millicuries (mCi)/milliliter. Set out a second small beaker or vial with water.
2. To test the geometry dependence for a 3 cc syringe, draw an additional 0.5 cc of water and assay again. Record the volume and activity indicated.
3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water, and assay again. Record the volume and activity indicated.
4. Repeat the process until you have assayed a 2.0 cc volume.
5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10.0% error lines above and below the chosen "standard volume."
6. Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the $\pm 10\%$ error lines.
8. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water, and assay again. Record the volume and activity indicated.
10. Repeat the process until a 19.0 cc volume has been assayed. The entire process must be completed within 10 minutes.
11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."

12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the $\pm 10\%$ error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g., cobalt-57 or barium-133) will be used. At least once reference source whose activity is within the range of activities normally assayed will be used.

1. Assay a calibrated reference source at the appropriate setting (i.e., use the cobalt-57 setting to assay cobalt-57) and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.
2. The measurement should be within $\pm 10\%$ of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for any other calibrated reference sources possessed.
4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.
5. Notify the RSO if the test results do not agree, within $\pm 10\%$, with the certified value of the reference source(s).
6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (if need not be a certified reference source) on all commonly used radionuclide settings.

APPENDIX G MODEL PROCEDURES FOR REMOTE AFTERLOADER SPOT-CHECKS

This model provides acceptable procedures for performing spot-checks of Remote Afterloader units, equipment, and facilities. Applicants may either adopt these model procedures or develop alternative procedures meeting the criteria of §289.256(nnn).

Periodic Spot-Checks for Remote Afterloader Units

Before the first use on a given day (or before each patient treatment for low-dose-rate remote afterloaders) and after each source installation, the following spot-checks will be performed:

- Electrical Interlocks at Each Room Entrance

Proper functioning of the treatment room door interlock will be performed using the remote afterloader source.

Expose the remote afterloader source inside the treatment room, open the treatment room door, and verify that the source retracts. The source should retract immediately, the area radiation monitor should alarm, and the control console should indicate that the door is open. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Source Exposure Indicator Lights

- Treatment Console Indicators and Status Lamps

Turn on the remote afterloader unit and verify that the indicator lights flash to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the treatment console are lit to indicate an exposed source.

- Remote Afterloader Indicators and Status Lamps

Turn on the remote afterloader unit and verify that the indicator lights flash on the remote afterloader to show proper function. In addition, when the source is exposed for the electrical interlock test above, verify that the source status indicator lights on the remote afterloader are lit to indicate an exposed source.

- Viewing and Intercom Systems

- Viewing System

Turn on the camera(s). Check that the camera(s) is (are) operable and that the treatment area can be viewed from the treatment console. Adjust, if necessary.

— Intercom System

Turn on the intercom system. The intercom system will be tested using a two-person method. One person will be at the treatment console while another person is in the treatment room. Both individuals will speak and confirm that the other is heard.

- Emergency Response Equipment

Verify the presence of the emergency equipment within the treatment room. This equipment includes but is not limited to a mobile lead container large enough to hold the largest applicator, long-handled forceps, wire cutter, flashlight, suture removal kit, and timer (timer located at unit console). If a portable radiation survey meter is included, verify the presence of the meter and check the operability using a radioactive check source.

- Radiation Monitors Used to Indicate the Source Position

Verify that the area radiation monitor located inside the treatment room is on with the indicator light flashing green. Expose the remote afterloader source inside the treatment room with the door closed and verify that the indicator light flashes red; indicating the presence of radiation. This test will be performed with the area radiation monitor on A/C power and on battery backup power.

- Timer Accuracy

Expose the remote afterloader source inside the treatment room with the door closed. Immediately start a stopwatch when the control console indicates that the source is exposed. Stop the stopwatch when the control console indicates that the source is retracted. Compare the stopwatch measured time to the irradiation time indicated on the control console. Verify that the comparison is within 1 percent.

- Clock Date and Time in the Remote Afterloader's Computer

Verify clock date and time printed on the control console documentation of the pretreatment checks against the actual date and time. The date must be exact and the time may be within 1 hour.

- Decayed Source Activity in the Remote Afterloader's Computer

Verify the source activity (or decay factor) displayed on the remote afterloader control console matches to within 0.5 percent of the manufacturer's provided decay table for today's date.

If the results of the above checks indicate the malfunction of any system, the control console shall be locked in the off position, as required by 25 TAC §289.256(nnn)(5), and not used except as may be necessary to repair, replace, or check the malfunctioning system.

In addition, consideration will be given to testing the following before the first use of the remote afterloader unit on a given day:

- Treatment Interrupt Button

Press the "Interrupt" button on the control console while source is exposed. Verify that the source retracts immediately and the control console indicates an alarm. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Emergency Off Button

Press the "Stop" button on the control console while the source is exposed. Verify that the source retracts immediately and the control console indicates an alarm. Repeat the test for all wall-mounted "Stop" buttons. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Dual Use Switch

An x-ray unit is also used in the remote afterloader treatment room, and a selector switch to limit operation to only one unit at a time is installed.

With the key switch on the wall set to x-ray, attempt to expose the remote afterloader source. Verify that the area radiation monitor and the control console source indicator lights do not illuminate; indicating that the source did not expose. Switch the key to remote afterloader. Expose the remote afterloader source and confirm that the area radiation monitor illuminates. With the remote afterloader source still exposed, switch the key back to x-ray, and confirm that the remote afterloader source retracts and the area radiation monitor flashes green. A physical survey of the unit will be performed to ensure that the source has fully retracted to the shielded safe prior to closing the door and clearing all alarms.

- Misconnected or Missing Transfer Tube and/or Applicator

Misconnect a transfer tube to the remote afterloader. This may either be performed by connecting the transfer tube to the wrong channel or by not fully inserting the transfer tube into the correct channel. Attempt to expose the remote afterloader source and verify that the source does not expose as indicated by the area radiation monitor. Additionally, verify that an error is indicated on the control console for the misconnection. Repeat the test with an applicator intentionally misconnected to a transfer tube that is correctly inserted into the remote afterloader.

- Mechanical Integrity of Applicators, Transfer Tubes, Connectors

Perform a visual inspection of all applicators, transfer tubes, and connectors to be used for patient treatments that day. Check for any potential mechanical defects. Replace if a defect is noted.

- Position of Remote Afterloader Within the Treatment Room

For some remote afterloader units located within minimally shielded rooms, the location of use within the room may have been specified in the application to ensure that the regulatory limits in 25 TAC §289.202(n) will be met. If this is the case, verify that the positioning of the remote afterloader unit within the treatment room is in accordance with the commitments made in the application.

APPENDIX H MODEL MEDICAL LICENSEE AUDIT

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit. Also, the audit notes may not be complete for nonmedical uses authorized on the license. Licensees should review audit lists in other volumes of the NUREG-1556 series, as appropriate, when completing the audit list that is specific to nonmedical uses.

Date of this audit: _____

Date of last audit: _____

Date of next audit: _____

Auditor:

<i>Signature</i>	<i>Date</i>
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Management review:

<i>Signature</i>	<i>Date</i>
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All references are to Title 25 Texas Administrative Code (25 TAC) Sections (§) unless noted otherwise.

License (License Condition)

1. License Number.
2. Current Amendment Number.
3. Are all of the tie-down documents on file? [Refer to the dates in the last condition of the license]
4. Has the Legal Entity having control over licensed activities changed since the last audit? Are materials, uses, and locations of use confined to those specifically described in the license?

Audit History

1. Were previous audits conducted annually [§289.202(e)(3)]?
2. Were records of previous audits maintained [§289.202(mm)]?
3. Were any deficiencies identified during previous audit?
4. Were corrective actions taken? (Look for repeated deficiencies.)
5. Any previous problem/deficiency not corrected or repeated?

Organization and Scope of Program

1. Radiation Safety Officer (RSO)
 - a) If the RSO was changed, was the license amended [§289.256(r)(2)(C)]?
 - b) Does the new RSO meet agency training requirements [§289.256(h), §289.256(l), §289.256(m)]?
 - c) If the scope of the program expanded, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [§289.256(h)(6)]?
 - d) Is the RSO fulfilling all duties [§289.256(g)]?
 - e) If the scope of the program expanded, have the RSO duties been updated to reflect the scope of the program [§289.256(g)]?
 - f) Has the agency been notified about a temporary RSO [§289.256(g)(5)]?

g) Are the written agreements and duties and responsibilities in place for the temporary RSO [§289.256(g)(5) and §289.256(1)]?

2. Multiple places of use? If yes, list locations. (License Condition [L/C])

3. Are all locations listed on license? (L/C)

4. Were annual audits performed at each location? If no, explain.

5. Describe the scope of the program (staff, number of procedures performed, etc.)

6. Licensed Material: (L/C)

a) Isotope, chemical form, physical form, quantity, and use as authorized?

b) Does the total amount of radioactive material possessed require financial assurance [§289.252(gg)]? If so, is financial assurance current based on NREG-1757, Volume 3?

c) Calibration, transmission, and reference sources [§289.256(y)]?

i) Sealed sources manufactured and distributed by a person licensed pursuant to §289.252(o), equivalent NRC or Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries (mCi) each [§289.256(y)(1) and (2)]?

ii) Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 mCi [§289.256(y)(3)]?

iii) Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries (μCi) or 1,000 times the quantities in §289.202(qqq)(3) [§289.256(y)(4)]?

iv) Technetium-99m (Tc-99m) in individual amounts as needed [§289.256(y)(5)]?

d) Unsealed materials used under §289.256(ff), §289.256(hh), and §289.256(kk), are:

i. Obtained from a manufacturer or preparer licensed under §289.252(r)?

OR

ii. Obtained from a producer of Positron Emission Tomography radioactive drugs under §289.252(kk)?

OR

iii. Prepared by a physician authorized user (AU), an authorized nuclear pharmacist (ANP), or an individual under the supervision of an ANP or physician AU?

OR

iv. Obtained and prepared for research in accordance with §289.256(ff), §289.256(hh), and §289.256(kk), as applicable?

7. Are the sealed sources possessed and used as described in the Sealed Source and Device Registry registration certificate in §289.252(v), §289.256(rr), §289.256(bbb), §289.256(ddd)? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
8. Are the actual uses of medical devices consistent with the authorized uses listed on the license? (L/C)
9. If places of use/storage changed, was the license amended [§289.256(r)(2)(E)]?
10. If control of the license was transferred or bankruptcy filed, was the agency's prior consent obtained or notification made [§289.252(x)(2) and (6), respectively]?
11. Is radioactive material regulated under §289.256(q) used in accordance with the license conditions and tie-down commitments? (L/C)

Radiation Protection Program

1. Content and implementation reviewed at intervals not to exceed 12 months by the licensee [§289.202(e)(3)]?
2. Records of reviews maintained [§289.202(mm)]?

Nationally Tracked Sources

1. Reports of transactions involving nationally tracked sources submitted to National Source Tracking System [§289.202(hhh)]

Use by Authorized Individuals (L/C)

1. Authorized Nuclear Pharmacist [§289.256(k), §289.256(l), §289.256(m)]
 - a) Listed on license?
2. Authorized User [§289.256(l), §289.256(m), §289.256(gg), §289.256(jj), §289.256(nn), §289.256(oo), §289.256(pp), §289.256(qq), §289.256(zz), §289.256(aaa), §289.256(ccc), §289.256(ttt)]

- a) Listed on license?
- b) Each AU only uses material for which they are authorized
- 3. Authorized medical physicist (AMP) [§289.256(j), §289.256(l), §289.256(m)]
 - a) Listed on license?
 - b) Each AMP only uses material for which they are authorized?
- 4. Non-medical use authorized users [§289.252(e)(1)]
 - Listed on license for same materials and uses?

Mobile Nuclear Medicine Service

- 1. Operates services per §289.256(dd), §289.256(ppp)?
- 2. Compliance with public dose limits evaluated and met [§289.202(n), §289.202(o)]?
- 3. Are all fixed facilities listed on the license? (L/C)
- 4. Mobile Nuclear Medicine Agreement letter signed by management of each client [§289.256(dd)(1)(A)]?
- 5. Licensed material not delivered to client's address, unless client was authorized [§289.256(dd)(2)]?
- 6. Dosage measuring instruments checked for proper function before use at each address of use or on each day of use, if more frequent [§289.256(dd)(1)(B)]?
- 7. Survey instruments checked for proper operation before use at each address of use [§289.256(dd)(1)(E)]?
- 8. Survey all areas of use prior to leaving each client address [§289.256(dd)(1)(F)]?
- 9. Adequate security maintained for mobile trailer? Keypad codes changed or keys retrieved when an employee terminates employment [§289.202(y)]?
- 10. AUs directly supervise each technologist at a reasonable frequency [§289.256(dd)(1)(D)]?
- 11. Compliance with additional technical requirements for mobile remote afterloaders evaluated and met [§289.256(ppp)]?

Amendments Since Last Audit

1. Any amendments since last audit [§289.256(r)]?
2. Security-related sensitive information was properly marked?

Training, Retraining, and Instructions to Workers

1. Is the training program implemented? Have workers been provided with required instructions [§289.203(c), §289.256(s)]?
2. Is the individual's understanding of current procedures and rules adequate?
3. Do appropriate individuals have adequate understanding of appropriate:
 - a) Operating procedures [§289.256(s)]?
 - b) Emergency procedures [§289.256(s)]?
4. Do appropriate individuals have access to the licensee's current operating use and emergency procedures?
5. Periodic training required and implemented [§289.256(ll), §289.256(uu), §289.256(ggg)]?
6. Were all workers who were likely to exceed 100 millirem [1 millisievert] in a year instructed and was refresher training provided, as needed [§289.203(c)]?
7. Was each supervised user instructed in the licensee's written operating, safety, and emergency procedures, administration of written directives (WD), agency rules and license conditions as appropriate [§289.256(s)]?
8. Are initial and periodic training records maintained for each individual [§289.256(ll), §289.256(uu), §289.256(ggg)]?
9. Briefly describe training program.
10. Hazardous Materials (HAZMAT) training [49 CFR Part 172]
11. Do additional therapy device instructions/training include:
 - a) Unit operation, inspection, associated equipment, survey instruments?
 - b) License conditions applicable to the use of the unit?

c) Emergency drills [§289.256(ggg)]?

12. §289.202 – Are workers cognizant of requirements for:

a) Radiation Safety Program [§289.202(e)]?

b) Annual dose limits [§289.202(f), §289.202(n), §289.202(o)]?

c) RC Forms 202-2 and 202-3?

d) 10% monitoring threshold [§289.202(q)]?

e) Dose limits to embryo/fetus and declared pregnant worker [§289.202(m)]?

f) “Grave Danger” posting [§289.202(aa)(3)]?

g) Procedures for opening packages [§289.202(ee)]?

13. Is supervision of individuals by AU in accordance with §289.256(s)?

14. Was training provided for workers involved with emerging technologies in accordance with the agency license and tie-downs?

Training for Manual Brachytherapy and Use of Unsealed Radioactive Material for Which a Written Directive is Required

1. Does safety instruction to personnel include [§289.256(ll), §289.256(uu)]:

a) Control of patient and visitors?

b) Routine visitation to patients in accordance with §289.202(n)?

c) Contamination control and size/appearance of sources?

d) Safe handling and shielding instructions?

e) Waste control?

f) RSO and AU notification if patient had a medical emergency or died?

g) Records retained?

Facilities

1. Facilities as described in license application? (L/C)

2. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?
3. Emergency source recovery equipment available [§289.256(vv), §289.256(hhh)]
4. Storage areas:
 - a) Material secured from unauthorized removal or access [§289.202(y)]?
 - b) Licensee controls and maintains constant surveillance of licensed material not in storage [§289.202(y)]?
 - c) Locations appropriately shielded to control public and occupational exposures in accordance with §289.202?
5. Therapy unit operation:
 - a) Unit, console, console keys, and treatment room controlled adequately [§289.256(ggg)(1)]?
 - b) Restricted to certain source orientations and/or gantry angles? (L/C)
 - c) Ceases to operate in restricted orientation(s)? (L/C)
 - d) Only one radiation device can be placed in operation at a time within the treatment room [§289.256(ggg)(3)]?

Dose or Dosage Measuring Equipment

1. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [§289.256(v)]:
 - a) Types of equipment listed?
 - b) Approved procedures for use of instrumentation followed?
 - c) Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
 - d) Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., $\pm 10\%$)?

- e) Records maintained and include required information [§289.256(v)]?
2. Determination of dosages of unsealed radioactive material [§289.256(x)]?
 - a) Each dosage determined and recorded prior to medical use [§289.256(x)(1)]?
 - b) Measurement of unit dosages of alpha-, beta-, or photon-emitting radionuclides made either by direct measurement or by decay correction of the activity provided by the licensed producer [§289.256(x)(2)]?
 - c) For other than unit dosages of alpha-, beta-, or photon-emitting radionuclides, measurement made by direct measurement of radioactivity [§289.256(x)] or by combination of radioactivity or volumetric measurement and calculation using the activity provided by the licensed producer [§289.256(x)(3)]?
 3. Licensee uses generators?
 - a) First eluate after receipt tested for molybdenum-99 (Mo-99) breakthrough [§289.256(ii)(2)]?
 - b) No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μ Ci per mCi of Tc-99m [§289.256(ii)(1)(A)]?
 - c) First eluate after receipt tested for strontium-82 (Sr-82) and strontium-85 (Sr-85) when eluting rubidium-82 (Rb-82) [§289.256(ii)(3)]?
 - d) No radiopharmaceuticals administered with Sr-82 concentrations over 0.02 μ Ci per mCi of Rb-82 or Sr-85 concentrations over 0.2 μ Ci per mCi of Rb-82 [§289.256(ii)(1)(B) and (C)]?
 - e) Records maintained [§289.256(ii)(4)]?
 4. Confirmation of source output or activity for manual brachytherapy sources? Alternatively, the manufacturer's measurements may be accepted if the criteria in §289.256(ww)(2) have been met.
 5. Dosimetry Equipment [§289.256(iii)]:
 - a) Calibrated system available for use [§289.256(iii)(1)]?
 - b) Calibrated by National Institute of Standards and Technology or an American Association of Physicists in Medicine (AAPM)-accredited lab within previous 2 years and after servicing [§289.256(iii)(1)(A)] OR calibrated by intercomparison per §289.256(iii)(1)(B)?

- c) Calibrated within the previous 4 years [§289.256(iii)(1)(B)]?
- d) Licensee has available for use a dosimetry system for spot-check measurements [§289.256(iii)(2)]?
- e) Record of each calibration, intercomparison, and comparison maintained [§289.256(iii)(3)]?

Radiation Protection and Control of Radioactive Material

1. Use of radiopharmaceuticals:

- a) Protective clothing worn?
- b) Personnel routinely monitor their hands?
- c) No eating/drinking in use/storage areas?
- d) No food, drink, or personal effects kept in use/storage areas?
- e) Proper dosimetry worn?
- f) Radioactive waste disposed of in proper receptacles?
- g) Syringe shields and vial shields used and are specific to the energy emitted?
- h) Proper use of remote handling tools and radiation shields?

2. Leak tests and inventories:

- a) Leak test performed on sealed sources and brachytherapy sources at appropriate intervals [§289.201(g)]?
- b) Inventory of sealed sources and brachytherapy sources performed at intervals not to exceed six months [§289.256(z)(2)]?
- c) If applicable, transactions associated with nationally tracked sources entered into the National Source Tracking System, including annual reconciliation [§289.202(hhh)]?
- d) Records maintained [§289.256(www)]?

Radiation Survey Instruments

1. Survey instruments used to show compliance with §289.202:
 - a) Appropriate operable survey instruments possessed or available [§289.202]?
 - b) Calibrations [§289.202(p)(3)]?
 - i. Before first use, annually, and after repairs?
 - ii. Within 20% on each scale or decade of interest, as applicable?
 - iii. Instrument sent to a licensed instrument service provider?
 - iv. Copy of instrument service provider license on file?
 - c) Records maintained [§289.202(nn)(2)]?
2. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [§289.202)(p), §289.256(bb)]?
 - a) Daily in all areas where radiopharmaceuticals requiring a WD are prepared or administered (except patient rooms) [§289.256(bb)]?
 - b) At least weekly in all areas where radiopharmaceuticals or wastes are stored?
 - c) At least weekly for wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
 - d) Trigger levels established?
 - e) Corrective action taken and documented if trigger level exceeded?
 - f) Techniques can detect 0.1 milliroentgen/hour, 1,000 disintegrations per minute?
 - g) Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry and records maintained [§289.256(qqq)]?
 - i. After new source installation?
 - ii. Following repairs to the source(s) shielding, the source(s) driving unit or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

1. Is licensed material used in a manner to keep doses below 100 mrem in a year [§289.202(n)(1)(A)]?
2. Has a survey or evaluation been performed per §289.202(p)(1)?
3. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
4. Do unrestricted area radiation levels exceed 2 mrem in any one hour [§289.202(n)(1)(B)]?
5. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [§289.202(y)]?
6. Are records maintained [§289.202(nn), §289.202(ss)]?

Patient Release

1. Individuals released when total effective dose equivalent (TEDE) is less than 0.5 rem [5 mSv] [§289.256(cc)(1)]?
2. Instructions to the released individual, including breastfeeding women, include required information [§289.256(cc)(2)]?
3. Release records maintained [§289.256(cc)(3)(A)]?
4. Records of instructions given to breastfeeding women maintained, if required [§289.256(cc)(3)(B)]?

Unsealed Radioactive Material for Which a Written Directive Is Required

1. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [§289.256(mm)]?
2. RSO and AU promptly notified if patient had a medical emergency or died [§289.256(mm)(5)]?

Brachytherapy or Brachytherapy Source Use

1. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [§289.256(vv)]?
2. Survey immediately after implant [§289.256(ss)(1)]?
3. Patients surveyed immediately after removing the last temporary implant source [§289.256(ss)(2)]?
4. RSO and AU promptly notified if patient had a medical emergency or died [§289.256(vv)(2)]?
5. Records maintained [§289.256(ss)(3)]?

Radioactive Waste

1. Disposal:
 - a) Decay-in-storage [§289.256(ee)]?
 - b) Procedures followed?
 - c) Labels removed or defaced [§289.256(ee)(1)(B)]?
2. Special procedures performed as required?
3. Authorized disposals [§289.202(ff)]?
4. Records maintained [§289.202(nn)(1), §289.202(tt), §289.256(ee)(2)]?
5. Effluents:
 - a) Release to sanitary sewer [§289.202(gg)]?
 - i. Material is readily soluble or readily dispersible [§289.202(gg)(1)(A)]?
 - ii. Monthly average release concentrations do not exceed Table III of §289.202(ggg)(2) values?
 - iii. No more than 5 curies (Ci) of H-3, 1 Ci of C-14, and 1 Ci of all other radionuclides combined, released in a year [§289.202(gg)(D)]?
 - iv. Procedures to ensure representative sampling and analysis implemented [§289.202(p)]?

b) No release to septic tanks except as specifically approved by the agency [§289.202(ii)]?

c) Waste incinerated?

i. License authorizes [§289.202(hh)]?

ii. Exhaust directly monitored?

iii. Airborne releases evaluated and controlled [§289.202(o), §289.202(p)]?

d) Air effluents controlled [§289.202(e), §289.202(f), §289.202(n)]?

i. Air effluent less than 10 mrem constraint limit [§289.202(e)(4)]?

1. If no, reported appropriate information to the agency?

2. If no, corrective actions implemented and on schedule?

ii. Description of effluent program:

1. Monitoring system hardware adequate?

2. Equipment calibrated, as appropriate?

3. Air samples/sampling technique (e.g., charcoal, high-efficiency particulate air) analyzed with appropriate instrumentation?

6. Waste storage:

a) Protection from elements and fire?

b) Control of waste maintained [§289.202(y)]?

c) Containers properly labeled and area properly posted [§289.202(aa), §289.202(cc)]?

d) Package integrity adequately maintained?

7. Waste disposal:

a) Sources transferred to authorized individuals [§289.202(jj), §289.202(ff), §289.252(cc)]?

b) Name of organization: _____.

c) Copy of waste disposal recipient's license on file?

8. Records of surveys and material accountability maintained [[§289.202(nn), §289.202(tt), §289.256(ee)(2)]?

Receipt and Transfer of Radioactive Material

1. Description of how packages are received and by whom?
2. Written package-opening procedures established and followed [§289.202(ee)]?
3. All incoming packages with a U.S. Department of Transportation (DOT) label monitored for radioactive contamination, unless exempted (gases and special form) [§289.202(ee)(2)(A)]?
4. Incoming packages surveyed [§289.202(ee)(2)(B)]?
5. Monitoring performed within time specified [§289.202(ee)(3)]?
6. Transfer(s) performed per [§289.252(cc)]?
7. All sources surveyed before shipment and transfer [§289.202(p)]?
8. Records of surveys and receipt/transfer maintained [§289.202(nn), §289.201(d)]?
9. Package receipt/distribution activities evaluated for compliance with §289.202(n)?

Transportation (25 TAC §289.257 and 49 CFR 171-178)

1. Shipments are:
 - a) Delivered to common carriers?
 - b) Transported in own private vehicle?
 - c) Both?
 - d) No shipments since last audit?
2. Return radiopharmacy doses to drug manufacture or commercial nuclear pharmacy or sealed sources to source or device manufacturer?
 - a) Licensee assumes shipping responsibility?

- b) If "NO," describe arrangements made between licensee and radiopharmacy for shipping responsibilities.

3. Packages:

- a) Authorized packages used [49 CFR 173.415, 416]?
- b) Performance test records on file?
 - i. DOT-7A packages
 - ii. special form sources
- c) Two labels (White-I, Yellow-II, Yellow-III) with Transport Index (TI), Nuclide, Activity, and Hazard Class?
- d) Properly marked [49 CFR 172.403, 172.441, 173.471]?
- e) Closed and sealed during transport [49 CFR 173.475(f)]?

4. Shipping Papers:

- a) Prepared and used [49 CFR 172.200(a)]?
- b) Contain proper entries [49 CFR 172.200-204]?
- c) Readily accessible during transport [49 CFR 177.817(e)]?

5. Any incidents reported to DOT [49 CFR 171.15, 171.16]?

Teletherapy and Gamma Stereotactic Radiosurgery

- 1. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [§289.256(rrr)]?
- 2. Needed service arranged for as identified during the inspection?
- 3. Service performed by persons specifically authorized to do so [§289.256(rrr)(2)]?
- 4. Were security requirements implemented, if applicable [§289.252(ii)]

Full Calibration – Therapeutic Medical Devices

- 1. Proper protocol(s) used (e.g., AAPM Task Group (TG)–21 (TG-21), AAPM 54,

AAPM TG-56, AAPM TG-40)?

2. Performed prior to first patient use [§289.256(jjj)(1)(A), §289.256(kkk)(1)(A), §289.256(III)(1)(A)]?
3. At intervals not to exceed 1 year for teletherapy, gamma stereotactic radiosurgery (GSR), and low dose-rate (LDR) remote afterloader; at intervals not exceeding 1 quarter for high dose-rate, medium dose-rate (MDR), and pulsed dose-rate (PDR) remote afterloaders [§289.256(jjj)(1)(C), §289.256(kkk)(1)(C) and (D), §289.256(III)(1)(C)]?
4. Whenever spot-checks indicate output differs from expected by $\pm 5\%$ [§289.256(jjj)(1)(B)(i), §289.256(III)(1)(B)(i)]?
5. After source exchange, relocation, and major repair or modification [§289.256(jjj)(1)(B), §289.256(kkk)(1)(B), §289.256(III)(1)(B)]?
6. Performed with properly calibrated instrument [§289.256(jjj)(3), §289.256(kkk)(3) and (D), §289.256(III)(3)]?
7. Includes:
 - a) For teletherapy:
 - i. Output measured within $\pm 3\%$ of expected for the range of field sizes, range of distances [§289.256(jjj)(2)(A)]?
 - ii. Coincidence of radiation field and field light localizer [§289.256(jjj)(2)(B)]?
 - iii. Uniformity of radiation field and beam angle dependence [§289.256(jjj)(2)(C)]?
 - iv. Timer accuracy and linearity over the range of use [§289.256(jjj)(2)(D)]?
 - v. On-off error [§289.256(jjj)(2)(E)]?
 - vi. Accuracy of all measuring and localization devices [§289.256(jjj)(2)(F)]?
 - b) For remote afterloaders:
 - i. Output measured within $\pm 5\%$ of expected [§289.256(kkk)(2)(A)]?
 - ii. Source positioning accuracy within ± 1 millimeter [§289.256(kkk)(2)(B)]?

- iii. Source retraction with backup battery upon power failure [§289.256(kkk)(2)(C)]?
- iv. Length of source transfer tubes [§289.256(kkk)(2)(D)]?
- v. Timer accuracy and linearity over the typical range of use [§289.256(kkk)(2)(E)]?
- vi. Length of the applicators [§289.256(kkk)(2)(F)]?
- vii. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [§289.256(kkk)(2)(G)]?
- viii. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [§289.256(kkk)(5)]?

c) For gamma stereotactic radiosurgery:

- i. Output measured within $\pm 3\%$ of expected [§289.256(III)(2)(A)]?
- ii. Helmet factors [§289.256(III)(2)(B)]?
- iii. Isocenter coincidence [§289.256(III)(2)(C)]?
- iv. Timer accuracy and linearity over the range of use [§289.256(III)(2)(D)]?
- v. On-off error [§289.256(III)(2)(E)]?
- vi. Trunnion centricity [§289.256(III)(2)(F)]?
- vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [§289.256(III)(2)(G)]?
- viii. Helmet micro switches [§289.256(III)(2)(H)]?
- ix. Emergency timing circuit [§289.256(III)(2)(I)]?
- x. Stereotactic frames and localizing devices (trunnions) [§289.256(III)(2)(J)]?

8. Output corrected mathematically for decay [§289.256(jjj)(7), §289.256(kkk)(9), §289.256(III)(7)]?

9. Records maintained [§289.256(jjj)(5), §289.256(kkk)(7), §289.256(III)(5)]?

Periodic Spot-Checks for Therapeutic Devices

1. Performed at required frequency [§289.256(mmm)(1), §289.256(nnn)(1), §289.256(ooo)(1)]?
2. Procedures established by AMP [§289.256(mmm)(2), §289.256(nnn)(2), §289.256(ooo)(2)]?
3. Procedures followed?
4. Medical physicist reviews results within 15 days [§289.256(mmm)(4), §289.256(nnn)(3), §289.256(ooo)(3)]?
5. Performed with properly calibrated instrument [§289.256(mmm)(1)(E), §289.256(ooo)(4)(B)(i)]?
6. Output and safety spot-checks include:
 - a) For teletherapy:
 - i. Timer accuracy and linearity over the range of use [§289.256(mmm)(1)(A)]?
 - ii. On-off error [§289.256(mmm)(1)(B)]?
 - iii. Coincidence of radiation field and field light localizer [§289.256(mmm)(1)(C)]?
 - iv. Accuracy of all measuring and localization devices [§289.256(mmm)(1)(D)]?
 - v. The output for one typical set of operating conditions [§289.256(mmm)(1)(E)]?
 - vi. Difference between measured and expected output [§289.256(mmm)(1)(F)]?
 - vii. Interlock systems [§289.256(mmm)(3)(A)]?
 - viii. Beam stops [§289.256(mmm)(3)(B)]?
 - ix. Source exposure indicator lights [§289.256(mmm)(3)(C)]?
 - x. Viewing and intercom systems [§289.256(mmm)(3)(D)]?
 - xi. Treatment room doors, inside and out [§289.256(mmm)(3)(E)]?

xii. Electrical treatment doors with power shut off [§289.256(mmm)(1)(F)]?

b) For remote afterloaders:

i. Interlock systems [§289.256(nnn)(4)(A)]?

ii. Source exposure indicator lights [§289.256(nnn)(4)(B)]?

iii. Viewing and intercom systems, except for LDR [§289.256(nnn)(4)(C)]?

iv. Emergency response equipment [§289.256(nnn)(4)(D)]?

v. Radiation monitors used to indicate source position [§289.256(nnn)(4)(E)]?

vi. Timer accuracy [§289.256(nnn)(4)(F)]?

vii. Clock (date and time) in the unit's computer [§289.256(nnn)(4)(G)]?

viii. Decayed source(s) activity in the unit's computer [§289.256(nnn)(4)(H)]?

c) For gamma stereotactic radiosurgery:

i. Treatment table retraction mechanism [§289.256(ooo)(4)(A)(i)]?

ii. Helmet microswitches [§289.256(ooo)(4)(A)(ii)]?

iii. Emergency timing circuits [§289.256(ooo)(4)(A)(iii)]?

iv. Stereotactic frames and localizing devices [§289.256(ooo)(4)(A)(iv)]?

v. The output for one typical set of operating conditions [§289.256(ooo)(4)(B)(i)]?

vi. Difference between measured and expected output [§289.256(ooo)(4)(B)(ii)]?

vii. Source output compared against computer calculation of output [§289.256(ooo)(4)(B)(iii)]?

viii. Timer accuracy and linearity over the range of use [§289.256(ooo)(4)(B)(iv)]?

ix. On-off error [§289.256(ooo)(4)(B)(v)]?

- x. Trunnion centricity [§289.256(ooo)(4)(B)(vi)]?
 - xi. Automatic positioning system?
 - xii. Interlock systems [§289.256(ooo)(5)(A)]?
 - xiii. Source exposure indicator lights [§289.256(ooo)(5)(B)]?
 - xiv. Viewing and intercom systems [§289.256(ooo)(5)(C)]?
 - xv. Timer termination [§289.256(ooo)(5)(D)]?
 - xvi. Radiation monitors used to indicate room exposures [§289.256(ooo)(5)(E)]?
 - xvii. Emergency off buttons [§289.256(ooo)(5)(F)]?
7. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [§289.256(mmm)(5), §289.256(nnn)(5), §289.256(ooo)(7)]?
 8. Records maintained [§289.256(mmm)(6), §289.256(nnn)(6), §289.256(ooo)(8)]?

Installation, Maintenance, and Repair of Therapy Devices

1. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [§289.256(fff), §289.256(rrr)]? Name of organization/individual.
2. License verification?
3. Records maintained [§289.256(fff)(4), §289.256(rrr)(3)]?

Emergency Procedures for Therapy Devices

1. Instructions on location of emergency procedures and emergency response telephone numbers posted at the device console [§289.256(ggg)(5)]?
2. Procedures include:
 - a) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions

[§289.256(ggg)(4)(A)]?

- b) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [§289.256(ggg)(4)(B)]?
- c) The names and telephone numbers of the AUs, the AMP, and the RSO to be contacted if the unit or console operates abnormally [§289.256(ggg)(4)(C)]?

3. AMP and AU:

- a) Physically present during initiation of patient treatment with remote after-loaders? (Note: for MDR and PDR, an appropriately trained physician under the supervision of the AU may be physically present instead of the AU) [§289.256(hhh)(6)(B)(i)]
- b) Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [§289.256(hhh)(6)(C)]

Patient Surveys and Therapy Devices

- 1. Radiation survey of patient is performed to ensure source is returned to shielded position [§289.256(eee)]
- 2. RSO and AU promptly notified if patient had a medical emergency or died [§289.256(hhh)(6)(D)]
- 3. Records of radiation surveys maintained for 3 years [§289.256(eee)(2)]

Personnel Radiation Protection

- 1. Exposure evaluation performed [§289.202(p)]?
- 2. As low as is reasonably achievable (ALARA) program implemented [§289.202(e)]?
- 3. External Dosimetry:
 - a) Monitors workers per [§289.202(q)(1)]?
 - b) External exposures account for contributions from airborne activity [§289.202(h)]?
 - c) Supplier Frequency_____
 - d) Supplier is National Voluntary Laboratory Accreditation Program –approved

[§289.202(p)(4)]?

e) Dosimeters exchanged at required frequency?

4. Internal Dosimetry:

a) Monitors workers per §289.202(q)?

b) Program for monitoring and controlling internal exposures [§289.202(v), §289.202(w)] briefly described?

c) Monitoring/controlling program implemented (includes bioassays)?

d) Respiratory protection equipment [§289.202(x)]?

5. Review of Records and Reports:

a) Reviewed by _____ Frequency _____

b) Auditor reviewed personnel monitoring records for period _____ to _____

c) Prior dose determined for individuals likely to receive doses [§289.202(j)]?

d) Maximum exposures TEDE _____ Other _____

e) Maximum committed dose equivalents (CDEs) _____ Organs

f) Maximum CEDE _____

g) Internal and external summed [§289.202(g)]?

h) Occupational limits met for adults [§289.202(f)]?

i) If applicable, occupational limits met for minors [§289.202(l)]?

j) Agency forms or equivalent [§289.202(j)(2) and (3)]?

i. RC Form 202-2 Complete:

ii. RC Form 202-3 Complete:

k) If a worker declared her pregnancy during the audit period, was the dose in compliance [§289.202(m)] and were the records maintained [§289.202(rr)(4)]?

6. Any planned special exposures (number of people involved and doses received) §289.202(k)?
7. Records of exposures, surveys, monitoring, and evaluations maintained [§289.202(mm), §289.202(nn), §289.202(rr)]?

Security Program for Category 1 and Category 2 Materials [§289.252(ii)]

1. Background investigations and access control program §289.252(ii)(3) – (8)
2. Security program content and implementation reviewed annually and maintain records for 3 years [§289.252(ii)(16)]
3. Physical protection in transit [§289.252(ii)(18) – (23)]?
4. Records [§289.252(ii)(24) and (25)]?

Confirmatory Measurements

1. Detail location and results of confirmatory measurements.

Medical Events

If medical events meeting the criteria in §289.256(uuu) have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering WDs using the existing guidance.

1. Event date _____ Information Source _____
2. Notifications:
 - _____ Agency
 - _____ Referring Physician
 - _____ Patient
 - _____ In writing
 - _____ By telephone

If notification did not occur, why not?

3. Written Reports [§289.256(uuu)]: Submitted to the agency within 15 days?
4. Patient intervention that resulted in the total dose or dosage not being administered? Describe each intervention.

Notification and Reports

1. In compliance with 25 TAC §289.202(aaa), and the "Reports" section of §289.202 (reports to individuals, public and occupational, monitored to show compliance with §289.202)?
2. In compliance with §289.202(ww) (theft or loss)?
3. In compliance with §289.202(xx) (incidents)?
4. In compliance with §289.202(yy) (overexposure and high radiation levels)?
5. Aware of agency Radiological Emergency Assistance number?
6. In compliance with §289.202(yy) (constraint on air emissions)?

Posting and Labeling

1. RC Form 203-1, "Notice to Workers" is posted [§289.203(b)]?
2. §289.202, §289.203, the license, operating procedures applicable to work under the license and any notice of violation are posted, or a notice indicating where documents can be examined is posted [§289.203(b)]?
3. Other posting and labeling per §289.202(aa) and (cc), and not exempted by §289.202(bb) and (dd)?

Recordkeeping for Decommissioning

1. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [§289.252(gg)]?
2. Records include all information outlined in [§289.252(gg)(7)]?

Special License Conditions or Issues (L/C)

Special license condition or issues to be reviewed:

1. If authorized for §289.256(q) medical uses, review the program for conformance with license application commitments, license conditions and rules.
2. Other special license conditions.

Performance-Based Review

1. Conduct performance-based reviews of radiation workers performing licensed activities:
 - a) to assess the capability of the radiation workers to maintain exposures ALARA;
 - b) to assess that radiation workers follow the operating procedures;
 - c) to assess the effectiveness of the operating procedures and compliance with the rules, license conditions and the licensee commitments submitted in support of a license (and incorporated by "tie-down" conditions);
 - d) to ensure the safe and secure use of radioactive material;
 - e) to verify that radiation workers are cognizant of the emergency procedures and, if necessary, would be able to implement them and maintain exposures ALARA; and
 - f) to ensure that emergency procedures have been developed for all likely scenarios.
2. Take the necessary actions to address programmatic and performance deficiencies with radiation workers and facilitate immediate corrective actions.

Evaluation of Other Factors

1. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight?
2. RSO has sufficient time to perform radiation safety duties and is not too busy with other assignments?
3. Licensee has sufficient staff?

Audits and Findings

1. Summary of findings
2. Corrective and preventive actions
3. Amendment required?

APPENDIX I MODEL PROCEDURES FOR OCCUPATIONAL DOSE PROGRAM

This model provides acceptable procedures for an external occupational dose program and references and resources for developing an internal occupational dose program. Applicants may either adopt these model procedures for an external occupational dose program or develop alternative procedures to meet the requirements of 25 TAC §289.202(e) and the "Occupational Dose Limits" and "Surveys and Monitoring" sections of 25 TAC §289.202. The model includes guidance as well as a discussion of regulatory requirements that are to be reflected in the elements of an occupational dose program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 25 TAC §289.202(q)(1). The occupational dose limits for adults are provided in 25 TAC §289.202(f), while 25 TAC §289.202(q), "Conditions requiring individual monitoring of external and internal occupational dose," provides, in part, that adults likely to receive in a year a dose in excess of 10% of those dose limits must be provided with dosimetry. Definitions of relevant terms such as total effective dose equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in 25 TAC §289.201(b), "Definitions." In addition, if monitoring is required pursuant to 25 TAC §289.202(q), each licensee shall maintain records of doses received (see 25 TAC §289.202(rr), "Records of individual monitoring results") and individuals must be informed of their doses on at least an annual basis (see 25 TAC §289.203(d), "Notifications and reports to individuals").

If an individual is likely to receive more than 10% of the annual dose limits, the agency requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of his or her dose.

The licensee must consider the dose that an individual may receive in the current year from all sources of employment where the individual's assigned duties involve exposure to sources of radiation. The licensee must obtain a record of the individual's occupational dose, as described in 25 TAC §289.202(j)(2) and reduce the dose that an individual is allowed to receive in the current year by the amount of occupational dose received while employed by any other person. If the licensee is unable to obtain a complete record of an individual's current occupational dose while employed by another licensee, the licensee must reduce the dose limit for the individual by 1.25 rems (12.5 mSv) for each quarter or 416 mrem (416 mSv) for each month for which records were not available and the individual could have received an occupational exposure.

The As-Low-As-Reasonably-Achievable “ALARA” Program

Rules in 25 TAC §289.202(e) state that “each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities” and “the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).” Additionally, 25 TAC §289.202(e) requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels.

There are three dose limits included in 25 TAC §289.202(f) that apply to external exposure: deep dose to the whole body [5 rem or 0.05 Sievert (Sv)], shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). According to the definitions in 25 TAC §289.201(b), the DDE to the whole body is considered to be at a tissue depth of 1 centimeter (cm) [1,000 milligram (mg)/square centimeters (cm²)], shallow-dose equivalent (SDE) to the skin or extremities at 0.007 cm [7 mg/cm²], and eye dose equivalent at 0.3 cm [300 mg/cm²]. In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Under 25 TAC §289.202(q)(1), the use of individual monitoring devices is required for the following:

- Adults likely to receive, in a year, from sources external to the body, a dose in excess of 10% of the occupational dose limits in §289.202(f)(1). Monitoring devices are accordingly required for adults with an annual dose in excess of
 - 0.5 rem [0.005 Sv] DDE
 - 1.5 rem [0.015 Sv] eye dose equivalent
 - 5 rem [0.05 Sv] SDE to the skin
 - 5 rem [0.05 Sv] SDE to any extremity
- Minors who are likely to receive an annual dose in excess of:
 - 0.1 rem [1.0 millisievert (mSv)] DDE
 - 0.15 rem [1.5 mSv] eye dose equivalent

- 0.5 rem [5 mSv] SDE to the skin, or
- 0.5 rem [5 mSv] SDE to any extremity
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem [1.0 mSv] DDE during the entire pregnancy.
- Individuals entering a high- or a very-high-radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, the agency does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

- Prior Experience: Reviews of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits.
- Area Surveys: Demonstrate through the conduct of appropriate radiation level surveys [e.g., using a radiation survey meter or area thermoluminescent dosimeters (TLDs)] in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (exposures associated with reasonable “accident” scenarios should also be evaluated).
- The licensee performs a reasonable calculation, based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters, or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program-approved, as required by 25 TAC §289.202(p)(4).

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year [25 TAC §289.202(f)(3)]. When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

If the radiation dose is highly nonuniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest

dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

Under 25 TAC §289.202(rr), individual monitoring must be recorded on RC Form 202-3, "Occupational Exposure Record for a Monitoring Period," or equivalent. RC Form 202-3 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

If an individual's dosimeter is lost, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record in order to demonstrate compliance with occupational dose limits in 25 TAC §289.202(f). Sometimes the most reliable method for estimating an individual's dose is to use his or her recent dose history. In other cases, particularly if the individual performs non-routine types of work, it may be better to use doses of coworkers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

Investigational Levels are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," Investigational Levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's dose or the dose for a group of workers needs to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table G-1 (i.e., 10% of the annual limit for occupational exposure), the radiation safety officer (RSO) or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence.

When the cumulative annual exposure exceeds the Investigational Level II in Table G-1 (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table G-1 Investigational Levels

Part of Body	Investigational Level I (mrem/year)	Investigational Level II (mrem/year)
whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee	500 [5 mSv]	1,500 [15 mSv]
hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin	5,000 [50 mSv]	15,000 [150 mSv]
lens of the eye	1,500 [15 mSv]	4,500 [45 mSv]

Review and record on RC Form 202-3, "Occupational Exposure Record for a Monitoring Period," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table G-1 are reached:

- Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than Table G-1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required, unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other

individuals engaged in similar tasks to determine if improvements or additional safety measures are needed to reduce exposures. Evaluate, in the context of ALARA program quality, and record the results of investigations and evaluations.

- Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. The RSO should consider actions to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Reestablishment of Investigational Level II to a level above that listed in Table G-1.

Declared Pregnancy and Dose to Embryo/Fetus

Rules in 25 TAC §289.202(m), "Dose equivalent to an embryo/fetus," state that the licensee shall ensure that the dose to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem [5 mSv]. The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo or fetus shall be taken as the sum of

- the DDE to the declared pregnant woman
- the dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman

Licensees should reference the NRC's RG 8.13, "Instructions Concerning Prenatal Radiation Exposure," June 1999, for information to help pregnant women and other personnel make decisions regarding radiation exposure during pregnancy and RG 8.36, "Radiation Dose to the Embryo/Fetus," July 1992, for calculating the radiation dose to the embryo/fetus.

Internal Exposure

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the annual limit on intake (ALI) from intakes in a year [25 TAC §289.202(q)]. Terms for radionuclide intakes by means of inhalation and ingestion (i.e., derived air concentration (DAC) and ALI) are provided in 25 TAC §289.202.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in microcurie (μCi)/milliliter that, if an occupational worker were to be continuously exposed to it for 2,000 hours (1 year), would result in either a CEDE of 5 rem [0.05 Sv] to the whole body or a committed dose equivalent of 50 rem [0.5 Sv] to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in §289.202(ggg)(2).

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem [0.05 Sv] or a committed dose equivalent of 50 rem [0.5 Sv] to any individual organ or tissue; again, with no consideration for the contribution of external dose.

The TEDE concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers in 25 TAC §289.202 reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (WT), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." Per 25 TAC §289.202(ggg)(2), when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the nonstochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities, require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include

- adequate equipment to perform bioassay measurements
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into microcurie or becquerel units
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue)
- the interval between bioassays

- action levels
- the actions to be taken at those levels

For additional guidance on developing occupational dose programs refer to the following NRC documents:

- Regulatory Guide (RG) 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," July 1993.
- RG 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses," July 1992.
- National Council on Radiation Protection and Measurements (NCRP) Report No. 87,
- "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," February 1987.
- NUREG/CR-4884, "Interpretation of Bioassay Measurements," July 1987.
- NUREG-1400, "Air Sampling in the Workplace," September 1993.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 25 TAC §289.202(rr). For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to the NRC's RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," November 2005.

Summation of External and Internal Doses

Pursuant to 25 TAC §289.202(g), "Compliance with requirements for summation of external and internal doses," the external and internal doses must be summed if required to monitor both under 25 TAC §289.202(q). Regulatory Issue Summary (RIS) 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," April 16, 2002, contains helpful information regarding occupational doses.

Copies of Regulatory Issue Summaries are available on the NRC Web site in the Electronic Reading Room <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues>.

APPENDIX J MODEL EMERGENCY PROCEDURES

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed, or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

The name and telephone number of the radiation safety officer (RSO) should be posted conspicuously in areas of use, so that it is readily available to workers in case of emergencies.

Licensee should have emergency equipment readily available for handling spills. Spill/contamination kits should include the following items:

- disposable gloves
- disposable lab coats
- disposable head coverings
- disposable shoe covers
- roll of absorbent paper with plastic backing
- masking tape
- plastic trash bags with twist ties
- "radioactive material" labeling tape
- marking pen
- prestrung "Radioactive Material" labeling tags
- contamination wipes
- instructions for "Emergency Procedures"
- clipboard with copy of Radioactive Spill Report Form
- pencil
- appropriate survey instruments, including batteries

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as

the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest annual limit on intake (ALI), an alternative spill/contamination procedure may be to restrict access pending complete decay. In most cases, determination of a major versus minor spill should be based on the lowest ALI.

The licensee should estimate the amount of radioactivity spilled and initiate a major or minor spill/contamination procedure. Use Table H-1 as general guidance to determine whether a major spill/contamination procedure or a minor spill/contamination procedure will be implemented. Spills above these millicurie (mCi) amounts are considered major, and spills below these levels are considered minor.

Table H-1 Relative Hazards of Common Radionuclides

Radionuclide	mCi	Radionuclide	mCi
Nitrogen-13	100	Technetium-99m	100
Carbon-14	10	Indium-111	10
Oxygen-15	100	Iodine-123	10
Fluorine-18	100	Iodine-125	1
Phosphorus-32	1	Iodine-131	1
Gallium-67	10	Samarium-153	10
Rubidium-82	10	Ytterbium-169	10
Strontium-82	1	Mercury-197	10
Strontium-85	10	Gold-198	10
Strontium-89	1	Thallium-201	100
Yttrium-90	1	Alpha emitters	*

*For radiopharmaceuticals where the primary emission is alpha, consider implementing major spill precautions.

Minor Spills of Liquids and Solids:

Instructions to Workers

- Notify persons in the area that a spill has occurred.
- Prevent the spread of contamination by covering the spill with absorbent paper.
- Wear gloves and protective clothing such as a lab coat and booties, and clean up the spill using absorbent paper.
- Carefully fold the absorbent paper with the clean side out and place in a bag labeled "caution radioactive material" for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.
- Survey the area with an appropriate low-range radiation detection instrument sufficiently sensitive to detect the radionuclide. Survey for removable contamination to ensure contamination levels are below trigger levels. Survey the area around the spill.
- Survey hands, clothing, and shoes for contamination prior to leaving the area.
- Report the incident to the RSO promptly.
- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Follow up on the decontamination activities and document the results.
- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If necessary, notify the agency.

Major Spills of Liquids and Solids

Instructions to Workers

- Clear the area. Notify all persons not involved in the spill to vacate the room.
- Prevent the spread of contamination by covering the spill with absorbent paper labeled "caution radioactive material," but do not attempt to clean it up. Paper should be dampened, if solids are spilled. To prevent further spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
- Shield the source only if it can be done without further contamination or a significant increase in radiation exposure.
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred.
- Notify the RSO immediately.
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap.
- Cooperate and follow the instructions of the RSO and the RSO staff (e.g., criteria for returning to the work area, investigation of root cause, provision of requested bioassay samples, decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO

- Supervise and confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.
- Document decontamination results, including all surveys, location of surveys, and decontamination results.
- Determine cause and needed corrective actions; consider need for bioassays if licensed material may have been ingested, inhaled, or absorbed through the skin.
- If necessary, notify the agency.

Personnel Contamination

- a. Contamination on any point other than the hands will usually be contained on the clothing.
- b. After contaminated clothing is removed, survey the individual to determine if other portions of the body are contaminated.
- c. Place contaminated clothing in a labeled plastic bag for storage until such time as radioactive decay assures background levels have been obtained.
- d. To decontaminate skin, gently wash with damp cloths soaked in tap water and a mild detergent, and/or irrigate open wounds or eyes that appear contaminated while avoiding spattering or rinsing contaminated wash water onto bodily areas;
- e. Particularly notice if contamination exists on the face or neck area when considering if internal contamination may have resulted and when suspected, nasal wipes and urine samples may yield valuable information.
- f. Skin contamination is usually local and would not indicate whole-body showers. Avoid using hot water and irritating brushes, which tend to increase absorption (internal deposition) through increased vascularity. Often skin contamination cannot be removed. These sites may be wrapped with gauze and with plastic taped over to promote "sweating" the isotope out.
- g. If the contaminated individual also has a health condition that necessitates prompt medical treatment, do not delay this treatment. Provide guidance and assistance to the medical caregivers to contain the further spread of any contamination from the individual. Decontamination can proceed after the individual is treated or stabilized.
- h. For serious contamination events, advice may be sought from health physicists at Radiation Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee, (865) 576-1005 (Ask for REAC/TS), or the State's Radiological Emergency Assistance Number (512) 458-7460.

Stolen, Lost or Missing Radioactive Material

Immediately notify RSO.

Conduct a complete search of the area with an appropriate survey meter capable of detecting the RAM.

RSO will notify management, appropriate local authorities and the agency at (512) 458-7460.

Within 30 days after making the initial report, submit a written report to DSHS that includes all of the information identified in 25 TAC §289.202(w).

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

For emergency surgery or autopsy of patients administered radioactive material, NCRP Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," 1991, may contain helpful information.

If emergency surgery is performed within the first 24 hours following the administration of iodine-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).

The radiation safety staff will direct personnel in methods to keep doses as low as reasonable achievable (ALARA) during surgical procedures.

If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

- Immediately notify the authorized user (AU) in charge of the patient and the RSO upon death of a therapy patient.
- An autopsy will be performed only after consultation and permission from the RSO.
- Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
- Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with phosphorus-32 and yttrium-90.

- Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accordance with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
- If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

Autopsy or Cremation of Patients Who Have Permanent Implants

Patients treated with seed implants will not usually represent a radiation hazard to persons dealing with the body unless there is to be an autopsy or cremation. For autopsy or cremation of patients with permanent implants, NCRP Report No. 155, "Management of Radionuclide Therapy Patients," December 2006, may contain helpful information.

If an autopsy or cremation is to be performed

- Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
- Consult and get permission from the RSO.
- Instruct pathologist to excise tissue containing radioactive seeds.
 - Make pathologist aware seeds may have migrated and additional tissue may need to be removed.
 - Instruct pathologist to consult with RSO about possibility of slicing through a seed and contaminating the facility.
- Seek municipal approval, if required, because the very high temperatures used in modern crematoria may cause seeds to burst, releasing radioactivity into the plume.

Nuclear Pacemakers

Medical licensees are often the first to come into contact with plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases, and when the licensee is not responsible for control or disposal of the pacemaker, notify the agency and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee that implanted the device is responsible for the follow-up,

explanation, and return of the pacemaker to the manufacturer for proper disposal. Information Notice (IN) 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," April 3, 1998, provides additional information.

APPENDIX K ORDERING AND RECEIVING PACKAGES

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- Authorize, through a designee (e.g., radiation safety officer), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user (AU) and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material; include the following information:
 - records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier
 - confirmation, through the above records, that material received was ordered through proper channels
- For deliveries during normal working hours, instruct carriers to deliver radioactive packages directly to a specified area and provide contact information to the carrier for any questions (e.g., delivery area not accessible, staff not present to receive package).
- For deliveries during off-duty hours, instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package _____, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

NAME

HOME TELEPHONE

Radiation Safety Officer _____

Director of Nuclear Medicine _____

Nuclear Medicine Technologist Supervisor _____

Nuclear Medicine Technologist on call _____
(call/page operator at extension ____)

Nuclear Medicine Physician on call _____
(call/page operator at extension ____)

APPENDIX L MODEL PROCEDURE FOR AREA SURVEYS

This model provides acceptable methods for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 25 TAC §289.202(e), 25 TAC §289.202(p), 25 TAC §289.202(eee), 25 TAC §289.202(ggg)(6), and 25 TAC §289.256(bb), "Surveys of ambient radiation exposure rate." Guidance for developing alternate trigger levels for contamination in restricted areas is included below. Before use of survey instrumentation, perform a daily check with a dedicated check source and battery checks.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys [reference 25 TAC §289.202(e), 25 TAC §289.202(p), and 25 TAC §289.256(bb)]:

- Perform surveys of dose rates in locations where
 - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits or
 - An individual is working in an environment with a dose rate of 2.5 millirem/hour (0.0025 millisievert (mSv)/h) or more [5 rem/year (yr) divided by 2,000 h/yr].
- 25 TAC §289.202(n) requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 0.1 rem [1 mSv] in a year, and that the dose in any unrestricted area from external sources does not exceed 0.002 rem [0.02 mSv] in any one hour. Appropriate surveys will be conducted to ensure that the requirements of 25 TAC §289.202(n) are met.
- Perform radiation level surveys with a radiation survey meter in the following areas, at the frequency specified:
 - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive [e.g., all therapy dosages and any iodine 131 (I-131) dosage exceeding 30 microcuries (μCi)].
 - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (less than 200 μCi at a time).
 - Survey weekly all radionuclide use, storage, and waste storage areas.

- Survey immediately after implanting sealed sources in a patient or research subject to locate and account for all sources that have not been implanted.
- Survey a patient or research subject immediately after removing the last temporary implant sealed source to confirm that all sealed sources have been removed

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table J–1.

Table L–1. Ambient Dose Rate Trigger Levels

Type of Survey	Area Survey	Trigger Level
Ambient Dose Rate	Unrestricted	0.05 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Procedures for contamination surveys [reference 25 TAC §289.202(eee) and 25 TAC §289.202(ggg)(6)]

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter. To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area.

Procedures for contamination surveys

- 25 TAC §289.202(eee) requires that no licensee use radioactive material in such a manner as to cause contamination or surfaces of facilities or equipment in unrestricted areas in excess of the limits specified in 25 TAC §289.202(ggg)(6).
- Contamination surveys are performed in areas where unsealed forms of radioactive materials are used:
 - to evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment
 - after any spill or contamination event
 - when procedures or processes have changed

- to evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used
- in unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly
- in areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply. Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:
 - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas.
 - Removable contamination surveys following administration and prior to releasing a room for unrestricted use for administrations made in patients' rooms, stress labs or any area that will be released for unrestricted use following the administration.
 - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (less than 200 μCi at a time).
 - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in counts per minute) to dpm.
- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Acceptable surface contamination levels [25 TAC §289.202(ggg)(6)] for unrestricted areas are presented in Table L-2. Contamination found on facilities, equipment and on personal clothing will be immediately decontaminated to background levels.

Table L-2 Acceptable Surface Contamination Levels

Nuclide^a	Average^{b,c,f}	Maximum^{b,d,f}	Removable^{b,c,e,f}
U-nat, U-235, U-238, and associated decay products except Ra-226, Th-230, Ac-227, and Pa-231	5,000 dpm al-pha/100 cm ²	15,000 dpm al-pha/100 cm ²	1,000 dpm al-pha/100 cm ²
Transuranics, Ra-223, Ra-224, Ra-226, Ra-228, Th-nat, Th-228, Th-230, Th-232, U-232, Pa-231, Ac-227, Sr-90, I-129	1,000 dpm/100 cm ²	3,000 dpm/100 cm ²	200 dpm/100 cm ²
Beta-gamma emitters (nuclides with decay modes other than al-pha emission or spontaneous fission) except Sr-90 and others noted above	5,000 dpm beta, gamma/100 cm ²	15,000 dpm beta, gamma/100 cm ²	1,000 dpm beta, gamma/100 cm ²
Tritium (applicable to surface and subsurface)	NA	NA	10,000 dpm/100 cm ²

^a Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides shall apply independently.

^b As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

^c Measurements of average contamination level should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each object.

^d The maximum contamination level applies to an area of not more than 100 cm²

^e The amount of removable radioactive material per 100 cm² of surface area shall be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels shall be reduced proportionally and the entire surface shall be wiped.

^f The radiation levels associated with surface contamination resulting from beta-gamma emitters shall not exceed 0.2 mrad/hr at 1 centimeter for an average and shall not exceed 1.0 mrad/hr at 1 centimeter as

a maximum, as measured through not more than 7 mg/cm² of total absorber. The external gamma exposure rate shall not exceed 5 microentgen per hour above background at 1 meter from the surface, and for soil 10 microentgen per hour above background at 1 meter.

- ⁹ Property recently exposed or decontaminated, shall have measurements (smears) at regular time intervals to ensure that there is not a build-up of contamination over time. Because tritium typically penetrates material it contacts, the surface guidelines in group 4 are not applicable to tritium. The agency has reviewed the analysis conducted by the Department of Energy Tritium Surface Contamination Limits Committee ("Recommended Tritium Surface Contamination Release Guides," February 1991), and has assessed potential doses associated with the release of property containing residual tritium. The agency recommends the use of the stated guideline as an interim value for removable tritium. Measurements demonstrating compliance of the removable fraction of tritium on surfaces with this guideline are acceptable to ensure that non-removable fractions and residual tritium in mass will not cause exposures that exceed dose limits as specified in this section and agency constraints.

Establishing Trigger Levels for Restricted Areas

Alternative action levels for cleanup of contamination in restricted areas may be established if the applicant demonstrates why the alternative trigger levels are needed and if

- the action levels maintain occupational doses as low as is reasonably achievable
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste)

Contents of Survey Records

- a diagram of the area surveyed
- a list of items and equipment surveyed
- exact description of the locations of the surveys
- ambient radiation levels in microentgen per hour or millirem per hour

- contamination levels in disintegrations per minute
- unique identification of survey instruments used
- background levels
- name of the person making the evaluation and recording the results
- the date of the survey

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX M MODEL PROCEDURES FOR DEVELOPING, MAINTAINING AND IMPLEMENTING WRITTEN DIRECTIVES

This model provides acceptable procedures for administrations that require written directives (WD). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 25 TAC §289.256(t).

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 25 TAC §289.256(t)(4) will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in 25 TAC §289.256(t) and be retained in accordance with 25 TAC §289.256(t)(3).

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures. A number of individuals may be involved in the delivery process. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be completed before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which 25 TAC §289.256(t) requires, or would require, a WD (as defined in 25 TAC §289.256(c), "Definitions"), the licensee should develop, implement, and maintain written procedures to meet the requirements and objectives of 25 TAC §289.256(t) and 25 TAC §289.256(x), outlined below:

- Confirm that the WD is signed and dated by the AU prior to the administration, in accordance with 25 TAC §289.256(t)(2) including the name of the patient or human research subject.
- Verify the identity of the patient or human research subject prior to each administration.
- Verify that the administration is in accordance with the treatment plan, if applicable, and the WD.
- Check both manual and computer-generated dose calculations.
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices.
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcuries of Iodine-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 25 TAC §289.256(t):

- An AU must date and sign a WD prior to the administration of any dose or dosage. WDs may be maintained in patients' charts.
- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (e.g. radionuclide, total dose or dosage) will be confirmed by the person administering the dose or dosage to verify agreement with the WD.

Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under 25 TAC §289.256(t) to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. for computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions)
2. for computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times)
3. for manually-generated dose calculations, verifying
 - a. no arithmetical errors
 - b. appropriate transfer of data from the WD, treatment plan, tables, and graphs
 - c. appropriate use of nomograms (when applicable)

d. appropriate use of all pertinent data in the calculations

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

After implantation but before completion of the procedure, record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose), as required by 25 TAC §289.256(t)(2)(F). For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The WD may be maintained in the patient's chart.

Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either

1. an individual who did not perform the full calibration (the individual will meet the requirements specified in 25 TAC §289.256(j)) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 25 TAC §289.256(iii))
2. an AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%

For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

For emerging technologies (e.g., Yttrium-90 Microsphere Brachytherapy, Leksell Gamma Knife Perfexion), the licensee should review the applicable guidance on

the NRC's Medical Uses Licensee Toolkit to ensure the written directive contains all necessary components.

A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes (i) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (ii) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused and must be relabeled in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high dose-rate brachytherapy, implant brachytherapy, teletherapy, and emerging technologies). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by 25 TAC §289.256(t)(4)(b)(ii), a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Medical Events

Notify the agency by telephone at 512-458-7460 no later than the next calendar day after discovery of a medical event and submit a written report within 15 days after the discovery of the medical event, as required by 25 TAC §289.256(uuu). Also notify the referring physician and the patient as required 25 TAC §289.256(uuu)(5).

APPENDIX N MODEL PROCEDURES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands and clothing for contamination after each procedure or before leaving any restricted area or temporary use location.
4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances when their use may compromise safe patient administration. In the exceptional cases where syringe shields may not be recommended for patient safety, then consider the use of a remote delivery with a butterfly valve or other device.
5. Do not store food or personal effects, eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
6.
 - a. Assay each patient dose, prepared from bulk or eluted from a generator, in the dose calibrator prior to administration.
 - b. Unit doses provided from a manufacturer should be determined according to the manufacturer's instructions.
 - c. Do not use any doses that are not within the prescribed dosage range or differ from the prescribed dose by more than 20% unless specifically approved by an authorized physician user.
 - d. For all doses, check the patient's name against the written referral, the radionuclide, the chemical form, and the activity against the authorized user's written order and/or standing medical orders.
7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated low background area, as should the control badge.
8. Wear an extremity exposure monitor with the detection media on the palmar side of the hand during the elution of generators, during the preparation, assay and injection of radiopharmaceuticals and when holding patients during procedures.

9. Dispose of radioactive waste only in specially labeled and properly shielded receptacles.
10. Never pipette by mouth.
11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at a minimum at the end of the day.
12. Any injections performed in a non-restricted area (Provision only authorized by license condition) should include: removal of absorbent coverings beneath the injection site, wipe test for external contamination, and removal of used alcohol and cotton swabs. Decontaminate and resurvey if necessary.
13. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
14. Always keep flood source, syringes, waste and other radioactive material in shielded containers when not in use.
15. Always transport radioactive material in shielded containers.
16. Work over surfaces that are easily cleaned or covered with disposable absorbent coverings when handling open solutions of radioactive material.
17. Work only in designated restricted areas.
18. Process volatile radioactive materials under fume hoods or in glove boxes when possible.
19. Always leave restricted areas secured when trained personnel are not present to assure security over such areas.
20. Treat all work material and gloves associated with radiopharmaceutical injections and preparations as contaminated until proven otherwise.

APPENDIX O RADIOACTIVE MATERIALS GUIDANCE FOR MOBILE NUCLEAR MEDICINE SERVICES

Mobile nuclear medicine service providers must comply with all applicable sections of Title 25 Texas Administrative Code §289.252 and §289.256 as well as U.S. Department of Transportation (DOT) regulations regarding approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. The sections below describe the type of information that should be submitted when requesting to conduct mobile medical service provider activities.

Type and Location of Use

In general, there are two types of mobile nuclear medicine service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van or trailer use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by either the mobile nuclear medicine service's employees (i.e., transport and use) or the client's employees (i.e., transport only).

A mobile nuclear medicine service provider that uses a "quiet room" and/or a patient waiting area in the client's facility may either be authorized for "in-van or trailer use only" or "transport and use," depending on whether the patients meet the criteria for release described in 25 TAC §289.256(cc) while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile nuclear medicine service licensee and should be under their control while onsite. In addition, for mobile nuclear medicine and PET imaging, the licensee should take into account the possibility of using the client's bathroom dedicated for their use for PET patients and finding the bathroom with low levels of radioactive contamination during the end-of-day surveys. In this event, the mobile licensee must provide direction to the client for restricting access to the bathroom until follow up surveys show the bathroom free of contamination (e.g., post and close off the patient bathroom for a designated period of time to allow for radioactive decay). The mobile nuclear medicine service provider should also survey "quiet rooms," provided for their use at the client's site, for contamination and radiation levels to ensure that public dose limits are not exceeded and that these areas are left free of contamination following use.

The locations of use for mobile nuclear medicine services are of two basic types. One type of location is the fixed facility where licensed material is received, stored, and sometimes used. The other type of location is the temporary jobsite at client facilities. The following two sections describe the type of information necessary for base locations and temporary jobsites.

Mobile Nuclear Medicine Service Agreement

Rules in 25 TAC §289.256(dd) require, in part, that a licensee providing mobile nuclear medicine service shall obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for the duration of the licensee/client relationship, as required by 25 TAC §289.256(dd) and 25 TAC §289.256(www), "Records/documents for agency inspection." Additionally, as required by 25 TAC §289.256(dd)(1)(F), the licensee must survey to ensure compliance with the requirements in 25 TAC §289.202 (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

The following is provided as an example of a PET mobile nuclear medicine service agreement:

SAMPLE MOBILE NUCLEAR MEDICINE SERVICE AGREEMENT

In accordance with Title 25 Texas Administrative Code §289.256(dd)(1)(A), management designee, Sam Curie of ABC Hospital, Inc. acknowledges that mobile nuclear medicine service provider, PET Mobile, Inc., will use radioactive material at client address 456 Rad Road, Somewhere, TX. Service will be provided every Monday beginning February 1, 2014. All radioactive material will be removed from the client facility prior to leaving the site. PET Mobile, Inc. will abide by all agency rules while on-site.

The following authority and responsibilities are delegated to the client:

- ordering of radioactive dosages.

The following authority and responsibilities are delegated to the mobile nuclear medicine service provider:

- Package receipt and return surveys.
- Quality control testing on equipment used to measure radioactive dosages (e.g., dose calibrator).
- Quality control testing and calibration of survey instrumentation (e.g., radiation survey meter, well counter).
- Sealed source inventories and leak testing.
- Shipping papers.

- Radiation safety and hazardous materials (HAZMAT) training for mobile nuclear medicine service personnel.
- Radiation safety training for client staff involved in: (i) controlling patient waiting areas used by the mobile nuclear medicine service provider in the hospital; (ii) performing surveys to support release of the patient bathroom located in the hospital; and (iii) providing patient escort.
- Surveys of all interior PET trailer areas.
- Surveys of areas exterior to the PET trailer to ensure compliance with 25 TAC §289.202(n) and roping off of any area (if necessary) to ensure that the dose rate is less than 2 millirem (mrem) in any one hour.
- Surveys of patient waiting area in the hospital to ensure compliance with 25 TAC §289.202(n) (2 mrem in any one hour and 0.1 rem in a year) since the patient has not yet been released under 25 TAC §289.256(cc) and is awaiting scanning.
- Surveys of dedicated PET patient bathroom located within the hospital prior to leaving client site.
- Decay in storage and disposal of radioactive material/waste. Radioactive waste will be removed to the PET trailer for storage. Non-radioactive waste that has been surveyed and shown to be at background may be disposed into the normal waste stream at the client's site.
- Confirming that AUs designated on the application are cognizant that they will be responsible for supervising the use of licensed material.
- Providing dosimetry to staff that would require it in accordance with 25 TAC §289.202(q).
- Maintaining security of mobile PET trailer (e.g. keys, keypad codes).
- Ensuring that all radioactive material is accounted for and removed from the client at the end of the day of service.
- Radiation safety program audits, including use at client sites, in accordance with 25 TAC §289.202(e).

Note: In the event that bathroom contamination is found in the dedicated PET bathroom on hospital property and cannot be cleaned to below trigger levels for an unrestricted area, the mobile nuclear medicine service provider will block off the bathroom and post it as a radiation area. The contamination will be reported to the client manager. The bathroom will be surveyed with a calibrated radiation survey

meter the next day and released for unrestricted use if radiation levels are below trigger levels for an unrestricted area described in the mobile nuclear medicine service provider license.

This agreement will be retained by the licensee for the duration of the licensee/client relationship, in accordance with 25 TAC §289.256(www).

Signed and Dated

Vice President of Operations

ABC Hospital

Signed and Dated

President

PET Mobile, Inc.

Fixed Facility

A mobile nuclear medicine service provided must have at least one fixed facility where records are maintained and radioactive material delivered, in accordance with 25 TAC §289.256(dd)(A) and (C). The fixed facility will be identified on the license, while a "temporary jobsite" (or client site) is a location that is other than a location of use identified on the license and where work is conducted for a limited period of time. A mobile licensee cannot provide a service to a private practice (nonlicensee) located within a licensed medical institution (e.g., hospital). The medical institution's management (i.e., hospital management) must be consulted in this event. As required by 25 TAC §289.252(e) and 25 TAC §289.256(f), applicants must submit a description and diagram(s) of the proposed fixed facility and associated equipment. The description and diagram of the proposed fixed facility should demonstrate security of licensed material from unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 25 TAC §289.202(n) (e.g., shielding and roping off of areas greater than 0.02 mSv [2 mrem] in any one hour). Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas.

- Applicants may request multiple fixed facilities. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Radioactive material is delivered directly to the van or trailer parked at a site owned by the mobile nuclear medicine service provider occupied by licensee personnel. In addition, for diagnostic uses only, the mobile nuclear medicine service provider may arrange to have licensed material delivered to the van or trailer parked at a client site only if the mobile nuclear medicine service provider submits information clearly demonstrating that they will have their

personnel at the van or trailer to accept delivery and ensure the security and control of the licensed material.

- The mobile nuclear medicine service provider may list a portion of a client's site as a base location for which there is a clear written agreement with the facility owner addressing security against unauthorized removal and establishing responsibility for the licensed material. This agreement should indicate the receipt and storage location and confirm that the mobile nuclear medicine service provider will have sole access to the receipt/storage location and will be granted access to the facilities to remove any licensed material or decontaminate the facility, as necessary. In this case, the mobile nuclear medicine service provider may arrange to have licensed material delivered to the base location without their personnel present.
- Perform surveys necessary to show that exposure rates do not exceed 0.02 mSv [2 mrem] in any one hour nor 1 mSv/yr [100 mrem/yr].

Client Site for Diagnostic Uses

In general, client facility information does not need to be submitted; however, the mobile nuclear medicine service provider may arrange to have licensed material delivered to the client site only if the licensee submits information clearly demonstrating that the mobile nuclear medicine service provider licensee will have its own personnel at the client site to accept delivery and ensure the security and control of the licensed material.

Client Site for Therapeutic Uses

This section applies only to therapeutic uses of radioactive material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained radioactive material services (e.g., in-van or trailer), the following additional facility information should be provided:

- For therapy treatments with radioactive material [e.g., high dosage-rate (HDR) remote afterloader], provide a separate drawing for each client site showing the location of the treatment device and vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public.
- As delineated in the letter required by 25 TAC §289.256(dd)(1)(A), a signed agreement that the location of the treatment device and vehicle will be on client-owned or controlled property.

- The protection from vehicular traffic that could adversely affect patient treatment(s), which could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility or site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If transportable services will be provided to the client's site for use within the client's facility by the mobile medical service's employees, the following client facility information and commitment should be provided:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 9.14 through 9.19 of this guide. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with 25 TAC §289.202(n). Include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by 25 TAC §289.256(dd)(1)(A), that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.
- The initial installation records and function checks of a remote afterloader device for each site of use, as required by 25 TAC §289.256(kkk), "Full calibration measurements on remote afterloader units;" 25 TAC §289.256(nnn), "Periodic spot-checks for remote afterloader units;" and 25 TAC §289.256(ppp) "Additional technical requirements for mobile remote afterloader units."

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:

- Each client is properly licensed for medical use of radioactive material (which now also includes accelerator-produced radioactive materials and discrete sources of radium-226). If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.

- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in 25 TAC §289.256(s), "Supervision," transfer to the client's authorized users (AU) upon transfer of the device to the client by the mobile medical service provider.
- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by 25 TAC §289.201(d), "Records," a formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

The mobile nuclear medicine service provider must agree to have an authorized user directly supervise each technologist at a reasonable frequency, in accordance with 25 TAC §289.256(dd). Applicant must identify the frequency at which technologists will be supervised (e.g. monthly, quarterly) and confirm that records of supervision will be maintained for inspection.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists will be properly trained in applicable transportation rules and emergency procedures in addition to the training requirements of 25 TAC §289.203(c), and 25 TAC §289.256(s). The training for these individuals will include, at a minimum, DOT regulations, shielding, as low as is reasonably achievable (ALARA), basic radiation protection, and emergency response.

Survey Instrument and Dose Measurement Instrument Checks

As required by 25 TAC §289.256(dd), instruments should be checked for proper operation before use at each address of use. Dosage measurement instruments

should be checked before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive Material

Radioactive material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. Additionally, if the mobile nuclear medicine service provider is specifically licensed for receipt and storage in the client's facility, radioactive material may be delivered to the client's address. Delivery of radioactive material to a van or trailer that is not occupied by the mobile nuclear medicine service personnel will not be permitted.

Alternatively, licensees may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

The mobile nuclear medicine service provider applicant should commit to develop, implement, and maintain emergency procedures, in accordance with the radiation protection program required by 25 TAC §289.202(e). Indicate typical response times of the radiation safety officer (RSO) and AU in the event of an incident, and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the radioactive material used in the mobile nuclear medicine service. The transportation emergency response plan should cover both the actions to be taken by the mobile nuclear medicine service provider's headquarters emergency response personnel and the "on-scene" hazardous-material (HAZMAT)-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile nuclear medicine service provider's emergency response personnel.
- The agency's 24-hour radiological emergency assistance number.
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist.
- Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached or dislodged to the extent that a

radiological hazard is created, which may require one or more emergency shielded source containers.

- Preplanned decontamination procedures, including ready access to all necessary materials.
- A calibrated, operational radiation survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys.
- Security of the transport vehicle against unauthorized access, including the driver's compartment.

Note: The type of response should be consistent with the level of the incident. The response may range from telephone contact for minor spills to prompt onsite response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

The mobile nuclear medicine service provider applicant should commit to develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170–178, "Transportation." Procedures will include
 - use of approved packages
 - use of approved labeling
 - conduct of proper surveys
 - complete and accurate shipping papers
 - bracing of packages
 - security provisions
 - written emergency instructions
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed material is secured during transport and use at the client's facilities.

- Radioactive waste is handled properly during transport. Describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Rule Guide 6.5 summarizes DOT requirements for Transportation of Licensed Material.

Radioactive Waste Management

If waste will be stored in vans or trailers, they must be properly secured and posted as radioactive material storage locations. Ensure that the van or trailer will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.

Develop, document, and implement final waste disposal procedures in accordance with Item 10 of this guide.

Excreta from individuals undergoing medical diagnosis with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewer system, in accordance with 25 TAC §289.202(gg). However, collecting excreta from patients in a van or trailer restroom with a holding tank is not considered direct disposal into the sanitary sewer system. If restroom facilities are provided in the van or trailer for patient use, submit the following information for agency review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van or trailer, and the driver of the van or trailer; a description of procedures to assess the tank for possible leakage;
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in 25 TAC §289.202(f) and 25 TAC §289.202(n), that the external surfaces of the van or trailer do not exceed 0.02 mSv/h [2 mrem/h], and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.
- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services with Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Conduct safety checks on a remote afterloader device and facility. The procedure will include the periodic spot-checks required by §289.256(nnn) and the additional spot-checks required by §289.256(ppp) before use at each address of use. Additionally, the procedure should include provisions for prompt repair of any system not operating properly.
- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.
- Such tests should be performed in accordance with written procedures.
- As required by §289.256(nnn)(6) and §289.256(ppp)(5), records showing the results of the above safety checks must be maintained for agency inspection and review for a period of 3 years.
- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of an HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

APPENDIX P MODEL PROCEDURE FOR RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS

This model provides acceptable procedures for the release of patients under 25 TAC §289.256(cc), "Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material," which permits a licensee to "authorize the release from its control any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 mrem (0.05 mSv)".

In this Appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Licensees should review the NRC's Information Notice (IN) 2003-22, "Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations," December 9, 2003, and Supplement 1, July 29, 2009, in developing instructions for patients that still contain detectable amounts of radiation and provide patients with an appropriate explanation about the potential of alarming radiation monitoring equipment.

Special Considerations and Guidance for Release of Patients Following I-131 Therapy

Although the regulations are not explicit, licensees should consider implementing the 0.5 rem [5 mSv] as an annual limit for multiple administrations during a calendar year. For more information on this topic see the U.S. Nuclear Regulatory Commission's Regulatory Issue Summary (RIS) 2008-07, "Dose Limits for Patient Release Under 10 CFR 35.75," March 27, 2008.

Although 25 TAC §289.256(cc) does not expressly prohibit the release of a radioactive patient to a location other than a private residence, the U.S. Nuclear Regulatory Commission (NRC) strongly discourages this practice, because it can result in radiation exposures to members of the public for which the licensee may not be able to fully assess compliance with 25 TAC §289.256(cc)(1) and may result in doses that are not as low as is reasonably achievable (ALARA). For more information on this topic, see RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences," January 25, 2011.

Licensees should take into account whether the released patient may come in contact with infants or young children. In such a situation, in order to protect infants and young children from possible iodine-131 (I-131) contamination, the licensee should provide the patient with additional instructions. These additional instructions are listed in Section P.2.3.1, "Instructions Regarding Radiopharmaceutical Administrations." For more information on this topic see RIS 2008-11, "Precautions to

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides." This report uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation P-1:

$$D(t) = \frac{34.6 \Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2}$$

where: $D(t)$ = Accumulated exposure at time t , in roentgens (R)
 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
 Γ = Specific gamma ray constant for a point source, R/millicuries (mCi)-hr at 1 centimeter (cm)
 Q_0 = Initial activity of the point source in mCi, at the time of the release
 T_p = Physical half-life in days
 r = Distance from the point source to the point of interest, in cm
 t = Exposure time in days

This appendix uses the NCRP equation (Equation P-1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Table P-5.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.

- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation P-1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation P-2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E , of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation P-2:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor 1.0 is used:

Equation P-3:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2}$$

Equations P-2 and P-3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (i.e. less than a few percent), relative to the external gamma dose. For some radionuclides, such as sodium iodide I-131, it may be necessary to also consider the internal dose from exposure to a released patient. The internal and external doses must be summed to determine the total dose. See Supplement B.3, "Internal Dose" for equations. Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Section P.1.1, "Release of Patients Based on Administered Activity."

P.1 Release Criteria

Licensees should use one of the following options (P.1.1, P.1.2 or P.1.3) to release a patient to whom unsealed radioactive material or implants containing radioactive material have been administered in accordance with regulatory requirements.

Licensees should perform an assessment in advance of the treatment to validate the factors used in release equations, including confirmation that default values used are appropriate for the patient's situation. Licensees should have a program that includes a structured series of questions and maintain documentation of responses. Examples of items to consider in the assessment can be found in "Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine ¹³¹I: Practice Recommendations of the American Thyroid Association."

P.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 25 TAC §289.256(cc), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table P-1. The activities in Table P-1 are based on a TEDE of 0.5 rem [5 mSv] to an individual using the following conservative assumptions:

- administered activity;
- physical half-life;
- occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- no shielding by tissue.

Because the values in Table P-1 are based on Equations P-2 and P-3, licensees should perform patient-specific dose calculations, if it is determined that a different occupancy factor is appropriate for the patient's situation. See Section P.1.3 and Supplement B for details on patient-specific dose calculations.

The TEDE is approximately equal to the external dose because the internal dose is a small fraction of the external dose. See Section P.3, "Internal Dose," of Supplement B. In this case, no record of the release of the patient is required unless the patient is breastfeeding an infant or child, as discussed in Section P.3.2, "Records of Instructions for Breastfeeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 25 TAC §289.256(t) and 25 TAC §289.256(x).

If the activity administered exceeds the activity in Column 1 of Table P-1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table P-1. In this case, 25 TAC §289.256(cc) requires a record because the

patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table P-1 were calculated using either Equation P-2 or P-3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table P-1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for agency inspection, a calculation of the release activity that corresponds to the dose limit of 0.5 rem [5 mSv]. Equation P-2 or P-3 may be used, as appropriate, to calculate the activity Q corresponding to 0.5 rem [5 mSv].

The release activities in Column 1 of Table P-1 do not include consideration of the dose to a breastfeeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breastfeeding an infant or child, the activities in Column 1 of Table P-1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Sections P.2.2 and P.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breastfeeding infant or child in excess of 0.5 rem [5 mSv], a record that instructions were provided is required by 25 TAC §289.256(cc)(3)(B).

P.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table P-1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table P-1 for that radionuclide. In this case, however, 25 TAC §289.256(cc)(3) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table P-1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 mSv [0.5 rem] dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 25 TAC §289.256(cc)(3). The dose rate at 1 meter may be calculated from Equation P-2 or P-3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q / 10,000 \text{ cm}^2$.

Because the values in Table P-1 are based on Equations P-2 and P-3, patient-specific dose calculations should be performed, if it is determined that a different occupancy factor is appropriate for the patient's situation. See Section P.1.3 and Supplement B for details on patient-specific dose calculations.

P.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 25 TAC §289.256(cc)(1), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 0.5 rem [5 mSv], the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table P-1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 25 TAC §289.256(cc)(3). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 25 TAC §289.256(cc)(3).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table P-1 Activities and Dose Rates for Authorizing Patient Release*				
Radionuclide	Column 1		Column 2	
	(GBq)	(mCi)	(mSv/h)	(mrem/h)
Silver-111	19	520	0.08	8
Gold-198	3.5	93	0.21	21
Chromium-51	4.8	130	0.02	2
Copper-64	8.4	230	0.27	27
Copper-67	14	390	0.22	22
Gallium-67	8.7	240	0.18	18
Iodine-123	6	160	0.26	26
Iodine-125	0.25	7	0.01	1
Iodine-125 implant	0.33	9	0.01	1
Iodine-131	1.2	33	0.07	7
Indium-111	2.4	64	0.2	20
Iridium-192 implant	0.074	2	0.008	0.8
Phosphorous-32	†	†	†	†
Palladium-13 implant	1.5	40	0.03	3
Rhenium-186	28	770	0.15	15
Rhenium-188	29	790	0.2	20
Scandium-47	11	310	0.17	17
Selenium-75	0.089	2	0.005	0.5
Samarium-153	26	700	0.3	30
Tin-117m	1.1	29	0.04	4
Strontium-89	†	†	†	†
Technetium-99m	28	760	0.58	58
Thallium-201	16	430	0.19	19
Yttrium-90	†	†	†	†
Ytterbium-169	0.37	10	0.02	2
<p>*The activity values were computed based on 0.5 rem TEDE</p> <p>+Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.</p> <p>Note: If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 25 TAC §289.256(cc), because the measurement includes shielding by tissue. See Section P.3.1 for information on records for release.</p>				

Notes:

- The mCi values were calculated using Equations P-2 and P-3 and the physical half-life. The gigabecquerel (GBq) values were calculated using the mCi values and the conversion factor from mCi to GBq. The dose rate values are calculated using the mCi values and the exposure rate constants.

- In general, the values are rounded to two significant figures; however, values less than 0.37 GBq [10 mCi] or 0.1 mSv [10 millirem (mrem)] per hour are rounded to one significant figure. Details of the calculations are provided in NUREG – 1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

P.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. Licensees may either adopt these model instructions or develop their own instructions to meet the requirements of 25 TAC §289.256(cc).

P.2.1 Activities and Dose Rates Requiring Instructions

Based on 25 TAC §289.256(cc)(2), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released. The agency cannot enforce patient compliance with the instructions, nor is it the licensee's responsibility to do so. Column 1 of Table P-2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table P-2 may be used for determining when instructions must be given. If the patient is breastfeeding an infant or child, additional instructions may be necessary. (See Section P.2.2, "Additional Instructions for Release of Patients Who Could Be Breastfeeding after Release.")

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 mSv [0.1 rem].

If a radionuclide not listed in Table P-2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 mSv [0.1 rem]. Equation P-2 or P-3, as appropriate, may be used.

P.2.2 Additional Instructions for Release of Patients Who Could Be Breastfeeding After Release

The requirement in 25 TAC §289.256(cc)(2)(A) and (B) that a licensee provide instructions on the discontinuation or the interruption period of breastfeeding, and the consequences of failing to follow the recommendation, presumes the licensee will inquire, as appropriate, regarding the breastfeeding status of the patient.

Note: The agency does not intend to enforce patient compliance with the instructions, nor is it the licensee's responsibility to do so. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breastfeeding an infant or child when the dose to the infant or child

could exceed 5 mSv [0.5 rem], if there is no interruption of breastfeeding.

If the patient could be breastfeeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table P-3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breastfeeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breastfeeding infant or child. Table P-3 also provides recommendations for interrupting or discontinuing breastfeeding to minimize the dose to below 1 mSv [0.1 rem] if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table P-3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table P-3 is administered to a patient who could be breastfeeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant in an article by Michael Stabin entitled "Internal Dosimetry in Pediatric Nuclear Medicine," published in *Pediatric Nuclear Medicine* (edited by S. Treves, Springer Verlag, New York, 1995).

P.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine therapy, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to Sections P.2.3.1 and P.2.3.2).

Table P-2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	Column 1 Activity Above Which Instructions Are Re- quired		Column 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/h)	(mrem/h)
Silver-111	3.8	100	0.02	2
Gold-198	0.69	19	0.04	4
Chromium-51	0.96	26	0.004	0.4
Copper-64	1.7	45	0.05	5
Copper-67	2.9	77	0.04	4
Gallium-67	1.7	47	0.04	4
Iodine-123	1.2	33	0.05	5
Iodine-125	0.05	1	0.002	0.2
Iodine-125 implant	0.074	2	0.002	0.2
Iodine-131	0.24	7	0.02	2
Indium-111	0.47	13	0.04	4
Iridium-192 implant	0.011	0.3	0.002	0.2
Phosphorous-32	†	†	†	†
Palladium-13 implant	0.3	8	0.007	0.7
Rhenium-186	5.7	150	0.03	3
Rhenium-188	5.8	160	0.04	4
Scandium-47	2.3	62	0.03	3
Selenium-75	0.018	0.5	0.001	0.1
Samarium-153	5.2	140	0.06	6
Tin-117m	0.21	6	0.009	0.9
Strontium-89	†	†	†	†
Technetium-99m	5.6	150	0.12	12
Thallium-201	3.1	85	0.04	4
Yttrium-90	†	†	†	†
Ytterbium-169	0.073	2	0.004	0.4
*The activity values were computed based on 0.5 rem TEDE				
†Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.				

Notes:

- The values for activity were calculated using Equations P-2 and P-3 and the physical half-life. The values given in International System of Units (GBq values) were using conversion factors.
- In general, values are rounded to two significant figures; however, values less than 0.37 GBq [10 mCi] or 0.1 mSv [10 mrem] per hour are rounded to one

significant figure. Details of the calculations are provided in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

Table P-3 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*					
Radiopharmaceutical	Column 1 Activity Above Which Instructions Are Required		Column 2 Activity Above Which a Record is Required		Column 3* Examples of Recommended Duration of Interruption of Breastfeeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation for this infant or child
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 10 mCi [370 MBq] 12 hours for 4 mCi [150 MBq]
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 4 mCi [150 MBq]
Tc-99m Per-technetate	100	3	600	15	24 hours for 30 mCi [1,100 MBq] 12 hours for 12 mCi [440 MBq]
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell <i>In Vivo</i> Labeling	400	10	2000	50	6 hours for 20 mCi [740 MBq]
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	6000	150	
Tc-99m Sulfur Colloid	300	7	1000	35	6 hours for 12 mCi [440 MBq]
Tc-99m DTPA Aerosol	1000	30	6000	150	

Table P-3 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*					
Radiopharmaceutical	Column 1 Activity Above Which Instructions Are Required		Column 2 Activity Above Which a Record is Required		Column 3* Examples of Recommended Duration of Interruption of Breastfeeding
	(MBq)	(mCi)	(MBq)	(mCi)	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 30 mCi [1,100 MBq] 12 hours for 12 mCi [440 MBq]
Ga-67 Citrate	1	0.04	7	0.2	1 month for 4 mCi [150 MBq] 2 weeks for 1.3 mCi [50 MBq] 1 week for 0.2 mCi [7 MBq]
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 0.5 mCi [20MBq]
Tl-201 Chloride	40	1	200	5	2 weeks for 3 mCi [110 MBq]
*The duration of interruption of breastfeeding is selected to reduce the maximum dose to a newborn infant to less than 0.1 rem [1 mSv], although the regulatory limit is 0.5 rem [5 mSv]. The actual doses that would be received by most infants would be far below 0.1 rem [1 mSv]. Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.					

Notes:

Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breastfeeding.

P.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

You have been administered radioactive material for therapeutic medical purposes. To minimize exposure to radiation to others from the radioactive material inside your body, you should do the following for _____ days:

- Maintain distance from other persons (e.g., use separate sleeping arrangements, no cuddling or holding children).
- Minimize time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Reduce the spread of radioactive contamination (e.g., do not share towels or washcloths; wash linens separately; and do not share cups, glasses, plates, or eating utensils).

Refrain from returning to work for _____ days.

Additionally, for some types of therapy:

- Drink one glass of water each hour and use the bathroom as soon as possible to empty bladder.
- Men should sit on the toilet while urinating to decrease splashing.
- Use a tissue to wipe up any urine on the toilet bowl and flush twice.
- Wash hands after urinating.
- Rinse the sink and tub after each use.
- Minimize time with children and pregnant women.
- Avoid direct or indirect contact (e.g., indirect contact includes contamination from shared living space) with infants and young children for a specific period of time (e.g., consider having children stay outside the home with other family members).
- Establish adequate living space at home (e.g., bedroom, bathroom) that can be used exclusively by the patient for a specific period of time.
- For women who are breastfeeding, consult physician before resuming breastfeeding.

Licensees should consider not releasing patients administered I-131, whose living conditions may result in the contamination of infants and young children. The licensee should provide information on the potential consequences, if any, from failure to follow these instructions (e.g., could result in significant doses to the child's thyroid and potentially raise the risk of subsequent radiation-induced thyroid cancer).

If additional instructions are required because the patient is breastfeeding, the instructions should include appropriate recommendations on whether to interrupt breastfeeding, the length of time to interrupt breastfeeding, or, if necessary, the discontinuation of breastfeeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The consequences should be explained so that the patient will understand that, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving sodium iodide I-131 is that continued breastfeeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breastfeeding. The requirement of 25 TAC §289.256(cc)(2) regarding written instructions to patients who could be breastfeeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in providing detailed instructions and recommendations.

P.2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days:

- Stay at a distance of feet from other individuals.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

- If you find a seed or pellet that falls out
 - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
 - Place the container with the seed or pellet in a location away from people.
 - Notify _____ at telephone number _____.

P.3 Records

P.3.1 Records of Release

- There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table P-1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 25 TAC §289.256(cc)(3). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information: **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this Appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.
- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, the date and time of release, and the results of the decay calculations.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the radiation survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 25 TAC §289.256(cc)(3), should be kept in a manner that ensures the patient's confidentiality; that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

P.3.2 Records of Instructions for Breastfeeding Patients

If failure to interrupt or discontinue breastfeeding could result in a dose to the infant or child in excess of 5 mSv [0.5 rem], a record that instructions were provided is required by 25 TAC §289.256(cc)(3)(B). Column 2 of Table P-3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breastfeeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breastfeeding an infant or child.

P.4 Summary Table

Table P-4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table P-4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained				
Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity \leq Column 1 of Table U-1	Yes – if administered activity $>$ Column 1 of Table U-2	No
	Retained activity	Retained activity \leq Column 1 of Table U-1	Yes – if retained activity $>$ Column 1 of Table U-2	Yes
	Measured dose rate	Measured dose rate \leq Column 2 of Table U-1	Yes – if dose rate $>$ Column 2 of Table U-2	Yes
	Patient-specific calculations	Calculated dose \leq 5 mSv [0.5 rem]	Yes – if calculated dose $>$ 1 mSv [0.1 rem]	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity $>$ Column 1 of Table U-3 or Licensee calculated dose from breastfeeding $>$ 1 mSv [0.1 rem] to the infant or child	Records that instructions were provided are required if: Administered activity $>$ Column 2 of Table U-3 or Licensee calculated dose from continued breastfeeding $>$ 5 mSv [0.5 rem] to the infant or child

Implementation

The purpose of this section is to provide information to licensees and applicants regarding the agency staff's plans for using this Guide. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 25 TAC §289.256(cc), the methods described in this Guide will be used in the evaluation of a licensee's compliance with 25 TAC §289.256(cc).

Supplement A

Table P-5 Half Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide	Physical Half-Life (days)*	Exposure Rate Constant[†] (R/mCi-h at 1 cm)
Silver-111	7.45	0.15
Gold-198	2.696	2.3
Chromium-51	27.704	0.16
Copper-64	0.529	1.2
Copper-67	2.578	0.58
Gallium-67	3.261	0.753
Iodine-123	0.55	1.61
Iodine-125	60.14	1.42
Iodine-125 implant [‡]	60.14	1.114
Iodine-131	8.04	2.2
Indium-111	2.83	3.21
Iridium-192 implant [‡]	74.02	4.594
Phosphorous-32	14.29	N/A [§]
Palladium-103 implant	16.96	0.865
Rhenium-186	3.777	0.2
Rhenium-188	0.708	0.26
Scandium-47	3.351	0.56
Selenium-75	119.8	2
Samarium-153	13.61	1.48
Tin-117m	50.5	N/A [§]
Strontium-89	0.251	0.756
Technetium-99m	3.044	0.447
Thallium-201	32.01	1.83
Yttrium-90	2.67	N/A [§]
Ytterbium-169	32.01	1.83
*K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.		

[†]Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, p. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D. E. Barber, J. W. Baum, and C. B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997.

[‡]R. Nath, A. S. Meigooni, and J. A. Meli, "Dosimetry on Transverse Axes of 125I and 192Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

[§]S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

^{||}Not applicable (N/A) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table P-1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential TEDE to any individual would be no greater than 5 mSv [0.5 rem].

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue, a record of the basis of the release is required by 25 TAC §289.256(cc)(3). The following equation can be used to calculate doses:

Equation B-1:

$$D(t) = \frac{34.6 \Gamma Q_0 T E (1 - e^{-0.693t/T_p})}{(r)^2}$$

where: $D(t)$ = Accumulated dose to time t , in rem;
 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
 Γ = Specific gamma ray constant for a point source, R/millicuries (mCi)-hr at 1 cm;
 Q_0 = Initial activity at the start of the time interval;
 T_p = Physical half-life, in days;
 E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
 r = Distance in cm. This value is typically 100 cm; and
 t = Exposure time in days

This calculation considers only the external dose to an individual from exposure to a released patient. For some radionuclides, such as sodium iodide I-131, it may be necessary to also consider the internal dose from exposure to a released patient. The internal and external doses must be summed to determine the total dose. See Section B.3, "Internal Dose," for a discussion of internal dose.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table P-1

In Table P-1 in this Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior [as discussed in the supporting regulatory analysis (Ref. B-11)], suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is

from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table P-1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E , at 1 meter, may be useful for patient-specific calculations:

- $E = 0.75$ when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- $E = 0.25$ when an effective half-life is greater than 1 day, if the patient has been given instructions, such as
 - Maintain a prudent distance from others for at least the first 2 days.
 - Sleep alone in a room for at least the first night.
 - Do not travel by airplane or mass transportation for at least the first day.
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days.
 - Have sole use of a bathroom for at least the first 2 days.
 - Drink plenty of fluids for at least the first 2 days.
- $E = 0.125$ when an effective half-life is greater than 1 day if the patient has been given instructions, such as
 - Follow the instructions for $E = 0.25$ above.
 - Live alone for at least the first 2 days.
 - Have few visits by family or friends for at least the first 2 days.

In a two-component model (e.g., uptake of sodium iodide I-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to 1 day but is greater than 1 day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely external dose to an individual exposed to a patient who has received 2,220 megabecquerels (MBq) [60 mCi] of sodium iodide I-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation P-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{(r)^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6 \left(2.2 R \cdot \frac{\text{cm}^2}{\text{mCi}} \cdot \text{hr} \right) (60 \text{ mCi})(8.04 \text{ d})(0.125)}{(100 \text{ cm})^2}$$

$$D(\infty) = 0.459 \text{ rem [4.59 mSv]}$$

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3, "Internal Dose," for a discussion of internal dose and sample calculations. Unless the internal dose is likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose.

If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 0.41 mSv [0.041 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. The patient may be released, but §289.256(cc)(2) requires that instructions be given to the patient on maintaining doses to others ALARA. A record of the calculation must be maintained, pursuant to 25 TAC §289.256(cc)(3)(A), because an occupancy factor of less than 0.25 at 1 meter was used.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 25 TAC §289.256(cc). The effective half-life is defined as

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

where: T_b = Biological half-life of the radionuclide and

T_p = Physical half-life of the radionuclide.

The behavior of sodium iodide I-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F1 and F2, respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p}$$

where: T_{b1} = Biological half-life for extrathyroidal iodide;

T_{b2} = Biological half-life of iodide following uptake by the thyroid;
and

T_p = Physical half-life of I-131.

However, simple exponential excretion models do not account for (i) the time for the I-131 to be absorbed from the stomach to the blood; and (ii) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of I-131.

Thus, an equation to calculate the dose from a patient administered sodium iodide I-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of I-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \text{ cm})^2} \{E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1\text{eff}} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2\text{eff}}\}$$

where: F_1 = Extrathyroidal uptake fraction;

F_2 = Thyroidal uptake fraction;

E_1 = Occupancy factor for the first 8 hours; and

E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 , and $T_{2\text{eff}}$ are shown in Table U-6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by §289.256(cc)(3) is described in Section P.3.1 of this Appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely external dose to an individual exposed to a patient to whom 5,550 MBq [150 mCi] of sodium iodide I-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose will be calculated by using Equation B-5 to account for the elimination of I-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table U-5. The uptake fractions and effective half-lives are from Table U-6. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the

second and third components, an occupancy factor of 0.25 will be used, because (i) the effective half-life associated with the dominant component is greater than 1 day; and (ii) patient-specific questions were provided to the patient to justify the occupancy factor. See Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations," of this Supplement.

Table P-6 Uptake Fractions and Effective Half-Lives for Sodium-Iodide Iodine-131 Treatments				
	Extrathyroidal Component		Thyroidal Component	
Medical Condition	Uptake Fraction F₁	Effective Half-Life T_{1eff} (day)	Uptake Fraction F₂	Effective Half-Life T_{2eff} (day)
Hyperthyroidism	0.201 [*]	0.322 [†]	0.801 [*]	5.21 [*]
Post-Thyroidectomy for Thyroid Cancer	0.953 [‡]	0.322 [†]	0.053 [‡]	7.32 [†]

^{*}M. G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," Journal of Nuclear Medicine, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the Journal of Nuclear Medicine document.

[†]ICRP Publication No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.

[‡]The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC Medical Visiting Fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100 \text{ cm})^2} \left\{ (0.75)(8.04)(0.8) \left(1 - e^{-\frac{0.693(0.33)}{8.04}} \right) + e^{-\frac{0.693(0.33)}{8.04}} (0.25)(0.95)(0.32) \right. \\ \left. + e^{-\frac{0.693(0.33)}{8.04}} (0.25)(0.05)(7.3) \right\}$$

$$D(\infty) = 0.340 \text{ rem } [3.40 \text{ mSv}]$$

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3, "Internal Dose," for a discussion of internal dose and sample calculations. Unless the internal dose is likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose.

If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 1.6 mSv [0.160 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. This patient would not have to remain under licensee control and could be released under 25 TAC §289.256(cc), assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the sum of the internal and external doses is not greater than 5 mSv [0.5 rem].

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely external dose to an individual exposed to a patient to whom 2,035 MBq [55 mCi] of sodium iodide I-131 have been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, the dose will again be calculated using Equation B-5, Table P-5, and Table P-6, to account for the elimination of I-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E , of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor. See Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations."

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100 \text{ cm})^2} \left\{ ((0.75)(8.04)(0.8) \left(1 - e^{-\frac{0.693(0.33)}{8.04}} \right) + e^{-\frac{0.693(0.33)}{8.04}} (0.25)(0.20)(0.32) \right. \\ \left. + e^{-\frac{0.693(0.33)}{8.04}} (0.25)(0.80)(5.2) \right\}$$

$$D(\infty) = 0.486 \text{ rem [4.86 mSv]}$$

Note that this calculation considers only the external dose to an individual from exposure to a released patient. For sodium iodide I-131, internal dose to an individual from exposure to a released patient should also be considered. See Section B.3 for a discussion of internal dose and sample calculations. Unless the internal dose is

likely to be less than 10% of the external dose, the internal and external doses must be summed to determine the total dose. If the internal dose from exposure to this patient is calculated to be less than 10% of the external dose or less than 0.14 mSv [0.014 rem], the sum of the internal and external doses is less than 5 mSv [0.5 rem]. The patient would not have to remain under licensee control and could be released under §289.256(cc) when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as sodium iodide I-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q(10^{-5})(DCF)$$

where: D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;

Q = Activity administered to the patient in mCi;

10^{-5} = Assumed fractional intake; and

DCF = Dose conversion factor to convert an intake in mCi to an internal committed effective dose equivalent¹

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb¹ was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental

¹ 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

airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies²³ regarding the intakes of individuals exposed to patients administered sodium iodide I-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 1221 MBq [33 mCi] of sodium iodide I-131 have been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/mCi from Table 2.2 of K.F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.017 \text{ rem [0.17 mSv]}$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv [0.5 rem]. Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose, if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake

² 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.

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

of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients." The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see NUREG-1492.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5,550 MBq [150 mCi] of sodium iodide I-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, the dose is again calculated using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.08 \text{ rem [0.80 mSv]}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 mSv [0.34 rem], while the internal dose would be about 0.80 mSv [0.08 rem]. Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose: 4.2 mSv [0.42 rem].

Other Reference Documents

- ANSI N13.54, "Fetal Radiation Dose Calculations," January 2008.
- ICRP Publication No. 53, "Radiation Dose to Patients from Radiopharmaceuticals," 1987.
- ICRP Report No. 80, "Radiation Dose to Patients from Radiopharmaceuticals (Addendum to ICRP Publication 53)," 1998.
- ICRP Report No. 106, "Radiation Dose to Patients from Radiopharmaceuticals (Addendum 3 to ICRP Publication 53)," 2008.
- NCRP Report No. 128, "Radionuclide Exposure of the Embryo/Fetus," 1998.
- Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Materials," April 1997.

Regulatory Analysis

- NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," February 1997, provides the regulatory basis and examines the costs and benefits.

APPENDIX Q VETERINARY USE OF RADIOACTIVE MATERIAL

This appendix provides additional information on the use of radioactive materials by veterinarians. Title 25 Texas Administrative Code §289.256 establishes the requirements and provisions for the veterinary use of radioactive material. Use of radioactive materials in animals for research is outside the scope of this guide.

Applicants should note that authorization from the agency for veterinary use of radioactive material does not relieve them of their responsibilities to comply with any other applicable Federal, State, or local regulatory requirements.

The most common veterinary uses of radioactive material in animals are the administration of iodine-131 for therapeutic treatment of cats and the administration of technetium-99m for diagnostic studies in horses. Veterinarians obtain radioactive compounds, radiopharmaceuticals, or sealed sources for diagnosis and therapy of animals from the same suppliers as medical facilities administering radioactive material to humans. The applicant should describe how licensed materials will be obtained, such as in unit doses from a radiopharmacy.

Most animals that veterinarians treat are pets that will be returned to their owners, and special care must be taken to ensure that doses to the owners, who are members of the public, will be as low as is reasonably achievable (ALARA). Therefore, the veterinary facility must also provide instructions to the pet owner on the care and handling of the animal when it is released. An authorized user for veterinary use must be licensed by the Texas State Board of Veterinary Medical Examiners and be certified by the American College of Veterinary Radiology for the use of radioactive materials in veterinary medicine or has received training in accordance with subsections (gg), (jj), (nn) – (qq), (aaa), (ccc), and (ttt) of 289.256 or is identified as an AU on an agency, NRC, agreement state license that authorizes the veterinary use of radioactive material.

Training for Staff Using Radionuclides in Animals

Before allowing an individual to care for animals that are treated with licensed material, the licensee must ensure that he or she has sufficient training and experience to, among other things, maintain doses ALARA, control contamination, and handle waste appropriately.

Classroom training may be by traditional lecture, online or recorded presentations, self-study, or other appropriate forms, and should cover the following subject areas:

- principles and practices of radiation protection
- radioactivity measurements, monitoring techniques, and using instruments
- mathematics and calculations basic to using and measuring radioactivity

- biological effects of radiation

Appropriate on-the-job-training should consist of

- Observing authorized personnel perform licensed activities with animals, including administration of the radioactive material to the animal, using survey equipment, proper contamination control techniques, and proper methods for disposal of radioactive material.
- Performing licensed activities with animals under the supervision of, and in the physical presence of, an individual authorized to handle animals treated with licensed material or otherwise containing licensed material. It is recommended that an individual practice new procedures without the use of radioactive materials prior to performing licensed activities. Activities should include the administration of radioactive material to an animal, use of survey equipment, proper contamination control techniques, and proper disposal of radioactive material.
- Training that is specific to the radionuclides (types, forms, and quantities; radiations emitted; chemical composition) used under the license, the procedures that will be performed, the animals used, and the surveys and contamination control activities necessary for the materials used and procedures performed.

Contamination Control

To minimize the spread of contamination, the animals administered licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages should be secured to prevent unauthorized access to the animals. Animal housing should be clearly posted or labeled so that caretakers know which animals have been involved in radioactive material studies. Care should be taken when posting/labeling cages to ensure that the posting or labeling does not become an ingestion or choking hazard to the animal. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, eye protection, or other protective clothing, as appropriate.

Special care should be observed when cleaning a cage or stall that may contain radioactive material in the bedding and waste (excreta) from the animal. Any radioactive material should be properly disposed of as described in Item 10 "Waste Management/Waste Disposal."

The use of some compounds in animals may require special procedures, equipment, or facilities. For example, carbon-14 labeled compounds used in animals may be eliminated as carbon dioxide in the animals' breath, and the animals may need to be contained in a facility with special ventilation and air-handling capabilities. Studies of fish with licensed materials may require separate water handling and testing.

Special precautions also may be needed for handling of animals and performing surveys if alpha-emitting radionuclides are used.

Waste Handling

Disposal of animal carcasses that contain radioactive material may require special procedures. Animal carcasses that contain less than 1.85 kilobecquerels [0.05 microcuries] of carbon-14 or hydrogen-3 per gram of animal tissue, averaged over the weight of the entire animal, may be disposed of by the same method as nonradioactive animal carcasses. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in-storage (DIS). The DIS animal carcasses may be disposed of as nonradioactive, if radiation surveys (performed with an appropriate radiation survey instrument, in a low background area, and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background. Animal carcasses containing other long-lived radioactive materials must be disposed of as radioactive waste.

Disposal of contaminated items such as animal bedding, syringes, protective gloves, booties, and paper coverings may be by DIS if the licensed materials have half-lives of 120 days or less, or by transfer to a licensed waste broker for long-lived radioactive materials. Some wastes may be suitable for disposal to the sanitary sewer, such as animal excreta, which is readily dispersible biological material and could meet the criteria in 25 TAC §289.202(gg). See Item 10, "Waste Management/Waste Disposal," and Appendix S of this guide for more information on waste disposal.

Release of Animals for Unrestricted Use

Any animal that has been injected with a radioactive compound or has had radioactive sources implanted cannot be released until the researcher or veterinarian ensures that the dose that members of the public will receive from the animal is within limits of 25 TAC §289.202(n), "Dose limits for individual members of the public." Title 25 TAC §289.202(n) requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 0.1 rem or 100 millirem (mrem) [1 millisievert (mSv)] in a year and that the dose in any unrestricted area from external sources does not exceed 0.002 rem or 2 mrem [0.02 mSv] in any 1 hour. **A member of the public is any individual, except when that individual is receiving an occupational dose. Members of the public, therefore, include bystanders, pet owners, family members, or other caretakers of the animal after the researcher or veterinarian has released it.**

Scientists or veterinarians may release animals that received radioactive material for diagnostic, therapeutic, or research purposes to animal caretakers after treatment. These animals are considered "radioactive" and placed in cages and rooms

that are posted/labeled with appropriate warning signs until the animals can be released to the "uncontrolled" population or their owners. Criteria should be developed by the licensee for assessing this release. Items to be considered for release of the animals include the type of radionuclide and concentration in the urine and/or feces; and the dose rate on contact (or at some distance from) the accessible side of the cage.

The most common example of a situation in which animals are treated with licensed materials and then released is the administration of iodine-131 (I-131) to cats for the treatment of hyperthyroidism. Therefore, this treatment will be used as an example for release of animals following administration of licensed material.

Cats can be released after treatment with I-131 when:

- cats are held not less than 4 complete days [96 hours] after administration

AND

- the dose rate is less than 1 milliroentgen (mR)/hour (h) [0.01 mSv per hour (mSv/h)] at 6 inches {or 0.25 mR/h [0.0025 mSv/h] at 1 foot}

AND

- written instructions are provided to the owners

AND

- the licensee can demonstrate that a member of the public would not receive a dose from the cat that would exceed 0.002 rem or 2 mrem [0.02 mSv] in any one hour or 0.1 rem or 100 mrem [1 mSv] in a year (the limits of 25 TAC §289.202(n))

The licensee must ensure that the dose from a cat treated with I-131 to individual members of the public (including members of the family) does not exceed the 0.002 rem or 2 mrem [0.02 mSv] in any one hour, and 0.1 rem or 100 mrem [1 mSv] annual public dose limit specified in 25 TAC §289.202(n). The licensee should provide the owner with written instructions (to avoid confusion) to reduce the dose to members of the public. The instructions should provide a margin for dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below the 0.1 rem or 100 mrem [1 mSv] public dose limit.

In applying the above criteria for release of cats, patient-specific information and radiation data should also be considered. The dose rate of 0.25 mR/h [0.0025 mSv/h] at 1 foot is a conservative release criteria. If the owner follows instructions to limit interaction with the cat for the first few days, it is unlikely that a person would receive a 0.1 rem or 100 mrem [1 mSv] dose. The applicant must include criteria for release of cats treated with licensed materials from veterinary or laboratory activities in its application for review and approval, before implementation.

The agency may accept alternate proposed criteria for veterinary cat release if (i) the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and (ii) the potential dose would be well below 0.002 rem or 2 mrem [0.02 mSv] in any one hour and 0.1 rem or 100 mrem [1 mSv] in a year. Such proposals will be reviewed on a case-by-case basis. Additional consideration may be necessary when establishing the date for release of a cat treated with I-131 to a home with small children.

For cats, release criteria above 0.5 mR/h at 1 foot are not recommended because it is unlikely that, if release criteria is less restrictive, doses to members of the public will be less than 0.002 rem or 2 mrem [0.02 mSv] in any one hour, and less than 0.1 rem or 100 mrem [1 mSv] in a year. In addition, cats released at higher radiation levels also may contain enough radioactive material that I-131 contamination of the owner and home from saliva, urine, and feces may be of concern.

Criteria for release of cats and other animals treated with licensed materials from veterinary or laboratory activities must be included in the application for review and approval, before implementation. Regardless of the release level used, the licensee should have records to document that the veterinary patient release criterion used for an individual veterinary patient will result in compliance with 25 TAC §289.202(n).

Instructions to Animal Caretaker upon Release

Once the veterinarian determines that the animal meets the dose criteria for release, instructions should be given to the animal's caretaker. Written instructions should address, at a minimum: (i) waste handling, (ii) contamination, and (iii) human interaction with instructions for isolation of the animal.

These instructions should be specific to the type of treatment given, such as permanent implants, or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions.

Although it is acceptable to immediately dispose of nonradioactive animal excreta in a landfill, radioactive waste may not be disposed of in this way. For animals treated with short-lived radioactive materials, instructions to caretakers should include storing animal excreta in an appropriate location for a designated period of time to allow the radioactive material to decay. Many solid waste disposal facilities have installed radiation detectors to prevent the disposal of radioactive material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a hazardous, costly, and time-consuming process.

Items to consider including in the instructions are

- the regulatory limits and the need to keep doses ALARA
- the potential radiation fields surrounding the animal and potential dose with time at various distances
- maintaining distance from people in public places and the home
- minimizing time in public places (e.g., walks on public sidewalks, parks, beaches, grooming salons)
- precautions to reduce the spread of radioactive contamination
- the handling and storage of animal excreta, and the duration of storage if held for decay
- the permitted extent and duration of contact by individuals with the animal, and handling of contaminated bedding and other objects with which the animal comes into contact
- the length of time each of these precautions should be in effect

Sample Instructions to Caretakers of Animals Administered Radiopharmaceuticals or Other Unsealed Radionuclides

The animal has been treated with radioactive material [Insert isotope] and still contains a low level of radioactivity. The present level of radioactivity is below the regulatory agency level necessary for isolating the animal from humans. Because some radioactivity will be present for the next few days, it is necessary that the following safety precautions be exercised for the next days:

- Avoid public transportation; avoid staying in public accommodations (e.g., hotels). Transport your animal in its carrier as far from passengers as is reasonable and safe for the animal.
- The animal should be kept inside or in his cage or stall following hospital discharge.
- The animal should not be permitted to have prolonged contact with children under the age of 12 for _____ days following hospital discharge. Close contact should be limited to less than _____ minutes per day.
- Pregnant women should avoid ANY contact with the animal or its urine and feces for at least _____ days after discharge.

- Family members should not be permitted to sleep with the animal for _____ days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next _____ day(s) to no more than _____ minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period.
- Use plastic litter pan liners and scoopable litter (for cats).
- Disposable gloves should be worn whenever handling animal waste, including changing the litter box for the next _____ days after discharge.
- Wash hands after contact with the animal or the litter.
- Call _____ to discuss any other radiation safety concerns.

Sample Instructions to Caretakers of Animals Implanted with Radioactive Sealed Sources

A small radioactive source has been placed (implanted) inside the animal. The source actually consists of many small metallic pellets or seeds, which are each about 1/4-inch to 1/3-inch long, similar in size and shape to a grain of rice.

The following precautions should be taken for _____ days, to minimize exposure to radiation to humans from the source inside the animal:

- Stay at a distance of _____ feet from _____.
- Avoid public transportation.
- Transport your animal in its carrier as far away from passengers as is reasonable.
- Maintain separate sleeping arrangements, and avoid staying in public accommodations (e.g., hotels).
- Minimize time that children and pregnant women are with the animal.
- Do not hold or cuddle the pet.
- Examine any bandages that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If a seed or pellet has fallen out, do the following:

- Do not handle it with fingers. Use something like a spoon or tweezers to place it in a jar or other container that can be closed with a lid.
- Place the container with the seed or pellet in a location away from people.
- Call _____ to discuss disposal of the released seed or pellet and any other radiation safety concerns.

APPENDIX R REPORTING REQUIREMENTS

The following table identifies relevant notification and reporting requirements that a licensee should make to the agency. Additional notification and reporting requirements are described in 25 TAC §289.

Event	Telephone Notification	Written Report	Regulatory Requirement
Removable surface contamination or external radiation levels from a RAM package exceeds the limits in §289.202(ee)(4)(A) and (B)	Immediate via either telephone, facsimile or electronic media transmission	**	§289.202(ee)(4)
Stolen, lost or missing radioactive material in an aggregate quantity $\geq 1,000$ times the quantity in §289.202 (ggg)(3)	Immediate	30 days after making the telephone report	§289.202(ww)(1)(A)
Stolen, lost or missing radioactive material in an aggregate quantity > 10 times the quantity in §289.202 (ggg)(3)	30 days	30 days after making the telephone report	§289.202(ww)(1)(B)
Event involving a source of radiation that may have caused or threatens to cause a TEDE dose ≥ 25 rems	Immediate	30 days	§289.202(xx)(1)(A)(i)
Event involving a source of radiation that may have caused or threatens to cause a lens dose ≥ 75 rem	Immediate	30 days	§289.202(xx)(1)(A)(ii)

Event	Telephone Notification	Written Report	Regulatory Requirement
Event involving a source of radiation that may have caused or threatens to cause a shallow dose equivalent to skin or extremities or a total organ dose equivalent ≥ 250 rads	Immediate	30 days	§289.202(xx)(1)(A)(iii)
Event involving loss of control of a source of radiation that may have caused or threatens to cause a TEDE > 5 rem in 24 hours	24 hours	30 days	§289.202(xx)(2)(A)(i)
Event involving loss of control of a source of radiation that may have caused or threatens to cause a lens dose equivalent > 15 rem in 24 hours	24 hours	30 days	§289.202(xx)(2)(A)(ii)
Event involving loss of control of a source of radiation that may have caused or threatens to cause a shallow dose equivalent to the skin or extremities or a total organ dose equivalent > 50 rem in 24 hours	24 hours	30 days	§289.202(xx)(2)(A)(iii)
The release of RAM, inside or outside a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake > 1 occupational ALI	24 hours	30 days	§289.202(xx)(2)(B)
Occupational dose greater than 5 rem (0.05 Sv)	None	30 days	§289.202(yy)(1)(B)(i)

Event	Telephone Notification	Written Report	Regulatory Requirement
Dose to a minor greater than 500 mrem (5 mSv)	None	30 days	§289.202(yy)(1)(B)(ii)
Dose to an embryo/fetus of a declared pregnant woman greater than 0.5 rem (5 mSv)	None	30 days	§289.202(yy)(1)(B)(iii)
Dose to individual member of public greater than 100 mrem (1 mSv)	None	30 days	§289.202(yy)(1)(B)(iv)
Event that prevents immediate protective actions necessary to avoid exposure to RAM that could exceed limits or releases of RAM that could exceed limits	Immediate	30 days	§289.202(xx)(6)
An unplanned contamination event that requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area	24 hours	30 days	§289.202(xx)(7)(A)(i)
An unplanned contamination event that involves a quantity of material > 5 times the lowest annual limit on intake specified in §289.202(ggg)(2) for the material	24 hours	30 days	§289.202(xx)(7)(A)(ii)

Event	Telephone Notification	Written Report	Regulatory Requirement
An unplanned contamination event has access to the area restricted for a reason other than to allow isotopes with a half-life < 24 hours to decay prior to decontamination	24 hours	30 days	§289.202(xx)(7)(A)(iii)
Equipment is disabled or fails to function as designed when...required to prevent radiation exposure in excess of limits	24 hours	30 days	§289.202(xx)(7)(B)(i)
...required to be available and operable when it is disabled or fails to function	24 hours	30 days	§289.202(xx)(7)(B)(ii)
...no redundant equipment is available and operable to perform the required safety function	24 hours	30 days	§289.202(xx)(7)(B)(iii)
Unplanned fire or explosion damaging any RAM or any device, container, or equipment containing RAM when the damage affects the integrity of the RAM or its container	24 hours	30 days	§289.202(xx)(7)(D)
The licensee shall submit a written report following any planned special exposure, informing the agency that a PSE was conducted and indicating the date it occurred and the information required by subsection §289.202(qq)	None	30 days	§289.202(zz)

Event	Telephone Notification	Written Report	Regulatory Requirement
Test for leakage or contamination indicates a sealed source is leaking or contaminated	Immediate	5 days	§289.202(bbb)
Vacating premises that possessed non-exempt source of radiation	None	30 days prior to vacating or relinquishing control	§289.202(ccc)
Change in licensee name, mailing address or RSO	None	15 days	§289.252(x)(5)
Voluntary or involuntary filing of bankruptcy by licensee or parent company	None	Immediately following the filing	§289.252(x)(6) & (7)
The license has expired or has been revoked	None	Within 60 days of occurrence	§289.252(y)(4)(A)
The licensee has decided to permanently cease principal activities at an entire site or in any separate building or outdoor area	None	Within 60 days of occurrence	§289.252(y)(4)(B)
No principal activities have been conducted for a period of 24 months at an entire site as specified on the license	None	Within 60 days of occurrence	§289.252(y)(4)(C)

Event	Telephone Notification	Written Report	Regulatory Requirement
No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release per §289.202(eee)	None	Within 60 days of occurrence	§289.252(y)(4)(D)
A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dose by more than 5 rem effective dose equivalent, 50 rem to an organ or tissue or 50 rem shallow dose equivalent to the skin AND EITHER:			
Total dose differs from the prescribed dose by 20% or more	The next calendar day	15 days	§289.256(uuu)(1)(A)(i)
Total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dose range	The next calendar day	15 days	§289.256(uuu)(1)(A)(ii)
The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more	The next calendar day	15 days	§289.256(uuu)(1)(A)(iii)
A dose that exceeds 5 rem EDE, 50 rem to an organ or tissue or 50 rem to the skin from any of the following:			

Event	Telephone Notification	Written Report	Regulatory Requirement
An administration of a wrong radioactive drug containing radioactive material	The next calendar day	15 days	§289.256(uuu)(1)(B)(i)
An administration of a radioactive drug containing RAM by the wrong route of administration	The next calendar day	15 days	§289.256(uuu)(1)(B)(ii)
An administration of a dose or dosage to the wrong individual	The next calendar day	15 days	§289.256(uuu)(1)(B)(iii)
An administration of a dose or dosage delivered by the wrong mode of treatment	The next calendar day	15 days	§289.256(uuu)(1)(B)(iv)
A leaking sealed source	The next calendar day	15 days	§289.256(uuu)(1)(B)(v)
A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem to an organ or tissue and 50% of more of the dose expected from the administration defined in the written directive	The next calendar day	15 days	§289.256(uuu)(1)(C)

Event	Telephone Notification	Written Report	Regulatory Requirement
Any event resulting from intervention of a patient or human research subject in which the administration of RAM or radiation from RAM, results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician	The next calendar day	15 days	§289.256(uuu)(2)
Any dose to an embryo/fetus that is greater than 5 rem dose equivalent that is a result of an administration of RAM or radiation from RAM to a pregnant individual, unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user	The next calendar day	15 days	§289.256(vvv)(1)
Any dose to a nursing child that is a result of an administration of RAM to a breast feeding individual that (A) is greater than 5 rem TEDE; or (B) has resulted in unintended permanent functional damage to an organ or a physiological system, as determined by a physician	The next calendar day	15 days	§289.256(vvv)(2)

APPENDIX S MODEL PROCEDURES FOR WASTE DISPOSAL BY DECAY-IN-STORAGE, LICENSED MATERIAL RETURN, AND DISPOSAL OF LIQUIDS INTO SANITARY SEWERAGE

This model provides acceptable procedures for waste disposal. Most licensees will dispose of material that fall within these procedures. Note that some short half-life radionuclide products [e.g., technetium-99m (Tc-99m)/molybdenum-99 (Mo-99) generator columns] may contain long half-life contaminants that may preclude disposal by decay-in-storage and may require disposal by alternate methods, such as return to the manufacturer. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements for waste management in 25 TAC §289.202(ff) – (kk), 25 TAC §289.202(e), 25 TAC §289.252(cc), and 25 TAC §289.256(ee).

Model Procedure for Decay-In-Storage

Rules in 25 TAC §289.256(ee) describe the requirements for decay-in-storage. Applicants should ensure that adequate space and facilities are available for the storage of waste for decay-in-storage (DIS). Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at as low as is reasonably achievable levels. Storage areas must be in a secure location.

- Only short-lived waste (physical half-life of less than or equal to 120 days) may be disposed of by DIS.
- Waste should be stored in suitable well-marked containers, and the containers should provide adequate shielding.
- Liquid and solid wastes should be stored separately.
- If possible, use separate containers for different types of waste (e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Because the waste will be surveyed with all shielding removed, the containers in which the waste will be placed must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container.
- The identification label should include the date when the container was sealed, the longest-lived radionuclide in the container. The container should be labeled in accordance with 25 TAC §289.202(cc) and (dd). The container may be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after many half-lives and persons performing surveys should be aware of the potential for measurable radiation.

- The contents of the container should be allowed to decay for a period of time after which it is expected that the radiation levels would not be distinguishable from background. The period of time depends on both the half-life of the radionuclide(s) and the original amount present.
- Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:
 - Use a survey instrument that is appropriate for the type and energy of the radiation being measured.
 - Check the radiation survey meter for proper operation and current calibration status.
 - Monitor in a low-level radiation area away from all sources of radioactive material, if possible.
 - Remove any shielding from around the container or generator column.
 - Monitor, at contact, all surfaces of each individual container.
 - Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in 25 TAC §289.256(ee)).
 - Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
 - Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive material recipient.
 - Short half-life radionuclide products such as samarium-153 (Sm-153), Tc-99m/Mo-99 generator columns, and Y-90 microspheres may contain long half-life contaminants that may preclude disposal by decay-in-storage. Licensees need to perform surveys and dispose of long half-life contaminants in accordance with 25 TAC §289.202 and 25 TAC §289.256 requirements.

Note: Check for any calibration sources with half-lives greater than 120 days (e.g., cobalt-57, germanium-68, gadolinium-153), as these may not be held for decay-in-storage and must be disposed of in accordance with 25 TAC §289.202 and 25 TAC §289.252.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m, strontium-82/rubidium-82, or germanium-68/gallium-68 generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 25 TAC §289.257 and U.S. Department of Transportation (DOT) regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with 25 TAC §289.201(d), "Records."

Model Procedure for Return of Licensed Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with 25 TAC §289.252(cc)(3), confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's radioactive material license issued by the agency, the NRC or an Agreement State).
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container.
- Assemble the package in accordance with the manufacturer's instructions.
- Perform the dose-rate and removable-contamination measurements.
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions.
- Retain records of receipts and transfers in accordance with 25 TAC §289.201(d).

Model Procedure for Disposal of Liquids into Sanitary Sewerage

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system or leach field.
- Confirm that the liquid waste being discharged is soluble (or is biological material that is readily dispersible) in water.
- Calculate the amount of each radionuclide that can be discharged by using the information from prior, similar discharges and the information in 25 TAC §289.202(ggg)(2).
- Make sure that the amount of each radionuclide does not exceed the monthly and annual discharge limits specified in 25 TAC §289.202(gg)(1)(D) and 25 TAC §289.202(ggg)(2)(F), Table III.
- If more than one radionuclide is released, the sum of the ratios of the average monthly discharge of a radionuclide to the corresponding limit in 25 TAC §289.202(ggg)(2)(F), Table III must not exceed unity.
- Confirm that the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 5 Curies (Ci) [185 gigabecquerel (GBq)] of H-3 (tritium), 1 Ci [37 GBq] of C-14, and 1 Ci [37 Gbq] of all other radionuclides combined.
- Record the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the name of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks, toilets, or other release points.
- Discharge liquid waste slowly to minimize splashing with water running, to be sure that the material moves out of the sink and into the sewer system.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remained in the sink or on work surfaces.
- Decontaminate all areas or surfaces if found to be contaminated.
- Maintain records of releases of licensed material to the sanitary sewer system. These records should include, for each release, the date, radionuclide(s), estimated activity of each radionuclide, location where the material is discharged, and the initials of the individual discharging the waste. For the licensed facility as a whole, records should be maintained of the quantity and concentration of radionuclides that are released into the sewer system that

demonstrate compliance with the regulatory limits for limits for total quantity released and concentrations released by the licensed facility.