APPLICATION GUIDE FOR MEDICAL USE OF RADIOACTIVE MATERIAL

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

I. Overview .......................................................................................................................... 4
  Scope and Purpose ........................................................................................................... 4
  Types of Licenses ............................................................................................................. 5
  Applicable Rules .............................................................................................................. 6
  Format of this Guide ......................................................................................................... 7
    Purpose of appendices and Note on Procedures .............................................................. 7

II. How to File an Application .............................................................................................. 8
  Application Preparation .................................................................................................... 8
  Agency Contacts ............................................................................................................... 8
  Where to File .................................................................................................................... 9

III. Management Responsibility .......................................................................................... 10

IV. Contents of an Application ............................................................................................. 11
  Introduction ...................................................................................................................... 11
  Item 1: License Action Type ........................................................................................... 11
  Item 2: Legal Business Name and Mailing Address of Applicant/Licensee ................... 11
  Item 3a: Address(es) of Radioactive Material Use and/or Storage .................................. 12
  Item 3b: Address Where Records Will be Maintained ..................................................... 12
  Item 4: Radiation Safety Officer ...................................................................................... 13
  Item 5: Radioactive Material Requested ......................................................................... 13
  Item 6: Individual(s) Responsible for the Radiation Safety Program and Their Training and Experience ......................................................................................................................... 15
    6.1 Radiation Safety Officer ......................................................................................... 15
    6.2 Authorized Users ................................................................................................... 18
  Item 7: Training for Individuals Working in or Frequenting Restricted Areas ................... 19
  Item 8: Facilities and Equipment .................................................................................... 21
    8.1: Facility Diagram .................................................................................................... 21
    8.2: Radiation Monitoring Instruments ......................................................................... 23
    8.3: Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material ......................................................................................................................... 25
    8.4: Other Equipment and Facilities ............................................................................ 27
  Item 9: Radiation Protection Program ........................................................................... 28
    9.1 Audit Program ........................................................................................................ 29
Chapter 9: Operations

9.2 Occupational Dose

9.3 Public Dose

9.4 Operating, Safety, and Emergency Procedures

9.5 Ordering and Receiving

9.6 Opening Packages

9.7 Material Receipt and Accountability

9.8 Leak Tests

9.9 Area Surveys

9.10 Procedures for Administrations When a Written Directive is Required

9.11 Safe Use of Unsealed Radioactive Material

9.12 Mobile Nuclear Medicine Service

9.13 Minimization of Contamination

9.14 Records of Dosages

9.15 Recordkeeping

9.16 Reporting

9.17 Transportation

Item 10: Waste Management/Waste Disposal

Item 11: Financial Qualification and Financial Assurance

Item 12: Certification

V. License Amendments

Timely Submittal of Amendments

Timely Notification of Transfer of Control

Notification of Bankruptcy Proceedings

Other

VI. License Renewals

Appendix A License Application Checklist

Appendix B RSO Responsibilities

Appendix C Model Training Program

Appendix D Supplemental Information for Use of Xe-133

Appendix E Model Procedures for Calibration of Dose Calibrators

Appendix F Model Medical Licensee Audit

Appendix G Model Procedures for Occupational Dose Program

Appendix H Model Emergency Procedures
Appendix I Ordering and Receiving Packages.................................................. 114
Appendix J Model Procedure for Area Surveys .............................................. 116
Appendix K Model Procedures for Developing, Maintaining and Implementing Written Directives ................................................................. 122
Appendix L Model Procedures for Safe Use of Radioactive Material .......... 124
Appendix M Radioactive Materials Guidance for Mobile Nuclear Medicine Services ................................................................. 126
Appendix N Reporting Requirements .............................................................. 134
Appendix O Model Procedures for Waste Disposal by Decay-In-Storage, Licensed Material Return, and Disposal of Liquids into Sanitary Sewerage .......... 138
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 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)
- Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries, under 25 TAC §289.256(kk) “Use of unsealed radioactive material that requires a written directive” (A written directive is required for any administration of sodium iodide I-131 greater than 30 microcuries.)
- Use of sealed sources for diagnosis under 25 TAC §289.256(bbb)
- 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/.
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, NRC or Agreement State license, (ii) on a permit issued by an NRC master materials licensee or an NRC master materials broad scope permittee that is authorized to permit the medical use of 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 (i) on an agency, NRC or Agreement State license that authorizes the veterinary use of radioactive material, (ii) on a permit issued by an NRC master materials licensee or an NRC master materials broad scope permittee that is authorized to permit the medical use of 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.

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). 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”
“Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services”

“Hearing and Enforcement Procedures”

“Exemptions, General Licenses, and General License Acknowledgments”

“Licensing of Radioactive Material”

“Medical and Veterinary Use of Radioactive Material”

“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 part or item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant’s response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – provides suggested response(s) or indicates that no response is needed on that topic during the initial licensing process.

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

**PURPOSE OF APPENDICES AND NOTE ON PROCEDURES**

Attached to this guidance document are appendices that may be submitted as an applicant’s procedures. The first appendix 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.
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. Print should be clear, sharp and clearly appear on the paper.
- 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 512-834-6688 ext 2052 or RadiationFeesandRecords@dshs.texas.gov.
- 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.
- 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).

AGENCY CONTACTS

For questions on the application and any related correspondence, please contact
Phone: (512) 834-6688 extension 2861
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.

**WHERE TO FILE**

New license applications must be submitted as paper applications to the address noted in the table below, as applicable. License renewal applications of greater than 50 pages must also be submitted in paper format.

Renewal applications of 50 pages or less 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

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, U. S. Nuclear Regulatory Commission (NRC), and U. S. Department of Transportation (DOT) regulations and the licensee’s operating and emergency procedures.
- 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.
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) which is also identified for renewal applications 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 U.S. Nuclear Regulatory Commission 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(e)(11), 25 TAC §289.252(x)(2), (3), (5)-(8)

Criteria: 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).

Discussion: The name provided must be the legal business name of the company with direct control over the proposed uses of radioactive material. A division or department within the business should not be identified as the primary business name.
If an applicant elects to have an assumed name or “doing business as” (dba) name listed on the license, then it must be registered with the SoS or office of the county clerk as an assumed 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).

---

**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(II)(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(II)(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(h).

**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 §289.256(y), 25 TAC §289.256(ff), 25 TAC §289.256(hh), 25 TAC §289.256(kk), 25 TAC §289.256(bbb), 25 TAC §289.256(q)

**Criteria**: This guide addresses medical use of radioactive material for the following categories:

- 25 TAC §289.256(ff) “Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies that Do Not Require a Written Directive”;
- 25 TAC §289.256(hh) “Use of Unsealed Radioactive Material for Imaging and Localization Studies that Do Not Require a Written Directive”;
- 25 TAC §289.256(kk) “Use of Unsealed Radioactive Material that Requires a Written Directive”;
- 25 TAC §289.256(bbb) “Use of Sealed Sources for Diagnosis” and
- 25 TAC §289.256(q) “License for other Medical or Veterinary Uses of Radioactive Material or a Radiation Source Approved for Medical and Veterinary Use …”

**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 Table 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” radioactive material 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 Table 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 U.S. 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 Tc-99m, which is based on the exemption criteria in 25 TAC §289.251(e)(2), “Exempt Quantities.”

§289.256(kk) Use: Applicants requesting use of I-131 for imaging and localization studies in quantities greater than 30 microcuries but less than 33 millicuries must request I-131 with a chemical/physical form of “Sodium iodide (in capsule form only)”. The total amount requested must be specified. The applicant should define the purpose of use by stating “Oral administration of Sodium Iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries permitted by Title 25 TAC §289.256(kk)”.

Use of Iodine-131 for therapeutic applications is beyond the scope of this guide.

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 §289.256(q) Use: Applicants requesting use of sealed sources for radioactive seed localization will be authorized under this section. Applicants must provide the radionuclide; the sealed source by manufacturer and model number; the activity per source and the total activity in microcuries (μCi), millicuries (mCi), or curies (Ci); and the maximum number of sources or activity possessed at any one time. 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 use as “Radioactive seed localization permitted by 25 TAC §289.256(q)”.

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 quantity specified in 25 TAC §289.256(y), is exceeded, the specific sources need to be listed on the license.

**Response from Applicant:** The applicant should submit the information as described above. Applicants may complete and submit Table 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 §289.252(f), 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(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(ccc).

**Criteria:** Under 25 TAC §289.252(e)(1), the agency requires that an applicant 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. Training and experience of RSOs and authorized users must be provided as part of an application for radioactive material that will be administered to humans as per 25 TAC §289.256(f)(3)(C).

**Discussion:** 25 TAC §289.256(g) describes the authority and responsibilities of the RSO including establishing and overseeing operating, radiation safety, emergency, and ALARA procedures. Other personnel who have a role in the radiation protection program are Authorized Users (AU), Authorized Medical Physicists (AMP), Authorized Nuclear Pharmacists (ANP), 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 agency rules. 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 and AU 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 and AU 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
AUs 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) [check the rules to determine this date].

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

6.1 RADIATION SAFETY OFFICER

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(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 §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 §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. The RSO should have independent authority to stop operations that he or she considers unsafe. In accordance with §289.256(g)(1), the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties.
Typical RSO duties are described in the list below and in Appendix B of this guide. 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 B 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 §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 §289.256(g)(4)

**Response from Applicant:** Provide the following:

1. 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.

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(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(ccc).

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) and 25 TAC §289.256(ccc).

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). Practitioners not in good standing (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. Visiting Authorized Physician Users (locum tenens) is not authorized. All AUs must be authorized by this Agency prior to using and/or directing the medical use of radioactive material.

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.
**Response from Applicant:** Provide the following:

1. Names of proposed authorized users and the uses with identifying which user will be involved with a particular use;
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, 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 §289.257(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.”

Rule 25 TAC §289.252(e)(1) requires that 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. Rule 25 TAC §289.256(s), requires a licensee to provide safety instruction to all personnel using radioactive material, such as nuclear medicine technologists, under the supervision of an authorized user.

**Discussion:** AUs, 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 will 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 C of this guide provides a training program acceptable to the agency for training these individuals.

In accordance with 25 TAC §289.256(s), individuals who receive, possess, use, transfer, or prepare radioactive material for medical use under the supervision of an AU must 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 with respect to the use of radioactive material.

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. Department of Transportation (DOT) regulations.

Appendix C of this guide provides a model training program that provides one way to satisfy the requirements referenced above.

**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 C for a model program.

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(e)(2) and (e)(9).

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”.

21
Response from Applicant: Provide a brief description of the proposed location to offer an idea of the scope and magnitude of use for the facility including:

- the number and types of rooms that may be assigned as restricted areas,
- anticipated number of procedures that will be done per month,
- number of technologists employed,
- number of imaging cameras,
- number of treadmills used for stress testing,
- radiation delivery devices (e.g. xenon delivery/traps, aerosol units), present at the facility.

Provide a full facility floor plan (See Figure 1 as an example), that identifies:

- the restricted area
- the direction of north;
- receipt and storage areas (including waste);
- preparation, measurement, and work counters;
- additional safety equipment (e.g. fume hoods or shielding).
- all facility diagrams should include the address of the facility and the applicant’s legal business name.

Applicants using Xe-133 must submit additional information to demonstrate establishment of a constraint on air emissions and implementation of the ALARA requirement as described in 25 TAC §289.202(e)(4). Appendix D provides further guidance on this topic.
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 authorized by the license shall be operable and calibrated in accordance with 25 TAC §289.202(p)(3).

The licensee shall ensure calibration of survey instruments as described by 25 TAC §289.256(w).

**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).

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

Radiation survey meter calibrations must be performed by persons, including licensed personnel, who are qualified and authorized to perform calibrations in accordance with an agency, NRC, or an Agreement State license. The licensee must retain records of the calibration of instruments and equipment used for quantitative radiation measurements for 3 years after the record is made in accordance with 25 TAC §289.202(nn).

**Response from Applicant:** Provide the following:

- 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.”
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(v), 25 TAC §289.256(x).

Criteria: 25 TAC §289.256(v), “Possession, use, and calibration of dose calibrators to measure the activity of unsealed radioactive material,” describe requirements for the use, possession, calibration, and check of dose calibrators used to measure patient dosages.

The licensee must determine the activity of each dosage of unsealed radioactive, in accordance with 25 TAC §289.256(x).

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 E.

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.

For applicants who 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 who will use unit doses only:**

- 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

  OR

**Applicants who will 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 E or develop and submit your own procedure.

  AND

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

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

- a description of test procedures that ensure the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer’s specifications. The licensee must perform the tests at least
every twelve months (and repeated after repair or replacement), and maintain records that document the performance and results of these tests. The radiation detector specifications are compared to the values obtained during tests of the detector’s electronics and the response to a radiation source in the static mode. You may use documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and radiation detector test.

- Confirm that all authorized users and the radiation safety officer 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.

8.4: OTHER EQUIPMENT AND FACILITIES

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

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 acknowledging he or she 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.

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.

**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: Refer to Items 9.1 through 9.17 for guidance.
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. Department of Transportation (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 F 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 F 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

9.2 OCCUPATIONAL DOSE


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 by 25 TAC §289.201(b)(17) 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 G 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.

**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.

### 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 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.
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).

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 9.17 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**


**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 9.6, “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 9.7, “Material Receipt and Accountability”)
- Testing sealed sources for leakage or contamination (See Item 9.8 “Leak Tests”)
- Instructions for conducting area radiation level and contamination surveys (see Item 9.9, “Area Surveys”).
- Instructions for administering licensed material in accordance with the WD (see Item 9.10, “Procedures for Administrations when a Written Directive Is Required”).
- Instructions for the safe use of unsealed radioactive material (see Item 9.11)
- Steps to ensure that patient release is in accordance with 25 TAC §289.256(cc) (see Item 9.13, “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.”).
- Making, maintaining and retaining records, including records of dosages (See Item 9.14 “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 H “Model Emergency Procedures” and Appendix N “Reporting Requirements”.

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: Radiopharmaceuticals can deliver significant doses in a short time, if not shielded. The security of licensed material is described in 25 TAC §289.202(y). 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.

Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking sources, medical events). 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 H 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 H 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 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 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 D.

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 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 I 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.

### 9.6 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.

### 9.7 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 §289.252(cc), 25 TAC §289.256(z)

**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))
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))

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)

Response from Applicant: Provide a description of how radioactive material will be secured from unauthorized removal or access.
9.8 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 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.

9.9 AREA SURVEYS


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

**Figure 2. Example Survey Diagram**

**Response from Applicant:** Provide your written procedures for performing surveys. Applicants may choose to adopt and submit the model procedure in Appendix J or develop their own procedure.
9.10 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

**Rules:** 25 TAC §289.256(t)

**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 AUAs.

**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.

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

**Response from Applicant:** For applicants who will administer quantities greater than 30 microcuries of sodium iodide I-131, provide procedures for ensuring each administration is in accordance with the written directive.

9.11 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 L 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.

9.12 MOBILE NUCLEAR MEDICINE SERVICE

Rules: 25 TAC §289.256(dd)

Criteria: In addition to the requirements in 25 TAC §289.256(dd), 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).

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 M 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

**9.13 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 H, 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.
9.14 RECORDS OF DOSAGES

Rules: 25 TAC §289.256(x), 25 TAC §289.256(ii)

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 \( \mu \text{Ci} [1.1 \text{ MBq}] \)
- 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 \( \mu \text{Ci of Mo-99 per mCi of Tc-99m} \) (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 $\mu$Ci of Sr-82 per mCi of Rb-82 chloride (kBq of Sr-82 per MBq of Rb-82)
• ratio of the measurements expressed as $\mu$Ci 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.

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.

9.15 RECORDKEEPING

Rules: 25 TAC §289.201(d); 25 TAC §289.202(ggg)(5); 25 TAC §289.202(ll) – (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(ll).

Licensees must maintain records as provided in 25 TAC §289.201(d); 25 TAC §289.202(ggg)(5); 25 TAC §289.202(ll) – (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.
9.16 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 N of this guide.

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

9.17 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 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.
- 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 haz mat 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.

---

**ITEM 10: WASTE MANAGEMENT/WASTE DISPOSAL**


**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 O 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 §289.202(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(ij) “Discharge by Release into 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.

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

---

**ITEM 11: FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE**


**Criteria:** 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”.

---

52
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 with the appropriate box under “Certification of Financial Qualification,” on page 1;
- If financial assurance is required, submit evidence of financial assurance.

**Notes on completing the Business Information Form:**

- All applicants using an assumed or doing business as (DBA) name in their application must include the name where noted on the form and must ensure that an assumed name certificate has been filed with either the Texas Secretary of State (TX SoS) or the office of the county clerk;
- Provide the state file or charter number in the applicable box on page 2 of the Business Information Form. This is a number assigned by the TxSoS when an entity is organized or registered with the TxSoS. A file number is commonly referred to as a "Charter Number." Government entities, General Partnerships and Sole Proprietorships should provide the Employer Identification Number (EIN).
- **General Partnerships and Sole Proprietorships ONLY**: Provide a copy of the EIN certificate or other documentation verifying the EIN.
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 B 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.
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.
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.

**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. Table A-1 may be used to describe Item 5 (Radioactive Material), and Table 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 N, and O of this guide are not model procedures; however, they are included in Table A-2 to remind licensees of reporting, and transportation requirements.

Table 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. h). An applicant may copy the checklist and include it in the license application.

Table 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.
Table 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.)

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Form or Manufacturer/Model No.</th>
<th>Max Quantity</th>
<th>Purpose Of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Any radioactive</td>
<td>Any radiopharmaceutical form, except gas and aerosol</td>
<td>As needed</td>
<td>Any uptake, dilution and excretion study permitted by 25 TAC §289.256(ff)</td>
</tr>
<tr>
<td>material permitted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by 25 TAC §289.256(ff)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Any radioactive</td>
<td>Any radiopharmaceutical form, except gas and aerosol</td>
<td>As needed</td>
<td>Any uptake, dilution and excretion study permitted by 25 TAC §289.256(hh)</td>
</tr>
<tr>
<td>material permitted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by 25 TAC §289.256(hh)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Xe-133</td>
<td>Any radiopharmaceutical</td>
<td>___ millicuries</td>
<td>Any imaging and localization study permitted by Title 25 TAC §289.256(hh)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ I-131</td>
<td>Sodium iodide (in capsule form only)</td>
<td>___ millicuries</td>
<td>Oral administration of Sodium Iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries permitted by Title 25 TAC §289.256(kk)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Mo-99/Tc-99m</td>
<td>Solid or liquid</td>
<td>___ millicuries</td>
<td>Elution of generator systems for preparation of technetium-99m radiopharmaceuticals for any imaging and localization study permitted by Title 25 TAC §289.256(hh)</td>
</tr>
</tbody>
</table>
### Table 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.)

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Form or Manufacturer/Model No.</th>
<th>Max Quantity</th>
<th>Purpose Of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Sr-82/Rb-82</td>
<td>Solid or liquid ____ millicuries</td>
<td>Elution of generator systems for preparation of rubidium-82 radiopharmaceuticals for any imaging and localization study permitted by Title 25 TAC §289.256(hh)</td>
<td></td>
</tr>
<tr>
<td>☐ Ge-68/Ga-68</td>
<td>Solid or liquid ____ millicuries</td>
<td>For 25 TAC §289.256(q) use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies</td>
<td></td>
</tr>
<tr>
<td>☐ Any radionuclide in excess of 30 mCi for use in calibration. List radionuclide:</td>
<td>Sealed source (Manufacturer ________________<strong>, Model No.</strong>________) _______millicuries per source and _______millicuries total</td>
<td>Instrument calibration and reference source in Device (Manufacturer ________________<strong>, Model No.</strong>________):</td>
<td></td>
</tr>
<tr>
<td>☐ I-125</td>
<td>Sealed source (Manufacturer ________________<strong>, Model No.</strong>________) _______microcuries per source and _______µCi/mCi total activity</td>
<td>Radioactive seed localization permitted by 25 TAC §289.256(q)</td>
<td></td>
</tr>
</tbody>
</table>
### Table 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.)

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>Form or Manufacturer/ Model No.</th>
<th>Max Quantity</th>
<th>Purpose Of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Pd-103</td>
<td>Sealed source (Manufacturer</td>
<td>_______µCi/mCi</td>
<td>Radioactive seed localization permitted by 25 TAC §289.256(q)</td>
</tr>
<tr>
<td></td>
<td>Model No.____________)</td>
<td></td>
<td>Purpose of use</td>
</tr>
<tr>
<td>☐ Other</td>
<td>Form or (Manufacturer</td>
<td>_______millicuries</td>
<td></td>
</tr>
<tr>
<td>List</td>
<td>Model No.____________)</td>
<td></td>
<td>Purpose of use</td>
</tr>
<tr>
<td>radionuclide:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>____________</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

**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 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 256-1a, 256-1b, or 256-1c, 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

AND, if applicable

☐ For consultant-RSO or contractor, 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 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
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 full facility floor plan that identifies each room of radioactive material use and/or storage and including:

- the restricted area
- the direction of north;
- room numbers and principal use of each room or area where radioactive material is used and/or stored;
- receipt and storage areas (including waste);
- preparation, measurement, and work counters;
- additional safety equipment (e.g. fume hoods or shielding)

☐ Provide a brief description of the proposed location to offer an idea of the scope and magnitude of use for the facility to include:

- anticipated number of procedures that will be done per month,
- number of technologists employed,
- number of imaging cameras,
- number of treadmills used for stress testing,
- radiation delivery devices (e.g. xenon delivery/traps, aerosol units)

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.”

☐ The manufacturer and model number of all instruments and detectors that will be used to perform required surveys.

☐ Applicants intending to use a portable survey meter or an imaging camera to analyze contamination wipes must wipe 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 who will use unit doses only:**
- 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 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 E or develop and submit your own procedure.
  
  AND

- A description of the equipment used to measure the dosages

**Applicants who will use Rb-82 generators must also provide:**
- Procedures that ensure the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer’s specifications. The licensee must perform the tests at least every twelve months (and repeat after repair or replacement), and maintain records that document the performance and results of these tests. You may use documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and radiation detector test.
  
  AND

- Confirm that all authorized users and the radiation safety officer 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: 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.

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

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: Ordering and Receiving**

Provide your procedure for ordering and receiving licensed material.

**Item 9.6: Opening Packages**

Provide your procedure for safely opening packages containing radioactive material.
Item 9.7: Material Receipt and Accountability

☐ A description of how radioactive material will be secured from unauthorized removal or access.

Item 9.8: 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 9.9: Area Surveys

☐ Provide your procedures for performing surveys.

Item 9.10: Procedures for Administrations When a Written Directive is Required

For applicants who will administer quantities greater than 30 microcuries of sodium iodide I-131:

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

Item 9.11: Safe Use of Unsealed Radioactive Material

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

Item 9.12: Mobile Medical Service

☐ Identify the type of mobile medical service to be offered

☐ Provide your procedures specific to mobile nuclear medicine service providers.
**Item 9.13: 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 9.14: Records of Dosages**

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

For 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)

**Item 9.15: Recordkeeping**

No response is necessary.

**Item 9.16: Reporting**

No response is necessary.

**Item 9.17: Transportation**

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

**Item 10: Waste Management/Waste Disposal**

- Provide your waste disposal procedures for licensed material. Applicants may adopt the model procedures in Appendix O or develop their own procedure. Applicants proposing to dispose of licensed material using methods not addressed by Appendix O must submit additional procedures.
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 for which the assumed name certificate has been filed with the office of the county clerk, provide:

  • a copy of the assumed name certificate
APPENDIX B 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 this chapter;

(2) ensure that required radiation surveys and leak tests are performed and documented in accordance with this chapter, 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 this chapter 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 this chapter;

(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 this chapter, 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 where 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 C 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.

The training will include the following:

- **General awareness/familiarization training:** to provide familiarity with Title 49, CFR requirements and enable employees to recognize and identify hazardous materials consistent with the hazard communication standards;
- **Function-specific training:** training concerning requirements of this subchapter, or exemptions or special permits issued under subchapter A of this chapter, that are specifically applicable to the functions the employee performs;
- **Safety training:** emergency response information required by subpart G of part 172; measures to protect the employee from the hazards associated with hazardous materials to which they may be exposed in the work place; and methods and procedures for avoiding accidents.
- **Security awareness training:** awareness of security risks associated with hazardous materials transportation and methods designed to enhance transportation security. This training must also include a component covering how to recognize and respond to possible security threats.

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 Non-Radiation Workers

For the purposes of this section, non-radiation workers includes personnel engaged in janitorial and/or housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 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)].
APPENDIX D 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 x 10^-7 microcuries per milliliter of air on an annual basis or 1.25 x 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 $1 \times 10^{-4}$ 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):

<table>
<thead>
<tr>
<th>Weekly Workload (mCi/wk)</th>
<th>Outside Exhaust Rate Using a Xenon Trap (cfm)</th>
<th>Outside Exhaust Rate Without a Xenon Trap (cfm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>* 50</td>
<td>70</td>
</tr>
<tr>
<td>25</td>
<td>* 50</td>
<td>175</td>
</tr>
<tr>
<td>50</td>
<td>90</td>
<td>350</td>
</tr>
<tr>
<td>100</td>
<td>175</td>
<td>700</td>
</tr>
<tr>
<td>250</td>
<td>450</td>
<td>1750</td>
</tr>
</tbody>
</table>

*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 $1 \times 10^{-4}$ 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:

\[ C = C_0 e^{-\frac{F}{V} t} \]

- \( C \) = Room concentration
- \( C_0 \) = 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.: ___________________________  PREPARATOR: ___________________________

LICENSEE: ___________________________  DATE: ___________________________

ROOM #: ___________________________

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

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

FORMULA SIMPLIFIED  \[ C = \frac{\mu \text{Ci/wk} \times 0.25}{\text{cfm} \times (1.699 \times 10^6 \text{ ml/cf/hr}) \times 40 \text{ hrs}} \]

* 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:  \[ C = \text{Maximum Allowed Room Concentration} \]
\[ C_0 = \text{Initial Room Concentration} \]
\[ F = \text{Flow rate (cfm)} \]
\[ V = \text{Room Volume (cubic foot)} \]
\[ t = \text{Time (min.)} \]

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

FORMULA SIMPLIFIED  \[ t_{(min)} = \left( \frac{\text{cf}}{\text{cfm}} \right) \times \ln_b \left( \frac{\text{cf} \times 2.832}{\mu \text{Ci}} \right) \]

\[ t = \left( \frac{\text{cf}}{\text{cfm}} \right) \times \ln_b \left( \frac{\text{cf} \times 2.832}{\mu \text{Ci}} \right) = \text{minutes} \]

ROOM #: ___________________________

XENON CONCENTRATION  \[ C = \frac{\mu \text{Ci/wk} \times 0.25}{\text{cfm} \times (1.699 \times 10^6 \text{ ml/cf/hr}) \times 40 \text{ hrs}} \]

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

\[ t = \left( \frac{\text{cf}}{\text{cfm}} \right) \times \ln_b \left( \frac{\text{cf} \times 2.832}{\mu \text{Ci}} \right) = \text{minutes} \]

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

RSO’s Signature

81
APPENDIX E 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, replaces, 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 additional, 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 +/- 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 +/- 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 +/- 10% error lines.
8. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water, and assay again. Record the volume and activity indicated.
10. Repeat the process until a 19.0 cc volume has been assayed. The entire process must be completed within 10 minutes.
11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen “standard volume.”
12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

**Accuracy** means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by 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., Co-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 +/- 10% of the certified activity of the reference source, mathematically corrected for decay.
3. Repeat the procedure for any other calibrated reference sources possessed.
4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.
5. Notify the RSO if the test results do not agree, within +/- 10%, with the certified value of the reference source(s).
6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (if need not be a certified reference source) on all commonly used radionuclide settings.
**APPENDIX F MODEL MEDICAL LICENSEE AUDIT**

**Annual Radiation Protection Medical Licensee Audit**

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

Date of this audit: ____________________

Date of last audit: ________________

Date of next audit: ________________

Auditor: ________________________

______________________________________________

Signature Date

Management review:

______________________________________________

Signature Date

All references are to Title 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?

Organizations 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) 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)]?

c) 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(bbb)? 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)]?

Mobile Nuclear Medicine Service

1. Operates services per §289.256(dd)?

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 briefed on responsibilities for supervising the use of licensed material [§289.256(s) and (dd)(1)(D)]?

Amendments Since Last Audit

1. Any amendments since last audit [§289.256(r)]?

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. 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)]?

6. 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)]?

7. Briefly describe training program.


9. §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 Form 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. Procedures for opening packages [§289.202(ee)]?

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

Facilities

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

2. Storage areas:
   a. Materials 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?

**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., ±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 μCi 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 μCi per mCi of Rb-82 or Sr-85 concentrations over 0.2 μCi per mCi of Rb-82 [§289.256(ii)(1)(B) and (C)]?

e. Records maintained [§289.256(ii)(4)]?

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 performed semiannually [§289.256(z)(2)]?
   c. 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?

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)]?

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. 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]?

**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. NRC 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. Records of exposures, surveys, monitoring, and evaluations maintained [§289.202(mm), §289.202(nn), §289.202(rr)]?

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:

a. If authorized for §289.256(q) medical uses, review the program for conformance with license application commitments, license conditions and rules.

b. Other special license conditions.

Performance-Based Review

1. Conduct performance-based reviews of radiation workers performing licensed activities:

a. to assess the capability of the radiation workers to maintain exposures ALARA;

b. to assess that radiation workers follow the operating procedures;

c. to assess the effectiveness of the operating procedures and compliance with the 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 G 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 that the allowable dose limit for the individual is reduced 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 (cm$^2$)], shallow-dose equivalent (SDE) to the skin or extremities at 0.007 cm [7 mg/cm$^2$], and eye dose equivalent at 0.3 cm [300 mg/cm$^2$]. In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Under 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 International Commission on Radiological Protection (ICRP) Report 26, “Recommendations of the International Commission on Radiological Protection,” Investigational Levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker’s dose or the dose for a group of workers needs to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table 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**

<table>
<thead>
<tr>
<th>Part of Body</th>
<th>Investigational Level I (mrem/year)</th>
<th>Investigational Level II (mrem/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee</td>
<td>500 [5 mSv]</td>
<td>1,500 [15 mSv]</td>
</tr>
<tr>
<td>hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin</td>
<td>5,000 [50 mSv]</td>
<td>15,000 [150 mSv]</td>
</tr>
<tr>
<td>lens of the eye</td>
<td>1,500 [15 mSv]</td>
<td>4,500 [45 mSv]</td>
</tr>
</tbody>
</table>

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


**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:
• National Council on Radiation Protection and Measurements (NCRP) Report No. 87,

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.

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

<table>
<thead>
<tr>
<th>Radionuclide</th>
<th>mCi</th>
<th>Radionuclide</th>
<th>mCi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen-13</td>
<td>100</td>
<td>Technetium-99m</td>
<td>100</td>
</tr>
<tr>
<td>Carbon-14</td>
<td>10</td>
<td>Indium-111</td>
<td>10</td>
</tr>
<tr>
<td>Oxygen-15</td>
<td>100</td>
<td>Iodine-123</td>
<td>10</td>
</tr>
<tr>
<td>Fluorine-18</td>
<td>100</td>
<td>Iodine-125</td>
<td>10</td>
</tr>
<tr>
<td>Phosphorus-32</td>
<td>10</td>
<td>Iodine-131</td>
<td>1</td>
</tr>
<tr>
<td>Gallium-67</td>
<td>10</td>
<td>Samarium-153</td>
<td>10</td>
</tr>
<tr>
<td>Rubidium-82</td>
<td>10</td>
<td>Ytterbium-169</td>
<td>10</td>
</tr>
<tr>
<td>Strontium-82</td>
<td>1</td>
<td>Mercury-197</td>
<td>10</td>
</tr>
<tr>
<td>Strontium-85</td>
<td>10</td>
<td>Gold-198</td>
<td>10</td>
</tr>
<tr>
<td>Strontium-89</td>
<td>1</td>
<td>Thallium-201</td>
<td>100</td>
</tr>
<tr>
<td>Yttrium-90</td>
<td>1</td>
<td>Alpha emitters</td>
<td>*</td>
</tr>
</tbody>
</table>

*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 that includes all of the information identified in 25 TAC §289.202(ww).
APPENDIX I 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 ________.

<table>
<thead>
<tr>
<th>NAME</th>
<th>HOME TELEPHONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Safety Officer</td>
<td></td>
</tr>
<tr>
<td>Director of Nuclear Medicine</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine Technologist Supervisor</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine Technologist on call</td>
<td></td>
</tr>
<tr>
<td>(call/page operator at extension ___)</td>
<td></td>
</tr>
<tr>
<td>Nuclear Medicine Physician on call</td>
<td></td>
</tr>
<tr>
<td>(call/page operator at extension ___)</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX J 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. If diagnostic administrations are occasionally made in patients’ rooms [e.g.,
bone scan injections, technetium 99m (Tc-99m) heart agents] and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table J–1.

Table J–1. Ambient Dose Rate Trigger Levels

<table>
<thead>
<tr>
<th>Type of Survey</th>
<th>Area Survey</th>
<th>Trigger Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Dose Rate</td>
<td>Unrestricted</td>
<td>0.05 mR/hr</td>
</tr>
<tr>
<td>Ambient Dose Rate</td>
<td>Restricted</td>
<td>5.0 mR/hr</td>
</tr>
</tbody>
</table>

Contamination Surveys

Procedures for contamination surveys [reference 25 TAC §289.202(eee) and 25 TAC §289.202(EEE)(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(EEE)(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 J–2. Contamination found on facilities, equipment and on personal clothing will be immediately decontaminated to background levels.
Table J–2 Acceptable Surface Contamination Levels

<table>
<thead>
<tr>
<th>Nuclidea</th>
<th>Averagebcef</th>
<th>Maximumbdf</th>
<th>Removabcef</th>
</tr>
</thead>
<tbody>
<tr>
<td>U-nat, U-235, U-238, and associated decay</td>
<td>5,000 dpm</td>
<td>15,000 dpm</td>
<td>1,000 dpm</td>
</tr>
<tr>
<td>products except Ra-226, Th-230, Ac-227,</td>
<td>alpha/100 cm²</td>
<td>alpha/100 cm²</td>
<td>alpha/100 cm²</td>
</tr>
<tr>
<td>and Pa-231</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transuranics, Ra-223, Ra-224, Ra-226, Ra-228,</td>
<td>1,000 dpm/100</td>
<td>3,000 dpm/100</td>
<td>200 dpm/100</td>
</tr>
<tr>
<td>Th-nat, Th-228, Th-230, Th-232, U-232, Pa-231,</td>
<td>cm²</td>
<td>cm²</td>
<td>cm²</td>
</tr>
<tr>
<td>Ac-227, Sr-90, I-129</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-gamma emitters</td>
<td>5,000 dpm</td>
<td>15,000 dpm</td>
<td>1,000 dpm</td>
</tr>
<tr>
<td>(nuclides with decay modes other than alpha</td>
<td>beta,</td>
<td>beta,</td>
<td>beta,</td>
</tr>
<tr>
<td>emission or spontaneous fission)</td>
<td>gamma/100 cm²</td>
<td>gamma/100 cm²</td>
<td>gamma/100 cm²</td>
</tr>
<tr>
<td>except Sr-90 and others noted above</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tritium (applicable to surface and subsurface</td>
<td>NA</td>
<td>NA</td>
<td>10,000 dpm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>dpm/100 cm²</td>
</tr>
</tbody>
</table>

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.
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.

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 microroentgen 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 K 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 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.

• 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.

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 L 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 palmer 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.
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 provider 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.

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.
## APPENDIX N 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.

<table>
<thead>
<tr>
<th>Event</th>
<th>Telephone Notification</th>
<th>Written Report</th>
<th>Regulatory Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removable surface contamination or external radiation levels from a RAM package exceeds the limits in §289.202(ee)(4)(A) and (B)</td>
<td>Immediate via either telephone, facsimile or electronic media transmission **</td>
<td>**§289.202(ee)(4)</td>
<td></td>
</tr>
<tr>
<td>Stolen, lost or missing radioactive material in an aggregate quantity ≥ 1,000 times the quantity in (ggg)(3)</td>
<td>Immediate</td>
<td>30 days after making the telephone report</td>
<td>**§289.202(ww)(1)(A)</td>
</tr>
<tr>
<td>Stolen, lost or missing radioactive material in an aggregate quantity &gt; 10 times the quantity in (ggg)(3)</td>
<td>30 days</td>
<td>30 days after making the telephone report</td>
<td>**§289.202(ww)(1)(B)</td>
</tr>
<tr>
<td>Event involving a source of radiation that may have caused or threatens to cause a TEDE dose ≥ 25 rems</td>
<td>Immediate</td>
<td>30 days</td>
<td>**§289.202(xx)(1)(A)(i)</td>
</tr>
<tr>
<td>Event involving a source of radiation that may have caused or threatens to cause a lens dose ≥ 75 rem</td>
<td>Immediate</td>
<td>30 days</td>
<td>**§289.202(xx)(1)(A)(ii)</td>
</tr>
<tr>
<td>Event</td>
<td>Telephone Notification</td>
<td>Written Report</td>
<td>Regulatory Requirement</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------</td>
<td>----------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>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</td>
<td>Immediate</td>
<td>30 days</td>
<td>§289.202(xx)(1)(A)(iii)</td>
</tr>
<tr>
<td>Event involving loss of control of a source of radiation that may have caused or threatens to cause a TEDE &gt; 5 rem in 24 hours</td>
<td>24 hours</td>
<td>30 days</td>
<td>§289.202(xx)(2)(A)(i)</td>
</tr>
<tr>
<td>Event involving loss of control of a source of radiation that may have caused or threatens to cause a lens dose equivalent &gt; 15 rem in 24 hours</td>
<td>24 hours</td>
<td>30 days</td>
<td>§289.202(xx)(2)(A)(ii)</td>
</tr>
<tr>
<td>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 &gt; 50 rem in 24 hours</td>
<td>24 hours</td>
<td>30 days</td>
<td>§289.202(xx)(2)(A)(iii)</td>
</tr>
<tr>
<td>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 &gt; 1 occupational ALI</td>
<td>24 hours</td>
<td>30 days</td>
<td>§289.202(xx)(2)(B)</td>
</tr>
<tr>
<td>Occupational dose greater than 5 rem (0.05 Sv)</td>
<td>None</td>
<td>30 days</td>
<td>§289.202(yy)(1)(B)(i)</td>
</tr>
<tr>
<td>Event</td>
<td>Telephone Notification</td>
<td>Written Report</td>
<td>Regulatory Requirement</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>------------------------</td>
<td>----------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Dose to a minor greater than 500 mrem (5 mSv)</td>
<td>None</td>
<td>30 days</td>
<td>§289.202(yy)(1)(B)(ii)</td>
</tr>
<tr>
<td>Dose to an embryo/fetus of a declared pregnant woman greater than 0.5 rem (5 mSv)</td>
<td>None</td>
<td>30 days</td>
<td>§289.202(yy)(1)(B)(iii)</td>
</tr>
<tr>
<td>Dose to individual member of public greater than 100 mrem (1 mSv)</td>
<td>None</td>
<td>30 days</td>
<td>§289.202(yy)(1)(B)(iv)</td>
</tr>
<tr>
<td>Event that prevents immediate protective actions necessary to avoid exposure to RAM that could exceed limits or releases of RAM that could exceed limits</td>
<td>Immediate</td>
<td>30 days</td>
<td>§289.202(xx)(6)</td>
</tr>
<tr>
<td>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</td>
<td>24 hours</td>
<td>30 days</td>
<td>§289.202(xx)(7)(A)(i)</td>
</tr>
<tr>
<td>Test for leakage or contamination indicates a sealed source is leaking or contaminated</td>
<td>Immediate</td>
<td>5 days</td>
<td>§289.202(bbb)</td>
</tr>
<tr>
<td>Vacating premises that possessed non-exempt source of radiation</td>
<td>None</td>
<td>30 days prior to vacating or relinquishing control</td>
<td>§289.202(ccc)</td>
</tr>
<tr>
<td>Event</td>
<td>Telephone Notification</td>
<td>Written Report</td>
<td>Regulatory Requirement</td>
</tr>
<tr>
<td>---------------------------------------------------------------------</td>
<td>------------------------</td>
<td>---------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>A change in business name, mailing address or RSO</td>
<td>None</td>
<td>Within 15 days</td>
<td>§289.252(x)(5)</td>
</tr>
<tr>
<td>Voluntary or involuntary filing of bankruptcy by licensee or parent company</td>
<td>None</td>
<td>Immediately following the filing</td>
<td>§289.252(x)(6) &amp; (7)</td>
</tr>
<tr>
<td>Expiration, revocation or cessation of principal activities as detailed in the rule</td>
<td>None</td>
<td>Within 60 days of applicable occurrence</td>
<td>§289.252(y)(4)</td>
</tr>
<tr>
<td>Medical event as detailed in the rule</td>
<td>Next calendar day after discovery</td>
<td>15 days after discovery</td>
<td>§289.256(uuu)</td>
</tr>
<tr>
<td>Dose to an embryo/fetus or nursing child that could exceed limits</td>
<td>Next calendar day after discovery</td>
<td>15 days after discovery</td>
<td>§289.256(vvv)</td>
</tr>
</tbody>
</table>
APPENDIX O 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.