



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.1a

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE MEDICAL DIAGNOSTIC USE OF RADIOACTIVE MATERIAL (RAM) IN UNIT DOSES OR DOSES DELIVERED IN BULK FROM RADIOPHARMACIES OR SUPPLIERS

I. INTRODUCTION

This guide describes the information the Texas Department of State Health Services (DSHS) staff needs to evaluate an application for a license authorizing the diagnostic medical use of RAM, only, in unit doses or doses delivered in bulk from radiopharmacies or suppliers, except for Positron Emission Tomography (PET).

Applicable regulations governing the medical and veterinary use of RAM are found in Title 25 Texas Administrative Code (TAC) Section (§) 289.256 "Medical and Veterinary Use of RAM" as well as 25 TAC §§289:

- .201 "General Provisions for RAM"
- .202 "Standards for Protection Against Radiation from RAM"
- .203 "Notices, Instructions, and Reports to Workers; Inspections"
- .204 "Fees for Certificates of Registration, RAM Licenses,
Emergency Planning and Implementation, and Other Regulatory Services"
- .205 "Hearing and Enforcement Procedures"
- .251 "Exemptions, General Licenses, and General License Acknowledgments"
- .252 "Licensing of RAM" and
- .257 "Packaging and Transportation of RAM"

II. FILING AN APPLICATION

BRC Form 252-1, "Business Information Form." Applicants must sign and submit, in duplicate, a completed Business Information Form, including a certification of financial qualification to conduct the requested activity, including any decontamination, decommissioning, reclamation, and disposal [25 TAC §289.252(ii)(8)].

BRC Form 252-2a, "Application for RAM License - Human Uses." An application for a license authorizing diagnostic medical uses of RAM must be submitted in duplicate. Applicants must complete items 1 through 15. Use supplemental sheets as necessary. Each separate sheet or document submitted with the application should be identified and keyed to the item number on the application to which it refers. All typed pages, sketches, and if possible, drawings should be on 8.5 x 11 inch paper to facilitate handling and storage.

BRC Form 252-2b, "Preceptor Statement for License Application." A preceptor's statement must be submitted, in duplicate, for each physician desiring to use RAM *who cannot document*:

- *certification by an accepted certification board; or*
- *status as an authorized physician user granted by any recognized jurisdiction within the past 7 years.*

Preceptor's statements must be signed by the authorized physician user who supervised the medical use of RAM during the physician's training.

Mail the above described forms, in duplicate, to:

<p><u>For Regular Mail:</u> Department of State Health Services RAM Licensing Group 1100 W. 49th Street Austin, TX 78756-3189 (512) 834-6688</p>
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<p><u>For Private Overnight Service Delivery:</u> Department of State Health Services RAM Licensing Group 8407 Wall Street Austin, TX 78754 (512) 834-6688</p>
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Our web address is: www.dshs.state.tx.us/radiation (Note: Web address can change).

III. LICENSE FEES

An application fee is required for all licenses and must be submitted with any NEW application. The applicant should refer to Title 25 Texas Administrative Code (TAC) §289.204 (Fees for Certificates of Registration, RAM Licenses, Emergency Planning and Implementation, and Other Regulatory Services) to determine the fee that should accompany the application. Review of the application will not begin until the proper fee is received by DSHS. The check or money order should be made payable to the Texas Department of State Health Services. A fee should NOT be submitted with the application for technical renewal or amendment. All current licensees will be billed according to the expiration month of their current license

IV. CONTENTS OF AN APPLICATION (Use RC Form 252-2a)

ITEM 1 LEGAL BUSINESS NAME AND BUSINESS MAILING ADDRESS OF APPLICANT (TEXAS ADDRESS ONLY):

If a physician is requesting the use of RAM at the physician's own practice, then the legal name of the physician's practice should be used as the applicant. If RAM is to be stored and used at an institution, the institution is named as the applicant and the applicant should be the corporation or other legal entity applying for the license. DSHS verifies the legal status of corporations and partnerships with the Texas Secretary of State's Office.

ITEM 2 LOCATIONS AT WHICH RAM WILL BE STORED AND/OR USED:

List the street address and location(s) where RAM will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place

of use. Separate locations may require separate licenses and may also impact the license application fee.

ITEM 3 THIS IS AN APPLICATION FOR:

Identify if the application is for a new license or renewal of an existing license. If the application is for renewal of a license provide the existing license number.

ITEM 4 LOCATION WHERE RECORDS WILL BE KEPT:

This is the location that will be listed on the license as the main site and the site to which all correspondence will be mailed. The main site is the site where the Radiation Safety Officer is routinely available and can receive correspondence without delay; and where copies of records for the entire license are maintained for inspection by DSHS (except for some sub-site utilization records). Provide the street address of the site to be designated the main site.

ITEM 5 PHYSICIAN USERS:

To use RAM in humans, an individual must be licensed in accordance with the laws of the state of Texas to dispense and use drugs in the practice of medicine, and either be certified by a professional board accepted by the Nuclear Regulatory Commission to qualify physicians as authorized users or have successfully completed the training and experience required by §289.256. Provide a listing of the full names of all physicians who will use or approve and supervise the use of RAM, their board certifications, and dates when certifications were awarded, or preceptors' statements certifying the successful completion of training and experience required in §289.256 and the achievement of a level of competence to function independently as an authorized user. If a physician has been authorized within the past seven years on another RAM license (regardless of jurisdiction), evidence of this authorization may be submitted in lieu of board certifications or preceptors statements. This should include the Texas license number or copy of out-of-state license, specific authorizations, and dates of practice.

ITEM 6 RADIATION SAFETY OFFICER:

The Radiation Safety Officer (RSO) is the person designated to be responsible for the day-to-day radiation safety program. The RSO ensures the records required by DSHS rules and is also the primary contact with the DSHS on matters pertaining to the license and the use of RAM. The RSO's training and experience with the types and quantities of RAM for which a license is being requested must be submitted. Qualifications may be found in §289.256(h), "Radiation Safety Officer." Provide the name and title of the person named by the applicant's management to be the Radiation Safety Officer (RSO). If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience.

ITEM 7 RAM DATA:

Under (a), make selections appropriate for intended licensed uses:

1. Any RAM used in accordance with (IAW) §289.256(y) for Uptake, dilution and excretion studies;

2. Any RAM used IAW §289.256(z) for Imaging and/or localization studies;
3. Any RAM used IAW §289.256(z) for Preparation of radiopharmaceuticals; Generators with kit Preparations; and/or
4. Any RAM used IAW §289.256(z) for Preparation of radiopharmaceuticals; Bulk technetium with kit Preparations.
5. Any RAM used as gases or aerosols waived IAW §289.256(z).
6. In vitro test kits used IAW §289.251.

ITEM 7 (Continued) ADDITIONAL ITEMS DESIRED:

For other diagnostic medical uses of RAM, including transmission scanning with sealed sources, list:

1. Under (a), the isotope, e.g., "fluorine-18," "germanium/galium-68," etc.
2. Under (b), each chemical and/or physical form of isotope. (If source is a sealed source and has an associated source holder, state the manufacturer and model number of the source, and device if evaluated separately.)
3. Under (c), maximum amount of material to be authorized in millicuries at any one time for each form of radiopharmaceutical or in each sealed source.
4. Under (d), the procedure to be performed. Example: transmission calibration source.

ITEM 8 ARE ALL THE PHYSICIANS LISTED UNDER ITEM 5 LICENSED TO PRACTICE MEDICINE IN THE STATE OF TEXAS?:

Circle or mark Yes or No.

ITEM 9 CERTIFICATION OF AUTHORIZED USERS:

Each physician listed in Item 5 must sign a statement certifying familiarity with and agreement to abide by the statements, representations, and radiation safety procedures being submitted with this application and any other subsequent correspondence that causes the license to be issued or amended.

ITEM 10 TRAINING OF AUTHORIZED PHYSICIANS, RADIATION SAFETY OFFICER, TECHNOLOGISTS, AND OTHERS:

See ITEM 5 and ITEM 6 for training requirements for authorized physicians and radiation safety officers. Technologists who will be authorized to handle RAM must be qualified through training and experience to use the licensed material for the purpose authorized in a manner to minimize danger to public health and safety or the environment. NOTE: The word technologist, is defined as someone delegated to and supervised by a medical doctor.

Technologists must be certified as a general certificate medical radiologic technologist (MRT) under Texas Civil Statutes, Article 4512m. In addition each individual must:

1. be certified by the Nuclear Medicine Technologist Certification Board (CNMT); or

2. be certified in nuclear medicine by the American Registry of Radiologic Technologists [ARRT(N)]; or
3. be board eligible to take the CNMT or ARRT(N) examinations; or
4. have graduated from an approved Joint Review Committee on Educational Program in Nuclear Medicine Technology (JRCNMT) program or be a student who is supervised and operating within such a program. (Contact JRCNMT at 406-883-0003 or www.jrcnmt.org to verify approved program); or
5. have performed full-time nuclear medicine for a minimum of two years prior to January 1, 2007. This experience must be certified in writing by an authorized physician user; or
6. have completed training in accordance with the outline in Appendix A, "Minimum Training Criteria for Cross Training Registered X-Ray Technologists for Nuclear Medicine." [NOTE: Registered X-Ray Technologists are currently registered by the American Registry of Radiologic Technologists.] If hiring an individual with this type of documentation, the prior training could be considered acceptable without need for additional training if the scope of practice was equivalent to that of the original training.

ITEM 11 FACILITIES: (See Appendix C)

Provide a brief description of the anticipated numbers of procedures per month, technologists employed, cameras and other clinical detection equipment in operation, associated treadmills, radiation delivery devices (e.g., xenon delivery/traps, aerosol units) by manufacturer and model number and rooms of use. Provide a facility floor plan that identifies and shows the location of each of the routine sites of use and its surroundings and provide a full page drawing showing each room of use, adjacent rooms, and describe the uses in each room (see Enclosure 1). Indicate the following:

1. The direction of north;
2. Room numbers and principal use of each room or area;
3. Receipt and storage areas (including waste);
4. Preparation, measurement, and work counters;
5. Restricted and unrestricted areas;
6. Any shielding available; and
7. Additional safety equipment (e.g., fume hoods, L-block, or area monitors).

Only use locations that are fully described will be authorized by the license, so areas such as nuclear stress labs, storage areas, in vitro labs, etc., will need to be included if RAM is periodically brought into these areas. See suggestions in Enclosure 2, "Facility Design Considerations for a Hospital's Nuclear Medicine Department." Specific details need not be provided on temporary injection sites, e.g., stress test treadmills, x-ray rooms and patient rooms; if temporary injection sites will be used, however, the applicant must indicate that they will be used.

ITEM 12 OPERATING, RADIATION SAFETY AND EMERGENCY PROCEDURES MANUAL:

Applicants must develop and implement radiation safety procedures that will be used by all persons working with RAM under the authority of the license issued by DSHS; the procedures must ensure compliance with all the sections listed in the introduction paragraph of this guide. Appendices A through V to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for their specific radiation safety needs. Applicants may submit a copy of the attached procedure or may develop and submit an equivalent procedure for approval.

Use Enclosure 3 to indicate if model procedures are being adopted or if other procedures are being submitted for review. Submit a copy of each model procedure being adopted or submit an equivalent procedure. Complete the application by marking the appropriate box for each procedure.

ITEM 13 RADIATION DETECTION INSTRUMENTATION:

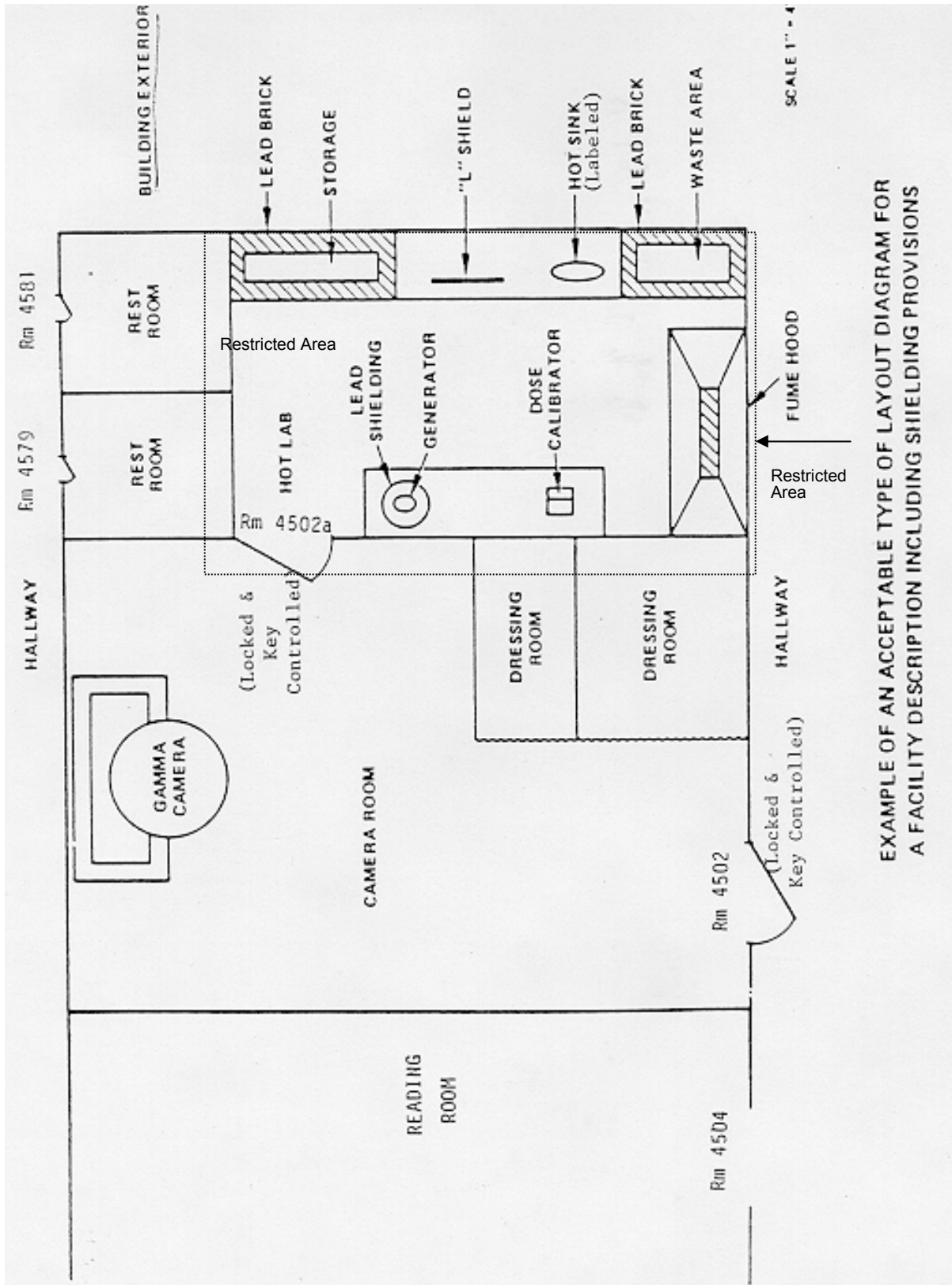
Applicants must use instruments meeting the criteria contained in Appendix B.

ITEM 14 FINANCIAL QUALIFICATION AND FINANCIAL ASSURANCE:

Financial assurance for decommissioning a license authorizing diagnostic nuclear medicine only should not be required; see §289.252(gg) to make this determination. If financial assurance is not required, self attestation of financial qualification to conduct the requested licensed activity, including any decontamination, decommissioning, reclamation, and disposal, must be made by checking the appropriate block in the appropriate section of RC Form 252-1.

ITEM 15 CERTIFICATION:

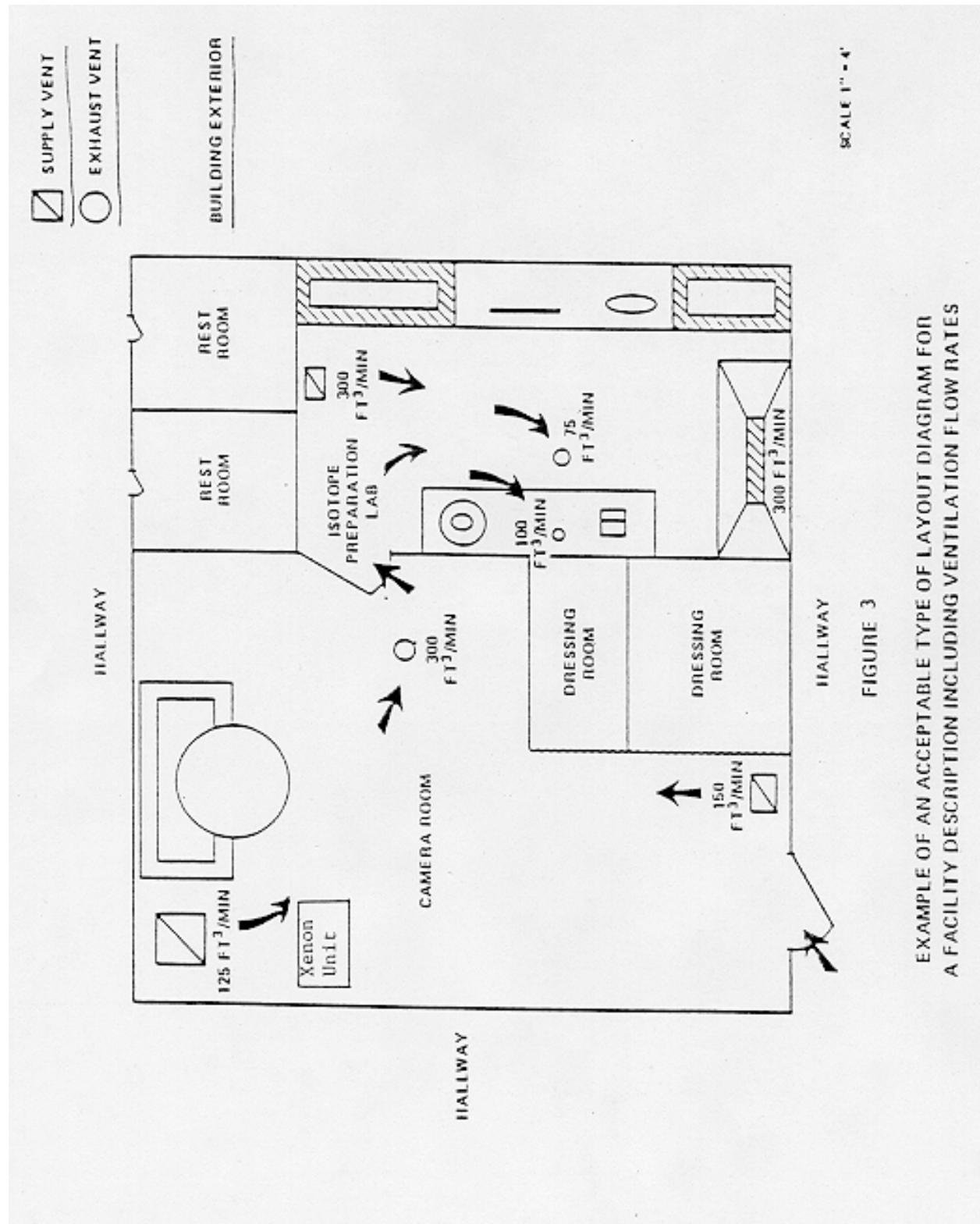
The application must be signed and dated by a certifying official. A certifying official is an individual authorized to make legally binding statements for the licensee such as the president, vice president, chief executive officer, or Radiation Safety Officer. Any statement of commitment made in the application must be followed.



EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING SHIELDING PROVISIONS

↑ NORTH

Enclosure 1



EXAMPLE OF AN ACCEPTABLE TYPE OF LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION INCLUDING VENTILATION FLOW RATES

FIGURE 3

Enclosure 2
FACILITY DESIGN CONSIDERATIONS FOR A
NUCLEAR MEDICINE DEPARTMENT

1. General

The DSHS recommends submission of facility plans while still in the design phase. Based on promises of facility completion, the DSHS may grant approval or make recommendations that can be implemented during the design phase, thereby avoiding costly remodeling and possible over-design.

2. Department Design

The layout of rooms should discourage utilization that promotes unnecessary traffic through restricted areas. Dedicated hot labs (isotope preparation labs), although recommended, would not be necessary for unit-dose-only operations. It would be desirable, however, to isolate reference sources and waste, even if it was only a lockable under-the-sink location. Hot labs should be near injection areas, centralized in larger departments, and access totally restricted to all but trained radiation workers. The ability to separate air circulation between rooms and camera systems associated with Xenon 133 gas, via engineered barriers, will minimize certain limitations and department closures/evacuations. Dedicated patient waiting areas are an ideal way to minimize concerns for public radiation exposure. Stress labs that are to be used as regular injection sites should be situated adjacent to, within, or between two imaging rooms. Clerical and/or office business (e.g., filing, report typing, dictation) should not be carried out in restricted areas. Care should be taken to not place radiographic film bins on walls adjacent to larger radiation sources generating elevated background radiation fields, without plans for shielding. Hand washing sinks should be routinely present.

3. Floor Covering

Floor covering should be composed of a material that can be easily cleaned (e.g., waxed tile or linoleum). Carpet is not compatible with decontamination procedures.

4. Work Counters

These surfaces should preferably be stainless steel (especially sinks that might someday be used for releasing RAM or decontaminating workers or small equipment). Smooth laminate surfacing however, works adequately in these settings. Unfinished wood or porous building materials that might absorb spilled liquids should not be used. NOTE: Most licensees will routinely cover work surfaces with absorbent paper (whose underlining is plastic).

5. Radiation Shielding

Leaded walls are rarely used in diagnostic nuclear medicine imaging rooms, hot labs, and stress/treadmill rooms but the need for shielding should be evaluated. Lead and/or other suitable shielding materials are commercially available in shielded covers for syringes, vials, trash cans, cabinets/drawers, lined refrigerators, sharps boxes, and small bricks for creating individually shaped counter-top caves. Sheet-

lead can also be purchased to line a cabinet and one-quarter inch sheets are usually more than sufficient for routine diagnostic uses.

6. Ventilation

See Appendix N for information that must be submitted if xenon gas will be used.

Xenon-133 releases may vary greatly. The facility/applicant should submit theoretical calculations demonstrating steady state concentrations (based on average use and worst case release levels) and exponential dilution calculations for establishing the emergency evacuation clearance time following a worst case accident. If the facility is designed such that return air re-circulates, they must also show their ability to meet acceptable concentrations throughout the facility. Routine ventilation conditions during xenon use (10 minute patient administration and an additional 30 minutes minimum clearance period) should comply with the following: a negative pressure differential of 50 to 100 cubic feet per minute, no communicating and/or re-circulating air, and dedicated exhaust to a restricted release point that is remote to fresh air intakes (greater than 25 feet). Activated (heat dried) charcoal filters are traditionally used to trap xenon-133 gas in a commercial shielded device rather than routinely releasing it to the environment. Rooms where this gas is used should maintain negative pressure in relation to other rooms and corridors.

NOTE: The higher the exhaust rate, the faster concentrations will return to acceptable levels and evacuated personnel may re-enter. Typically designed exhaust rates for temporary xenon clearance in a single room with a volume of 1600 cubic feet often ranges from 500 to 800 cubic feet per minute removal rate, yielding 20 to 30 room air exchanges per hour. Re-circulating air is only discouraged during xenon handling/clearance, and may be engineered for temporary termination or may be rerouted into a dedicated exhaust duct during these periods. The placement of air exhaust and supply registers should move air such that lowest concentrations of contamination might exist at work stations and the room's exit.

7. Security

Locking RAM away and securing potentially contaminated areas is necessary if trained staff is not physically present to prevent unauthorized removal or access. In addition, if restricted areas (to include imaging rooms associated stress/treadmill labs) are not comprehensively surveyed at the close of each day to ensure the unrestricted release criteria of §289.202(ggg)(6) is not exceeded, personnel from laundry, central supply, maintenance, and housekeeping should not have routine key access to these areas.

8. Waste Disposal Needs [See Appendix T]

If radioactive waste is intended for routine disposal into the sanitary sewerage system, as is common in an in vitro laboratory, a sink should be dedicated for disposal and decontaminating instruments/containers. This should be posted as to this limited use and drain rapidly to prevent the hold-up or concentration of radioactive solutions.

Enclosure 3

Check the appropriate boxes and submit a detailed description of all requested information.
Begin each item on a separate sheet and label it as instructed in the Medical Application Guide.

APPENDIX	TITLE	ATTACHED	EQUIVALENT ATTACHED	N/A
A	MINIMUM TRAINING CRITERIA FOR CROSS TRAINING REGISTERED X-RAY TECHNOLOGISTS FOR NUCLEAR MEDICINE			
B	RADIATION DETECTION INSTRUMENTATION			
C	FACILITY DESIGN; INSTITUTIONAL CONTROLS			
D	CALIBRATING A DOSE CALIBRATOR			
E	PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM			
F	GENERAL RADIATION AND HAZARDOUS MATERIAL TRAINING PROGRAM			
G	ORDERING/RECEIVING RAM			
H	OPENING PACKAGES CONTAINING RAM AND RETURN OF RADIOACTIVE WASTE AND UNUSED DOSAGES			
I	RECORDS OF RADIOPHARMACEUTICAL USE			
J	SAFE USE OF RADIOPHARMACEUTICALS			
K	EMERGENCY PROCEDURES			
L	AREA SURVEYS			
M	CONDUCTING A MEMBER OF THE PUBLIC DOSE COMPLIANCE STUDY			
N	USE OF XE-133			
O	DIAGNOSTIC PROCEDURES REQUIRING A WRITTEN DIRECTIVE			
P	ALARA FOR PRIVATE PRACTICE OR UNIT DOSE NUCLEAR MEDICINE FACILITIES			
Q	LEAK-TESTING SEALED SOURCES			
R	SURVEY METER CALIBRATIONS			
S	WASTE DISPOSAL			
T	INVENTORY OF SEALED SOURCES			
U	RADIATION SAFETY AUDIT PROGRAM			

Enclosure 3

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APPENDIX A

MINIMUM TRAINING CRITERIA FOR CROSS TRAINING AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS (X-RAY) FOR NUCLEAR MEDICINE (NOT POSITRON EMISSION TOMOGRAPHY (PET))

1. A training outline shall be documented and retained to include the following:
 - (1) Instructor(s) specific qualifications;
 - (2) Course syllabus;
 - (3) Lesson plan (e.g. how the material is provided to the student);
 - (4) Minimum supervisory requirements of the trainee at each phase of on-the-job-training (OJT);
 - (5) List of supplied texts and workbooks;
 - (6) Testing criteria (quizzes, final exam, and passing score) determining successful completion of each step of the training and tasks mastered. Quizzes following each didactic section and a final examination will be applied.

2. Classroom Training - The format to complete the following outline may include a combination of lecture and audio/videos. If audio/video training is utilized, it shall always be less than 50% of the total hours.

<u>Classroom Subjects</u>	<u>Hours</u>
Radiation physics (atomic structure, modes of decay, interaction with matter, units of dose and activity, conversion of units)	6
Principles of radiation detection and detectors	6
Principles of electronic instruments (pulse-height analyzers, scalars, count-rate meters and computers)	2
Mathematics pertaining to use and measurement of radioactivity (statistics, logarithms, exponentials, decay formula, dilution/concentration, inverse square law)	4
Radiation protection (time, distance, shielding, routes of intake, techniques for radioactive storage and disposal)	4
Radiation biology and measurement techniques (thermoluminescent dosimeters, film badges, bioassays)	2
Radiopharmaceutical preparation (quality control testing and biodistribution)	4
Radiation worker rights and responsibilities (orientation with regulatory and record keeping requirements in the following: §289; U.S. DOT rules; 49 CFR Parts 171-178; documented radiation protection program; DSHS approved Operating, Safety, and Emergency Procedures Manual; Clinical Procedures Manual; and Standing Medical Orders (SMOs)). <i>Clinical Procedures Manual and SMOs are typical names for documents approved by authorized physician users delineating what radiopharmaceutical, the activity, imaging protocol, exam sequence, contra-indications, and under what clinical indications or conditions radiation shall be approved for patient delivery.</i>	4
Total Classroom Training Hours	32

3. Laboratory Training

<u>Laboratory Subjects</u>	<u>Hours</u>
Instrumentation testing (cameras, dose calibrators, scalers and survey instruments)	4
Surveying packages and facilities, performing decontamination and monitoring procedures	4
Total Laboratory Training Hours	8

4. OJT - OJT shall consist of a minimum of three months training and shall be a full-time commitment, averaging a minimum of four patients per day for single organ imaging and six months for multi-organ imaging. During the OJT, the trainer must document and sign-off on the trainee's mastery of all procedures (detection equipment, clinical testing, radiation protection, surveys, and packaging.) The following minimum OJT shall be followed unless extended periods are deemed necessary by the trainer:

- a. Observation of procedures - two weeks.
- b. Performance of procedures with trainer in room - two weeks.
- c. Performance of procedures with trainer accessible in the building - two or five months.

5. Trainer Credentials

- a. Didactic Trainer. The following individual or combination of individuals will serve as didactic trainers:
 - (i) Authorized physician user;
 - (ii) Board certified nuclear pharmacist;
 - (iii) Certified Medical Physicist or Certified Health Physicist (CHP);
 - (iv) Licensed medical physicist; or
 - (v) Nuclear medicine technologist, CNMT or ARRT(N), with a minimum of five years experience.
 - b. On-The-Job-Trainer. The following individual or some combination of individuals will serve as on-the-job-trainers:
 - (i) Authorized physician user;
 - (ii) Licensed medical physicist with specialty in medical health physics or nuclear medicine;
 - (iii) Nuclear medicine technologist, CNMT or ARRT(N), with one year experience.
 - (iv) RSO; or
 - (v) a Board certified nuclear pharmacist could supervise some aspects of training as appropriate.
6. OJT Period - The training period must be a full-time commitment and the work-load shall support a minimum average of at least four patients per day. In addition to the number of varying procedures, considerations should include the complexity of

program, and scope of practices and delegated tasks. Assuming a simple unit-dose, diagnostic only practice performing only the most common procedures, three months of laboratory practices will be applied. No licensed program averaging less than ten patients a week should consider an in-house training program. The applicant may choose to expand the OJT period beyond six months, even up to twelve months, depending of the scope and complexity of the program.

7. Trainee Evaluation - Multiple quizzes (one with each didactic section), a final exam, and trainer signed-off recognition of successful mastery for the various tasks expectations, will demonstrate successful trainee comprehension. Any trainee testing yielding unacceptable scores, must include documentation of remedial training and successful retesting. Trainees shall be limited to unit dose only practices based on this training and PET imaging has not been addressed.
8. Record Keeping Requirements - The following records should be maintained:
 - a. Classroom attendance sheets identifying trainee, dates, time, and signature of trainer.
 - b. Credentials of didactic and on-the job trainers.
 - c. All graded quizzes and final exam.
 - d. Copy of certificate and/or document indicating successful completion of training with original going to the trainee.

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Appendix B

Radiation Detection Instrumentation

AMBIENT SURVEYS

Survey instruments will have a detection limit of at least 0.01 mR/hr.

When the primary meter is out of service for calibration or repair, a calibrated survey meter and probe with detection range equivalent to our primary meter is onsite and functional.

CONTAMINATION SURVEYS

Survey instruments will have these detection limits:

1. at least 1000 dpm/100 cm² to determine compliance with 25 TAC §289.202(ggg)(6), Acceptable Surface Contamination Levels; and/or
2. at least 0.005 uCi (if applicable) to determine compliance with 25 TAC §289.201(g), Tests for Leakage and/or Contamination of Sealed Sources.

CALIBRATION

Survey instruments are calibrated before first use, at least every 12 months thereafter, and after repair. Calibrations are performed by individuals identified on a U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State radioactive material license to perform these services.

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APPENDIX C

Facility Design and Institutional Controls

Facility Design

1. Receipt, Storage, and Preparation of doses:
 - A dedicated hot lab will be established.
 - A counter-top area will be used to receive and prepare doses.
2. Radioactive material will be secured in locked spaces when not accompanied.
3. Work surfaces will be constructed of easily decontaminated materials.
4. Floors will be constructed using easily decontaminated materials (no carpets).
5. Rooms will contain wash sinks with running water for personnel decontamination.
6. Rooms will contain waste containers for disposal of contaminated items.
7. Stress labs used as regular injection sites will be close to imaging rooms.
8. A dedicated nuclear medicine patient waiting area will be established.
9. Clerical/office business will not be conducted in storage/use areas.

Institutional Controls

1. Access to radioactive material will be limited to trained radiation workers.
2. Housekeeping, maintenance, laundry, central supply staff will not have unescorted access to rooms in which radioactive material is stored and used.

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APPENDIX D

Verifying Operability of A Dose Calibrator

1. These tests will be performed at the indicated frequency. If the test results deviate by more than plus or minus 10 percent, the RSO will be notified and the dose calibrator will be repaired, replaced, or corrected mathematically.
 - ◆ Constancy will be performed each day prior to assay of patient dosages.
 - ◆ Linearity will be performed at installation and at least quarterly thereafter.
 - ◆ Geometry dependence will be performed at installation.
 - ◆ Accuracy will be performed at installation and at least every 12 months thereafter.
2. After repair or relocation of the dose calibrator to a new address, the above tests will be repeated as appropriate.
3. The person performing the tests (RSO or his/her designee, e.g., Licensed Medical Physicist) will sign the records of all geometry, linearity, and accuracy tests.

Constancy Test Procedures

Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137 using a reproducible geometry each day before using the calibrator, using this procedure:

- A. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
- B. Before using the instrument, assay the long lived isotope on each isotope setting present on the dose calibrator. Be sure to record the results of each assay.
- C. On a daily basis, assay the same long lived isotope, using the same geometry, on each isotope-setting the user anticipates using on that day. Record results.
- D. Compare the daily results with results from the last assay performed on the unit on that particular isotope setting; allow for mathematical decay. The deviation should be less than 10% from the calculated activity for that isotope setting.
- E. If the daily constancy assay exceeds the 10% deviation, the RSO should be notified and an accuracy evaluation performed to determine if the problem is with the dose calibrator or with the individual isotope setting.

Linearity Test Procedures

Linearity means that the calibrator is able to indicate the correct activity over the entire range of use of that calibrator. This test will be done using a vial or syringe of Tc-99m whose initial activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit or in a unit dosage syringe,

whichever is largest. The test shall continue until the activity contained in the vial or syringe is smaller than the smallest activity assayed.

Decay Method

- A. Assay the Tc-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. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.
- B. If starting at 8:00 a.m., attempt to repeat the assay at 2:00 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity normally assayed. For dose calibrators with a range switch, select the range normally used for the measurement.
- C. Convert the time and date information recorded for each assay to hours elapsed since the first assay.
- D. On a semi-log graph, the logarithmic vertical axis is in millicuries and the linear horizontal axis is in hours elapsed. At the top of the graph, date and the manufacturer, model number, and serial number of the dose calibrator should be noted. Plot the data.
- E. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.

$$\frac{A_{\text{observed}} - A_{\text{line}}}{A_{\text{line}}} = \text{deviation}$$

- F. If the worst deviation is more than plus or minus 10 percent, the dose calibrator should be repaired.

Shield Methods [Follow manufacturers protocols; maintain copies of protocol]

Geometry Test Procedures

Geometry dependence means that the indicated activity does not change with volume or configuration. This test will be done using a syringe that is normally used for injections. When using generators and radiopharmaceutical kits we will also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc vials. If volumes of syringes and vials differ from above, the procedures will be changed so that syringes and vials are tested throughout the range of volumes commonly used.

Accuracy Test Procedures

Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie 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 two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) will be used. One source will have a principal photon energy between 100 keV and 500 keV. If a Ra-226 source is used, it will be at least 10 microcuries; other sources will be at least 50 microcuries. Use at least one reference source with an activity in the range of activities normally assayed.

- A. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
- B. Average the three determinations. The average value should be within 10 percent of the certified activity of the reference source, mathematically corrected for decay.
- C. Repeat the procedure for other calibrated reference sources.
- D. If the average value does not agree, within 10 percent, with the certified value of the reference source, the dose calibrator must be repaired or replaced.

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APPENDIX E

Personnel External Exposure Monitoring Program

PROGRAM

1. The Radiation Safety Officer (RSO) will review all exposure reports when received to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated luminescent dosimeter (OSLD).
2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film, TLD, or OSLD whole body monitor that will be processed by a contract service on a routine basis (e.g., quarterly).
3. All individuals who, on a routine basis, handle RAM that emits ionizing photons will be issued a film, TLD, or OSLD extremity monitor that will be processed by a contract service on a frequency approved by the National Voluntary Laboratory Accreditation Program (NVLAP).
4. All individuals occupationally exposed to radiation in excess of 500 mrem in a year, will be issued a whole body monitor when caring for such patients.
5. Individuals who are exposed to radiation on an occasional basis are not normally issued exposure monitors. Examples of these individuals are: security personnel who receive or deliver packages; secretarial personnel who work in the nuclear medicine clinic but do not work with patients; and floor nurses.
6. All personal dosimeters will be processed and evaluated by a dosimetry provider holding NVLAP accreditation.

RECORDS

1. For each individual who is likely to receive in a year an occupational dose requiring monitoring the facility will determine the occupational radiation dose received during the current year and attempt to obtain the records of cumulative occupational radiation dose for the current year.
2. We will prepare for each employee requiring personnel monitoring a report of the radiation exposure data and the results of any measurements, analyses and calculations of RAM deposited or retained in the body by the individual. This report will include data and results obtained as required by the regulations.
3. We will provide each employee requiring personnel monitoring an annual report of the workers exposure to radiation as required by the regulations. Copies of reports will be maintained on file for 3 years from the date of the report.
4. We will maintain records of the dose to an embryo/fetus with the records of dose to declared pregnant women.
5. Upon receiving a written request from a former employee requiring personnel monitoring, a written report of the worker's exposure to radiation at this facility will be mailed to employee. This report will be furnished to the former employee within 30 days of the date of the request or within 30 days after the exposure of the individual has been determined by the facility, whichever is later.

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APPENDIX F

General Radiation Training Program

All individuals who, in the course of employment, are likely to receive an occupational dose in excess of 100 millirem (1mSv) in a year will be:

- Informed about the storage, transfer, or use of sources of radiation in the facility;
- Instructed in the health protection problems associated with exposure to radiation and the precautions or procedures to minimize such exposures, and the purposes and functions of protective devices employed;
- Instructed in and observed to the extent applicable the provisions of these regulations and licenses for the protection of personnel from exposures to radiation;
- Instructed of their responsibility to report promptly to the radiation safety officer (RSO) any condition that may cause a violation of the facility's license or any unnecessary exposure to radiation;
- Instructed in the appropriate response in the event of any unusual occurrence that may involve exposure to radiation; and
- Advised of the radiation exposure reports that workers are furnished pursuant to TAC 25 289.202.

The following categories of personnel will be trained:

- Support staff Housekeeping (if allowed access to RAM use areas)
 Cardiac Stress Other _____

The method of training may include any or all of the following:

- Lectures Videos Self-study Demonstrations Other _____

Hazardous Material Training

All employees whose duties require them to receive, handle or prepare hazardous RAM for transportation will receive training within 90 days of employment.

The training will include the following:

- ◆ **General awareness/familiarization training:** to provide familiarity with 49 CFR requirements and enable employees to recognize and identify hazardous materials;
- ◆ **Function-specific training:** USDOT requirements which are specifically applicable to the functions the employee performs;
- ◆ **Safety training:** emergency response, measures to protect the employee from the hazards posed by materials, and methods and procedures for avoiding accidents.

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APPENDIX G

Ordering and Receiving RAM

Ordering RAM

1. The radiation safety officer (RSO) or a designee will place isotope orders for RAM and ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded. A designee will be someone who has the appropriate training.
2. The RSO will establish and maintain a system for ordering and receiving RAM. For routinely used diagnostic materials, utilization records will be made that identify the authorized user, isotope, chemical form, activity, and suppliers.

Receiving RAM (Check all that apply)

- Deliveries will be received during normal working hours; the RSO will instruct the carriers to deliver radioactive packages directly to the nuclear medicine department. The person receiving the material will check the physician's written request to confirm that the material is what was ordered.
- Deliveries may be received during off-duty hours. The nuclear pharmacy delivering the RAM will place the goods in a locked box as described in the attached drawing. The nuclear pharmacy personnel have keys to lock and unlock the box.
- Deliveries may be received during off-duty hours. The nuclear pharmacy delivering the RAM will place material in the nuclear medicine hot lab. The nuclear pharmacy personnel have keys to lock and unlock the hot lab.
- Deliveries may be received during off-duty hours; the RSO will instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with the procedure outlined below.

The security guard on duty or designated persons will accept delivery of packages containing RAM that arrive during off-duty hours. Packages will be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____.

Unlock the door, place the package in the room, and relock the door. If the package appears to be damaged, immediately contact the RSO; if the RSO is not available, one of the other individuals identified below. Ask the carrier to remain at the facility until it can be determined if the driver or the delivery vehicle is contaminated.

Below is a sample form that can be used:

Name_____ Home Phone_____
Radiation Safety Officer:_____
Chief of Nuclear Medicine: _____
Chief Nuclear Medicine Tech: _____
Nuclear Medicine Tech on call (call page operator at extension _____): _____
Nuclear Medicine Physician on call: _____

APPENDIX H

25 TAC 289.202 (ee)

Opening Packages Containing RAM and Return of Radioactive Waste and Unused Dosages

During normal working hours, packages known to contain RAM will be monitored for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, as soon as practical after receipt (not to exceed 3 hours). Packages received after normal working hours will be monitored within 3 hours from the beginning of the next working day.

Each licensee must monitor the outside or external surface of a labeled package, labeled with Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49 CFR 172.403 and 172.436-440, for radioactive contamination unless the package contains only RAM in the form of gas or in special form as defined in 289.201(b).

Each licensee must monitor the external surfaces of a labeled package, labeled with Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations Title 49, CFR, 172.403 and 172.436-440, for radioactive contamination unless the package contains quantities of RAM that are less than or equal to the Type A quantity, as defined in 289.201(b) and specified in 289.257(s)(1).

OPENING PACKAGES CONTAINING SPECIFICALLY LICENSED MATERIAL

1. Put on gloves to prevent hand contamination.
2. Check the survey meter for proper operation.
3. Measure the exposure rate of the package at one meter (3.3 feet) and then measure the exposure rate at the surface of the package. Record the survey results and compare to the limits on the below listed DOT Shipping Label Chart. *If survey measurements exceed the values listed on the chart, stop the procedure and immediately notify the radiation safety officer (RSO).*
4. Visually inspect the package for any sign of damage (e.g., wet or crushed). *If damage is noted, stop the procedure and notify the RSO.*

DOT Shipping Label Chart

Label Category	Surface Level (mR/hr)	Transportation Index (TI) at 1 meter (mR/hr)
White I	0-0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

5. Open the package with the following precautionary steps:
 - A. Remove the packing slip.
 - B. Open the outer package following the supplier's instructions when provided.

- C. Open the inner package and verify that the contents agree with the packing slip.
 - D. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - E. If anything is other than expected, *stop and notify the RSO*.
6. Check the user request to ensure the material received is the material that was ordered.
 7. Records of package opening survey results are maintained for 3 years as specified in section 25 TAC 289.202(ggg)(5)
 8. Section 289.202(ee)(2) allows certain exemptions from package contamination surveys for RAM in the form of gas or special form. "Special form" means RAM that satisfies all of the following conditions:
 - A. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
 - B. The piece or capsule has at least one dimension not less than 5 millimeters; and
 - C. It satisfies the test requirements of 49 CFR, section 173.469. Special Form encapsulations designed in accordance with the requirements of 49 CFR section 173.389 in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985, must meet the requirements of this part.

RETURN OF WASTE AND UNUSED DOSAGES-LIMITED QUANTITIES

Under the provision of 49 CFR section 173.421, packages of RAM returned to pharmacies are labeled as "Limited Quantity Shipments." Limited Quantity is defined as a "maximum amount of a hazardous material for which there is a specific labeling or packaging exception." 49 CFR section 173.421 states that if a package meets the following requirements it is exempted from the specifications of packaging, marking, and labeling.

1. The amount of radioactivity in the package does not exceed a specified amount. (see attached table specifying limits for each commonly used radiopharmaceutical.)
2. The radiation level at any point on the external surface of the package does not exceed 0.5 millirem per hour.
3. The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm/300 cm².(49 CFR section 173.443[A][2]).

LIMITED SHIPMENT QUANTITIES FOR EACH COMMONLY USED
RADIOPHARMACEUTICAL

<u>Radionuclide</u>	Limited Shipment Quantity (mCi) $A_2 \times 10^{-4}$
Co-57	27.0
Co-58	2.7
Cs-137	1.6
F-18	1.6
Ga-67	8.1
Ga-68	1.4
Ge-68	1.4
I-123	8.1
I-125	8.1
I-131	1.9
In-111	8.1
Mo-99	1.6
P-32	1.4
Sm-153	1.6
Sr-89	1.6
Se-75	8.1
Tc-99m	11.0
Tl-201	11.0
Xe-133 (uncompressed, $A_2 \times 10^{-3}$)	270
Y-90	0.81
Yb-169	2.7

The above values have been calculated using information from 49 CFR 173.423, Table 7, and 49 CFR 173.435, Table of A_1 and A_2 Values for Radionuclides. When shipping more than one type of RAM in the same package, the limit on the radioactivity that may be shipped is determined by the lowest curie quantity assigned for items shipped.

Example: If Tc-99m and Se-75 were being shipped in same package, only 8.1 mCi of total activity could be shipped.

Procedures

1. Ensure that the radioactive waste being returned does not exceed the specified limits for "Limited Quantity Shipments."
2. Determine that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr by surveying the package prior to shipment.
3. Determine that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR

subsection 173.443(a), for example, 22 dpm/cm² when wiped over a 300 cm² area. A wipe of the package will be performed, analyzed and evaluated in the dose calibrator for activity. The activity will be the number of microcuries multiplied by 2.22 x 10⁶ to convert activity in microcuries to disintegration per minute.

4. If the package exceeds the limited shipment quantity, surface dose rate or removable contamination in excess of 22 dpm/cm², the package may not be shipped as limited quantities and will be held at the facility.

RETURN OF WASTE AND UNUSED DOSAGES-OTHER THAN LIMITED QUANTITIES

Ensure that the radioactive waste being returned does not exceed the specified A₁ for special form and A₂ for normal form material as described Type A quantity, as defined in TAC 289.201(b) and specified in 289.257(s)(1)

1. The RAM will be placed into appropriate shielding.
2. The shielded RAM will be placed in a DOT Type A shipping container. The container will also include absorbent material sufficient to absorb the liquid contents of the container.
3. A copy of the Type A container testing methods and results for each Type A package in use will be on file, for at least one year after the latest shipment.
4. The appropriate label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package one meter from a calibrated GM meter, then reading the transport index on the scaler in mR/hr. Determination of the radioactive White I, Yellow II, or Yellow III, is accomplished by taking surface readings of the package as well as the T.I. The following criteria will used to determine the proper labeling:

DOT Shipping Label Chart

Label Category	Surface Level (mR/hr)	Transportation Index (TI) at 1 meter (mR/hr)
White I	0 - 0.5	background
Yellow II	0.5 - 50	0.1 - 1.0
Yellow III	50 - 200	1.0 - 10

6. A wipe test shall be performed over 300 cm² external package area to ascertain that the container has removable contamination less than 6600 dpm/300 cm².
7. The package will be marked on the outside "USDOT 7A Type A" and "RAM." The package will be labeled on at least two sides of the package and near the proper shipping name marking.
8. The radioactive label will state the radionuclide or radionuclides, its chemical form, the quantity.
9. Each package will state the name/address of the pharmacy receive the package.
10. Shipping papers will be completed and the package transferred nuclear pharmacy.

APPENDIX I

Records of Radiopharmaceutical Use

RECORDS OF UNIT DOSAGE USE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Lot number or control number, if assigned;
5. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
6. Date of administration or disposal;
7. If administered,
 - Prescribed dosage;
 - Patient name and identification number if one has been assigned; and
 - Initials of the individual who assayed and administered the dose.
8. If discarded, the date and method of disposal; and
9. Initials of the individual who made the record.

RECORDS OF MULTIDOSE VIAL USE

For each multidose vial received from a supplier or prepared in-house, make a record of the:

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt or preparation;
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);
5. If administered,
 - Prescribed dosage;
 - Date and time dosage was drawn and measured;
 - Calculated volume that is needed for the prescribed dosage;
 - Measured activity in millicuries or microcuries; and
 - Patient name and identification number if one has been assigned.
 - Initials of the individual who assayed and administered the dose.
7. If discarded, the method of disposal and date; and
8. Initials of the individual who made the record.

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APPENDIX J

Rules for Safe Use of Radiopharmaceuticals

1. Wear disposable gloves at all times while handling RAM.
2. Either after each procedure or before leaving the area of use, monitor your hands for contamination in a low-background area with a survey meter or camera.
3. Areas where RAM is prepared, administered or stored will be covered with impervious material.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve.)
5. Do not eat, drink, smoke, or apply cosmetics in any area where RAM is stored, used or disposed.
6. Do not store food, drink, or personal effects in areas where RAM is stored, used or disposed.
7. Wear personnel monitoring devices at all times while in areas where RAM are stored, used or disposed. These devices should be worn as prescribed by the radiation safety officer. When not being used, personnel monitoring devices should be stored, in the work place, in a designated low-background area.
8. Wear an extremity exposure monitor with the film, TLD or OSLD 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 designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multi-dose diagnostic vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages must be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

12. Always keep flood source, syringes, waste, and other RAM in shielded containers when not in use.

13. Ensure security of RAM. Do not leave RAM unattended in unsecured areas.

APPENDIX K

Emergency Procedures

STOLEN, LOST OR MISSING RAM

1. Immediately notify the Radiation Safety Officer (RSO).
2. RSO will notify management and appropriate local authorities.
3. Conduct a complete search of the area with an appropriate survey meter capable of detecting the RAM.
4. RSO will contact DSHS at (512) 458-7460.
5. Within 30 days after making the initial report, submit a written report to DSHS that includes all of the information identified in 25 TAC 289.202(ww).

SPILLS OF RADIOACTIVE LIQUIDS AND SOLIDS

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing disposable gloves, clean up the spill using absorbent paper. With the clean side out, carefully fold the absorbent paper and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check hands, clothing, and shoes for contamination.
5. Report the incident to the radiation safety officer (RSO).
6. The RSO will follow-up on the cleanup of the spill and will determine if DSHS must be notified in accordance with 25 TAC 289.202(xx).

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APPENDIX L

Procedures for Area Surveys

AMBIENT DOSE RATE SURVEYS

1. Survey at the end of each day of use with a radiation detection survey meter in preparation and administration areas.
2. Survey weekly with a radiation detection survey meter in radiopharmaceutical storage and radiopharmaceutical waste storage areas,
3. Immediately notify the radiation safety officer (RSO) if you find unexpectedly high or low levels.

REMOVABLE CONTAMINATION SURVEYS (WIPES)

1. Survey weekly for removable contamination in all radiopharmaceutical storage, preparation, administration and waste storage areas.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 1000 dpm/100 cm² of removable contamination while maintaining a fixed geometry.
3. Immediately notify the RSO if you find unexpectedly high levels.

RECORDS

Keep a record of dose rate and contamination survey results. It must include the following information:

1. The date, area surveyed;
2. A sketch of each area surveyed;
3. Action levels established for each area;
4. Measured dose rate at several points in each area, expressed in millirads per hour and/or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 cm².
5. The serial number and the model number of the instrument used to make the survey or analyze the samples; and
6. The initials of the person who performed the survey.

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Appendix M

Procedures for Conducting a Member of the Public Dose Compliance Study

If licensed for, or seeking licensure for possession and use of RAM, in accordance with section 25 TAC 289.256, the radiation hazard resulting from licensed operations must be evaluated to demonstrate compliance with the member of public (MOP) dose limits described in section 25 TAC 289.202(n).

Total Effective Dose Equivalent

1. Each Licensee shall conduct operations so that the total effective dose equivalent to MOP from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered RAM and released in accordance with 25 TAC 289.202, from voluntary participation in medical research program, and from the licensee's disposal of RAM into sanitary sewerage in accordance with 25 TAC 289.202(gg). This may be demonstrated in one of the following ways:

(check applicable method of determination)

- A. Area monitor radiation dosimeters may be positioned in locations adjacent to restricted areas that are accessible to MOP for a period of one year to assure that the total effective dose equivalent does not exceed 0.1 rem (1 mSv) in a year. The Radiation Safety Officer shall evaluate the Radiation Protection Program monthly to determine if there have been changes to the physical layout of restricted areas or increases in RAM use that require reevaluation of MOP dose compliance.

- OR -

- B. Physical radiation surveys may be performed during the workday when radiation levels in the restricted area are at a maximum level for operations under the license. The radiation survey instrument is set to the most sensitive scale and surveys are conducted in all areas adjacent to restricted areas that are accessible to MOP. The following calculation may be utilized to demonstrate the total annual MOP dose:

(for diagnostic nuclear medicine operations, mR/hr is converted to 0.001 rem/hr)

Example: The highest detected radiation level at a wall adjacent to the nuclear medicine lab that is accessible to MOP, during peak utilization of RAM, is 0.06 net mR/hr. Utilization time at this location is a maximum of 6 hours per day, 5 days per week, 50 weeks per year:

$0.06 \text{ net mR/hr} \times 6 \text{ hrs/wk} \times 5 \text{ days/wk} \times 50 \text{ wks/yr} = 90 \text{ mrem or } 0.09 \text{ rem}$

The Radiation Safety Officer shall evaluate the Radiation Protection Program periodically to determine if there have been changes to the physical layout of restricted areas or increases in RAM uses that require reevaluation of MOP dose compliance.

2. Each licensee shall conduct operations so that the dose in any unrestricted area from licensed external source, exclusive of the dose contributions from patients administered RAM and released in accordance with 25 TAC 289.202, does not exceed 0.002 rem (0.02 mSv) in any one hour. Physical radiation surveys may be performed during the workday when radiation levels in the restricted area are at a maximum level for operations under the license. The radiation survey instrument is set to the most sensitive scale and surveys are conducted in all locations adjacent to restricted areas that are accessible to MOP.

Evaluation of Member of the Public Dose compliance must be maintained until the license is terminated.

Appendix N

Supplemental Information for Use of Xe-133

Applicants wanting to use Xe-133 must submit the following information for Agency review and approval:

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 attached worksheet.

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 effect all calculations.

XENON-133 WORKSHEET

RAML NO.: L0

PREPARER: _____

LICENSEE: _____

DATE: _____

ROOM #: _____

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

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

FORMULA SIMPLIFIED $C = \frac{\mu\text{Ci/wk} \times .25}{\text{cfm} \times (1.699 \times 10^6 \text{ ml/cf/hr}) \times 40 \text{ hrs}} = \frac{\text{ } \times 10^{-7}}{\text{ } \times 40 \text{ hrs}} \mu\text{Ci/ml}$

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

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

Legend} C = Maximum Allowed Room Concentration C₀ = Initial Room Concentration
 F = Flow rate (cfm)
 V = Room Volume (cubic feet)
 t = Time (min.)

$$C = C_0 e^{-FV \times t}$$

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

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

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

ROOM #:

XENON CONCENTRATION $C = \frac{\mu\text{Ci/wk} \times .25}{\text{cfm} \times (1.699 \times 10^6) \times 40 \text{ hrs}} = \frac{\text{ } \times 10^{-7}}{\text{ } \times 40 \text{ hrs}} \mu\text{Ci/ml}$

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

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

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

 RSO's Signature 0

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

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

II. Collection and/Disposal of Xe-133

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

If exhaled Xe-133 is exhausted directly outside, **into an unrestricted location**, the exhaust rate must comply with 25 TAC §289.202(o), for the total amount of Xe-133 used (i.e., the average concentration of Xe-133 in the unrestricted area, closest to the point of discharge, must not exceed 5×10^{-7} microcuries per milliliter of air on an annual basis or 1.25×10^{-4} in any one hour). *Because the hourly limit is 50 times larger than the annual limit (2 mrem in any one hour vs. 100 mrem per year) and the*

time for each procedure is less than one hour, the annual limit becomes more restrictive when greater than 50 procedures are performed per year.

If a xenon trap is used, the exhaust rate must be sufficient for just the Xe-133 that leaks during administration. A conservative estimate would be 25% of the total amount used. If Xe-133 is trapped, the room exhaust air flow rate can be 25% of the flow rate necessary to exhaust the Xe-133 directly outside the facility.

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

III. Exhaust Flow Rate

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

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

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

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

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

IV. Safety Considerations

A. If a major accidental release of Xe-133 occurs during a procedure, the room must be evacuated and air exhausted from the room until Xe-133 concentration is below 1×10^{-4} microcuries per milliliter (100 microcuries per cubic meter).

- B. If a xenon trap is used, the air exhausted from trap filters should be periodically collected and counted to determine whether Xe-133 is leaking through the filters. When trap filters no longer trap Xe-133 efficiently, they must be replaced or made effective, as prescribed by the manufacturer. An automatic monitoring and alarm system is therefore more convenient for the user.
- C. The equation used to demonstrate room concentration(s), after any accidental release, is:

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

- C = Room concentration
C₀ = Initial room concentration (assume total mixing)
F = Exhaust flow rate in cubic feet per minute (cfm)
V = Room volume in cubic feet
t = Minutes

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

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APPENDIX O

Diagnostic Procedures Requiring a Written Directive

A written directive will be provided prior to administration of a diagnostic ~~or therapeutic~~ dose except where a delay would jeopardize the patient's health.

This facility will perform the following types of procedures:

- Diagnostic nuclear medicine procedures using greater than 30 μCi of iodine-131 as sodium iodide;

An oral directive will be acceptable if a delay to write a directive would jeopardize the patient's health because of the emergent nature of the patient's condition. The information contained in the oral directive will be immediately documented in the patient's record and a written directive will be prepared within 24 hours.

An oral revision to an existing written directive will be acceptable when a delay to provide a written revision to an existing directive would jeopardize the patient's health. The oral revision will be immediately documented in the patient's record and a revised written directive will be signed by the authorized user within 48 hours of the oral revision.

A written directive that changes an existing written directive can be made for any procedure if the revision is dated and signed by an authorized user prior to the administration of RAM or radiation.

Patients will be identified by more than one method. Prior to the treatment, staff will determine the patient name, the patient date of birth or verify from the hospital identification bracelet the patient's identity.

Each administration agrees with the written directive.

Any unintended deviation from the written directive is identified, evaluated and appropriate action will be taken at time of discovery.

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ALARA Component of the Radiation Protection Program for Private Practice or Unit Dose Nuclear Medicine Facilities

RADIATION SAFETY OFFICER (RSO) RESPONSIBILITIES

1. Ensure that licensed material will be used safely. This includes review as necessary of training program, equipment, facility, supplies, and procedures.
2. Ensure that licensed material is used in compliance with DSHS regulations and the license.
3. Ensure that the use of licensed material is consistent with the ALARA philosophy.
4. Identify program problems and solutions.
5. Review the training and experience of the proposed authorized users to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and in accordance with the regulations and the license, if applicable.
6. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use RAM under the license.
7. Prescribe special conditions that will be required during a proposed method of use of RAM such as requirements for bioassays, physical examinations of users, and special monitoring procedures.
8. Review and initial at least every three months the reports of occupational radiation exposure records for all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive.
9. Establish a program to ensure that all persons who in the course of employment are likely to receive an occupational dose in excess of 100 millirem in a year (e.g., floor nursing, security, housekeeping, physical plant) are appropriately instructed as required, to include the ALARA philosophy and radiation safety as described in the training program.
10. Review at least annually the radiation safety program's contents and implementation to determine that all activities are being conducted safely, in accordance with DSHS and the conditions of the license, and consistent with the ALARA philosophy. The review will include an examination of records, reports, results of DSHS inspections, written safety procedures, and the adequacy of the management control system.
11. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
12. Ensure that the RAM license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

13. The RSO shall promptly investigate and implement corrective actions as necessary; and provide management a written report of these investigations and the corrective actions taken for the following:

- (1) Overexposures;
- (2) Accidents;
- (3) Spills;
- (4) Losses;
- (5) Thefts;
- (6) Unauthorized receipts, uses, transfers and disposals;
- (7) Other deviation from approved radiation practices.

The RSO will review and initial the results of personnel monitoring not less than once in any calendar quarter.

APPENDIX Q

Procedure for Leak-Testing Sealed Sources

- Leak testing of sealed sources will be performed by individuals licensed by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform leak testing analysis

RECORDS

Records of leak tests must be maintained for 3 years. The records must include the model number and serial number (if assigned of each source tested), the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, the date of the test, and the signature of the radiation safety officer.

LEAK TEST SAMPLES

1. If testing sources stronger than a few millicuries, a survey meter, preferably with a speaker, will be used to monitor exposure rates.
 2. A separate wipe sample for each source is prepared. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
 - A. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
 - B. For larger sealed sources and devices (instrument calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- Leak testing of sealed sources will be performed in-house following the procedures listed below.

LEAK TEST ANALYSIS

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microCurie. For beta sources, use a proportional flow counter or liquid scintillation counter. For gamma sources, a NaI crystal with a scaler will be appropriate. (Dose calibrators used in nuclear medicine are not sufficiently sensitive.)
2. Sensitivity of Instrument
Determine the minimum sample counting times needed to distinguish 0.005 microCurie from the background for each instrument. List instrumentation in Appendix B.

Measure the background count rate (R_b) in counts per minute (cpm) and record.

Measure the correction factor using a known National Institute of Standards and Technology (N.I.S.T.) source and record. Assay a certified check source that has the same isotope as the sealed source being tested. If a certified check source is not available, it will be necessary to use one with a different isotope that has a similar energy spectrum.

$$CF = \frac{R_{st} - R_b}{A(\mu\text{Ci})} \quad R_{st} = \text{count rate of standard (cpm)}$$

Example: Background is 30 cpm and a 10 μCi source measures 40,030 cpm on the instrument.

$$CF = \frac{40,030 - 30}{10 \mu\text{Ci}} = 4000 \text{ cpm}/\mu\text{Ci}.$$

Calculate minimum sample counting time (t_{ms}) in minutes for the instrument.

$$\text{Lower Limit of Detection (LLD)} = \frac{4.66}{CF} \sqrt{\frac{R_b}{t_{ms}}}$$

$$t_{ms} = \left(\frac{4.66}{CF(.005)} \right)^2 R_b$$

$$t_{ms} = \frac{868,624 \times R_b}{CF \times CF} \quad (\text{minutes})$$

3. Results

Count each wipe at least t_{ms} .

Determine count rate for each sample $R_s = \frac{N_s}{t_s}$ (cpm)

N_s = number of counts t_s = sample counting time

Determine activity as follows:

$$A(\mu\text{Ci}) = \frac{R_s - R_b}{CF} \quad \text{Record in units of microCuries}$$

4. Continue the same analysis procedure for all wipe samples.

5. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or properly disposed. A report shall be filed within 5 days of the test with DSHS.
6. Sign and date the list of sources, data, and calculations.

Example

Background is 150 counts in 5 minutes or $\frac{150}{5} = 30$ cpm

10 μ Ci Cesium standard measures 40,030 cpm

$$CF = \frac{40,030-30}{10 \mu\text{Ci}} = 4000 \text{ cpm}/\mu\text{Ci}$$

$$CF = 4000 \text{ cpm}/\mu\text{Ci} \quad R_b = 30 \text{ cpm}$$

$$t_{ms} = \frac{868,624 \times 30}{(4000)(4000)} = 1.63 \text{ minutes}$$

Must count at least 1.63 minutes.

Have chosen to count each sample 5 minutes.

Wipe #1 159 counts in 5 minutes

$$R_1 = \frac{159}{5} = 31.8 \text{ cpm}$$

$$A_1 = \frac{31.8-30}{4000} = 0.00045 \mu\text{Ci}$$

Wipe #2 164 counts in 5 minutes.

$$R_2 = \frac{164}{5} = 32.8 \text{ cpm}$$

$$A_2 = \frac{32.8-30}{4000} = 0.0007 \mu\text{Ci}$$

Both are < 0.005 microCurie.

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APPENDIX R

Survey Meter Calibrations

CHECK APPLICABLE ITEMS

- Survey meters will be calibrated by individuals licensed to perform this service by the Texas Radiation Control Program, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

RECORDS

The facility will assure that all survey instruments will be calibrated at least every 12 months and after repair. The calibration record shall include:

1. A description of the source used;
2. The certified dose rates from the source;
3. The rates indicated by the instrument being calibrated;
4. The correction factors deduced from the calibration data;
5. The signature of the individual who performed the calibration; and
6. The date of the calibration.

This record will be maintained for 3 years for inspection.

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APPENDIX S

Procedures for Waste Disposal

The following methods of waste disposal will be used: release to the environment through the sanitary sewer; decay-in-storage (DIS); and return to the manufacturer. Records will be maintained of the disposal of licensed material.

DISPOSAL OF RADIOACTIVE LIQUIDS AND GASES

Liquids disposed by release to the sanitary sewer shall be in accordance with these regulations for disposal in the sanitary sewer as they appear in 25 TAC §289.202(gg).

1. Material discharged by release into the sanitary sewerage system will be readily soluble or dispersible in the water. RAM released into the sewer in 1 month divided by the average monthly volume of water released into the sewer will not exceed the concentration listed in Table III of 25 TAC §289.202(ggg)(2)(F) "Tables - Values for Annual Limits." (Excreta from patients undergoing medical diagnosis is exempt from all the above limitations). Records will be maintained indicating the date, radionuclide, estimated activity of the release (in millicuries or microcuries), and the sink or toilet where the material is released.
2. Dose limits from effluents to unrestricted areas to members of the public will be maintained as required by 25 TAC §289.202(m) and Table II of 25 TAC §289.202(ggg)(2)(F) "Tables - Values for Annual Limits." These limits apply at the boundary of the restricted area. Records will be maintained indicating the date, radionuclide, estimated activity released (in millicuries or microcuries), estimated concentration, and the vent site at which the material is released.

DISPOSAL BY DECAY-IN-STORAGE (DIS) $T_{1/2} < 65$ DAYS

1. RAM with a physical half-life less than 65 days will be segregated according to half-life, when disposed by DIS.
2. One container for all waste for DIS - or -separate containers for different types of waste for DIS (e.g., one container for needles and syringes, a second container for gauze, etc., and a third container for unused doses) will be used.
3. Waste will be surveyed with all shielding removed, including any shielding provided by the container.
4. When a waste container is full, it will be sealed with string or tape and an identification tag will be attached. The tag will include the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container will be transferred to a DIS area.
5. Radioactive waste will be held for decay for at least 10 half-lives.
6. Each DIS container will be monitored prior to disposal as in-house trash, according to the following procedure.
 - A. Check the radiation detection survey meter for proper operation (waste will be monitored using a survey instrument with a sodium iodide detector or the imaging camera).
 - B. Remove any shielding from around the container.
 - C. Monitor DIS waste in a low-level (less than 0.05 millirem per hour) area.

- D. Monitor all surfaces of each individual container.
 - E. Monitor waste such that the container does not provide any radiation shielding.
 - F. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date that the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation labels are visible.
7. A record of all decay in storage RAM will be retained for 3 years. This record will include the date of the disposal; the date on which the RAM was placed in storage; the radionuclides disposed; the model and serial number of the radiation survey instrument used; the background dose rate; the radiation dose rate measured at the surface of each waste container; and the name of the individual who performed the disposal.

RETURNING RADIOACTIVE SOURCES TO THE MANUFACTURER

Packages will be prepared for shipment following the manufacturer's recommendations.

APPENDIX T

Inventory of Sealed Sources

Sealed Source Inventory Requirements

An inventory of sealed sources every six months and records will be maintained, for three years for inspection. The inventory record will contain the following information:

1. Model number of each sealed source;
2. Serial number or unique identification number of each sealed source;
3. Radionuclide;
4. Date of original assay and original activity;
5. Location of each sealed source;
6. Date of the inventory; and
7. Signature of the person performing the inventory.

The attached inventory form will be used to satisfy the requirements of the regulations or we will use an equivalent form that contains the above listed information.

Date of Inventory: _____ Signature of Person performing inventory: _____

#	SEALED SOURCE RADIONUCLIDE	SEALED SOURCE MODEL NUMBER	SEALED SOURCE S/N, if applicable	ESTIMATED ACTIVITY	LOCATION

Appendix U

RADIATION SAFETY AUDIT PROGRAM

The applicant recognizes that radiation safety audits are necessary to ensure that the radiation safety procedures specified in the operating, safety, and emergency procedures manual are followed. The applicant further recognizes that supervision of radiation workers should include regular and direct observation in all use areas for adherence to general laboratory procedures. The applicant therefore commits to and will adhere to the following radiation safety audit program: (Check items that apply to your program; provide justification for items that you feel do not apply to your program)

On a quarterly basis the RSO shall review the following documentation -

- Surveys (contamination and radiation field) for completeness, frequencies, results, and trends.
- RAM receipt a utilization logs for completeness, legibility, and retention in accordance with §289.201(d) "Records".
- Quality control tests on imaging and analytic detection equipment (thyroid probe, well counter, scaler(s), rate meter(s), etc.) against acceptable parameters.
- Waste disposal/transfer logs for completeness, documented evaluations, and acceptable methods.
- Dose calibrator test results to ensure appropriate time frames and acceptable manufacturer's tolerances are met.
- Employee training records.
- Survey meter calibration.
- Leak test results.
- Inventory of licensed sealed sources (make, model, and activity).
- Posting requirements of §289.202 (z) through (cc), "Caution Signs", "Posting Requirements", "Exceptions to Posting Requirements", and "Labeling Containers". Also §289.203(b) "Posting of Notices to Workers".
- All records of safety tasks (calibrations, package receipt, monitoring) delegated by the RSO.

At least annually, the RSO shall review current Operating, Safety, and Emergency Procedures manual and needed changes; identify current needs (equipment, staff,

resources, license amendments); implement the documented Radiation Protection Program (RPP), to include the RSO's annual audit of the RPP; and identify any other changes to the program.

The applicant is aware that the RSO must ensure that approved procedures, frequencies, and specification limits are met when radiation safety tasks (dose calibrator testing, contamination and radiation field surveys) are sub-contracted. Therefore, the applicant will oversee and perform quality assurance of all sub-contracted radiation safety related activities.