



Texas Department of State Health Services Radiation Safety Licensing Branch

REGULATORY GUIDE 3.2

GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR BROAD MEDICAL USE OF RADIOACTIVE MATERIALS

I. Introduction

This guide describes the information the Texas Department of State Health Services (DSHS) Radiation Safety Licensing Branch (Branch) uses to evaluate applications submitted by a medical institution for a license to use unspecified quantities and multiple types of radioactive material for medical research, diagnosis, and therapy. This type of license is known as a specific license of "broad authorization" and is intended to accommodate those institutions involved in research programs where the demand is great for a variety of radioactive materials for many types of medical uses.

In order for an institution to have a license of broad authorization, it must have a full-time Radiation Safety Officer (RSO) and/or supporting staff, establish a sub-licensing program, and conduct an internal inspection program to audit the users of radioactive material. This type of license allows the licensee to review and approve the users of radioactive material within the institution and to use any beta/gamma emitting material for purposes approved by the licensee's Radiation Safety Committee (RSC).

II. DSHS Contacts

The DSHS Radiation Control Program maintains an Internet site. The site contains the rules and forms referenced in this regulatory guide, as well as information on who to contact at DSHS with questions, information on the activities and structure of the DSHS Radiation Control Program (RCP), topics of interest about radiation, and links to other radiation-related web sites. The DSHS RCP universal resource locator is located at: <http://www.tdh.state.tx.us/radiation>

Regulatory Guides are issued to describe acceptable methods of implementing specific sections of Title 25 Texas Administrative Code Chapter 289, to delineate techniques used by the staff in evaluating specific issues, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are NOT substitutes for regulations and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Texas Department of State Health Services, Radiation Safety Licensing Branch, to make necessary determinations to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Manager, Radiation Safety Licensing Branch, Texas Department of State Health Services, 1100 W. 49th Street, Austin, Texas 78756-3189. Regulatory guides may be reproduced or may be obtained by contacting the Branch at (512) 834-6688 or accessing the Texas Radiation Control Program web page at www.tdh.state.tx.us/radiation

If you do not have access to the world-wide web and need additional information, please call (512) 834-6688 and ask for the following.

1. Medical and Academic Licensing Program, Radiation Safety Licensing Branch - for questions regarding the regulation of medical uses of radioactive material and the application for a radioactive material license and any related correspondence, including regulatory guides.
2. Radioactive Materials Inspection Group, Radiation Branch, Inspection Unit - for questions regarding compliance actions.
3. Radiation Group, Policy/Standards/Quality Assurance Unit - for questions regarding rules or the development of and any revisions to the rules.
4. Operations and Records Group, Radiation Safety Licensing Branch - for questions regarding fees.

III. Applicable Regulations

- A. The requirements of the following sections of Title 25, Texas Administrative Code (TAC), Chapter 289 (also known as the *Texas Regulations for Control of Radiation*) apply to the use of radioactive material in moisture/density gauge operations:

§289.201 General Provisions for Radioactive Material

§289.202 Standards for Protection Against Radiation from Radioactive Material

§289.203 Notices, Instructions, and Reports to Workers; Inspections

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

§289.205 Hearing and Enforcement Procedures

§289.251 Exemptions, General Licenses, and General License Acknowledgements

§289.252 Licensing of Radioactive Material

§289.256 Medical and Veterinary Use of Radioactive Material

§289.257 Packaging and Transportation of Radioactive Material

- B. You will be provided one printed copy of the applicable sections of the rules. It is the licensee's responsibility to ensure that its facility and any additional authorized sites are provided with copies of the applicable rules. These rules may be duplicated or can be downloaded from the agency Internet site. For a charge, you may request rules on disk or additional hard copies.

IV. License Fees

- A. A fee shall be submitted with each new application. Refer to 25 TAC §289.204 to determine the fee that should accompany the application. Review of the application will not begin until the proper fee is received by the Branch. The check or money order should be made payable to the Texas Department of State Health Services.

- B. Once a license has been issued, a nonrefundable 2-year fee must be paid for each radioactive material license. The fee must be paid in full each 2 years on or before the fee due date. You will receive a bill from DSHS for your fee approximately 60 days prior to the fee due date. If DSHS does not receive full fee payment by the fee due date, a notice of violation for failure to pay fees will be issued.

V. Instructions For Completing The Application

- A. Provide an overview of the scope of radioactive material use within the facility (e.g., number of users, number of laboratories, number of studies per month or year).
- B. Complete all items of BRC Form 252-2a (Human Uses) in full, so that a comprehensive evaluation can be made of the institution's ability to conduct all phases of an extensive radioisotope safety management program. The space provided on the application is limited, so the applicant should append additional sheets as necessary.

Specific items of the application are listed below with explanatory comments.

Item 1 - Self-explanatory. [Note the requirement to submit a completed BRC Form 252-1 (Licensee Business Information Form).]

Item 2 - Provide building names or numbers and their street addresses for all individual locations where radioactive material is to be used (floor and room numbers may also be listed if these areas are to remain dedicated for radioactive material use). Provide a map of multiple buildings on a single campus. Identify building owners where facilities or space has been leased.

Item 3 and 4 - Self-explanatory.

Item 5 - Put "Individuals approved by the Radiation Safety Committee." Submit separately the committee composition in accordance with paragraph VII, below.

Item 6 - The RSO is responsible for day-to-day operation of the radiation safety program, maintenance of the license and associated records, and being the primary contact with DSHS in administering the license. The RSO must have written authority from executive management to carry out radiation safety policy, suspend activities deemed unsafe, and require remedial action when necessary (see paragraph III.).

Item 7 - As appropriate to the licensee's requirements, the broad authorization for possession/use of radioactive material will be formatted as provided in Appendix A. Appendix A's Item C of Conditions 5, 6, 7 and 8 is intended to authorize sealed sources already possessed by the Licensee but for which no safety evaluations are available. In addition to the broad authorizations, the licensee should separately list requests for gases, aerosols, high activity sources and any alpha emitters; for example, the broad authorizations of the license do not allow persons licensed under broad licenses to:

- A. Conduct tracer studies in the environment involving the direct release of radioactive material (applies to field users);
- B. Receive, acquire, own, possess, use, transfer or import devices containing 100,000 curies or more of radioactive material in sealed sources for irradiation of materials;
- C. Conduct activities for which a specific license issued by DSHS is required under 25 TAC §§289.252(i)-(j) [e.g., special requirements for specific licenses to manufacture, assemble, repair or commercially distribute commodities, products or devices containing radioactive material]; 25 TAC §289.255 (Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography); or
- D. Add or cause the addition of radioactive material to any food or other product designated for ingestion or inhalation by, or application to, a human being.

Item 8 - Check yes, because this will be a requirement to be placed upon users.

Item 9 - Certification of Authorized Users - Confirm that the Authorized Physician Users will be required to certify in writing that they are familiar with and agree to abide by 25 TAC §289.256, the license conditions, and the institution's Radiation Safety Procedures, and that the RSO will keep a copy of such certifications for inspection.

Item 10 - Training.

- A. Authorized Physicians.
- B. Radiation Safety Officer.
- C. Technologists.
- D. Others.

Item 11 - Facilities. Provide either scaled drawings (approximately 1/4" = 1 foot) of areas where radioactive material will be used or provide detailed criteria that will be used by the applicant for approval of such facilities.

Specify each proposed location of use by the street address and city or other descriptive address (e.g., 5 miles east on Highway 10, Anytown, Texas). A Post Office Box address is not acceptable. If radioactive material is to be used at more than one location, give the specific address of each location. In addition, identify facilities designed or established for special uses, e.g., panoramic dry or wet irradiators, waste storage facilities used for long-term storage, high-level laboratories (e.g., iodination labs or individual labs processing licensed material in quantities greater than 100 mCi per single use). If radioactive material is to be used in field studies, the activities must be

specifically identified and authorized on the license. Appendix B contains information required for field use of licensed material.

Item 12 - Operating, Radiation Safety and Emergency Procedures Manual.

Provide a copy of the manual that will be made available to each person at the institution who will use radioactive material. In addition to the information required by 25 TAC §289.256(f)(3)(A), the Operating, Safety and Emergency Procedures Manual (OSEPM), should outline the administrative responsibilities in the management of the radiation safety program (see paragraph VIII below for the content of the procedures.) The procedures should be the applicant's rules for the safe use of radioactive material within the institution. Following DSHS approval, a copy of the procedures should be made available to each person at the institution who uses radioactive material. (See paragraph IX below for the content of the procedures.) The applicant will maintain future responsibility to assure that copies are updated to reflect approved policies.

Item 13 - Radiation Detection Instrumentation.

List radiation safety office instruments used for surveys. Include instrument description, purpose (kinds of surveys), minimum detectable activity and typical action level.

Item 14 - Financial Qualification and Financial Assurance. Self-explanatory.

Item 15 - The application must be signed and dated by the Chief Executive or a representative who is duly authorized to commit the institution to the performance of the activities and resources as specified in the application.

VI. Radiation Safety Officer (RSO)

An RSO must be appointed and be responsible day to day for the over-all radiation protection program within the institution.

- A. A description of the RSO's training and experience with radioactive materials, experience with broad licenses, and in the field of radiation safety, must be provided (25 TAC §289.256(h)(2) contains training and experience requirements for RSOs of medical licenses of broad authorization.)
- B. The applicant must commit to ensuring the RSO performs the duties prescribed in 25 TAC §289.256(g)(1)(B). (This may be included in the Administrative Procedures as described in paragraph VIII below.)

VII. Radiation Safety Committee (RSC)

An RSC must be established in conformance with 25 TAC §289.256(i). This committee shall have an approved Chairperson and should be composed of at least five members to evaluate all proposals with respect to radiation safety. The RSO should normally

serve as Secretary to the RSC and membership should be held to no more than a dozen individuals. Membership of the committee should include physicians and a single technical staff member from each specialty using radioactive material (e.g., research, diagnostic and therapeutic uses). In addition, this committee must have in its membership the RSO and appropriate representation from nursing and executive management of the institution. Names and summaries of their qualifications of the committee members must be submitted for review and approval by DSHS. Amendments are required as the RSC will be named on the license. Identical role replacements, however, may function as replacements (pending approval by DSHS) so long as the overall composition of the RSC remains unchanged.

Broad scope licenses that involve medical or nonmedical research using human subjects require establishing specialized committees and using committees established in accordance with criteria promulgated by the U.S. Food and Drug Administration (FDA), e.g., Radioactive Drug Research Committees (RDRCs) or Institutional Review Boards (IRBs), when evaluating research requests. Appendix C to this guide provides a flow diagram that may be used in determining the need for a human use subcommittee or one or more of the FDA (or other federal agency) committees to supplement the RSC and its review process.

VIII. Administrative Procedures

The applicant must submit two copies of the Administrative Procedures outlining how the RSC, the RSO and Executive Management will work together to manage the use of radioisotopes within the institution. The Administrative Procedures should delineate the following:

- A. Outline of the specific duties, responsibilities and authority of (1) Executive Management, (2) the RSO and (3) the RSC. Discussion should include but not be limited to, establishing policy for safe use of radioactive material, requiring corrective action by sub-licensees, and suspending operations deemed to be unsafe. Sufficient authority must be delegated to the RSO by executive management to permit timely action to be taken in the event of a threat or hazard to public or employee health.
- B. Frequency at which the full RSC meets and specifics of a defined quorum. Most licensees find quarterly meetings effective and you should develop and provide a typical agenda.
- C. Method employed for maintaining records of the RSC's proceedings such as sample minutes.
- D. The means by which the RSC will determine whether or not a physician is qualified to use radioisotopes clinically or experimentally within the institution. Training and experience requirements shall at least meet but may exceed those of 25 TAC §289.256(ff)(1).

- E. Appropriate forms and conditions for making application to the RSC for use of radioactive material in humans and for research, and for the RSC to authorize such use (issues which must be addressed, as well as an example of a sub-license permit, may be found in Appendix D). These forms should include all appropriate items of the DSHS application and license forms.
- F. Procedures for procuring radioisotopes, maintaining inventories, controlling possession limits, and managing waste.
- G. Procedures and criteria for periodic inspection of sub-licensees by the RSO to see that sub-license conditions and the institution's safety procedures are being followed. Procedures defining internal compliance and enforcement program must be provided (Appendix E). The frequency may vary in range depending on the types and quantities of radioactive material usage.
- H. Appendix F contains specific issues which must be addressed.
- I. If human research is to be performed, evidence of a duly constituted and officially approved Radioactive Drug Research Committee and Investigational Review Board must be provided.

IX. Radiation Protection Procedures

A formal set of rules and procedures for procurement, safe handling, and disposal of radioisotopes within the institution shall be submitted and approved with the application. Proposed changes must be established by the RSC prior to future amendments. Centralized receipt and inventory of all packages is preferable where laboratory research is prevalent. A copy of these rules and procedures should be given to all personnel under the jurisdiction of the Radiation Safety Committee. Two copies must accompany the license application. The written radiation protection procedures should be prefaced with a table of contents, have serially numbered pages and should clearly define (a sample table of contents is provided as Appendix G):

- A. Procedures for ordering radioactive materials, for receipt of materials during on and off-duty hours, and for notification of responsible persons upon receipt of radioactive materials. These procedures should be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured against unauthorized removal at all times, and that radiation levels in unrestricted areas do not exceed the limits specified in 25 TAC §289.202(m).
- B. Procedures for examining incoming packages for leakage, contamination or damage, and for safely opening packages. (The monitoring should be performed as soon as practicable after receipt of the package of radioactive material, but no later than three hours after the package is received at the institution during normal working hours; immediately if package integrity appears compromised.) The

procedures may vary depending upon the quantity of radioactive material received, but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination after opening or disposing of this material [see 25 TAC §289.202(ee)].

- C. Method of recording receipt, use, transfer, and disposal of radioactive materials to include a reference to the authorized user. Provide sample recording keeping forms that reflect the minimum details.
- D. Guidelines for restricting access to radioactive material to authorized users and for posting radiation warning signs [see 25 TAC §289.202(aa)].
- E. General guidelines for handling liquid or loose radioactive materials and the laboratory equipment to be used in working with them. For example, explain what materials and what operations should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when hard beta and/or gamma emitting materials are handled in millicurie amounts.
- F. Procedures for storing, logging in and out, handling and returning to storage sealed sources that are used for therapy. Also, the procedures for handling sources including descriptions of special equipment used to minimize exposure and minimum qualifications of all personnel handling sources.
- G. For sealed sources of radioactive material, a description of the method and frequency used to test the sources for leakage. For example, if a commercial leak test kit is used, commit to using a kit approved by DSHS, an Agreement State or the U.S. Nuclear Regulatory Commission (NRC). If the applicant wishes to test his/her own sources for leakage, the procedure for wiping, counting, converting to microcuries, etc., must be submitted. (Regulatory Guide 5.01, "Guide for the Preparation of Leak Test Applications," may be obtained from DSHS.)
- H. The instructions given to nurses who will attend patients containing radioactive material to assure proper protection of other patients, nursing personnel, and visitors. These should include disposal of waste from patient's rooms who receive therapeutic amounts of P-32 or I-131.
- I. Procedures for performing radiation surveys about patients containing therapeutic quantities of gamma-emitting radioisotopes and for restricting the area about each patient. Private rooms are required and these should be corner rooms with outside walls. Also, provide procedures for surveying patients to verify all sources have been removed prior to their release from the hospital [in accordance with 25 TAC §289.256(w)]. Include instructions to be provided to patients who receive permanent implants, especially iodine-125.
- J. Method and frequency of monitoring for personnel exposure (film badges, TLD, etc). Include provisions for use of ring badges or other extremity monitoring when

millicurie amounts of radioactivity are handled. Dosimetry must be provided personnel when it is likely that they will receive greater than ten percent of the allowable occupational limits [see 25 TAC §289.202(q)].

- K. General laboratory rules for preventing contamination when handling uncontained radioactive material (see Appendix H).
- L. Method of coping with spills, contamination, and accidents if they occur within the institution. (See sample instructions in Appendix I.)
- M. A description of the users' routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, instrumentation used and provisions for maintaining records of surveys (see Appendix J). Supply example survey form. Also, describe any special area radiation field monitoring or effluent concentration monitoring.
- N. A description of the Radiation Safety Division's routine audit/survey program. The Agency recommends that the Radiation Safety Division visit each use area at least once a quarter, perhaps using a scheme similar to that presented in Appendix K.
- N. If radioisotopes will be used in animals, provide a description of the animal housing facilities and a copy of instructions provided to animal caretakers for the handling of animals, animal waste and carcasses. Include procedures for cleaning and decontamination of animal cages and procedures for ensuring that animal rooms will be secured unless attended by authorized users of radioactive material.
- O. A complete description of the specific methods for waste management and disposal of radioactive material should be provided. A licensee may dispose of waste by:
 - 1. Transferring it to a person properly licensed to commercially receive such waste.
 - 2. Releasing it into a sanitary sewer in conformance with 25 TAC §289.202(gg).
 - 3. Discarding it without regard to its radioactivity in conformance with 25 TAC §289.202(fff).
 - 4. Segregation, labeling [25 TAC §289.202(cc)] and storage until activity has decayed to a specified level (or concentration) and release to sewer or dump after labels have been removed and surveyed to background levels (i.e., decay-in-storage).

Note: Unless specifically authorized by DSHS, no licensee may dispose of radioactive waste material by:

incineration [see 25 TAC §289.202(hh)], burial, discharge by release into septic tanks [see 25 TAC §289.202(ii)] or release to the atmosphere; or

disposing of 300-day half-life radioactive waste material in a Type I municipal solid waste site [see 25 TAC §289.202(fff)(4)].

- P. Procedures for calibration of dose calibrators, scintillation detectors and for quality assurance of imaging equipment. (Model procedures may be obtained from DSHS upon request.)
- Q. State how often and by whom the survey instruments will be calibrated. (Regulatory Guide 5.02, "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the if survey instrument calibration is to be done by the licensee.)
- R. If a technetium-99m generator is to be used or if any radiopharmaceuticals are to be prepared from a kit, the applicant must include the following information in the procedures:
1. Confirm that finger badges will be worn on the dominant hand by technicians who prepare kit preparations.
 2. Confirm that the manufacturers instructions will be strictly followed when eluting the generators or preparing the kits.
 3. Method of assaying doses that are prepared from the generator and/or kits.
 4. Confirm that syringe/vial shields will be used as per manufacturer's recommendations.
 5. Name and model of the high range survey meter (up to 1 R/hour measurement capability) that will be used if a generator is to be possessed.
 6. If generators are held for decay, confirmation that the unshielded cores are to be monitored for acceptable levels prior to disposal.
 7. Confirm that each generator elution will be tested for molybdenum-99 breakthrough and a description of the criteria for assuring that at injection, acceptable limits are not exceeded. (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m and less than 5 microcuries of molybdenum-99 per dose.)

Note: linearity of dose calibrators must be performed to the limit measurements will be made.

- S. If the applicant desires to use Xenon-133 (or other free gases or aerosols), a description of the program to ensure that facilities and procedures are appropriate to limit personnel exposures and control releases to the environment must be submitted. (A guide may be obtained from the DSHS.) If review and approval shall

be performed by the licensee, commit to using DSHS's guide and calculation worksheet and specify basic operating/emergency procedures.

- T. If the applicant desires to use therapeutic quantities of radioiodine, a description of the program to ensure that facilities and procedures are appropriate to control releases to the environment and exposures to personnel (including the use of fume hoods, covered containers, ventilation and spill provisions where doses are administered, and routine bioassay (thyroid counting) of personnel) must be submitted. Bioassay (thyroid counting protocols) shall be highly descriptive; a DSHS guide is available upon request.
- U. Initial and refresher training must be provided to all individuals who will use, or may come in contact with, radioactive material. Employees who will need training include all users; laboratory supervisors and technicians; radioactive material incinerator and waste compactor operators; housekeeping, nursing and security personnel; and radiation safety office staff. It is understood that training programs will vary from license to license. The detail and content will depend on the scope of the program, possession limits, type of isotopes used, size of the program in terms of the number of laboratories and users, laboratory classification scheme, types of studies being performed, etc. A system for retraining needs to be developed that is performance based (i.e., hands-on), as well as didactic. See Appendix L.

X. Pharmaceutical Quality of Radioactive Material

It is necessary that radioisotopes for human use be assayed for quantity (activity) and for radiochemical purity prior to use. They are also to be sterilized and pyrogen free for parenteral administration. If radioisotopes are procured pharmaceutically unrefined, information should be submitted stating the procedures for identifying and assaying the radioactive material and carrying out such other testing and processing (sterilization, pyrogen tests, etc.) as may be appropriate. Information on instrumentation/equipment used for this purpose should be submitted or indicated as requested under Item 13 of the application (BRC Form 252-2a).

XI. Technologist and Technician Training

As radioactive material is not used and handled exclusively by physicians or principal investigators who are authorized through the RSC, describe the minimum training technologists and technicians must have before they will be allowed to use or handle radioactive material (see Appendix M). If training is not verified through recognized certification in their various subspecialties (e.g., laboratory, therapy, nuclear medicine), describe the subjects and classroom hours of formal training to be given in basic radioisotope handling techniques, and the on-the-job experience under close supervision to be required. Indicate how the technologist's and the technician's work will be supervised and how their performance will be evaluated.

XII. Financial Assurance.

25 TAC §289.252(gg) requires licensees possessing a radioactive material license, of the types described in 25 TAC §289.252(gg)(1) and (2), to provide financial assurance for decommissioning. The financial assurance must be provided to and accepted by DSHS via one of the mechanisms described in 25 TAC §289.252(gg)(6). See Appendix N for instructions on determining how to comply with 25 TAC §289.252(gg).

Appendix A

EXAMPLE (page 1/2)

A. Any radioactive material with Atomic Number less than 84	A. Any (except sealed sources, gases or aerosols)	A. 500 mCi of any single radionuclide; Total not to exceed 200 Ci	A. Medical research, diagnosis, therapy and education.
B. Any radioactive material with Atomic Number less than 84	B. Sealed sources and devices	B. Any single source not to exceed 500 mCi; Total not to exceed 200 Ci	B. Medical research, diagnosis, therapy and education.
C. Any radioactive material (as per letter dated Month Day, Year)	C. Sealed sources and devices	C. Any single source not to exceed 5 Ci Total not to exceed 200 Ci	C. Medical research, diagnosis, therapy and education.
D. Any radioactive material with Atomic Number of 84 or greater, except special nuclear material	D. Any (except sealed sources)	D. 500 mCi of any single radionuclide Total not to exceed 200 Ci	D. Medical research, diagnosis, therapy and education.
E. Any radioactive material with Atomic Number of 84 or greater, except special nuclear material	E. Sealed sources and devices	E. Any single source not to exceed 10 mCi Total not to exceed 50 mCi	E. Medical research, diagnosis, therapy and education.

Appendix A (continued)

**EXAMPLE
(page 2/2)**

F. Tc-99m/ Mo-99	F. Tc-99m generators	F. 10 Ci	F. Medical research, diagnosis, and education.
G. I-131	G. Any except aerosols	G. 1 Ci	G. Medical research, diagnosis, therapy and education.
H. Xe-133	H. Any	H. 250 mCi	H. Medical research, diagnosis, and education.
I. Ir-192	I. Sealed Sources (Manufacturer and Model Number)	I. Two sources not to exceed 12 Ci; Total 23 Ci	I. One source (set) for treatment of humans with a <u>Manufacturer</u> HDR remote control brachytherapy unit and the other source (set) for storage in its authorized shipping container during periods of source exchange.
E. Any radio- active material with Atomic Number of 84 or greater, except special nuclear material	E. Sealed sources and devices	E. Any single source not to exceed 10 mCi Total not to exceed 50 mCi	E. Medical research, diagnosis, therapy and education.

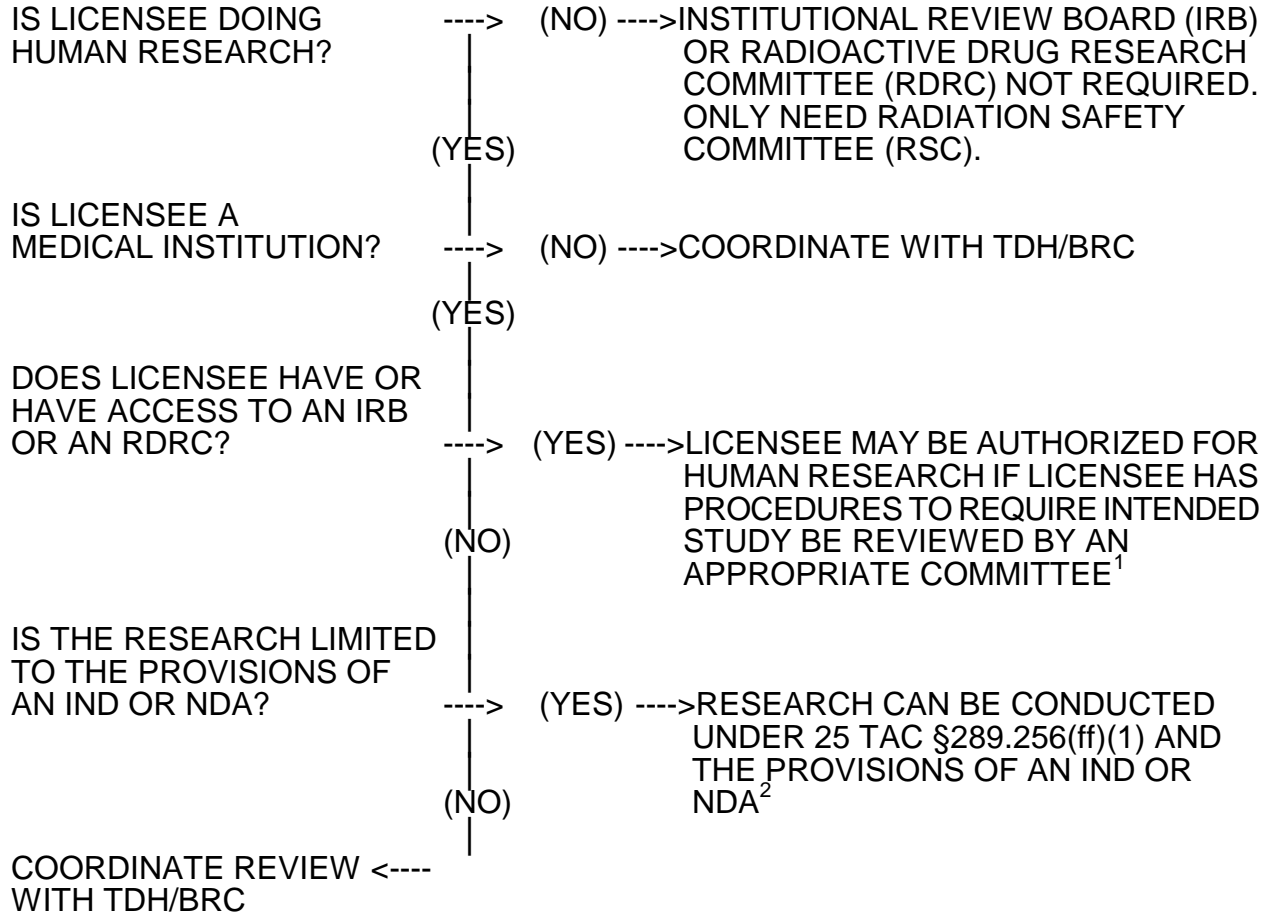
Appendix B

Information Required for Field Use of Radioactive Material

1. A complete license application describing the type and amount of material to be used, the location of use, and training and experience of the individual using the material.
2. A complete experimental protocol.
3. A description of the amount of radioactive material to be released in the field, decontamination procedures at the conclusion of the experiment, if appropriate, and procedures for minimizing releases.
4. A description of the expected radiation dose to humans.
5. The written permission of the property owner to use radioactive material at the proposed site.
6. A letter from the Texas Natural Resources Conservation Commission indicating that they have reviewed your application and concur with your request.

Appendix C

Flow Diagram to Aid in Determining the Need for Committees for Human Research



¹For example: IRB required for such studies as development of emerging medical technologies, physiological studies using radioactive tracers, IND studies, RDRC-approved studies. RDRC required for such studies as biodistribution studies, radioactive drug studies when IND is for nonradiolabeled form of drug.

²For example: Phase II/Phase III Clinical Trials.

Appendix D

RADIATION SAFETY DIVISION REVIEW CRITERIA FOR SUB-LICENSE APPLICATIONS UNDER THE SCOPE OF A BROAD LICENSE

The licensee must emulate DSHS by maintaining formal licensing, compliance and inspection programs. If your current license does not explicitly authorize internal (Radiation Safety Committee) approval and close-out of individual laboratories or areas of use within the confines of the campus, and your institution has adequate Radiation Safety Division staff with a large program creating frequent changes in use due to the large numbers of investigators, then flexibility to review and approve the opening and closing of labs internally may be beneficial. Should you wish to pursue this internal authorization capability, you will need to describe what information you seek from sub-licensees and the criteria to be used when evaluating the addition of new laboratory facilities, new protocols and users, and the decommissioning of laboratory facilities. Below are suggested Items you will need to identify as standard review criteria if requesting the authorizations described above. Additionally, discussions of what should be detailed in your Sub-Licensing and Compliance/Enforcement Programs have also been enclosed.

REVIEW CONSIDERATIONS FOR NEW LAB APPROVAL:

- Scope of use (frequency of RAM use, types of procedures, and protocols with emphasis on potential for releases)
- Quantities and physical and chemical forms handled per use/experiment
- Maximum possession per isotope
- Labeled diagrams of each room of use or storage with expected traffic patterns, waste storage, disposal sinks
- Identify special safety equipment, tools, or environmental controls needed for work, shielding provided, decontamination equipment or supplies
- Specification and performance of effluent control (plumbing, drainage, heating/cooling/ventilation systems, hoods, stacks, other exhaust)
- Facility layout to limit area of RAM use and minimize distribution
- Facility design to minimize traffic through RAM areas and identify assessable storage
- Security against unauthorized removal
- Floor and work surface construction and coverings to enhance decontamination efforts
- Availability of convenient wash facilities
- Sinks designated for disposal should be labeled, use limited, and properly constructed
- Potential airborne RAM or gases (used or stored) limited to laboratory fume hoods, whose function is evaluated at a regular frequency
- Gases like ^{133}Xe should be handled and disposed per DSHS Xenon Regulatory Guide
- Adequate RAM waste storage space and segregation/disposal plans
- Ability of user (or staff) to perform routine surveys effectively on a specified frequency
- Adequacy of shielding when handling or storing gamma or high energy beta emitters
- Appropriate detection instrumentation and methods for conducting contamination surveys for the physical plant/protocol submitted
- Posting of appropriate signage and emergency contacts (names and numbers)

Appendix D (continued)

REVIEW CONSIDERATIONS FOR A NEW USER AND PROCEDURES:

- Appropriate training and experience of any new user not currently authorized
- Identify users and supervised staff and/or assistants to work under this sublicense
- Documentation of radiation safety inservicing for any handler of RAM (prior to issuance)
- Determine the need for appropriate personnel monitoring and/or bioassay program
- Determine a frequency for surface contamination surveys to be performed by the primary user
- Determine the need for personnel frisks prior to exiting a restricted area
- Determination of independent inspection frequency by the Radiation Safety Division
- Primary users availability to perform adequate and frequent supervision of subordinate staff

LAB CLOSE-OUT CRITERIA & RADIATION SAFETY DIVISION SURVEYS:

- Sealed source disposition records
- Survey measurements keyed to a room drawing indicating locations surveyed
- Thorough contamination sampling to meet removable limits of TRCR, Appendix 21-C to release for unrestricted use (shall include fume hoods, storage areas, and any authorized disposal sinks/drain pipes)
- Identification of calibrated detection equipment used and of the surveyor
- Documentation of remedial results required to achieve acceptable limits
- Signature of the Radiation Safety Officer concurring with the room release
- Removal of all RAM signage
- Survey retained for review
- If terminating the last authorized location within a billable sub-site, submit to the associated details and request termination to avoid future billing.

THE SUB-LICENSE DOCUMENT

The Radiation Safety Division for each Broad License must include in its responsibilities, the processing and issuing of sub-licenses. Your Manual must delineate the form and substance of the formal document called the sub-license. This document must identify the granting of authorizations to the individual user applicant(s) following the RSC approval, document issuance, and authenticated by the RSC Chair's signature. The Sub-License document must clearly authorize and limit authorizations, while answering the following questions:

- What radioactive material can be used? Possession limits, form, isotope, purpose.
- Where can it be used? Room number, building names, and/or street address.
- Who can use it? If delegation to non-approved authorized users shall occur, identify by names and/or titles (technologist, students) and clarify by license condition, minimums for supervision, handling limits, and training.
- What types of tasks can be performed? May be adequately addressed with your isotope authorizations or you may tie-down the authorized users application date.

Appendix D (continued)

- What are the minimum safety expectations (e.g., limitations, equipment maintained, supervision, etc.) of those authorized users? These are typically unique license conditions that may expand upon safety considerations or specify further limitations from those found in the Radiation Safety Manual.
- When does authorizations under this document expire? This may vary anywhere from 1 to 5 years based sub-licensee stability and commitments made to DSHS.
- What unique sub-license number and amendment number is currently in effect and what date was it approved by the Radiation Safety Committee.
- Whose signature certifies approval of significant events (new applications, amendments, renewals) on these documents.

When looking for examples, don't overlook specific licenses (those without broad authorizations) written by DSHS. Each of these Items must be addressed by each Broad Licensee, as the issuance of sub-licenses is a common bond among Broad Licensees, regardless of what other broad privileges may have been approved. Sub-licenses may be issued to each individual applicant, to each laboratory (authorizing several users), and/or in slightly larger units where operations and workers are identical (departments functioning within a single cost center). These concepts must be considered and described. However, details of each authorized user and their approved privileges must be clearly identified in the Sub-License document. If frequent turnover in users is common on a multi-user sub-license, then frequent amendments thereof may result. We have attached a sample form that should be emulated if at all possible.

Note that renewed or amended sub-license documents must clearly indicate that all previous sub-licenses issued in that document's authorization number are voided upon issuance of the current amendment. Hence, a need for numbering sequential amendments with each issuance. Additionally, failure to maintain a proficient and accurate Sub-Licensing Program can prompt the DSHS' elimination of broad authorizations granted under your specific license.

Appendix D (continued)

SUB-LICENSE PERMIT

****PREVIOUS AMENDMENTS ARE VOID****

SUB-LICENSEE: _____ PERMIT ID: _____
RECORDS ROOM: _____ AMENDMENT NO: _____
PURSUANT TO APPLICATION DATED: _____ EXPIRATION DATE: _____

RADIOACTIVE MATERIAL AUTHORIZED

ISOTOPE	FORM	MAXIMUM ACTIVITY	USE
A.	A.	A.	A.
B.	B.	B.	B.
C.	C.	C.	C.
D.	D.	D.	D.

CONDITIONS AND RESTRICTIONS OF USE:

1. Radioactive material may only be used by (or supervised by, or in the presence of)....
2. Radioactive material may only be used and stored in...(Bldg. & Laboratory Room Nos. & or temporary-job-sites if TDH/BRC approved)....
3. The sub-licensee shall...(appropriate to clarify issues associated with waste processing, maximum activity handled at any one time, availability of an operable survey instrument, personnel monitoring, security, supervision, description of suppliers of human-use approved isotopes, and/or considerations for animal pens/carcasses)....
4. Etc.
5. Except as specifically provided by this license, the licensee shall possess and use the radioactive material authorized by this sub-license in accordance with the facility's Radiation Safety Manual and statements, representations, and procedures contained in the following:

application dated ..., and
letter(s) dated....

The TRCR shall prevail over statements contained in the above documents unless statements are more restrictive than the regulations.

FOR THE (FACILITY) OPERATING UNDER L0####

ISSUE DATE

XXXXXXXXXXXXXXXXXXXX, RSC CHAIR

Appendix E

COMPLIANCE AND ENFORCEMENT

COMPLIANCE NOTIFICATION

Provide a section for your Manual that address compliance actions the RSC will be routinely taking against discovered violations exposed during routine Radiation Safety audits. An example would be a formal written "Notice of Violation", signed by the RSC Chair requiring the sub-licensee to respond in writing (e.g., within 30 days), and that identifies the date compliance was achieved and identifies what steps would be implemented to avoid repeating those violations.

ESCALATED ENFORCEMENT

Additionally, describe samples of remedial or escalated enforcement actions that the RSC may impose for repeat non-compliance or individuals acting in gross willful disregard for public health and safety, that goes beyond letter notifications. Examples might include: 1) additional sub-licensee training, 2) escalated inspection frequency, 3) have the sub-licensee justify to RSC in-person (enforcement conference) why they should be granted future authorizations, 4) formal reprimands to the employees performance file, and/or 5) immediate sub-license termination and impoundment of all radioactive material.

Appendix F

Radiation Safety Program Management

The following deals strictly with the management of your program. Guidance was derived from DSHS documents, U. S. Nuclear Regulatory Commission (NRC) guides and National Council on Radiation Protection and Measurements (NCRP) Report numbers 59 and 105. Some of what follows is partially excerpted from the NRC's NUREG 1516, "Management of Radioactive Material Safety Programs at Medical Facilities."

1. Provide a specific list of duties and responsibilities for the RSC. These duties and responsibilities must include an annual review of the institution's radiation safety program as required by 25 TAC §289.202(d) and should be incorporated into the institution's bylaws as a description of a standing RSC.
2. If the RSC is a standing committee within your organization's management structure, please provide that documentation. If not, then TDH recommends that this formal accountability be established. NRC's NUREG 1516 recommends establishing a "Management Triangle" concept into radiation safety programs, a triangle in which three primarily responsible entities are formally incorporated such that "no element is considered more important than the other." To this end, we recommend that the CEO (e.g., University President) appoint a suitable representative from executive management to serve on the RSC. The appointee should have sufficient lines of authority and communication to effectively administer the program as well as having the capability to commit resources that may be identified by the RSC as being necessary to maintain an effective radiation safety program. Please provide documentation of this CEO/Presidential appointment and include an official organizational chart to show this executive's relative rank within the institution.
3. Provide an organizational chart showing the reporting level for the RSO and the RSC. DSHS is aware that there are formal lines of communication and authority that must be respected within most large organizations. Recognizing this situation and realizing that the RSO could be prohibited from interacting directly with executive management, DSHS would recommend that the organizational lines have the RSO at a level where restraints to communication and authority will not hamper that role. Your organizational chart should demonstrate that the RSO, like the RSC, has a direct reporting path to the CEO/President or his/her designee.
4. Specify a minimum frequency for formal meetings (attached are sample RSC Agenda and sample RSC Minutes) and define what will constitute a quorum, which is typically 50% of the membership, including the Chairperson, the RSO and the representative from executive management. Provide, as an appendix, a standard RSC agenda and sample minutes for deliberations.
5. Submit a description of the RSC program for review of sub-licenses. This should include a review of the authorized users' safety and compliance history, types and quantities of radioactive material authorized versus what is actually possessed,

adequacy of facilities and equipment for the workload, and training and supervision of radiation workers in the users' laboratory. This stated frequency should be no less than the issuance period granted upon the sub-license permit. Note that this type of review could be delegated to a sub-committee for summation reports presented to and discussion thereof by the full RSC.

6. Indicate if there are any occasions when temporary approval is sought by a new or visiting authorized user. If so, describe how is this handled before the RSC can have a chance to meet. Describe if the RSC Chairperson and/or RSO has limited review authority to permit interim use prior to a regular meeting of the RSC and what documentation will be maintained of those reviews. Provide a description of this process if you wish authorization for this privilege.
7. Explain how the RSC will determine if a user applicant is qualified to use radioactive material for laboratory research and/or veterinary applications within the institution (provide minimum qualifying criteria to be used). Indicate if communication will be effected between your institution and other institutions where user applicants obtained prior experience to determine if the user applicant was a user in good standing, documenting recentness in training and experience (DSHS recommends requesting a copy of the prior institution's license or sub-license upon which the user applicant was designated as an authorized user). Also commit to complying with 25 TAC §289.256(ff)(1) for human-use user qualifications.
8. Provide a description of the Radiation Safety Office staff and the duties/responsibilities of the staff positions. This should include an assessment regarding staffing levels and qualifications of the support staff as well as how much of their time may be devoted to non-radiation safety duties. The assessment should be sufficient to demonstrate that the technical staff are adequate to implement, support and oversee the radiation safety program. If current staffing is not considered adequate, include a projected timetable when full staffing will be achieved or one will be imposed by DSHS. Do not overlook radioactive waste collection, processing, surveying and records keeping.
9. Indicate who can review, grant and sign minor amendments to sub-license permits (e.g., adding or deleting assistants, adding or terminating laboratories and/or making small changes to possession quantities for approved isotopes). If any minor amendment should be approved and permitted without RSC approval, confirm that any such amendments will be summarized and presented at the next RSC meeting. Verify that new applications (human-use or non-human-use) and new users must be approved by the RSC and signed by the RSC Chairperson prior to issuing the sub-license permit.
10. Indicate that substantive changes in radiation safety program policy or staffing will be submitted to DSHS under the signatures of all three of the following officials: the RSC Chairperson, the RSO and the representative from executive management. This is so all responsible parties of the Management Triangle formally acknowledge sharing responsibility in licensed commitments. Use of devices issued an Investigational Device Exemption must be specifically authorized by DSHS.

11. If you desire authorization to use a broad range of radiopharmaceuticals for diagnostic and therapeutic human-use research which are outside of specific United States Food and Drug Administration's (FDA) approval through traditional IND, NDA and PLA authorizations, provide FDA documentation recognizing proper constitution and associated privileges of your Institutional Review Board (IRB) and/or Radioactive Drug Research Committee (RDRC). Confirm that your IRB will review and approve all human-use research projects and the FDA-recognized, properly constituted RDRC will review and approve human-use research isotopes that do not currently possess prior FDA approval and/or biodistribution studies performed outside of an approved on-going IND or Investigative Biologic Application pending before the FDA.

12. Describe how you will limit key access for hot labs and storage closets (e.g., keys only for permitted researchers and security), so that the opportunity for accidental or deliberate exposures to the either the public or occupational workers is minimized. Describe control of access to areas in which radioactive materials are used/stored and inventory audits.

Appendix F (continued)

SAMPLE AGENDA FOR A RADIATION SAFETY COMMITTEE MEETING

1. OLD BUSINESS

- 1.1 Verification that a quorum is established.
- 1.2 Approval of previous RSC minutes.
- 1.3 Update on status of action items from last meeting

2. NEW BUSINESS

2.1 Regulatory Issues:

- Review of inspection results and status of corrective actions
- Reports of follow-up enforcement actions
- Discussion of license amendment or renewal
- Proposed or final rules

2.2 Incident and Event Reports:

- Misadministrations and recordable events
- Other incidents or reportable events

2.3 Review of Doses and ALARA Program

2.4 Review of Applications for New Uses, Visiting Authorized Users and Use Facilities

2.5 Review of Radiation Safety Program:

- Patient therapy procedures requiring confinement
- Radiation safety training schedule
- Results of required periodic radiation surveys
- Radioactive material waste storage program
- Results of periodic quality control tests on measurement, detection and imaging equipment, and spot-checks and calibration tests on the cobalt-60 teletherapy or linear accelerator units
- Resource needs

2.6 Review of Audits and Consultant Reports

Appendix F (continued)

SAMPLE MINUTES OF A RADIATION SAFETY COMMITTEE MEETING

Meeting Date:

RSC Members Present

Chair: (name)
RSO: (name)
Management: (name)
Radiation Therapy: (name)
Teletherapy: (name)
Nuclear Medicine: (name)
Nursing: (name)
Research: (name)
Laboratory: (name)

1. OLD BUSINESS:

1.1 Quorum verified.

1.2 Previous minutes approved

1.3 The recent problem of timely return of personnel monitoring devices to the "film-badge" company was discussed. To follow-up, the radiation safety staff will place a collection container in each use area and will send a memo to each department, to be signed by the RSC Chairperson, which stresses the importance of timely return.

2. NEW BUSINESS:

2.1 Regulatory Issues:

It has been approximately 2 years since the last inspection was conducted by the regulatory agency; therefore, the facility is due for an unannounced inspection.

The license is due for renewal in approximately 5 months and the renewal package should be submitted by 30 days prior to the expiration date.

2.2 Incident and Event Reports:

An event almost qualifying as a recordable event was described. A person operating under the supervision of an authorized user did not verify a patient's identity before preparing a patient for a scan. The technologist caught the error and the correct patient was found. The cause was determined to be that the training program for persons working under the supervision of authorized users, e.g., residents, was too narrowly focused. The committee agreed that additional training was necessary.

2.3 Doses and ALARA Program:

Radiation exposure report from RSO: No monitored workers exceeded the in-house investigational level. The highest whole-body exposure was 60 mrem (nuclear pharmacist) and the highest extremity exposure was 150 mrem (brachytherapy).

The committee discussed the need to identify a "long-term" brachytherapy source storage area to store sealed sources no longer used for therapy procedures (radium-226). This will reduce radiation exposure levels to therapy personnel while working in the current small, overcrowded source storage room. Mr. Anderson (executive management representative) will work with facilities management to identify proposed storage areas for approval by the RSC at the next regularly scheduled meeting.

2.4 Applications for New Uses, Visiting Authorized Users, and Use Facilities

The committee discussed the qualifications of two individuals who want to be authorized users. One user (Dr. Smith) was unanimously approved for diagnostic use on the basis of a review of documented training and experience criteria. The committee voted (5-2) to require the second physician (Dr. Jones) to obtain more experience with high-dose-rate after-loaders before being approved.

2.5 Radiation Safety Program:

The committee followed up on the discussion from the last meeting regarding the possibility of using the teletherapy machine to irradiate blood. The RSO looked into the regulatory requirements and worked with the teletherapy physicist to calculate doses based on the proposed new use factors (report attached). The committee voted (6-1) to approve the teletherapy machine to irradiate blood.

One cesium-137 brachytherapy implant procedure was performed on the 5th floor since the last RSC meeting. The procedure went smoothly except that, during day two, the RSO discovered that the evening shift nurse had not received the necessary radiation safety training regarding care of the therapy patient. At that time, the RSO provided a 30-minute training session including the use of dummy sources to simulate the sealed sources in use. After discussions with the nursing supervisor, it was apparent that the newly hired nurse had not attended the radiation safety training session as scheduled and will attend the next one. The RSC chairperson instructed the RSO to determine the root cause of the lack of training and report those findings at the next meeting.

The five-year calibration of the cobalt-60 teletherapy unit was completed last week by the service contractor. A full report is expected within the next 30 days and will be discussed with the RSC at the next regularly scheduled meeting. Findings requiring more immediate attention will be coordinated with the RSC chairperson.

2.6 Audits and Consultant Reports:

Nothing to report.

Appendix G

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Appendix H

GENERAL GUIDELINES FOR SAFE USE OF RADIOACTIVE MATERIAL IN A NUCLEAR MEDICINE LABORATORY

The applicant is encouraged to develop his own set of rules that are specific to his needs and reflect his actual laboratory situation. Use of radioactive material that may become airborne (e.g., aerosols, ^{133}Xe , ^{125}I , ^{131}I) will require added rules, as will preparation and use of therapeutic doses and sealed sources. Rules should be written in the form of directions to be followed.

1. Wear lab coats at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Monitor hands/clothing for contamination after procedures or before leaving the area.
4. Always use syringe shields for preparation and administration of patient doses, except in circumstances such as pediatric cases when the patient's well-being would be risked.
5. Do not eat, drink, smoke, or apply cosmetics in areas where radioactive material is stored or used. Do not store food, drink, or personal effects with radioactive material.
6. Assay patient doses in the dose calibrator; do not use doses that differ from the prescribed dose by more than 10 percent. For all doses, check the patient's name, nuclide, chemical form, and activity against physician's written order.
7. Wear personnel monitoring devices at all times; devices should be worn at chest or waist level. Store devices with the control badge in a designated low background area.
8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.
9. Dispose of radioactive waste only in 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 the end of the day. Decontaminate if necessary.
12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.
13. Always transport radioactive material in shielded containers.
14. Work over easily cleaned surfaces when handling open radioactive material. Work only in designated areas. Process volatile radioactive materials under fume hoods.

Appendix I

SAMPLE DECONTAMINATION PROCEDURES

Facilities using radiopharmaceuticals should maintain a decontamination (DECON) kit to consolidate emergency DECON supplies that might be needed. Supplies for this kit should include necessary items for spill containment, cleaning, disposal packaging, labeling, universal precautions, and area posting needs. For those occasions that the handler appears to be included in the solution spill, having this kit well labeled and accessible for an assistant to return will be paramount.

SAMPLE PROCEDURES (excluding volatile airborne and noble gasses)

Minor Surface Contamination (< a few mCi's of short-lived γ emitters or < 150 μ Ci of a β):

- o when contamination appears to involve individuals or multiple locations, notify RSO of the events pending;
- o if unsure of contamination levels and extent, survey first and verify if removable;
- o should a single laboratory work surface become contaminated, simply remove the work surface's temporary protective covering to waste, rolling or folding the contaminated surface to the middle, and replace; if not,
- o don protective garments (double rubber gloves, lab jacket, and shoe coverings);
- o return with DECON kit (supplies) and survey instrument;
- o using the least amount of water possible (e.g., damp wash-cloths), scrub surfaces;
- o cleaning efforts should work from the point of lowest to highest contamination;
- o placing all contaminated waste generated into plastic labeled bags;
- o avoiding further spread, and avoid tossing contaminated articles;
- o initiate detailed surveys (removable and fixed) of the involved surfaces and responders to determine if efforts have been successful or must continue;
- o abandon efforts after a couple of attempts or when levels can't be further reduced;
- o carefully survey staff and their protective clothing, removing all waste to storage;
- o remedial steps may include taping an impermeable cover over any remaining removable contamination, and add shielding to reduce fixed high exposure rates.*

Major Surface Contamination (> 150 μ Ci of a β emitter; > 3 mCi of a γ emitter):

- o instruct staff nearby not to enter the area, and to phone the RSO for assistance;
- o have someone uncontaminated return with the DECON KIT and survey instrument;
- o with the RSO's supervision, remove and decontaminate involved persons, using universal precautions, bagging contamination and changing outer gloves often;
- o utilize two persons when possible, one "clean" assistant documenting survey findings and providing supplies, and another performing tasks outlined previously under minor surface contamination; and
- o aggressive surface decontamination may be required and equipment may need to be isolated, secured and posted for decayed-in-storage.*

Emergency Contamination (ruptured sealed therapy sources; > 100 mCi of γ emitters; > 3 mCi of a β emitter):

- o shield the source, but only if able to do so without risks for further contamination or significant radiation exposure;
- o remove staff and patients at risk, if individuals are believed to be contaminated, contain them in a nearby safe location;
- o secure all points of access and immediately contact the RSO (if inaccessible, contact his alternate) to take "charge" of all further DECON tasks, environmental and/or facility ventilation considerations;
- o if fire, explosion and/or a natural disaster creates a potential hazard of this nature, remove all individuals from harms way, deal with individual contamination, and warn responders of the associated radiological hazards ahead of them;
- o in all such events, the RSO must assume responsibility, and initiate any required contacts with the DSHS staff via their emergency telephone number. *

Personnel Contamination:

- o surveys indicating contamination on any point other than the hands will usually be contained on the clothing, remove and survey to determine involvement;
- o contaminated clothing will be placed in a labeled plastic bag for storage until such time as physical decay assures background levels have been obtained;
- o to DECON skin, gently wash with damp clothes soaked in tepid tap water and a mild detergent, and/or irrigate open wounds or eyes that appear contaminated while avoiding splattering or rinsing contaminated wash water onto other bodily areas;
- o particularly, notice if contamination exist on the face or neck area when considering if internal contamination may have resulted, and when suspected, nasal wipes and urine samples may yield some valuable information;
- o skin contamination is usually focal and would not indicating whole-body showers;
- o avoid using hot water and irritating brushes, which tend to increase absorption (internal deposition) through increase vascularity;
- o often skin contamination cannot be removed, these sites may be wrapped with gauze and then with plastic taped over, to promote "sweating" the isotope out;
- o finally, should a health condition co-exist, that necessitates prompt medical treatment before the individual was DECON'ed, do not delay this treatment, but provide guidance and assistance to contain the further spread of any contamination from the individual in whatever setting is required; and
- o with the most serious contamination events, advice may be sought from local health physicists, Radiological Emergency Assistance Center/Training Site (REAC/TS) at (615) 576-3131, or the State's Radiological Emergency Assistance Number (512) 458-7460.*

*FOR ALL THE ABOVE EVENTS:

- o document the entire process and associated survey results;
- o consider risks and potential for internal contamination of all involved; and
- o determine appropriate notifications and reporting based on 25 TAC §§289.202(xx) and (yy).

Appendix J

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

I. Introduction

When radioactive material is received, handled, and/or stored within a medical facility, surveys are: 1) required by the regulations, 2) necessary to release areas for unrestricted uses, and/or 3) needed to assure that both the public and radiation worker exposures are maintained consistent with the "AS LOW AS REASONABLY ACHIEVABLE" (ALARA) principle. Radiation area surveys are performed to assess ambient exposure levels in occupiable areas about radiation sources (those stored, being handled, or in patients), to detect or localize contamination and/or find mislaid (or lost) sources. Contamination surveys are performed by wiping a surface over specific dimensions and counting the wipe, to determine if removable contamination exists. This is done to prevent: 1) internal uptake of radioactive material, 2) cross-contamination, 3) deposition of radioactive material in excess of 25 TAC §289.202(ggg)(6), and/or 4) rendering equipment unusable. Surveys of waste prior to transfer or disposal must comply with the requirements of 25 TAC §§289.202(ff), (gg), and (jj), and package receipt surveys must be compliant with 25 TAC §289.202(ee)(4)(A)(ii).

II. Frequency of Surveys

- A. Low Level Laboratories - Persons working within restricted areas using no more than microcurie levels of radioactive solutions, should perform limited area and personnel surveys at the conclusion of each day of use. No less than once a month, both area and contamination surveys should be performed thoroughly and documented.
- B. Medium Level Laboratories - Persons working within restricted and secured areas (imaging or dedicated stress rooms) where millicurie levels are routinely handled, should perform limited area surveys each day of use. Contamination should be checked for in areas like waste baskets, drawers, door or control knobs, keypads, and injection trays. These same areas should have detailed area and removable contamination surveys performed no less once than each week.
- C. High Level Laboratories - Persons working within restricted and secured areas (e.g., hot labs) where Mo/Tc generators are used or reagent kits are prepared from bulk technetium eluate, should perform and document area and removable contamination surveys each day of use.
- D. Labeled packages are required to have receipt and shipping surveys performed on them to comply with the specifications found in 25 TAC §289.202(ee), 25 TAC §289.252(ff), and to meet U. S. Department of Transportation (DOT) regulations found in the Code of Federal Register 49, Parts 171 - 177.

- E. Rooms and Equipment that are occasionally used (remote stress labs or patient rooms) and then released for unrestricted use, must have both contamination and area surveys performed on them to demonstrate compliance with 25 TAC §289.202(ccc) and 25 TAC §289.202(ggg)(6). Following a patient administration within a hospital room, only a survey to search for removable contamination would be necessary unless evidence suggests that wide spread contamination may be within that room. Note that if further remedial actions were necessary, it would necessitate removing the patient prior to area surveys due to the high background levels emanating from the patient.
- F. Storage areas where inventory is changing often, should be surveyed for ambient radiation exposure rates weekly. If inventory rarely changes, surveys of ambient fields should be documented no less than monthly.
- G. Staff surveys (otherwise known as personnel frisking) must be performed on individuals' hands and protective clothing after handling non-sealed forms of radioactive material and before leaving a restricted area. Any positive contamination findings should be reported (to the RSO) and additional area surveys should be performed promptly. It is not necessary to document these surveys unless evidence of contamination has been found.

III. Survey Methods

- A. Ambient field surveys of radiation exposure rates in areas of use, areas of storage or areas adjacent thereto, should be performed with a suitably calibrated instrument and documentation should reflect the highest radiation exposure rate detected in an occupiable location.
 - B. Area surveys should be performed in use areas for (1) contamination or (2) misplaced sources with the most sensitive portable detector available that is appropriate for the radioactive material used in that location. The detector should be moved slowly and within one inch of surfaces (staff, facilities, equipment), using care not to touch any potentially contaminated objects. Attention should also be given to radioactive markers, syringes, or materials which might have been discarded or placed in unauthorized containers or areas.
 - C. Removable contamination surveys involving multiple wipe samples should be evaluated in a low background area with the most sensitive detection system available that can be calibrated to detect and quantify low levels of routinely handled radionuclides. Any surface that is routinely touched while not wearing gloves is a potential location for cross-contamination which can lead to internal deposition.
- IV. Acceptable Levels - Survey action levels must be established and must be at least as restrictive as those which are required by 25 TAC §289 when addressed. Action levels must be address for the items that follow:
- A. Ambient radiation levels in restricted areas must be maintained so as to comply with

25 TAC §289.202(f) and reflect ALARA to trigger an investigation. In public areas, the license must comply with 25 TAC §§289.202(n), (ccc) and (ggg)(6). Note that continuous radiation fields as low as 0.06 mR/hr could cause a non-radiation worker to receive an annual (2000 working hours) exposure of 120 mrem, which exceeds regulatory limits. Methods of surveys to determine exposure to the public in adjacent non-restricted areas must be determined to show compliance with 25 TAC §289.202(n).

B. Contamination:

1. Fixed contamination surveys should be performed using the most sensitive portable detector available. Every location that is frequently touched by radiation workers who might unknowingly cross-contaminate equipment and facilities should be checked. Of particular concern are locations where radiopharmaceutical injection paraphernalia or reference sources might be inadvertently left unattended or accidentally discarded. Following brachytherapy implants, surveys should be performed where seeds might have been accidentally dropped, sloughed from the body, or collected in drainage tubes or suction canisters. 25 TAC §289.202(ggg)(6) establishes a 5000 dpm/100 cm² average for fixed contamination-level for staff or equipment that can be permitted outside of a restricted area.
2. Removable contamination surveys should be performed using the most sensitive counting system available. Wipe samples should be taken of a known surface area (100 cm²) when feasible. This should be coded match to coded locations on a room diagram, and then taken to be counted in a low background setting. Counting displayed on the counting system (e.g., counts per minute) should be mathematically converted to units of activity (dpm, microcuries, etc) to determine is an action level has been exceeded. CPM can be converted to DPM by either (1) dividing by the unit's efficiency or (2) multiplying by the inverse of the counting system's efficiency. Established action levels for restricted facilities should be consistent with ALARA. However, when outside a restricted area, 25 TAC §289.202(ggg)(6) sets the action levels at 1000 dpm/100 cm² for beta/gamma contamination and 200 dpm/100 cm² for ¹³¹I contamination.

C. Waste disposal surveys for radioactive material that is decayed-in-storage (DIS), must be surveyed so that it can be declared as indistinguishable from background or non-radioactive prior to releasing this waste into other waste streams.

D. Package surface contamination surveys (for removable contamination) shall not exceed 6,600 dpm/300 cm², or if delivered via an exclusive-use shipment (carrier delivering exclusively radioactive material by a single, radiological trained consignor, performing all loading tasks per written instructions) shall not exceed 66,000 dpm/300 cm².

E. Patient release survey levels can be found in 25 TAC §289.256(w). Patients undergoing permanent implant therapy can be released room their medical

treatment facility when the exposure rate from the patient's implant has fallen to 6 mR/hr at one meter. Patients undergoing a radiopharmaceutical therapy can be released when the activity within the patient has fallen to less than 30 mCi or the exposure rate from the patient has fallen to 5 mR/hr at one meter. Care should be taken to use a suitable and calibrated instrument particularly when dealing with low energy gamma or beta emitting radionuclides.

- V. Instrumentation - Minimum detectability and sensitivity should be considered in selecting survey and counting instruments. One can commit to specific instrumentation models and authorized replacements that are either equivalent to the specified instrument or possess greater detection/measurement capabilities than the specified instrument. For most G.M. instruments, instrument specifications should address ranges, scales and the instrument's associated probes. Specifications for counting scalers that are independent of the committed detection device need not be given, as they can be interchanged without significant changes in sensitivity.
- A. Waste disposal measurements used to declare the waste as non-radioactive must be performed with an instrument highly sensitive to the types of radiations and the energies of the radiations. A scintillator detector (e.g., probe or unshielded gamma camera) for gamma emitters and a pancake probe for beta emitters possess the sensitivities of choice.
- B. Removable contamination counting equipment must be adequate to meet the action levels to which the licensee is committing. Note that instrument calibration, and in this case, unit efficiency, are required at intervals not to exceed 12 months by 25 TAC §289.202(p)(2). As this type of survey is meant to assure that only safe amounts of contamination may be ingested or absorbed, a detector that is capable of detecting/measuring picocuries or nanocuries is required. Typically, a shielded, fixed-counting geometry, well-type scintillation detector is used for this low-level of detection. Some portable instruments now have built in scalers that, if equipped with a scintillation detector, can achieve the required sensitivity when wipes are evaluated in a low background area. Instrumentation will often read in units of CPM which must be converted to units of activity (e.g., microcuries or dpm) for positive findings.
- C. Contamination of staff, equipment and facilities should be performed daily, with the most sensitive portable detector available. Recommendations for this type of surveys would include either a scintillation probe (low-energy, thin-crystal or one-by-one crystal) or a G.M. pancake probe.

Appendix K

Radiation Safety Division Audit/Survey Program

25 TAC §289.202(e)(3) requires that the licensee review the radiation protection program content and implementation at least annually. DSHS recommends that an audit and appraisal program be part of the management review. Please provide the following information regarding the management review program:

- a. Confirm that the Radiation Safety Committee performs an audit of the overall radiation safety program, the Radiation Safety Officer performance and the radiation safety staff performance at least annually, and that the results of the audit will be reported to senior management.
- b. Provide an example of the audit worksheet which you and/or your radiation safety staff will use during your audits of sub-licensee use areas. DSHS recommends that the audits include, at least, reviews of users' inventory and survey records, evaluation of users' training through observation and discussion, and performance of work area surveys.
- c. Please provide an example of the survey worksheet which you and/or your radiation safety staff will use during your surveys at all use-sites, both on-campus and off-campus. Confirm that surveys will include both unrestricted and restricted areas. The survey frequency may be based on hazard/risk analysis (see next page) and should be performed at least quarterly.

It is suggested that licensees adopt a program similar to the one that follows:

	<u>Audits</u>	<u>Surveys</u>
Labs in which most radiotoxic isotopes are used in the largest quantities using the most hazardous handling procedures.	Monthly	Monthly or Quarterly
Labs in which moderately radiotoxic isotopes are used in moderately large quantities using moderately hazardous handling procedures.	Quarterly	Quarterly or Semi-annually
Labs in which minimally radiotoxic isotopes are used in minimal quantities using minimally hazardous handling procedures.	Semi-annually	Semi-annually

RADIONUCLIDES CLASSIFIED ACCORDING TO RELATIVE RADIOTOXICITY

(Exerpted from IAEA Safety Standard, Safety Series No. 1, Handling of Radionuclides, 1973 Edition@)

Group 1: Very High Radiotoxicity

²¹⁰Pb ²²⁶Ra ²²⁷Th ²³¹Pa ²³³U ²³⁸Pu ²⁴³Am ²⁴⁴Cm ²⁴⁹Cf ...

Group 2: High Toxicity

²²Na ⁵⁶Co ⁹⁵Zr ¹²⁵Sb ¹³¹I ¹⁴⁴Ce ¹⁸¹Hf ²⁰⁷Bi ²²⁸Ac ³⁶Cl
⁶⁰Co ¹²⁵I ¹⁹²Ir ...

Group 3: Moderate Toxicity

⁷Be ⁴⁸Sc ⁶⁵Zn ⁹¹Sr ¹⁰³Ru ¹²⁵Te ¹⁴⁰La ¹⁵³Gd ¹⁸⁷W ¹⁹⁸Au
¹⁴C ⁴⁸V ^{69m}Zn ⁹⁰Y ³²P ³⁵S ⁵¹Cr ²⁴Na ...

Group 4: Low Toxicity

³H ^{58m}Co ⁷¹Ge ⁸⁷Rb ⁹⁷Nb ^{103m}Rh ^{131m}Xe ¹²⁵Cs ¹⁹¹Os ²³²Th
¹⁵O ⁸⁵Kr ^{99m}Tc ...

LIMITATIONS ON ACTIVITIES IN VARIOUS TYPES OF WORKING PLACES OR LABS

Radiotoxicity of radionuclides	Minimum Quantity μ Ci	Type of Working Place or Laboratory Required		
		Type C	Type B	Type A
1. Very High	0.1	< 10 μ Ci	10 μ Ci-10mCi	10mCi or more
2. High	1.0	<100 μ Ci	100 μ Ci-100mCi	100mCi or more
3. Moderate	10.0	< 1mCi	1mCi-1Ci	1Ci or more
4. Low	100.0	< 10mCi	10mCi-10Ci	10Ci or more

NOTE: Laboratory types correspond to the laboratory classification of IAEA Safety Standard, Safety Series No. 1. Type C is a good-quality chemical laboratory. Type B is a specially designed radioisotope laboratory. Type A is a specially designed laboratory for handling large activities of highly radioactive material. In the case of a conventional modern chemical laboratory with adequate ventilation and nonporous work surfaces, it may be possible to increase the upper limits of activity for Type C laboratories toward the limits for Type B for toxicity groups 3 and 4.

Appendix L

Concept and Elements of a Broad Scope Training Program

1. Concept

The Radiation Safety Committee (RSC) (in consultation with the Radiation Safety Officer (RSO)) is responsible for developing and instituting the radiation safety program. The program for training should provide a commitment to initial training, retraining and continuing education. The type and amount of instruction may be based on past training and experience, and it should be commensurate with potential radiological health protection problems in the areas in which employees are expected to work. Performance-based training and continuing education, based on site-specific (laboratory classification) criteria, are important aspects of the training program.

2. Elements

All radiation workers must receive instruction in accordance with 25 TAC §289.203(c) prior to beginning work with licensed materials. This instruction may be in the form of an orientation session led by the RSO or a qualified staff member under his or her direction. This orientation is to include the following subjects:

- Applicable regulations and license conditions,
- Areas where radioactive material is used and stored,
- Potential hazards associated with radioactive material,
- Appropriate radiation safety procedures,
- Special in-house rules,
- Individual's obligation to report unsafe conditions to the RSO or applicable authorities,
- Appropriate response to emergencies or unsafe conditions,
- Worker's right to be informed of occupational radiation exposure and bioassay results, and
- Locations of pertinent regulations, licenses, and other material required by regulations.

3. Nonmedical Users Authorized by RSC

In addition to the training above, the training and experience of users authorized by the RSC to independently use or supervise the use of radioactive material should be:

- (1) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and
- (2) at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units or radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

The above citation is generally for users authorized under a license for microcurie to low millicurie quantities. Any program of instruction should be correlated to the

licensee's specific laboratory classification scheme. Additional training would be required for laboratories using larger quantities of radioactive material. Training and experience for authorized physician users must meet the criteria outlined in 25 TAC §289.256(ff)(1) (as clarified in Appendix O of this Guide).

4. Radiation Workers (Under the Supervision of a User Approved by the RSC)

In addition to the 25 TAC §289.203(c) instruction, each radiation worker supervised by a user must receive specific written instruction from the user and the Radiation Safety Office staff. The user is to work directly with new staff members until the user is confident in the worker's abilities and understanding of DSHS regulations, license conditions and in-house safety instructions. The user is responsible for documenting the staff member's completion or his or her instruction and certification of the worker's use of radioactive material with limited supervision, i.e., not in the presence of the user.

5. Performance-based Training

In addition to basic classroom and laboratory instruction, it is recommended that there be an emphasis on performance-based (on-the-job) training, i.e., hands-on training specific to the individual's duties, to ensure safe handling of radioactive material in accordance with the ALARA philosophy. The Radiation Safety Office should instruct the users, at least annually, regarding the authorized users' specific responsibilities for providing training to the staff. An assessment of the comprehension and abilities of the staff through random interviews with the users or the radiation workers should be included in the Radiation Safety Audit program.

6. Other Radiation Workers and Ancillary Staff

The RSO is responsible for developing a comprehensive radiation training program such that all other users, e.g., technical radiation safety staff, nurses, waste handlers, animal caretakers, and ancillary staff (janitorial, housekeeping, security, etc.) understand the radiation hazards associated with their work and are able to take appropriate actions to prevent unnecessary exposure. Special programs must be developed to instruct each different group with appropriate information in accordance with 25 TAC §289.203. This information may be conveniently incorporated into an institution's general safety orientation training program. For example, waste handlers need to be trained in the radiological aspects of their duties as well as the chemical and biological considerations.

7. Supplementary Continuing Education

To supplement education and to update training, the DSHS staff strongly recommends that the Radiation Safety Office issue a regular (at least quarterly) radiation safety newsletter or memo to users and supervisors. The newsletter or memo should contain information important to the operation of the Radiation Safety Program and the safe handling of radioactive material. This information should be shared with the radiation workers and filed by the user or supervisor along with the material authorizing the use

of licensed material. Thus, it is the responsibility of the user to provide evidence that each worker has received this and other pertinent information. The Radiation Safety Office should be responsible for auditing this program.

8. Emergency Procedures and Specialized Training

Emergency procedures, specialized training and retraining should be provided to all applicable workers. All individuals who work with radioactive material and who frequent radioactive use and storage areas should understand emergency procedures applicable to their duties. Reliance on introductory orientation and review of tapes pertaining to accidents involving radioactive material is not normally sufficient to ensure appropriate, timely and adequate response to accident situations. Instruction in emergency procedures is considered an excellent performance-based training opportunity that could be incorporated into a retraining program.

9. Records of Training

Training records should include:

- a list of topics,
- the approximate time spent on each topic,
- the names of instructors and students,
- the dates of the training,
- a written assessment or test for each student that documents satisfactory completion of the training,
- the location of the training and the materials involved in the training.

Details of in-house training programs should be provided, including the following information:

- the names, training and experience of the individuals providing the formal training, and
- an outline of the program for providing the necessary instruction. Confirm that, in addition to providing relevant instruction before assuming duties, appropriate training will be provided whenever there is a significant change in duties, instructions, procedures, or regulations, and confirm that continuing, site-specific training will be provided (state the frequency and the methods to be used).

Appendix M

Nuclear Medicine Technologist Training

Technologists - All personnel who will be authorized to handle radioactive material must be qualified through training and experience to use the material in question for the purpose requested, and in such a manner as to minimize danger to public health and safety or the environment. Multi-modality operations authorized under a single license may require several descriptions, each unique to the delegated specialty tasks (therapy, diagnostic imaging, *in vitro*).

[Note that the word technologist, as someone delegated to by a medical doctor, will be used synonymously with any delegation within the following career fields: physicist, dosimetrist, nurse, or physician's assistant. Note that in addition to meeting commitments to the Agency for training criteria, final technologist approval should always rest with the physician who is obligated to supervise and is ultimately responsible for the performance of all clinical tasks he/she has delegated.]

Minimum Training (Submit documentation of the following):

Individuals must be certified as a general certificate Medical Radiologic Technologist (MRT) under Chapter 1096, Acts of the 70th Legislature, Regular Session, 1987 (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 Programs in Nuclear Medicine Technology (JRCNMT) program or be a student who is supervised and operating within such a program. (Contact JRCNMT at 801-364-4310 to verify approved programs); or
5. demonstrate grand-fathering based on full-time nuclear medicine experience (e.g., have performed full-time nuclear medicine for a minimum of two years during the past five year period. This experience must be certified in writing by an authorized physician user; or
6. have completed training in accordance with the outline in DSHS Radiation Safety Licensing Branch's Regulatory Guide 3.1's Appendix H, "Sample of a Minimum Radiation Safety Training Outline for Radiation Handlers."

[Note: If hiring an individual with this type documentation, the prior training could be considered acceptable without need for additional training, if the scope of practice was equivalent to the original training site.]

SAMPLE OF A MINIMUM RADIATION SAFETY OUTLINE FOR RADIATION HANDLERS (TECHNOLOGISTS) IN THE NUCLEAR MEDICINE DEPARTMENT

Outline should include the following:

- (1) Instructor(s) qualifications;
- (2) Course Syllabus;
- (3) Lesson plan (e.g. how the material is provided to the student);
- (4) Minimum supervisory requirements of trainees at each phase of on-the-job-training (OJT);
- (5) Reference 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 committed to, but not submitted. If didactic training is sub-contracted and not structured to your program's specifications, supplemental training and independent creation of quizzes and a final examination will likely be necessary.

Classroom Training

Format may include lecture and audio/videos. Audio/video training should be less than 50% of the total hours.

<u>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, scalers, count rate meters and computers)	2
Mathematics pertaining to use/measurement of radioactivity (statistics logarithms, exponentials, decay, 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 (TLD's, film badges, bioassays)	2
Radiopharmaceuticals (preparation, quality control testing, and biodistribution)	4
Radiation worker rights and responsibilities (orientation with regulatory and record keeping requirements in the following: 25 TAC §289, U. S. DOT rules, Code of Federal Regulations Parts 171 - 178, documented Radiation Protection Program, DSHS approved Operating, Safety, and Emergency Procedures Manual, Clinical Procedures Manual, **Standing Delegation Orders**)	4
 <u>Laboratory Training</u>	
Instrumentation testing (cameras, dose calibrators, scalers and instruments)	4
Surveying packages and department, performing monitoring and decon	4
 <u>Total Classroom and Laboratory Training</u>	 40 HRS

**Typical names for documents approved by authorized physician users delineating what radiopharmaceutical, the activity, imaging protocol, exam sequence, contra-indications, and under what conditions radiation shall be delivered to a patient.

On-The-Job-Training (OJT)

OJT should consist of a minimum of three months training and should be a full-time commitment, averaging a minimum of four exams per day. The OT period may extend up to six months or longer depending on the scope of the program and the abilities of the trainee. During the OJT, the trainer should 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 should be followed unless extended periods are deemed necessary by the trainer:

1. Observation of procedures - 2 weeks.
2. Performance of procedures with trainer in room - 2 weeks.
3. Performance of procedures with trainer accessible within the building - 2 months.

Trainer Credentials

Didactic Trainer

The following individuals or combination of individuals may be didactic trainers:

1. Authorized physician user.
2. Board certified nuclear pharmacist.
3. Certified Health Physicist (CHP).
4. Licensed medical physicist with specialty in health physics or nuclear medicine.
5. Nuclear medicine technologist, CNMT or ARRT(N), with 5 years experience.

On-The-Job-Trainer

The following individuals or combination of individuals may be on-the-job-trainers:

1. Authorized physician user.
2. Licensed medical physicist with specialty in medical health physics or nuclear medicine.
3. Nuclear medicine technologist, CNMT or ARRT(N), with 1 year experience.
4. RSO.
5. Board certified nuclear pharmacist could supervise some aspects of training as appropriate.

OJT PERIOD

The training period should be a full-time commitment if the work-load supports such (e.g., averaging at least 4 exams/day). In addition to the number of 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, 3 months (equivalent to 480 hours) of laboratory practices would be expected. No licensed program averaging less than 10 exams a week should consider an in-house training program. The OJT period may run as long as 6 or even 12 months depending of the scope of program and/or infrequency of exams due to low referral numbers.

TRAINEE EVALUATION

Multiple quizzes (one with each didactic section), a final exam (minimum 50 questions), 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.

RECORD KEEPING REQUIREMENTS

The following records shall be maintained:

1. Classroom attendance sheets identifying trainee, dates, time, and signature of trainer.
2. Credentials of didactic and on-the job trainers.
3. All graded quizzes and final exam.
4. Copy of certificate and/or document indicating successful completion of training with original going to the trainee.

Appendix N

Decommissioning Funding Plans

25 TAC §289.252(gg) describes who must submit a decommissioning funding plan (DFP), what is required in the plan, methods of providing the funding, and records required for decommissioning which will document the funding and/or decommissioning costs.

Licensees who must submit a DFP will fall into one of four categories depending on possession limits for radionuclides listed on their license. Only licensees whose licenses authorize radionuclides with a half-life greater than 120 days and activities greater than quantities specified in 25 TAC §289.252(ii)(2), adjusted by the appropriate multipliers in 25 TAC §289.252(gg), will need to file a DFP. The table below lists the isotopes with half-lives greater than 120 days that are found in 25 TAC §289.252(ii)(2), with activities adjusted by the multipliers in 25 TAC §289.252(gg).

Three of the categories [described in 25 TAC §289.252(gg)(3)] have a specific amount of funding set by rule. The fourth category represents the highest decommissioning costs and funding is determined specifically by the estimated cost of operations necessary in decontaminating the facility for release to unrestricted use and disposing of waste.

If the possession limit of unsealed radioactive material on the license is greater than 10^5 times the value in 25 TAC §289.252(ii)(2) (Column 3 of Table I) for any of the radionuclides with a half-life greater than 120 days, the licensee will be required to complete a DFP that contains a cost estimate for the decommissioning and describes how the funds will be assured when decommissioning becomes necessary. If the possession limit for a single radionuclide does not exceed the value in Column 3 of the Table (10^5 times 25 TAC §289.252(ii)(2) values), then a unity rule must be applied. The activity of each radionuclide authorized on the license must be divided by the corresponding value for that radionuclide in column 3 of the Table. If by summing these ratios, one obtains a value R greater than one, then a DFP that contains a cost estimate for the decommissioning and describes how the funds will be made available when decommissioning becomes necessary must be completed.

If the possession limit of unsealed radioactive material on the license is greater than 10^4 times the value in 25 TAC §289.252(ii)(2) (Column 2 of Table I) for any of the radionuclides with a half-life greater than 120 days, but less than 10^5 times the 25 TAC §289.252(ii)(2) value (Column 3 of Table I), the licensee will be required to complete a DFP that describes how the \$750,000 surety will be presented upon decommissioning. If the possession limit for a single radionuclide does not exceed the value in Column 2 of Table I, then a unity rule must be applied. The activity of each radionuclide authorized on the license must be divided by the corresponding value for that radionuclide in column 2 of the table. If by summing these ratios, one can obtain a value greater than one, then the licensee must complete a DFP that describes how the \$750,000 surety will be made available upon decommissioning.

If the possession limit of unsealed radioactive material on the license is greater than 10^3 times the value in 25 TAC §289.252(ii)(2) (Column 1 of Table I) for any of the radionuclides with a half-life greater than 120 days, but less than 10^4 times the 25 TAC §289.252(ii)(2) value (Column 2 of Table I), the licensee will be required to complete a DFP that describes how the \$150,000 surety

will be presented upon decommissioning. If the possession limit for a single radionuclide does not exceed the value in Column 1 of Table I, then a unity rule must be applied. The activity of each radionuclide authorized on the license must be divided by the corresponding value for that radionuclide in column 2 of the table. If by summing these ratios, you obtain a value R. If R is greater than 1, then you must complete a DFP that describes how the \$150,000 surety will be made available upon decommissioning.

The last group described in 25 TAC §289.252(gg)(3) is for sealed sources. If the possession limit on the license is greater than 1010 times the value in 25 TAC §289.252(ii)(2) (Column 4 of Table I) for any of the radionuclides in the form of sealed sources, the licensee will be required to complete a DFP that describes how the \$75,000 surety will be made available upon decommissioning or the licensee may submit a certification that financial assurance in the amount of \$75,000 has been provided. If the possession limit for a single radionuclide does not exceed value in Column 4 of Table I, then a unity rule must be applied. The activity of each radionuclide in the form of sealed sources authorized on the license must be divided by the corresponding value in Column 4 of Table I. If by summing these ratios, one obtains a value, R, that is greater than one, the licensee will be required to complete a DFP that describes how the \$75,000 surety will be made available upon decommissioning or a certification that financial assurance in the amount of \$75,000 has been provided may be submitted.

Three methods of financial assurance for decommissioning are available to all licensees, with a fourth method available to government licensees. For federal, state or local government licensees, a Statement of Intent (SOI) signed by the appropriate authority must be provided which will indicate that funds for decommissioning will be obtained when necessary. The other methods of financial assurance are: prepayment, surety and an external sinking fund. These methods of financial assurance are more fully explained in 25 TAC §289.252(gg)(6) with additional explanation provided in 25 TAC §289.252(ii)(7).

Here are a few examples to show how to determine if the licensee is affected by this rule. If a license has a broad authorization for unsealed radionuclides with a no single source to exceed authorization, the licensee will be required to provide a DFP, because an authorization for possession of as little as 100 μ Ci of unsealed iodine-129 or strontium--90 will place the license into the lowest category requiring funding.

If the licensee is authorized for more than 100 curies of americium-241 sealed sources, the licensee will fall into the sealed source category. Likewise, authorization for possession of over 10,000 curies of cobalt-60 sealed sources will require \$75,000 of decommissioning funds. However, if the licensee is authorized for 50 curies of sealed sources containing americium-241 and 5,000 curies of sealed sources containing cobalt-60, \$75,000 of decommissioning funding would still be required.

A decommissioning funding plan may be avoided by changing the authorization on the license so that R is less than one. For example, by lowering limits on total possession of unsealed sources or certain radionuclides that are needed by the licensee, financial assurance for decommissioning can be lowered or avoided all together.

Table I

Radionuclide	10 ^{3*}	10 ^{4*}	10 ^{5*}	10 ^{10*}
Am ²⁴¹ , Pu ²³⁹ , Po ²¹⁰ , Ra ²²⁶ , U ²³³ , U ²³⁴ /U ²³⁵ and other alpha emitters not listed	10 ¹ μCi	10 ² μCi	10 ⁰ mCi	10 ² Ci
I ¹²⁹ , Sr ⁹⁰ and any other radionuclides or beta emitters not listed	10 ² μCi	10 ⁰ mCi	10 ¹ mCi	10 ³ Ci
Na ²² , Co ⁶⁰ , Ru ¹⁰⁶ , Ag ^{110m} , Cs ¹³⁴ , Ce ¹⁴⁴ , Eu ¹⁵² , Eu ¹⁵⁴ , Bi ²¹⁰	10 ⁰ mCi	10 ¹ mCi	10 ² mCi	10 ⁴ Ci
Cl ³⁶ , Ca ⁴⁵ , Mn ⁵⁴ , Ni ⁶³ , Zn ⁶⁵ , Se ⁷⁵ , Rb ⁸⁷ , Zr ⁹³ , Nb ^{93m} , Cd ¹⁰⁹ , In ¹¹⁵ , Sb ¹²⁵ , Ba ¹³³ , Cs ¹³⁵ , Cs ¹³⁷ , Gd ¹⁵³ , Eu ¹⁵⁵ , Tm ¹⁷⁰ , Tm ¹⁷¹ , W ¹⁸¹ , T ¹²⁰⁴	10 ¹ mCi	10 ² mCi	10 ⁰ Ci	10 ⁵ Ci
C ¹⁴ , Fe ⁵⁵ , Co ⁵⁷ , Ni ⁵⁹ , Kr ⁸⁵ , Tc ⁹⁷ , Tc ⁹⁹ , Xe ¹³⁵ , Pt ¹⁹³ , Ir ¹⁹⁴ , Th(natural), U(natural)	10 ² mCi	10 ⁰ Ci	10 ¹ Ci	10 ⁶ Ci
H ³	10 ⁰ Ci	10 ¹ Ci	10 ² Ci	10 ⁷ Ci

*Multipliers for 25 TAC §289.252(ii)(2) values.

Appendix O

INTERPRETATION AND CLARIFICATION OF 25 TAC §289.256(ff)(1)

I. Establishment of Recency

25 TAC §289.256(ff)(1)(I) requires physicians who are not currently identified as Authorized Physician Users on a radioactive material license to have received their training within the past five years. This can be demonstrated through submission of training documents or submission of an appropriate board certification that is dated no more than five years prior to the amendment request. If this documentation is greater than five years old, the following documentation can be accepted as demonstration that the physician is still current in the appropriate category:

A certification statement by the Program Director of an appropriate ACGME- or COPT-BOA-accredited medical training program (e.g., nuclear medicine, radiology, nuclear cardiology) that the physician possesses clinical skills equivalent to those possessed by physicians who successfully complete the Program Director's specialty training.

[Note that this documentation is in addition to the training requirements of 25 TAC §289.256(ff)(1).]

For physicians whose most recent experience was under the auspices of a specific radioactive material license of broad authorization:

A specific license or sub-license issued by a license of broad authorization which shows that the physician had been reviewed and designated as an Authorized Physician User of a duly constituted Radiation Safety Committee; or

A letter from the Chair of the Radiation Safety Committee (Broad Licensee) which states that the physician's training had been reviewed, privileges granted and has been active in the appropriate clinical area.

NOTE: Some medical specialty boards may require continuing education and experience to maintain certification. In those cases, a physician with an appropriate board certification should be designated as an Authorized Physician User if (1) the board documents that such continuing education and experience is required to maintain active certification and (2) the board submits documentation demonstrating the physician's certification is still active.

II. Non-Radiologist Authorized Users [For Medical Imaging Procedures]

Successful completion of an ACGME-accredited 6-month Residency Program can not be used to qualify non-Radiologists as Authorized User Physicians because the ACGME criteria for acceptable non-Radiologist medical training programs does not include an adequate requirement for didactic training and experience in working with (handling) radioactive material

or in radiation safety procedures. Neither is a non-Radiologist board certification acceptable, for the same reasons.

Non-Radiologist physicians wishing to become designated as Authorized Physician Users for the purpose of performing Imaging and Localization Studies must provide preceptor's statements from appropriately qualified preceptors [see 25 TAC §289.256(ff)(1)(B)(i)] who certify that the applicant physician has received the clinical and work experience required by 25 TAC §289.256(ff)(1)(B)(i)(II). (500 hours each; may be obtained concurrently).

In addition to the 500 hours of clinical experience and 500 hours of work experience (which may be obtained concurrently), 200 hours of classroom and laboratory training in radiation safety-related topics must also be obtained. The 200 hours of classroom and laboratory training must be either provided within a medical teaching institution (i.e., in buildings of the institution or its officially affiliated hospitals and by staff/faculty of the institution) or the Program Director must certify that:

"I am the Program Director of an ACGME-accredited medical training program which involves the use of radiopharmaceuticals and within this accredited training program, Dr. ____ has successfully completed 200 hours of classroom and laboratory training that includes:

- a. radiation physics and instrumentation;
- b. radiation protection;
- c. mathematics pertaining to use and measurement of radioactivity;
- d. radiopharmaceutical chemistry; and
- e. radiation biology.

III. Locum tenums

The use of radioactive material under the auspices of a radioactive material license by *Locum tenums* physicians is only appropriate for small medical licensees granted a specific license condition and should not be appropriate for a specific license of broad authorization.

IV. Investigational New Drugs

Physicians wishing to be designated as Authorized Physician Users of Investigational New Drugs (INDs) must be named on an FDA Form 1571 as a participating physician, signed by the IND sponsor. Note this is in addition to basic qualification as an Authorized Physician User in accordance with 25 TAC §289.256(ff)(1).

V. High Dose Rate, Remote Control Brachytherapy

Prior to being designated as an Authorized Physician User for the purpose of practicing High Dose Rate, Remote Control Brachytherapy (HDR/RCB) in the medical treatment of humans, physicians should actively participate in at least ten cases under the direct supervision of a physician already designated as an Authorized Physician User for HDR/RCB. Note this is in addition to basic qualification as an Authorized Physician User in accordance with 25 TAC §289.256(ff)(1). A guide for licensing the use of HDR/RCB is available from DSHS.