Texas Department of State Health Services
Radiation Safety Licensing Branch

REGULATORY GUIDE 3.15

GUIDELINES FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE VETERINARY USE OF RADIOACTIVE MATERIAL

I. Introduction.

This guide describes the information required by the Texas Department of State Health Services Radiation Control Program (Agency) to evaluate a license application for the veterinary use of radioactive material. Rules governing the basics of licensing the use of radioactive material are found in Title 25 Texas Administrative Code (TAC) Section (§) 289.252; rules specific to medical/veterinary use are found in 25 TAC §289.256.

An application for veterinary uses of radioactive material must be submitted in duplicate on the "Application for Radioactive Material License - Medical Uses" BRC Form 252-2a because the Agency does not use a different form for veterinary uses. Page 3 and 4 of Form 252-2a, the Preceptor Statement, must be submitted in duplicate for each veterinarian desiring to use radioactive material, if the training occurred within the last five years. In lieu of a Preceptor Statement, reference may be made to a Texas Radioactive Material License which names the veterinarian as an authorized user, or a copy of an out-of-state radioactive material license may be provided which shows such an authorization. The application forms with supporting documents should be mailed to the address specified at the top of BRC Form 252-2a. The applicant should retain an additional copy of the application, once the application has been approved, because the applicant will be committed to operate under the procedures that have been submitted and approved. Requests for amendment of existing radioactive material licenses should be submitted in a letter stating how the license should be amended.

II. License Fees.

An application fee is required for all licenses and must be submitted with any NEW application; the fee is based on the type of clinical use and does not distinguish between medical or veterinary use. The applicant should refer to Title 25 Texas Administrative Code (TAC) Section (§) 289.204 to determine the amount of fee that should accompany the application. Review of the application will not begin until the proper fee is received by the Agency. The check or money order should be made payable to the Texas Department of State Health Service.

A fee should not be submitted with a request for renewal or amendment of a license. All current licensees will be billed according to the expiration date of their license.

III. Instructions For Completing The Application.

The separate items of the application are discussed below:

Item 1 - If a veterinarian is requesting use of radioactive material at a private office the veterinarian's private company is named as the applicant; if radioactive material is to be stored and used at an institution the institution is named as the applicant. This guide covers the veterinary use of radioactive material except that used in teletherapy or brachytherapy. Guides for those uses are available from the Agency upon request.

Items 2 through 4 - Self-explanatory.

Item 5 - Nuclear medicine procedures must be ordered and supervised by a licensed and trained nuclear medicine veterinarian. Acceptable training and experience are discussed in Item 10 and specified in Appendix A.

Item 6 - The Radiation Safety Officer (RSO) is responsible for the radiation safety program. See Item 10 for a discussion of RSO training/experience requirements.

Item 7 -

A. Check the appropriate box(es). Ensure the applicant physician user has obtained the required training and experience for the type use being requested:

If the veterinarian-user applicant has appropriate training and experience in the use of radioactive materials [see §289.256(ff)(1)(A)-(G) or §289.256(ff)(1)(H) and (I), "Acceptable Training and Experience for Medical Uses of Radioactive Material," "Training for experienced authorized users" and "Recentness of Training"], the applicant may select:

(a) Element and mass number (Check Groups desired)	(b) Chemical/physical form (sealed source make/model number)	(c) Maximum number of millicuries to be possessed	(d) Use of each form
☐Any RAM used IAW §289.256(y)	Radiopharmaceuticals	As needed	Uptake, dilution, and excretion studies
☐Any RAM used IAW §289.256(z)	Radiopharmaceuticals	As needed	Imaging and/or tumor localization studies

If the veterinarian-user applicant has appropriate experience in the use of radioactive materials (See §289.256(ff)(1), "Acceptable Training and Experience for Medical Uses of Radioactive Material"), he/she may request all uses of radioactive material for uptake, dilution, and excretion studies for which the United States Food and Drug Administration (FDA) has accepted a New Drug Application (NDA); and for

imaging and localization studies that do not require a written directive for which the FDA has accepted an NDA.

NOTE: Investigative, therapeutic, gas and aerosol uses, and some calibration/check sources must be specifically authorized as line items on the license.

The typical diagnostic nuclear medicine license would use these authorizations:

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
A. Any radioactive material with $T_{1/2}$ < 120 days except positron emitters	A. Any radiopharmaceutical except gas and aerosol	A. As needed for diagnostic purposes	A. Any diagnostic use indicated in Title 25 TAC §289.256(y), in unit dosage only.

If authorizations other than those listed immediately above are required, provide other information as indicated in B., immediately below; otherwise, skip B.

B. Additional Items Desired -
Under (a) list isotope, i.e., "Iodine-131," "Technetium-99m," etc.
Under (b) list each chemical and/or physical form of isotope. (If source is a sealed source, state the manufacturer and model number.)
Under (c) list maximum amount of material to be possessed in millicuries at any one time for each form of radiopharmaceutical or in each sealed source.
Under (d) for radiopharmaceuticals, give the procedure to be performed. Examples: Liver imaging, hyperthyroid therapy.

Item 8 - Self explanatory.

Item 9 - Certification of Using Veterinarians - Submit signed statements from each of the using veterinarians that certify that they are familiar with and agree to abide by the statements representations, and procedures submitted with the application and any other correspondence that causes the license to be issued or amended.

Item 10 - Training of Authorized Veterinarians, Radiation Safety Officer, Technologists.

A. Authorized Veterinarians - To use radioactive materials in animals, an individual must be licensed in accordance with the laws of the state of Texas to dispense and use drugs in the practice of veterinary medicine, and have didactic and clinical radioisotope training and experience commensurate with the proposed use of radioactive material. Training and experience are specified in §289.256(ff)(1) and reproduced in Appendix A. If a veterinarian has been authorized in the past five years on another Texas radioactive material license, evidence of this authorization may be submitted in lieu of training descriptions. This should include license number, specific authorizations, and dates of use of radioactive material.

B. Radiation Safety Officer (RSO) - The RSO is responsible for the day-to-day radiation safety program. The RSO maintains all records required by agency rules and is also the primary contact with the agency on matters pertaining to the license and the use of radioactive material. The RSO's training and experience with the types and quantities of radioactive material for which a license is being requested must be submitted. Qualifications may be found in §289.256(h). The RSO should routinely supervise use and records to ensure delegated workers are using approved procedures.

C. Technologists - If radioactive materials will be used/handled by technologists, describe technologist training, testing, and supervision as indicated here:
   1. What minimum training must technologists receive before they will be allowed to use or handle radioactive material? If training is not verified through recognized certification, describe the subjects and classroom hours of formal training to be given in radioisotope handling techniques and the on-the-job experience under close supervision to be required. See Appendix G for recommended training.
   2. How will performance be gauged in the training program? What written tests and on-the-job performance tests will be given to judge whether or not the trainee has satisfactorily completed the educational program? What periodic training, testing, and evaluation will be given thereafter?
   3. How will technologists be supervised on-the-job? How frequently will technologist-performance be observed by a licensed-user to verify that established procedures are being followed? How will the licensed user verify that established procedures are followed in his/her absence (review of records, observation by others)? Describe the availability of the licensed user (time and distance away) during routine operations, should a problem arise.

Item 11 - Facility - Describe facilities to include:
   1. full page scale drawings or "blueprints" of each room where radioactive material is to be received, used, or stored;
   2. labeling of locations of shielding, sinks, floor drains, storage areas;
   3. drawings of patient confinement/isolation kennels, stalls, or cages, including a schematic drawing of the areas used for quarantining radioactive animals;
   4. imaging areas, including stocks and tables;
   5. structures used for support/movement of the gamma camera (include confirmation of electrical safety and load testing for camera holders, hoists, and related equipment);
   6. descriptions of adjacent rooms and buildings; and
   7. locations, and methods of isotope transport, for any use area outside of submitted floor diagrams.

If volatile radioactive materials (radioiodines principally) are to be used, include a description of the fume hood or other controlled ventilation device for dose storage and preparation, and diagram the facility air flow patterns and ventilation rates. Address specifications of dedicated exhausts including flow rate, location of exhaust, filtration, and air monitoring (if applicable).

Item 12. Operating, Radiation Safety and Emergency Procedures Manual - The applicant's Radiation Safety Procedures must be submitted in duplicate with serially numbered pages and a table of contents, and must include the following items as appropriate for the uses desired.

1. A description of the radiation safety program management. If the applicant is an institution with several veterinarians using two or more modalities of therapeutic radioactive material, the institution must establish a Radiation Safety Committee of at least three persons to coordinate the use of all radiation sources throughout the institution. The membership of the committee may be limited to specialists in veterinary nuclear medicine, radiation safety, and the institution's management.

2. A description of the functions of the RSO, the Radiation Safety Committee (if required), and the program for periodically checking the use of radioactive material to assure the proper safety procedures are followed. (The committee or RSO should have authority to set radiation safety policy, to stop any use of radioactive material deemed unsafe, and to require remedial action by users.)

3. Method of receiving radioactive material, promptly notifying responsible persons, monitoring for contamination, and storing securely. Receipt of materials after normal working hours should be specifically addressed.

4. Method of recording receipt, authorized use, transfer, inventory, and disposal of radioactive material. This should include records to indicate that only authorized users are ordering procedures, and records to indicate the presence of an authorized user during each diagnostic or therapeutic procedure.

5. Method of limiting access to radioactive material to authorized users; method of controlling access to restricted areas, radiation areas, and high radiation areas.

6. For sealed sources of radioactive material such as used with dose calibrator, gamma camera, or survey meter check sources, a description of the frequency and method that will be used to test the sources for leakage and document physical inventory. For example, if a commercial kit is used, confirm the use of a licensed vendor. If the applicant wishes to test sources for leakage in-house, comprehensive procedures for wiping, counting, converting to microcuries, etc. must be submitted. (Regulatory Guide 5,1, "Guide for the Preparation of Leak Test Applications," may be obtained from the Agency.) Note, also, rules governing the authorization of calibration and reference sources can be found in 25 TAC §289.256(s).

7. A description of the routine visual and radiation/contamination surveys (fixed and removable) to be made in areas where radioisotopes are used and stored, including animal confinement areas (see Appendix B). Address also methods for surveying facility areas such as imaging areas after a procedure prior to release for unrestricted use and provide instructions and procedures for patient surveys

for determining restricted areas for isolation of the patients or permissible handling times and distances for attendants. (See also Item 11.)

8. Method of monitoring personnel exposure (e.g., film badges, TLD). Title 25 TAC §289.202(q) specifies when monitoring for occupational exposure is required. If millicurie amounts of activity are used at one time, confirm that ring badges will be used by persons handling those amounts of activity.
   NOTE: Title 25 TAC §289.202(p)(3) details supplier accreditation requirements.

9. General laboratory rules for preventing contamination when handling uncontained radioactive material (see Appendix D).

10. Method of responding to spills, radiation incidents, and facility and personnel contamination. Provide a copy of instructions posted in appropriate locations.

11. Dose administration, patient handling, and imaging - submit procedures that includes detailed descriptions of dose preparation, administration, and handling. Use the following as a checklist for the information to be included for each clinical procedure. For single species practices, some of these descriptions may have considerable commonality, but for multi-species practices, unique descriptions may be needed for each. Indicate:
    a. categorization of animal procedures by size of animal and size dose activity;
    b. specification of procedures, radiopharmaceuticals, appropriate doses, and how to determine the planned doses;
    c. preparation and measurement of appropriate doses: activity tolerance for proper administration;
    d. how patient is immobilized (restraints, stocks, or tranquilization) to minimize imaging and handling time after patient is dosed;
    e. protective clothing (gloves, lab coats, shoe covers) to be worn;
    f. technologist dose reduction through the use of pre-placed needles, catheters, and syringe shields;
    g. safety precautions and instructions in the case of patient urination;
    h. safe movement of the camera;
    i. how imaging procedures utilize principles of time, distance, and shielding for radiation protection (minimizing close handling of the patient, minimizing imaging times, and use of protective devices);
    j. how access is restricted to patient after dosing, prior to and after imaging;
    k. markers/tags to identify the radioactive animal and its confinement area; and
    l. survey procedures for measurement of radiation field at 1 meter from target organ after injection to determine safe handling techniques and restrictions;

12. Release of patients containing radioactive materials - Provide procedures for:
    a. determination of acceptable release limits for patients containing residual activity. Two cases are discussed in Appendices to this guide. The underlying considerations may be used to address other situations.

1. Appendix E: Assessment of 1-131 Risk for Release of Patient to Owner Feline Thyroid Therapy
2. Appendix F: Release Limits Based on Radiation Fields - Animals Containing Gamma Emitting Radionuclides

b. performing radiation surveys about patients containing quantities of gamma-emitting radioisotopes, for release of the patient
c. instructions to patient owners, and owner certification, for safe handling upon release. See Appendix G - Criteria For Written Home Care Instructions for Radiation Safety and Length of Time for Precautions to be followed.

13. Waste - Describe methods for handling, security and ultimate disposal of waste which may contain radioactive material following animal uses. Include waste generated and/or stored in operatories, injection and imaging areas, kennels, stalls, and other isolation areas by addressing procedures for:
    a. collecting wastes - use of dedicated implements and protective clothing;
    b. managing and restricting access to wastes;
    c. monitoring prior to disposal;
    d. disposing of unused foods, bedding, excrement, and deceased animals; and
    e. complying with applicable release limits of §289.202 for disposal of wastes.

    Address risk of contamination from excretions (urine, feces, saliva, sweat glands, and oil glands) and control of inhalation of gaseous radioiodine vapors from the isolation and/or defecation areas, if I-131 is to be authorized for therapy.

14. Procedures for calibration, in accordance with manufacturer, the American National Standards Institute (ANSI), or U.S. Nuclear Regulatory Commission (NRC) recommendations, for constancy, linearity, geometry, and accuracy. Also, procedures for quality assurance of other diagnostic and imaging equipment used with radioactive material (daily flood studies, weekly resolution tests for gamma cameras, for example).

15. State how often and by whom the survey instruments will be calibrated and describe how corrections are made for the energy of the isotopes being used. (Regulatory Guide 5.2 "Guide for the Preparation of Survey Instrument Calibration Applications," may be obtained from the Agency if the licensee will calibrate survey instruments.)

16. If a nuclide generator will be used or if any radiopharmaceuticals are to be prepared from kits, the applicant must include this information in the procedures:
    a. confirmation that finger badges will be worn on the dominant hand by technologists who prepare kit radiopharmaceuticals;
    b. confirmation that the manufacturer's instructions, recommendations, and specifications will be strictly followed when eluting the generators, preparing the kits, and storing the resultant radiopharmaceuticals;
    c. method of assaying doses that are prepared from the generator and/or kits;

d. confirmation that syringe and vial shields will be used according to manufacturer's guidance, particularly when doses exceed 20 mCi; and that pre-placement of needles will be attempted when doses exceed 100 mCi;
e. name and model of the high range survey meter (up to 1 R/hr capability) that will be used if a generator will be used, or if doses will exceed 100 mCi;
f. if generators are held for decay, confirmation that the bare cores are to be monitored for acceptable levels prior to disposal;
g. confirmation 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 µCi Mo-99m per 1 mCi of Tc-99m).

17. Procedures for handling millicurie quantities of iodine solutions including provisions for ventilation (fume hoods), covering and shielding containers, and bioassays (thyroid counts) for personnel handling the material. Procedures for minimizing the spread of contamination from the patient confinement areas should also be addressed. (A bioassay guide for personnel bioassays may be obtained, if needed, from the Agency.)

Item 13 - Radiation Detection Instrumentation - Self-explanatory.

Item 14 - Financial Qualification and Financial Assurance - See 25 TAC §289.252(gg) to determine if financial assurance must be provided. Unless licensed authorization include large amounts of long-lived radioactive material (i.e., half-lives of greater than 120 days), financial assurance is not required and financial qualification can be established via self-attestation on BRC Form 252-1, Business Information Form.

Item 15 - The application must be signed and dated by the applicant or an individual duly authorized by the applicant to act for or on the applicant's behalf. Unsigned and undated applications will be returned to the applicant. Retain one copy for your files and mail the license applications and appropriate fee to:

Texas Department of State Health Services
Radiation Safety Licensing Branch
Medical and Academic Licensing Program
1100 West 49th Street
Austin, Texas 78756-3189

APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES
OF RADIOACTIVE MATERIAL

I. Training For Imaging and Localization Studies

To qualify as trained to use or directly supervise the use of diagnostic radioactive material a veterinarian should have:

A. Training in basic radioisotope handling techniques consisting of lecture, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory in the following areas: (200 hours)

1. Radiation physics and instruments (100 hours)
2. Radiation protection (30 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
4. Radiation biology (20 hours)
5. Radiopharmaceutical chemistry (30 hours)

(The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

B. Experience with types and quantities of radioactive materials for which the application is being made, or equivalent (500 hours). The laboratory experience should include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
3. Calculating and safely preparing patient dosages;
4. Using administrative controls to prevent the misadministration of byproduct material;
5. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
6. Eluting technetium-99m from generators, measuring and testing the eluate for molybdenum-99m and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

C. Supervised clinical training in an institutional nuclear medicine program (500 hours), preferably a teaching hospital. The clinical training should cover all appropriate types of diagnostic procedures and include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements, and plotting data.

3. Follow-up of patients, when required.

4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

NOTE: The requirements specified in Sections A., B., and C. may be satisfied concurrently in a six-month nationally accredited training program IF all areas are integrated into the program. (The accreditation body should be equivalent to the American Council on Graduate Medical Education, for example.) If this program is not accredited, all areas of training must be documented in detail separately and concurrent training credit for these sections may be not given. Also, if training occurred more than five years prior to application for use, evidence of licensed practice in the field or additional current training will be needed.

ALTERNATIVE: Certification within the past five years by the American Board of Nuclear Medicine, the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology, or an appropriate national veterinary practice board whose requirements are equivalent to these boards (submit details), will be accepted as evidence that a veterinarian has had adequate training and experience for the use of radioactive materials.

II. Training Requirements For Therapy Procedures Involving Radiopharmaceuticals

To qualify as adequately trained to use or directly supervise the use of radiopharmaceuticals for therapeutic procedures, a physician should have:

A. Training in basic radioisotope handling techniques including: (80 hours)

1. Radiation physics and instrumentation (25 hours)
2. Radiation protection (25 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (10 hours)
4. Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those in Section I.A.)

B. Clinical training in specific therapy procedures:

(i) iodine-131 for treatment of hyperthyroidism:
- clinical experience in the diagnosis of thyroid function and active participation in the treatment of 10 patients.

(ii) phosphorus-32 for treatment of polycythemia vera, leukemia, and/or bone metastasis:

- treatment of three patients with any combination of these three conditions.

(iii) colloidal phosphorus-32 for intracavitary treatment:

- active participation in the treatment of three patients.

(iv) iodine-131 for treatment of thyroid carcinoma:

- clinical experience in diagnosis of thyroid function, active treatment of 10 patients for hyperthyroidism, and active participation in the treatment of three patients with thyroid carcinoma.

(v) colloidal gold-198 for intracavitary treatment:

- active participation in the treatment of three patients.

III. Training Requirements For Therapy Procedures Involving Sealed Sources

Guides for teletherapy or veterinary brachytherapy are available from the Agency. However the requirements for such uses are also presented here for completeness.

To qualify as adequately trained to use or directly supervise the use of sealed radioactive sources in the healing arts, the veterinarian should have:

A. Training in basic radioisotope handling techniques (200 hours) as described in Section I.A., except for beta applicator users where 24 hours is sufficient.

B. Clinical training in specific therapy procedures:

1. Radiation sources for interstitial, intracavitary, or surface treatment of cancer:

- Active participation in therapeutic radiology with three years experience.

2. Beta ray applicators:

- Active practice in therapeutic radiology or ophthalmology with clinical training and active participation in the treatment of at least five patients with a beta ray applicator. This clinical training must be under the supervision of a preceptor and include examination of patients, determination of the suitability of using the beta applicator in the treatments, actual treatment of superficial eye conditions, calculation of the radiation doses, management of the patient, and discussion with the preceptor of case histories. The preceptor must verify the training by

completing and signing a preceptor's statement which includes this information (such as Pages 3 and 4 of BRC Form 41-2a)

ALTERNATIVE: Active practice in therapeutic radiology and evidence of certification within the last five years by the American Board of Radiology in Radiology or Therapeutic Radiology or an appropriate national veterinary practice board with equivalent requirements (submit details) may be submitted in lieu of the information specified in subsections A and B above.

APPENDIX B

METHODS AND FREQUENCY FOR CONDUCTING RADIATION SURVEYS

I. Introduction

When radioactive material is handled in the form of solutions at the licensee's facility, both radiation surveys and contamination surveys should be performed to prevent unnecessary radiation exposure to personnel and to prevent the spread of contamination throughout the facility. Radiation area surveys are performed using an appropriate radiation survey meter, and contamination surveys are performed by taking wipe samples from surfaces in the facility that are likely to be contaminated and counting samples with a detector/scaler combination with adequate sensitivity.

II. Frequency of Surveys

Surveys frequency depends upon the amount and type of radioactive material used. Listed below are examples, which may be useful in determining how often to perform surveys. The greater the workload, the more often the surveys should be performed.

A. Low Level Areas - Not less than once a month - Areas where in vitro tests are performed, dilution and excretion samples analyzed, etc. (Samples usually less than 100 microcuries each.)

B. Medium Level Areas - Not less than once per week - Areas such as active waste storage and patient confinement locations.

C. High Level Areas - Daily after use or not less than once a day - Areas where injections are performed, patients are imaged, wastes are handled and/or packaged for storage, and also areas used for storage of active solutions, preparation of kits, elution of generators, preparation of therapeutic doses, etc.

III. Methods of Surveys

Suggested methods for performing two types of surveys are given below. Records of these surveys are required for inspection by the Agency and should be maintained for reference to determine whether the radiation levels or the contamination levels remain constant or increase over a period of time.

A. Radiation Area Surveys - A survey meter capable of measuring 0.1 mR/hr should be used and the results recorded on a form showing location, date, person performing survey, instrument used, exposure levels, and corrective action taken, if any. A sketch of the area should be used to make an easily prepared and easily understood survey record when annotated with this information.

B. Contamination Surveys - A series of wipes using filter papers or swatches of cloth should be taken from surfaces where contamination could be expected or where radiation levels are fairly high; e.g., areas where doses are drawn, incoming packages are received, pipetting is performed are areas that may be contaminated. Wipes should be numbered or labeled and the location where they are taken shown on the sketch the radiation survey. The wipes should each be rubbed over a surface area of about 100 square centimeters when taking the wipe to maintain a consistent means of determining the amount of removable contamination. The wipes may be counted using a gamma scintillation well counter, a Geiger counter, or any other detector capable of detecting the small amount and type of contamination on the sample. The amount of removable activity should be recorded in activity units (dpm, becquerels, or microcuries) per unit area if above acceptable limits (see IV. below). Calculations for converting instrument readings to activity are usually required. If the reading is less than acceptable limits, the instrument reading may be recorded.

IV. Acceptable Limits

A. Radiation Levels - In no area that is unrestricted (uncontrolled) should radiation levels exist such that a person could receive 100 mrem in any one year or 2 mrem in any one hour. If such areas are found to exist, measures should be taken to eliminate the excessive radiation levels. Additional shielding or relocation of radioactive material may be required.

In restricted areas, the exposure limits do not apply because personnel are monitored to determine their exposure. Exposure rates, however, should be reduced to the minimum where practicable to reduce doses to the general public. If visitors are allowed in restricted areas, their exposure should be as low as reasonably achievable. In the case of patient visits by members of the general public, in accordance with 25 TAC §289.256(aa)(2), applicants can apply for Agency approval to allow doses to patient-visitors of up to 500 mrem.

B. Contamination Limits - If wipe samples of an area indicate more than 1,000 disintegrations per minute (dpm), the area should be cleaned until the contamination has been reduced to background activity. Because it is difficult to determine exactly when a wipe sample has 1,000 dpm, it is recommended when such samples show an easily detectable amount of activity above background, the areas be cleaned to remove all radioactive contamination. This action should help prevent the spread of contamination and ingestion of activity by personnel whose hands or clothing have become contaminated.

APPENDIX C

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

The following is an example of typical rules that could be specified for a veterinary laboratory using or preparing radioactive material for animal diagnostic studies. The applicant is encouraged to develop their own set of such rules that are specific to their needs and reflect their actual laboratory situation. Use of material that may become airborne (aerosols, xenon-133, iodine-125/131) will require additional rules, as will therapeutic preparation and use of radiopharmaceuticals and sealed sources. Rules should be written in the form of directions to be followed by employees.

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor self (e.g., hands and clothing) for contamination after each procedure and when leaving the use area.

4. Always use vial and syringe shields for routine preparation of patient doses and administration to patients, except in circumstances when their use would compromise the patient's well being. (These circumstances should be listed.) When doses exceed 20 mCi, consider pre-placement of needles, and when doses exceed 100 mCi, pre-placement should always be used.

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For all doses, check the patient’s name, the radionuclide, the chemical form, and the activity against the veterinarian's written order.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waste level. Personnel monitoring devices, when not being worn to monitor occupational exposure, should be stored in a designated low background area, as should the control badge.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially labeled and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at 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 surfaces that are easily cleaned or covered with disposable absorbent coverings when handling open solutions of radioactive material. Work only in designated restricted use areas. Process volatile radioactive materials under fume hoods or in glove boxes when possible.

APPENDIX D

ASSESSMENT OF 1-131 RISK FOR RELEASE OF PATIENTS TO OWNERS FOR FELINE THYROID THERAPY

I. Because the effective half-life of radioiodine in cats appears to be on the order of 2.4 days, ranging from 1.4 to 3.6 days, cat-to-cat, the licensee will need to establish suitable quarantine times to minimize hazards to staff and owners from administration of therapeutic quantities of radioiodine to cats.

II. Quarantine Times - Estimates should be confirmed by survey:

Activity Administered	Time
1 - 3 mCi	24 hours
4 - 8 mCi	36 hours
9 - 30 mCi	48 hours

III. Release Limits - In lieu of performing a comprehensive pathway analysis to justify your release limits for therapeutic administrations, the Agency will accept the following protocol.

Households with children who can be supervised or with pregnant women:
Release limit: 25 uCi residual radioactivity in the animal

For this situation, there exists a likelihood that a radiosensitive target will be exposed to the pet. A child or pregnant woman might handle the pet and ingest radioiodine. Inadequate control could result in significant exposure. Therefore, an animal containing I-131, even in amounts below 25 uCi, should not be released to this household unless adequate supervision can be imposed. Children must be instructed and supervised to see that contact with the animal in prohibited and in instances where contact occurs, careful washing to remove any possible contamination from the child must occur rapidly.

Households with non-pregnant women and children over the age of 18
Release limit: 100 uCi

Adults are to be instructed in isolation and handling procedures to minimize exposure to 1-131. In the event of possible contamination, adults are to be instructed to wash carefully to remove any 1-131.

IV. Certification of Pet Owners - the licensee should secure, for each animal treated therapeutically with 1-131, a signed statement that the owner has read and agrees to abide by all necessary restrictions, including procedures for death of the patient. The licensee will need to submit a sample copy of such a statement and accompanying instructions.

APPENDIX E

RELEASE LIMITS BASED ON RADIATION FIELDS FOR ANIMALS CONTAINING RADIONUCLIDES OTHER THAN I- 131

I. In lieu of providing the Agency with a comprehensive evaluation of potential exposure to owners and other individuals from diagnostic doses of Tc-99m labeled radiopharmaceuticals, the Agency will accept adherence to the following protocol.

- Unrestricted release to the owner may occur only when the radiation field measured at one meter from the target organ with a suitably calibrated survey meter falls below 2 mR/hour.

II. Unrestricted release protocols for radiopharmaceuticals labeled with nuclides other than 1-131 or Tc-99m must be developed by the licensee based on these precepts:

A. When the nuclide represents principally an external exposure hazard, the Agency will accept protocols that result in less than 50 mrem total exposure at one meter from the target organ through complete decay of the radionuclide.

B. For nuclides where the internal exposure threat to others is greater than the external exposure hazard subsequent to patient release (radioiodine procedures with iodine other than 1-131, procedures with pure or strong beta emitters), an activity limit for release should be established which includes comprehensive excretion rate estimates and ingestion pathway analyses. The protocol should limit exposure to owners and others to one tenth that customarily associated with release of human patients for the same nuclide, or if no limits are usually placed on human release (example: P-32 therapy), to 50 mrem committed effective dose equivalent. The licensee should be prepared to justify and defend each assumption and estimate of the submitted excretion rates and pathway analyses.

APPENDIX F

CRITERIA FOR WRITTEN HOME CARE INSTRUCTIONS FOR RADIATION SAFETY AND LENGTH OF TIME FOR PRECAUTIONS TO BE FOLLOWED

Instruction to owners should be comprehensive. The following is a checklist for items that generally should be included for two situations.

A. Feline Thyroid Therapy

1. Handling the Pet

    a. Restriction of areas within the home
    b. Wearing of protective gloves or clothing
    c. Controlling contact with pet to avoid inhalation of expired air

2. Handling Excrement and Wastes at Home

    a. Home location of absorbent litter box
    b. Wear of disposable rubber gloves when handling absorbent litter box
    c. Absorbent litter disposal - bag in plastic and send to sanitary landfill
    d. Disposal of deceased animal
    e. Disposal of unused food

3. Restriction of Children or Pregnant Women

4. Hazard Instructions:

    a. Cleaning suspected contamination
    b. Instructions in the case of death of the patient

5. Emergency Telephone Number Where Veterinarian (RSO) can be reached

6. Duration that Instructions are to Be Followed

    NOTE - Certification of Pet Owners Shall Be Obtained - A signed statement that the owner has read and agrees to abide by all necessary restrictions, including those emergency procedures to be followed in case of the death of the patient during the time period that restrictions are necessary.

B. Imaging Procedures for Small Animals

1. Handling the Pet
    a. Restriction of contact with the animal

2. Handling Excrement and Wastes at Home

a. Home location of the absorbent litter box, if applicable
b. Handling of waste prohibited

3. Restriction of Contact with Children or Pregnant Women

4. Hazard Instructions

   a. Cleaning suspected contamination
   b. Instructions in case of death of the patient

5. Emergency Telephone Number Where Veterinarian (RSO) can be Reached

6. Duration that Instructions are to Be Followed

NOTE - Certification of Pet Owners Shall be Obtained - A signed statement that the owner has read and agrees to abide by all necessary restrictions, including those emergency procedures to be followed in case of the death of the patient during the time period that restrictions are necessary.

A copy of the instructions for each case applicable should be submitted with the application.

C. Other Procedures

Instructions for procedures other than the two cases described above should follow along these same lines and should ensure that the criteria (exposure limits to owners and others) of the release protocol for such nuclides and patients are actually achieved in practice.

APPENDIX G

MINIMUM REQUIRED TRAINING FOR VETERINARIAN TECHNOLOGISTS TO HANDLE OR WORK IN THE VICINITY OF RADIOACTIVE MATERIALS

In order for Veterinary Technologists to work with radioactive materials or animals that have been injected with radioactive materials the licensee must confirm that the technologist has had a minimum of eight (8) hours of classroom training covering the basics of radiation and radiation safety, including:

1. Radiation physics;
2. Principles of radiation detection;
3. Radiation protection;
4. Radiation biology;
5. Procedures for surveys and decontamination;
6. Procedures for personnel bioassays;
7. Animal release calculations; and
8. Waste monitoring/disposal

This training must be administered by a Licensed Medical Physicist and must be documented by the licensee.

In addition to the above described classroom training the Physicist or an Authorized Physician User must confirm in writing the technologists' competence in the following tasks following observation of the performance of each task at least three (3) times:

1. Area surveys
2. Decontamination
3. Personnel bioassays
4. Animal release calculations
5. Waste monitoring/disposal
6. Drawing of doses