RADIOACTIVE MATERIALS PROGRAM

VETERINARY LICENSING GUIDE

REVISION 3

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1. INTRODUCTION

1.1 GENERAL

The Georgia Department of Natural Resources, Radioactive Materials Program (Department) regulates the intentional internal or external administration of radioactive material, or the radiation from it, to animals. This type of use is called "veterinary use", and a specific license is required.

The Department usually issues a single radioactive materials license to cover a veterinarian's radioisotope program, other than teletherapy. Separate licenses, except teletherapy, are not normally issued to different departments of a veterinary medical institution, nor are they issued to individuals associated within the institution. A license applicant should carefully study this guide and all the Regulations identified in Section 1.2 and should complete the application form, "Application for Radioactive Materials License" (Form 1). The Department may request additional information when necessary to insure a reasonable Radiation Protection Program.

1.1.1 Purpose of Guide

This guide outlines the type and extent of information needed by the Department to evaluate an application for a veterinary-use license and to describe the veterinary-use Regulations. The guide is intended to provide you, the applicant and the licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to veterinary-use programs. The information contained in this guide does not cover the use of high dose rate (HDR) afterloaders, brachytherapy, or teletherapy. You will need to refer to other licensing guides for information needed to support those uses, and such programs will be reviewed for approval on a case-by-case basis.

1.1.2 Purpose of Appendices to Guide

The Regulations require that the licensee develop and carry out procedures that will ensure compliance with the Regulations. Appendices A through S to this guide describe model radiation safety procedures, equipment, and training requirements. Each applicant should carefully read the applicable Regulations and model procedures and then decide if the model procedures are appropriate for their specific radiation safety needs. In the application, applicants may certify that they will follow the model procedure (appropriate certification language is given at the beginning of each Appendix); or, the licensee may say that he has developed a procedure enclosed for review (appropriate reference language is given at the beginning of each Appendix).

1.2 APPLICABLE REGULATIONS

The following Georgia Regulations apply to you and should be used with this guide. The applicant or licensee should carefully read the applicable Regulations. This guide does not substitute for an understanding of the Regulations. Nor does it substitute for training in radiation safety or for developing and carrying out an effective Radiation Protection Program. All Rules referenced in this guide refer to Chapter 391-3-17, "Rules and Regulations for Radioactive Materials", unless otherwise stated. The following rules need to be referenced when applying for a Radioactive Material License for veterinary use:

Rule 391-3-17-.01 "General Provisions. Amended."

Rule 391-3-17-.02 "Licensing of Radioactive Materials. Amended."

Rule 391-3-17-.03 "Standards for Protection Against Radiation. Amended."

Rule 391-3-17-.05 "Use of Radionuclides in the Healing Arts. Amended."

Rule 391-3-17-.06 "Transportation of Radioactive Material. Amended."

Rule 391-3-17-.07 "Notices, Instructions and Reports to Workers; Inspections. Amended."

Rules .02 (9)(b), (c), (d), and (e), "Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material", outlines the requirements applicable to a veterinary-use license. While Rule .05 is mainly for the practice of the healing arts on humans, there are portions to which the veterinarian will be held, as stated throughout this guide.

You may request copies of the above documents from the Radioactive Materials Program (RMP) at: Atlanta Tradeport, Suite 100, 4220 International Parkway, Atlanta, Georgia, 30354, or from our website: http://www.gaepd.org/.

The applicant should carefully study the Regulations and this guide and should submit all information requested. The Radioactive Materials Program will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate Radiation Protection Program. Such requests will delay final action on the application.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Rule .03(4) states in part:

(a) Each licensee shall develop, document, and implement a Radiation Protection Program sufficient to ensure compliance with the provisions of this Rule.
(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
(c) The licensee shall, at least annually, review the Radiation Protection Program content and implementation.

Components of a Radiation Protection Program are listed in Item 10.

1.4 TYPES OF LICENSES

The Department issues three types of licenses for radioactive material use in the practice of veterinary medicine. They are described below. This guide is only for persons who want to apply for a specific veterinary use license. However, persons who are applying for other types of licenses may find the information in this guide useful in designing their Radiation Protection Program.

1.4.1 General License

Rule .02(6)(g), "General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing", establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small

quantities of radioactive material for in vitro clinical or laboratory tests not involving administering radioactive material to humans. Rule .02(6)(g) explains the requirements for using materials in that section and the possession limits for a general license. If the general license alone meets the applicant's needs, only the Department form, "Certificate - In Vitro Testing with Radioactive Material Under General License", needs to be filed. Veterinary-use licensees do not need to file the form.

If you need more material than allowed by the general license, you may request an increased inventory limit as a separate line item on your "Application For Radioactive Materials License" application. If you request an increased limit for inventory (which includes wastes), you will be subject to the requirements of the Rules and Regulations.

1.4.2 Specific License

Specific licenses for veterinarians in private practice are generally limited to veterinarians who are located in private offices and not on hospital premises. A Radiation Safety Committee would thus not be required.

A specific license may also be issued for a mobile nuclear medicine service. The Rules and additional requirements for a mobile service are outlined in Rules .05(6)(j) and (7)(l). Both private practitioners and institutions may apply for authorization to use radioactive material in a mobile service.

2. FILING AN APPLICATION

A license application for a specific license for veterinary use should be submitted on Form 1, "Application for Radioactive Materials License". The application form, Form 1, is located in Part 1 of this guide. You should complete items 1 through 4, 12, and 13 on the form itself. For items 5 through 11, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number of the application to which it refers. All of the information, including drawings, should be on 8-1/2 x 11 inch paper to ease handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

You should complete all items on the application form in enough detail for the Department to determine that your equipment, facilities, training and experience, and Radiation Protection Program are adequate to protect health and minimize danger to life and property.

The Department recommends that the applicant not include in any submission trade secrets or personal information about your employees, unless the information is directly related to radiation safety or is specifically required by the Department. For example: (1) information submitted on training and experience of employees should be limited to training related to radiation safety; (2) home addresses and home telephone numbers should not be submitted; and (3) dates of birth, social security numbers, and radiation dose information should be submitted only if specifically required by the Department.

If you submit trade secrets, proprietary information, or personnel information that you want withheld from public disclosure, you must request its being withheld in accordance with procedures specified in the Georgia Open Records Law[1]. Failure to follow this procedure may result in disclosure of the information to the public and/or substantial delays in processing your submissions. Using labels

such as "confidential" or "restricted" may not guarantee that your documents will be withheld.

You should prepare your application in duplicate. Submit the original to the Department where it will become a part of the license if approved. Retain a copy for your records, as the license will require that you possess and use licensed material in accordance with the statements and representations in your application and in any supplements to it.

Applicants should remember that all documents submitted to the State of Georgia may be made available to the public.[1]

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on the "Application for Radioactive Materials License" Form. The appendices to this guide serve several different purposes: to provide additional information on certain subject areas, to provide a model procedure the licensee may adopt in response to an item on the application form, and to provide an outline the applicant may use to develop a procedure for the Department's review.

If you have specific questions after careful review of this guide, please contact the Radioactive Materials Program (RMP) staff at (404) 362-2675.

ITEM 1 LICENSE INFORMATION

Check subitem A for a new license. For an amendment to an existing license, check subitem B. Check subitem C for renewal of an existing license.

ITEM 2 APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence so that all Department correspondence will reach persons responsible for the Radiation Protection Program. This may or may not be the same as the address at which the material will be used as specified in Item 3.

ITEM 3 LOCATIONS OF USE

You should specify each location of use by the street address, city, and county or other descriptive address (such as 5 miles East on Highway 41, Anywhere, Georgia) to allow us to find your facilities easily. A post office address is not acceptable. If radioactive material is to be used at more than one location, you must give the specific address of each location. You also need to provide the latitude and longitude coordinates for each place of use. In items 5 through 11 of the application, describe the intended use and the facilities and equipment at each location.

[1] A copy of the Georgia Open Records Law is available from the Georgia Law Library, which may be contacted at (404) 656-3468.

If you desire multiple sites of use, give the location(s) where a **complete** set of records will be maintained for the license.

Specify if you are applying for a license for a mobile nuclear medicine service, and list the name and location of each client.

ITEM 4 PERSON TO BE CONTACTED ABOUT APPLICATION

You should provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer questions about the application. This individual, usually the Radiation Safety Officer (RSO) or a principal user of radioactive materials, will serve as the point of contact during the review of the application and for the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the Department if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment. However, changing the RSO requires a license amendment.

ITEM 5 AND ITEM 6 RADIOACTIVE MATERIAL AND PURPOSE

Rule .05 divides radioactive material for veterinary use into five types of use. Using the table format of Table 1 as a guide, you may show only the types of use you want and the maximum amount. You may say "As needed" in the "Amount" column as shown.

TABLE 1

RADIOACTIVE MATERIAL	AMOUNT	PURPOSE
5.a. Material authorized by Rule .05(8)(a) [Uptake, Dilution & Excretion Studies]	As Needed	**6.a.** Veterinary use
5.b. Material authorized by Rule .05(9) [Reagent Kits for Imaging & Localization Studies], excluding aerosols, gases, and generators	As Needed	**6.b.** Veterinary use
5.c. Iodine 131 for feline Radiopharmaceutical Therapy	As Needed	**6.c.** Veterinary use
5.d. Material listed in Rule .02(6)(g) [In Vitro Clinical or Laboratory Testing]	As Needed	**6.d.** In Vitro Studies

If you need generators for veterinary use in Rule .05(9), specifically list that item with the Rule [i.e., "Material authorized in Rule .05(9) (including generators) "]. You must specifically request generators to be authorized for their use. You must submit all elution and purity-determination procedures.

If you need other therapy radiopharmaceuticals or sealed sources, you must specifically request them, making a separate line entry for each item. You must submit all administration, radiation safety, and storage procedures.

Rule .02(6)(g), "General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing", lists the quantities of radioactive material that may be possessed under a general license. If you need to possess quantities of radioactive material for in vitro studies greater than those listed in Rule .02(6)(g), then request in vitro material as listed in the table above. Use of aerosols or radioactive gases is not usually accepted; if you need them, you must request their use

specifically and explain how they will be administered.

If you need other items (for example, a survey meter calibration source, constancy check source, or material for in vivo), make a separate line entry for each item. [You do not need to list the calibration and reference sources authorized by Rule .05(7)(f). Please ensure that they are listed on your inventories.] Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in millicuries (mCi), and the purpose for which the material will be used.

If you will be utilizing a mobile medical service, the sources used by the mobile medical service must be on your license. This is because the mobile medical service becomes a place of use on your license. For example, if you are using a mobile PET service the transmission and calibration sources in the PET unit must be submitted for inclusion on your license. You will need to submit the Sealed Source and Device (SS&D) registry information as well as the maximum activity. This information may be provided by the mobile PET service.
If you do not want all of the material listed in each section of Rule .05 identified in Table 1, you must identify, line by line, the material that you want from the section (for example: "thallium 201, 50 millicuries, for cardiac studies").

ITEM 7 INDIVIDUALS RESPONSIBLE FOR RADIATION PROTECTION PROGRAM

"Responsible individuals" are the authorized users and the Radiation Safety Officer (RSO). Rule .05(16) requires an applicant to be qualified by training and experience to use the requested radioactive materials for the medical purposes requested in a way that protects health and reduces danger to life or property. Again, Rule .05 was designed for medical practice with humans; the Department will consider individuals qualified if they meet the criteria in Appendix R.

Note that curricula vitae do not usually supply all the information needed to evaluate an individual's training and experience. Please send us copies of all diplomas and board certificates, and also letters from the directors of training institutions for proof of training. Please also submit copies of all users' licenses to practice veterinary medicine in the State of Georgia.

The RSO is the individual responsible for the safe use of radioactive materials under the license. Appendix F lists his duties and areas of responsibility.

Authorized users involved in veterinary use have the following special responsibilities:

1. Examination of animals and medical records to decide if a radiation procedure is appropriate;

2. Prescribing the radiation dosage or dose and how it is to be administered;

3. Actual use of radioactive material;

4. Interpretation of results of diagnostic procedures and evaluation of results in therapy procedures; and

5. Directing the safe disposal of the waste materials in a manner authorized by the Department.

7.1 AUTHORIZED USERS

1. Make a separate attachment for the RSO and each authorized user. Number the attachments "ATT 7.1.1", "ATT 7.1.2", etc. Type the full name of the individual and indicate their authorized uses (see Table 1 for examples).

2. If a veterinarian has been previously authorized for veterinary use on a license, and only wants to use material permitted by that previous license, you need only submit a copy of that license on which he was specifically named as an authorized user.

3. If a veterinarian is not already named as an authorized user on a license, please submit documentation proving that he meets the criteria listed in Appendix R.

7.2 RADIATION SAFETY OFFICER (RSO)

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, please submit documentation proving that he meets the criteria listed in Appendix R, using Supplement A. The RSO should be an employee of the licensee. Even if the licensee employs a consultant to help the RSO, the licensee is still responsible for the Radiation Protection Program as required by the license.

It is permissible to have more than one RSO to see that all requirements of the license are met. This may be the case if a veterinarian who is named as a user or RSO on another license that does not use all of the material requested for the new license in question. Therefore, an additional RSO will need to be named on the license to cover the use of radioactive material not used by the other veterinarian.

ITEMS 8 THROUGH 11

Your responses to these items should consist of one statement either that you will follow the model procedure in Appendix A through S in the Veterinary Licensing Guide Revision 3 or that you have enclosed your procedure for review, or simply the initials "NA" for "not applicable". Follow the instructions in the Applicability Table (Table 2) on the next page to decide whether you must provide information or may respond "NA" to each item that follows. Before you respond to an item, read the introductory paragraphs of that referenced appendix. Your short sentence or "NA" responses to Items 8 through 11 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to identify responsible individuals, equipment by name or model, room numbers, or other site-specific information, there is no need to submit that procedure for review.

TABLE 2

APPLICABILITY TABLE

To decide those items to which you must respond, "highlight" the columns under the categories of material you requested in Item 5. If there is a "Y" (for "yes") beside an item, you must provide information in response to the item. If the letters "NA" (not applicable) are beside an item, you may respond "NA" in your application.

		Found in Rule Section 391-3-17-.05			
Item	Topic	(41)	(44)	(48)	Appendix
8	Training Program	Y	Y	Y	A, R, S
9.1	Annotated Drawing	Y	Y	Y	FORM 3
9.2	Survey Instrument Calibration	Y	Y	Y	B
9.3	Dose Calibrator Calibration	Y*	Y*	Y*	C
9.4	Personnel Monitoring Program	Y	Y	Y	D
9.5	Mobile Imaging	Y	Y	NA	E
10.1	Radiation Safety Officer	Y	Y	Y	F
10.2	Leak-Test	Y	Y	Y	G
10.3	Safe Use of Radiopharmaceuticals	Y	Y	Y	H
10.4	Spill Procedures	Y	Y	Y	I
10.5	Ordering and Receiving	Y	Y	Y	J
10.6	Opening Packages	Y	Y	Y	K
10.7	Unit Dose Records	Y	Y	Y	L
10.8	Multi-dose Vial Records	Y	Y	Y	L
10.9	Area Survey Procedure	Y	Y	Y	M
10.10	Radiopharmaceutical Therapy (Iodine-131)	NA	NA	NA	N
10.11	Animal Release and Owner Safety Procedures	NA	NA	Y	O
11	Waste Disposal	Y	Y	Y	P

*-Not required if material received from radiopharmacy in unit doses.

ITEM 8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Describe your training program for individuals who work with or in the vicinity of radioactive material. Append it as ATT 8. See Appendices A and R of this guide.

Individuals starting to work as nuclear medicine technologists using therapy doses of unsealed radioactive materials (I-131, for example) after July 1, 2003, must meet the requirements of Appendix S.

ITEM 9 FACILITIES AND EQUIPMENT

9.1 ANNOTATED DRAWING

Submit an annotated drawing of the room or rooms and adjacent areas where radioactive material will be used. Append it as ATT 9.1. Note the following:

1. Room numbers and principal use of each room or area (for example: in vitro, hot lab, waiting, examining, imaging, office, file, fresh materials, storage, radioactive-waste storage, film processor, bathroom, closet, hallway, isolation kennels, stalls, cages, confinement areas for radioactive animals in quarantine).

2. Any shielding available.

3. Additional safety equipment (for example: fume hoods, L-blocks, or fixed area monitors).

The drawing should be in sufficient detail to show that adequate steps have been taken to ensure that radiation levels in unrestricted areas do not exceed the limits specified in Rule .03.

9.2 SURVEY METER CALIBRATION

Submit your procedure for calibrating survey instruments and attach it as ATT 9.2. See Appendix B.

9.3 DOSE CALIBRATOR CALIBRATION

Submit your procedure for calibrating the dose calibrator and attach it as ATT 9.3. See Appendix C. Dose calibrators are not required if radioactive material is only received in unit doses from a radiopharmacy.

9.4 PERSONNEL MONITORING PROGRAM

Describe your monitoring program for occupationally-exposed personnel and attach it as ATT 9.4. See Appendix D of this guide. See Rule .03(5) for complete requirement for dose limitations and Rule .03(8) for complete monitoring requirements; a summary is below:

Personnel Monitoring Equipment for External Dose

Rule .03(8)(b) requires the use of individual monitoring devices to monitor occupational exposures to adults, minors and declared pregnant doses in excess of 10 percent of the limits in Rule .03(5)(a), (5)(g), or (5)(h). The operations of some licensees may require the use of individual monitoring devices to determine both the deep-dose (commonly called “body dose”) and the extremity dose. It should be noted that the requirement for monitoring devices is based on the dose likely to be received. You should comment on your plans for use of individual monitoring devices or explain why such devices are not needed. If you are uncertain about the doses you are likely to receive, you may propose initially to use monitoring devices and then to discontinue their use if your experience over a fixed period, perhaps six months or a year, shows that the doses are sufficiently low. Your plans should clearly state any proposed discontinuance of the use of monitoring devices.

Monitoring of Internal Dose

Rule .03(8)(b)(2) requires the monitoring of the occupational intake of radioactive material and assessment of the committed effective dose equivalent if an adult is likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) (Annual Limits of Intake) in Appendix B of 10 CFR Part 20, and minors are likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem, and declared pregnant women during the entire pregnancy a committed dose equivalent in excess of 0.1 rem.

You should comment on your plans for determining intake of radioactive material or explain why such an intake is not likely to cause doses in excess of the applicable 10 percent of the ALI(s) or 0.05 rem (minors) or 0.1 rem (pregnant women).

9.5 MOBILE IMAGING

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. Attach it as ATT 9.5. See Appendix E. In addition, call the Georgia Department of Motor Vehicle Safety [(404) 675-6171] to apply for a Hazardous Material Permit for intrastate transportation of radioactive materials.

ITEM 10 RADIATION PROTECTION PROGRAM

10.1 RADIATION SAFETY OFFICER

Submit the list of the Radiation Safety Officer 's duties and also his Delegation of Authority, and attach them as ATT 10.1. See Appendix F.

10.2 LEAK-TEST

Submit your procedure for leak-testing sealed sources and attach it as ATT 10.2. See Appendix G.

10.3 SAFE USE OF RADIOPHARMACEUTICALS

Submit a copy of your rules/procedures for the safe use of radiopharmaceuticals and attach it as ATT 10.3. See Appendix H.

10.4 SPILL CONTROL PROCEDURES

Submit a copy of your spill-control procedures and attach it as ATT 10.4. See Appendix I.

10.5 ORDERING AND RECEIVING

Submit a copy of your procedure for ordering and receiving radioactive material and attach it as ATT 10.5. See Appendix J.

10.6 OPENING PACKAGES

Submit a copy of your procedure for opening packages that contain radioactive material and attach it as ATT 10.6. See Appendix K.

10.7 UNIT DOSE RECORDS

Submit your procedure for keeping records of unit dosage use and attach it as ATT 10.7. See Appendix L.1.

10.8 MULTI-DOSE VIAL RECORDS

Submit your procedure for keeping records of multi-dose vial use and attach it as ATT 10.8. See Appendix L.2.

10.9 AREA SURVEY PROCEDURES

Submit your area survey procedures and attach it as ATT 10.9. See Appendix M.

10.10 RADIOPHARMACEUTICAL THERAPY (I-131)

Submit your procedure for radiation safety during radiopharmaceutical therapy and attach it as ATT 10.10. See Appendix N. The use of radioiodine, I-131, for the treatment of felines with hyperthyroidism is the only radiopharmaceutical therapy presently being conducted in the field of veterinary medicine. If you wish to be licensed for any other uses or therapy radio-pharmaceuticals, the Department will consider your application on a case-by-case basis.

10.11 ANIMAL RELEASE AND OWNER SAFETY PROCEDURES

Submit all safety procedures for the release of the animals to their owners. Append them as ATT 10.11. See Appendix O. There are <u>two sets</u> of procedures needed for the process of allowing an animal given a therapy dosage to return to its owner:

1. First, you must have criteria to determine that the owner will follow the instructions you will give him for caring for his animal once it is released, <u>before you treat the animal</u>.

2. Second, you must have release procedures, which include the following:

    (a) The assessment of the risk to the owner from the radioisotopes used. Include the calculations used to show that radiation levels at one meter from the animal are less than or equal to 0.5 mR/hour.

    (b) The written list of instructions, which the owner is to follow after you release the animal to him. Include the length of time that he is to follow the instructions.

The procedures in Appendix O must be modified for the use of radioactive materials other than I-131.

*NOTE: Animals dosed with radioiodine must not be released before 72 hours after dosing, ***<u>and</u>*** not until radiation levels at one meter from the animal's throat are less than or

equal to 0.5 milliroentgen/hour. If animals so dosed are released less than 5 days after dosing, the owners must use flushable litter for excreta, instead of holding it for decay.

ITEM 11 WASTE DISPOSAL

Submit your procedures for the disposal of waste and attach it as ATT 11. See Appendix P.

ITEM 12 LICENSE FEES

The applicant should contact the Department to determine the applicable licensing fee and category. Note that, in addition to licensing fees for a new, renewed or amended license, licensees are required to pay inspection fees and annual fees. No action will be taken on applications filed without the proper fee. Checks for the fees should be made payable to the **Department of Natural Resources, Radioactive Materials Program**, and mailed to the following address:

Radioactive Materials Fees
P.O. Box 101161
Atlanta, GA 30392

Mail license applications, amendment requests, renewal requests, and requests to terminate the license to the following address:

Radioactive Materials Program
4220 International Parkway
Atlanta Tradeport, Suite 100
Atlanta, GA 30354

ITEM 13 CERTIFICATION

If you are an individual applicant acting in a private capacity, you must sign and date the completed application form. Otherwise, the application must be dated and signed by a representative of the corporation or legal entity authorized to sign official documents and to certify that it contains information that is true and correct to the best of your knowledge and belief. Identify the title of the office held by the individual who signs the application. Unsigned applications will not be reviewed and will be returned for proper signature.

4. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with: (1) the statements, representations, and procedures contained in your application and other correspondence with the Department; (2) the terms and conditions of the license; and (3) the Department's Regulations.

It is your obligation to keep your license current. Anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit an application for an amendment. Meanwhile, you must comply with the terms and conditions of your license until it is actually amended. Department Regulations do not allow you to implement changes based on a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application form, Form 1, in a letter, or via the Internet (see the top of Form 1 for the Internet address). The application should be prepared in duplicate as stated in Section 2 of this guide. Retain one copy, because the license requires that you possess and use licensed material according to the statements and representations in your amendment request and in any supplements to it.

Your application should state your license name and number and clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and identify the pertinent information by date, page, and paragraph. For example, if you wish to change the RSO, your application for a license amendment should specify the proposed RSO's name, training, and experience. The qualifications of the proposed RSO should be equivalent to those specified in Appendix R of this guide.

Items requiring an amendment are listed in Rule .05(4)(a) through (f). Examples of items not requiring an amendment, but requiring written notification to the Department of the change, include: deleting an authorized user no longer at facility; the remodeling of a room in which material is used; telephone number changes; and address changes due to Post Office or Emergency Medical System (EMS - 911) requirements, when the licensee has not physically moved to a new location.

Contrary to what is stated in Rule .05(5)(b), a license amendment is required prior to permitting qualified individuals to work as authorized users under a veterinary-use license.

5. RENEWAL OF A LICENSE

Licenses are usually issued for five-year periods. Prepare an application for renewal in duplicate, and send the original to the address specified in Section 2 of this guide. Keep one copy for your records, as the license requires that you possess and use licensed material according to the statements and representations in your renewal request and in any supplements to it.

You should submit an entirely new application for a renewal, as if it were an application for a new license without referring to previously submitted information. Submitting an entirely new application allows you to re-evaluate your program periodically and consolidate the description of your program. A new application ensures that your program contains all needed information as requested in current licensing guidance.

If you file your application for license renewal at least 30 days before the expiration date of your license and include a copy of the fee for license renewal, your present license will automatically remain in effect until the Department takes final action on your renewal application. However, if you file an application less than 30 days before the expiration date and the Department cannot process it before that date, you will be without a valid license when your license expires.

If you do not wish to renew your license, dispose of all licensed radioactive material possessed in a manner authorized by Rule 02(19), "Transfer of Material". Complete the Department's "Request to Terminate Radioactive Materials License" (Form 3) and send it to the Department before the expiration date of your license with a request that your license be terminated.

6. TERMINATION OF A LICENSE

You may request termination of your license at any time. This notification should include a request to terminate the license and must include the completed "Request to Terminate Radioactive Materials License" (Form 3), certifying that all sources have been disposed of properly. An application for license termination does not relieve the licensee from its obligations to comply with Department's Regulations and the terms and conditions of the license. There is not a fee for license terminations.

APPENDICIES and FORMS

MODEL PROCEDURES AND EQUIPMENT THAT APPLICANTS MAY USE TO PLAN RADIATION PROTECTION PROGRAMS

Georgia Department of Natural Resources
Environmental Protection Division
Radioactive Materials Program

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE

INSTRUCTIONS - Complete Items 1 through 13 if this is an initial application or renewal of a license. Use supplemental sheets where necessary. Item 13 on the application must be completed and signed. Retain one copy for your records. Submit original application to: Georgia Department of Natural Resources, Radioactive Materials Program, 4220 International Parkway, Suite 100, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Georgia Radioactive Materials Licenses are issued in accordance with the general requirements contained in the Georgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17. **The Department can be reached via the Internet. The address is rad_materials @ dnr.state.ga.us.**

1.This is an Application for: (Check appropriate item) A.__ New License B. __ Amendment to License C. __ Renewal of License
If B or C , Please indicate GA. License Number

2.a. Name and Mailing Address of Applicant

Name:
Address:
City, State, Zip Code:
County:
Telephone Number ( ) _____ -_____
Internet Address:

2.b. Address where licensed material will be stored and/or used (Street Address)

A. Permanent B. Coordinates
1. Latitude:
2. Longitude:

C. Temporary sites throughout Georgia?
Yes _____ No_____

3. Person to Contact Regarding this Application
Name:
Title:
Telephone Number ( ) _____ - _____
Radiation Safety Officer:
Telephone Number( ) _____ - _____

4. Locations where records will be kept:

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. Chemical and/or physical form; and c.. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESONSIBLE FOR RADIATION PROTECTION PROGRAM AND THEIR TRAINING & EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION PROTECTION PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (SEE DEPARTMENT'S FEE SCHEDULE)
FEE CATEGORY : AMOUNT ENCLOSED $

CHECK MAILED _____ PLEASE INVOICE_____

MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM

MAIL FEES TO: RADIOACTIVE MATERIALS PROGRAM, P.O. BOX 101161 ATLANTA, GEORGIA 30392

13. CERTIFICATION (Must be completed by the applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH GEORGIA DEPARTMENT OF NATURAL RESOURCES RULES AND REGULATIONS, DESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

CERTIFYING OFFICER -- TYPED PRINTED NAME AND TITLE	SIGNATURE	DATE

Supplement A
TRAINING AND EXPERIENCE
AUTHORIZED USER/RADIATION SAFETY OFFICER

1. APPLICANT AUTHORIZED USER/RADIATION SAFETY OFFICER NAME AND ADDRESS (use separate form for each user or RSO)

FULL NAME:_____

ADDRESS:_____

CITY: _____

STATE: _____ ZIP: _____

DAYTIME TELEPHONE#:_____

2.a. Radiation Safety Officer or Authorized User at other Medical Facility within last 7 years?

□ Yes License #: _____ (Attach Copy of License if Out-of-State)

□ No

2.b. GEORGIA LICENSED VETERINARIAN ?

□ Yes (Submit Copy of Current License to Practice Veterinary Medicine in the State of Georgia)

□ No

3. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	LECTURE/LABORATORY HOURS
RADIATION PHYSICS		
RADIATION PROTECTION		
MATHEMATICS AND INSTRUMENTATION PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		
RADIATION BIOLOGY - HUMANS AND ANIMALS		

4. EXPERIENCE WITH RADIATION

TYPE OF EXPERIENCE	PLACE OF EXPERIENCE	DURATION OF EXPERIENCE / NUMBER OF CASES

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
REQUEST TO TERMINATE RADIOACTIVE MATERIAL LICENSE

1. Licensee Name _____ 2. License Number _____

3. Address _____
Street No. City State Zip Code

4. Contact Person _____ 5. Telephone Number _____

6. Request is hereby made that the Radioactive Material License above be terminated for the following reason:
_____

_____

7. Radioactive Material possessed under this license has been disposed of as indicated below:

☐ No materials have been possessed or procured by the licensee under this licensee.

☐ All material was used for the licensed purposes; none remains.

☐ All material was leased, and has been returned to lessor.

Name of lessor _____ License Number _____

☐ Copy notice of receipt attached

☐ Material has been transferred to the following licensee:

Licensee Name _____ License Number _____
Address _____
Street Number City State Zip Code

Date of transfer: _____

☐ Copy of receipt attached

☐ Material has been disposed of in the following manner:
_____

_____

☐ A radiation survey was conducted to confirm the absence of radioactive material and to determine whether any contamination remains at the facility covered by the license.

☐ Copy of survey results attached.

6. Management Official or Radiation Safety Officer

_____ _____
Signature of certifying officer Date

_____ _____
Print name Title

Keep one copy for your records and send original to:

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
4220 INTERNATIONAL PARKWAY, SUITE 100
ATLANTA, GEORGIA 30354

Form 3

APPENDIX A

MODEL TRAINING PROGRAM

This Appendix describes information that you should know about developing a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to the Veterinary Licensing Guide, Revision 3."

Rule .07(3) specifies who should be given instruction and what minimum instruction is required. You may implement the model program outline below, or if you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of the rule. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1."

It may not be assumed that safety instruction has been adequately covered by prior occupational training, etc. Site-specific training should be provided for all workers. As a minimum, training shall be provided to authorized users and ancillary personnel. Training may be in the form of lectures, taped presentations, professional conferences, demonstrations, or any combination of these.

Ancillary personnel (e.g., handlers, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with or in the vicinity of radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by Rule .07(2).
10. Question and answer period.

APPENDIX B

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to the Veterinary Licensing Guide, Revision 3."

If you choose to have calibrations done by an outside contractor, you may say on you application, "We will have survey instruments calibrated by (list name of company) who holds Radioactive Materials License number (list license number)."

If your procedure does not follow the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features of the model and carefully review the requirements of Rule .05(7)(c). Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated before first use, annually, and following any repair that would affect the calibration (Battery changes are not considered "servicing").

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Calibration sources shall be certified to within five percent accuracy by the National Institute of Standards and Technology (NIST).

3. A source which has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for changes in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 20 percent.

8. Three kinds of scales are frequently used on survey meters:

    a. Meters with a linear scale must be calibrated at no less than two points on each scale. The points should be approximately 1/3 and 2/3 of full scale.

b. Meters with a multi decade logarithmic scale must be calibrated at least one point on each decade and at least two points on one of the decades. Those points should be approximately 1/3 and 2/3 of the decade.

c. Meters with automatic range digital display device for indicating rates must be calibrated at three points between 2 mrem and 1,000 mrem (0.02 mSv and 10 mSv).

9. The apparent exposure rate from a built-in or manufacturer supplied check source must be determined and recorded at the time of calibration.

10. Readings above 1,000 mR/hr need not be calibrated. However, these scales should be checked for operation and approximately correct response.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

a. The owner or user of the instrument;

b. Instrument description that includes the manufacturer, model number, serial number and type of detector;

c. Calibration source description that includes the exposure rate at a specific distance on a specific date, and the calibration procedure;

d. The calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument for each calibration point.

e. The "battery check" reading indicated (if available on the instrument);

f. The angle between the radiation flux field and the detector (For external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular". This indicates photons traveling either parallel with or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.);

g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

h. The apparent exposure rate of the check source; and

I. The name of the person who performed the calibration and the date on which the calibration was performed.

12. The following information shall be maintained for each instrument calibrated:

a. A description of the source used, and the certified dose rates from the source;

b. The rates indicated by the instrument being calibrated;

c. The correction factor deduced from the calibration data; and

d. The signature of the individual who performed the calibration, and the date of the calibration.

13. One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

14. On the following page is an example of a form that contains the required information needed for the Survey Meter Calibration Form and Calibration Sticker.

SURVEY METER CALIBRATION REPORT

Facility

Owner/User:
Department:

Instrument

Manufacturer:

Type: ( ) Ion Chamber ( ) GM ( ) NaI(Tl) ( ) Other, Describe:

Meter Model Number: _____ Serial Number:

Probe Model Number: _____ Serial Number:

Calibration Source: ___mCi of _____. ____mR/hr at ___inches on date:

Instrument Checks: Battery Check: ____mR/hr or

Constancy Check: ( ) integral check source indicates _____ mR/hr.

( ) mCi of _____ indicates _____ mR/hr.

Calibration Geometry:

Window: ( ) Open ( ) Closed ( ) Fixed

Calibration Data

Distance (feet)	Source mR/hr	As Found Scale Reading	Scale Reading	Correction Factor

Correction Factors:

CALIBRATION STICKER

Cal. date ____- ___- ___ with _____

window:_____
scale Corr. Fac. Bat:_____ mR/hr
_____ _____ Chk:_____mR/hr
_____ _____
_____ _____

APPENDIX C

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C in the Veterinary Licensing Guide, Revision 3."

If you develop your own dose calibrator procedure for review, you should carefully review Rule .05(7)(b) and all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

The dose calibrator must be checked for accurate operation at the time of installation and periodically after that. The manufacturer's recommendations and instructions or other nationally-recognized standards will be followed. The dose calibrator will be tested for constancy, accuracy, linearity, and geometry dependence according to Rule 391-3-17-.05(7)(b), titled "Possession, Use, Calibration, and Check of Dose Calibrators." Reference and calibration sources used will be traceable to the National Institute of Standards and Technology (NIST) according to Rule 391-3-17-.05(7)(b)6. Record-keeping requirements of these tests are described in Rule 391-3-17-.05(7)(b)5. As part of these requirements the Radiation Safety Officer will review and sign the records for the geometry dependence, linearity, and accuracy tests.

The following procedures will be used to test for constancy, linearity, accuracy and geometry dependence.

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerance.

    a. Constancy at least once each day prior to assay of patient dosages. A tolerance of $\pm$ 5% of the stated activity is recommended. This recommended tolerance is more restrictive than the regulation to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.

    b. Linearity at installation and at intervals not to exceed three months after that. Linearity error may not exceed $\pm$10% .

    c. Geometry dependence at installation and after repair. Geometry error may not exceed $\pm$10%.

    d. Accuracy at installation, and at least annually after that. Accuracy error may not exceed $\pm$10%.

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility by measuring a constant source over a long period. Assay at least one relatively long-lived source, such as Cs-137, Co-60, or Co-57, using a reproducible geometry each day before using the calibrator. The source must meet the requirements described in Rule 391-3-17-.05(7)(b)2.(i). Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

   a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

   b. Measure background at the same setting. Subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

   c. For each source used, record the readings for each setting, the background level and the net activity of each constancy source.

   d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Record the results.

   e. Establish an action level or tolerance for each recorded measurement to notify the user of a suspected malfunction of the calibrator. These action levels should be recorded or posted on the calibrator.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the dose calibrator is able to show the correct activity over the range of use of the calibrator. This test is done using a vial or syringe of Tc-99m whose activity is equal to the highest dosage that will be administered. Two different methods can measure linearity: (1) the Decay Method and (2) the Shield Method.

   Decay Method

   a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.

   b. Repeat the assay about every four hours until the end of the work-day. Continue the assay each day until the activity is below the lowest dose that you would use. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

   c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point furthest from the line, calculate the deviation from the value on the line.

$$[(A_o - A_l)/(A_l)]100 = \% \text{ Deviation}$$

Where:

A_o = Activity Observed
A_l = Activity Read from Line

f. If the worst deviation is more than 10 percent, the dose calibrator will be repaired or replaced.

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

You may decide to use a set of "sleeves" of various thicknesses to test for linearity. It will be necessary to establish the true linearity of the dose calibrator by using the decay method above before calibrating the "sleeves". The shield method uses devices sold under brand names such as Calichek or Lineator. You may use similar devices, when they have been accepted by the Department, an Agreement State or the U. S. Nuclear Regulatory Commission (NRC). If you use the shield method, you must follow the procedures provided by the manufacturer of the device.

6. Geometry Dependence means that the indicated activity does not change with volume or shape. Geometry dependence should be tested using a syringe that is normally used for injections. If generators and radiopharmaceutical kits are used, geometry dependence will be tested using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these sizes of vials and syringes, change the procedure to include the sizes commonly used.

Syringe Procedure

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated.

c. Remove the syringe from the calibrator, draw an additional 0.5cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is the volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume".

f. If any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, be sure to label the table or graph "syringe geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

Vial Procedure

a. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

b. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

c. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

d. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume".

e. If any correction factors are greater than 1.1 or less than 0.9 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity". If this is necessary, be sure to label the table or graph "vial geometry dependence", and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by NIST or equivalent. The activity of the calibrated reference sources will be within 5% of their stated activity. At least two sources with different principle photon energies (such as cobalt 57, cesium 137, cobalt 60) will be used. The sources will have a minimum activity of 50 microcuries. At least one reference source whose activity is within the range of activities normally assayed will be used.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

b. Average the three determinations. The average value should be within five percent of the certified activity of the reference source, mathematically corrected for decay.

c. Repeat the procedure for other calibrated reference sources.

d. If the average value does not agree, within five percent, with the certified value of the reference source, the dose calibrator needs to be removed from service for repair or adjustment.

e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

APPENDIX D

MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of Rule .03 and Rule .07(4). Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 9.4", and append your monitoring program.

MODEL PROGRAM

1. The Radiation Safety Officer (RSO) will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescence dosimeter (TLD), optically-stimulated luminescence device, or other approved device.

2 All individuals who are occupationally exposed, as defined in Rule .01(2)(ppp) and .03(8)(b), to radiation will be issued a film badge or TLD whole body monitor. The film badge or TLD will be processed monthly by a dosimetry processor who meets the requirements of Rule .03(8)(a)3.

3. All individuals who regularly handle radioactive material will be issued a film or TLD finger monitor that will be processed monthly by a dosimetry processor who meets the requirements of Rule .03(8)(a)3.

4. All individuals who are occupationally exposed to radiation on an occasional basis, such as handlers caring for animals undergoing radiopharmaceutical therapy, will be issued a whole body monitor when caring for such patients.

5. Other individuals who are occasionally exposed to radiation, such as security personnel who deliver packages and secretarial personnel who work in the nuclear medicine clinic but do not work with animals, will not normally be issued exposure monitors.

6. All individuals who have been issued a personnel monitoring device will be given a written annual report of their exposure as required by Rule .07(4).

APPENDIX E

MODEL PROCEDURE FOR CHECKING EQUIPMENT USED IN MOBILE NUCLEAR MEDICINE SERVICE

When delicate imaging equipment is transported from one location to another, it is reasonable to assume that it may suffer damage in transit. Therefore, mobile nuclear medicine services need an imaging equipment quality assurance program to ensure that the use of radioactive material will not be inimical to public health and safety. Such services should also check ventilation equipment if gases or aerosols will be used.

You may use the following procedures to ensure the proper operation of imaging equipment that has been transported. If you will follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix E to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model procedure and the procedures recommended by the manufacturer and carefully review the requirements of Rule .05(6)(j) and .05(7)(l). Say on your application, "We have developed a procedure for ensuring equipment performance for your review that is appended as ATT.9.5", and append your imaging equipment quality assurance procedure.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source for proper operation before each use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering radioactive material:

    a. Peak each camera according to the manufacturer's instructions.

    b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of the animal.

    c. Do not administer material until an authorized user approves the camera for use.

    d. You do not have to make a permanent record of these checks.

2. Perform the following checks weekly:

   a. With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH), or resolution-quadrant phantom with the flood field as a source.

   b. If a PLES or bar phantom is used, rotate it 90^{o} so that the camera is tested for both vertical and horizontal geometric linearity.

   c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

   d. Process the images as it they were images of the animal. Mark them clearly to indicate image orientation, source activity, and date.

   e. Retain the images for two years.

3. Perform the following safety checks after repairs and quarterly:

   a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

   b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch of the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for two years.

<u>Ventilation</u>

If gases or aerosols will be used, check the ventilation supply, exhaust vents, and collection devices for operation with tissue paper or a velometer. There is no need to keep a record of these checks.

APPENDIX F

RADIATION SAFETY OFFICER DUTIES AND DELEGATION OF AUTHORITY

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Officer Duties and Delegation of Authority that was published in Appendix F to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of Rule .05(6)(e) and (g). Say on your application, "We will issue the Radiation Safety Officer Duties and Delegation of Authority that are appended as ATT 10.1", and append your charter and delegation.

DUTIES

The Radiation Safety Officer Shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with Department Regulations and the veterinary radioactive materials license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigation levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

6. Be familiar with all pertinent Department Regulations, the license application, the license, and amendments;

7. Review the training and experience of the proposed authorized user to determine their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the Regulations and the license;

8. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the facility;

9. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassay, physical examinations of users, and special monitoring procedures;

10. Review quarterly the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

11. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., handlers, security, housekeeping,) are appropriately instructed as required in Rule .07(3);

12. Review at least annually the entire Radiation Protection Program to determine that all activities are being conducted safely, according to Department Regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of Department inspections, written safety procedures, and the adequacy of the management control system;

13. Review, at least annually, the ALARA/Radiation Protection Program in accordance with Rule 391-3-17-.03(4).

14. Recommend remedial action to correct any deficiencies identified in the Radiation Protection Program;

15. Ensure that the radioactive material license is amended prior to any changes in facilities, equipment, policies, procedures, and personnel.

MODEL DELEGATION OF AUTHORITY

M E M O R A N D U M
To: All Employees
From: Chief Executive Officer
Subject: Delegation of Authority

_____ has been appointed Radiation Safety Officer and is (or _____ and have been appointed as Radiation Safety Officers and are) responsible for ensuring the safe use of radiation. The Radiation Safety Officer(s) is(are) responsible for managing the Radiation Protection Program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer(s) is(are) hereby delegated the authority necessary to meet those responsibilities.

RADIATION SAFETY OFFICER CERTIFICATION

We certify that the individual(s) to be named on this license to perform the function of Radiation Safety Officer (RSO):

1. Has read and understands the Department Regulations applicable to this license and the specific conditions in the license,

2. Has sufficient technical knowledge to perform duties of the RSO;

3. Has and will continue to have sufficient time to perform the duties of the RSO;

4. Has and will continue to get sufficient resources to accomplish the tasks of the RSO;

5. Is completely willing to perform the functions of the RSO; and

6. Has and will continue to receive the support of the management of this licensee in ensuring that all licensed activities will be conducted according to Department regulations and the specific terms of the license.

RADIATION SAFETY OFFICER APPLICANT _____

AREAS OF RESPONSIBILITY, IF NOT ALL _____

SIGNATURE AND DATE SIGNED _____

RADIATION SAFETY OFFICER APPLICANT _____

AREAS OF RESPONSIBILITY, IF NOT ALL _____

SIGNATURE AND DATE SIGNED _____

CORPORATE OFFICER / CERTIFYING OFFICIAL _____

SIGNATURE AND DATE SIGNED _____

APPENDIX G

MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources. If you follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix G to the Veterinary Licensing Guide, Revision 3."

If you choose to have leak-testing done by an outside contractor, you may say on you application, "We will have leak-testing done by (list name of company) who holds Radioactive Materials License number (list license number)."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule .05(7)g. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.2," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

    b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

    c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor cross hairs. Also wipe the primary and secondary collimators and trimmers.

    d. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a rate meter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

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

   f. If any wipe samples activity is 0.005 microcurie or greater, notify the RSO. Follow the procedures required by Rule .05(7)(g)5.

   g. The leak test record will contain the information required in rule .05(7)(g)4.

APPENDIX H

MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix H of the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider including all the items in the model rules and carefully review the requirements of Rules .03 and .05. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review appended as ATT 10.3," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Always wear laboratory coats or other protective clothing in areas where radioactive materials are used.

2. Always wear disposable gloves while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area in a low background area with an appropriate survey instrument.

4. Always use syringe shields for routine preparation of patient doses and administration of doses to animals.

5. a. Always use vial shields when preparing or handling a vial that contains a radiopharmaceutical.

   b. Always store syringes that contain radioactive material in a radiation shield.

6. 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 in areas where radioactive material is used or stored.

7. a. Assay each animal dose in the dose calibrator before administration of a therapy dose. Do not use any doses that differ from the prescribed dose by more than 10 percent, except prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the animal's identity and the prescribed radionuclide, chemical form, and dosage before administration.

   b. For therapeutic doses, also check the animal's identity, the radionuclide, the chemical form, and the activity versus the order written by the veterinarian who will perform the procedure.

8. Always wear personnel monitoring devices (film badge, TLD, etc.) while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer (RSO). Personnel monitoring devices should be stored in a designated low background area when not being worn to monitor occupational exposures.

9. Wear TLD finger badges during the elution of generators and preparation, assay, and injection of radiopharmaceuticals and when holding patients during procedures.

10. Dispose of radioactive waste only in specially designated, labeled and properly shielded containers.

11. Never pipette by mouth.

12. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day with an appropriate survey instrument and probe (i.e., HP 260). If necessary, decontaminate or secure the area for decay as appropriate.

13. Wipe test radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

14. Confine radioactive solutions in covered containers that are clearly labeled. Multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation.

15. Always transport radioactive material in shielded containers.

16. Minimize imaging and handling time after patient is dosed through judicious use of immobilization (using restraints, stocks or tranquilization).

17. Restrict access to the animal after dosing, prior to and after imaging or therapy.

18. Identify the radioactive animal and its containment area through markers and tags.

19. Take safety precautions in case of animal urination (using diuretic prior to imaging or therapy).

APPENDIX I

MODEL SPILL CONTROL PROCEDURES

You may use the following model spill control procedures as they appear here, saying on your application, "We will establish and implement the model spill control procedures published in Appendix I to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own spill control procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application," We have developed spill control procedures for your review that are appended as ATT 10.4", and append your spill control procedures.

The decision to implement a major spill control procedure instead of a minor spill control procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill control procedure may be to restrict access pending complete decay. In the event all contamination has been removed except fixed contaminants, the area may be put back into use if the fixed contamination is less than 2 mR/hr at the surface.

FORMS

You may want to use, Radioactive Spill Report and Radioactive Spill Contamination Survey Forms on Pages I-3 and I-4 of this appendix.

SPILL KIT

You may also want to consider assembling a spill kit that contains:

- 6 pairs disposable (latex or butyl-nitrile) gloves, 1 pair housekeeping gloves
- 2 disposable lab coats
- 2 paper hats
- 2 pairs shoe covers
- 1 roll absorbent paper with plastic backing
- 6 plastic trash bags with twist ties
- 2 pair of remote handling tongs
- "Radioactive Material" labeling tape
- 1 china pencil or marking pen
- 3 pre-strung "Radioactive Material" labeling tags
- Supplies for 10 contamination wipe samples
- Instructions for "Emergency Procedures"
- Clipboard with one copy of Radioactive Spill Report Form
- Pencil

MODEL PROCEDURES

MINOR SPILLS OF LIQUIDS AND SOLIDS:

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves, remote handling tongs, and absorbent paper. Carefully fold the absorbent paper and pad with the clean side out. Place into a plastic bag and dispose of in the radioactive waste container. Also put all other contaminated, disposable materials into the bag.

4. Survey the area with a low range radiation detection survey meter with a thin end window. Check the area around the spill, hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the clean up of the spill and will complete the Radioactive Spill Report (page I-3) and the Radioactive Spill Contamination Survey (Page I-4).

MAJOR SPILLS OF LIQUIDS AND SOLIDS:

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. Limit the movement of all personnel potentially contaminated to prevent the spread of contamination.

3. Shield the source if possible. This should be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contaminant remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

RADIOACTIVE SPILL REPORT

The spill occurred at _____ am/pm on _____ in room _____.
(time) (date) (location)

Instrument used to check for personnel contamination:

Meter Model: _____ Meter S/N: _____ Probe Model: _____ Probe S/N: _____

PERSONNEL PRESENT	PERSONNEL CONTAMINATION RESULTS*

*On the back of the sheet, indicate any personnel decontamination, additional monitoring, or care instituted.

Survey the spill area to identify hot spots, then begin decontamination. When finished, conduct a post cleaning contamination wipe test.

RADIOISOTOPES PRESENT OR SUSPECTED IN THE SPILL

Millicuries	Isotope	Form

GIVE A BRIEF DESCRIPTION OF THE ACCIDENT:

GIVE A BRIEF DESCRIPTION OF FOLLOW UP ACTIONS TAKEN TO PREVENT RECURRENCE:

NAME_____ DATE_____

RADIOACTIVE SPILL CONTAMINATION SURVEY

The spill occurred at: _____ am/pm on _____ in room _____.
(time) (date) (location)

Decontamination completed at: _____ am/pm on _____.
(time) (date)

Location	Pre-clean	Post Clean		Location	Pre-clean	Post Clean	
	mR/hr	mR/hr	Dpm/100cm^2		mR/hr	mR/hr	dpm/100cm^2

dpm = cpm/instrument efficiency

SKETCH OF CONTAMINATED AREA:

NAME:_____

APPENDIX J

MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material published in Appendix J to the "Veterinary Licensing Guide, Revision 3".

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider including all of the features of the model. You must also meet the requirements of Rule .03(12)(f). Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review appended as ATT 10.5," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a person designated by the RSO must authorize each order for radioactive materials. The RSO must ensure that the license authorizes the requested materials and quantities for use by the requesting authorized user. The person ordering material will ensure that possession limits are not exceeded.

2. The Radiation Safety Officer will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:

    a. For ordering routinely-used materials

        (1) Written records which identify the authorized user or department, isotope, chemical form, activity, and supplier.

        (2) The above records will be checked to confirm that material received was ordered through proper channels.

    b. Ordering occasionally-used materials (i.e., therapeutic doses)

        (1) A written request will be obtained from the veterinarian who will perform the procedure. The request must show the isotope, radiopharmaceutical, activity and supplier.

        (2) Persons receiving the material will check the veterinarian's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages following the procedures outlined in the sample memorandum (found on the following page).

SAMPLE MEMORANDUM

M E M O R A N D U M

To: Chief of Security

From: Radiation Safety Officer

Subject: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of any packages containing radioactive material that arrive during other than normal working hours. Packages will be taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door and place the package on top of the counter. Close the door and re-lock it.

If the package is damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the facility until we determine that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum call our Radiation Safety Officer, (name)

	Name	Office Phone	Home Phone	Pager
Radiation Safety Officer:				

Nuclear Medicine Veterinarian on Call:

	Name	Office Phone	Home Phone	Pager

APPENDIX K

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

You may use the following procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to the Veterinary Licensing Guide, Revision 3."

If you develop your own package- opening procedure for review, you should consider for inclusion all the features of the model and the requirements of Rule .03(12)(f) and Rule .06(15)(h). Say on your application, "We have developed a package opening procedure for your review that is appended at ATT 10.6", and append your package opening procedure.

MODEL PROCEDURE

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity as defined in Rule .06(3)(n). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours according to Rule .03(12)(f)3. The licensee shall immediately notify the final delivery carrier and the Department by telephone, telegram, mailgram, or facsimile, when the removable radioactive surface contamination exceeds the limits of Rule .06(15)(h) or when the external radiation levels exceed the limits of Rule .06(15)(j)2. as required by Rule .03(12)(f)4.

2. For packages received under the specific license, the following procedures for opening each package will be followed:

    a. Put on gloves to prevent hand contamination.

    b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

    c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirems per hour, at 1 meter from the package surface. The surface dose rate for such packages should not exceed 200 millirems per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface.

    d. Open the package with the following precautionary steps:

        (1) Remove the packing slip.

        (2) Open the outer package following the supplier's instructions if provided.

        (3) Open the inner package and verify that the contents agree with the packing slip.

(4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. You should specify in the procedure manual which instruments should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. A dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in Rule .02(6)(g), the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage. If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure the material received is the material that was ordered.

APPENDIX L

MODEL PROCEDURE FOR RECORDS OF RADIOACTIVE MATERIAL USE

GENERAL

Many suppliers include pressure sensitive stickers or forms, or bar codes that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to enter whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures.

L.1. RECORDS OF UNIT DOSAGE USE

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix L.1 to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rule .03(14) and .05(7)(d). Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.7", and append your unit dosage record procedure.

See Page L-4 for a Unit Dosage Receipt and Use Log Form you may want to use.

MODEL PROCEDURE

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

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;

8. If administered,

    a. Prescribed dosage (unless already recorded in clinical procedure manual);

    b. Measured activity in millicuries or microcuries and date and time of measurement;

    c. Patient name and identification number if one has been assigned;

    d. Time of measurement;

9. If discarded, the date and method of disposal; and

10. Initials of the individual who made the record.

L.2 RECORDS OF MULTI-DOSE VIAL USE

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a multi-dose vial record system that was published in Appendix L.2 to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should carefully consider for inclusion all the features in the model system and carefully review the requirements of Rule .03(14) and .05(7)(d). Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.8", and append your unit dosage record procedure.

See Page L-5 for a Multi-dose Vial Preparation and Use Log Form you may want to use.

MODEL PROCEDURE

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml);

5. Supplier or kit manufacturer;

6. If administered,

    a. Prescribed dosage (unless already recorded in clinical procedure manual),

    b. Date and time dosage was drawn and measured,

    c. Calculated volume that is needed for the prescribed dosage,

d. Measured activity in millicuries or microcuries,

e. Patient name and identification number if one has been assigned;

7. If discarded, the date and method of disposal; and

8. Initials of the individual who made the record.

UNIT DOSAGE RECEIPT AND USE LOG

DATE DELIVERED	SUPPLIER	LOT	DOSAGE mCi	LABEL TIME	DATE DISPENSED	TIME	MEASURED mCi	ANIMAL / ID NUMBER	INITIALS

MULTI-DOSE VIAL PREPARATION AND USE LOG

DATE DELIVERED	TIME	GENERATOR RECEIVED	KIT SOURCE	KIT LOT	mCi/cc	cc	MEASURED mCi	ANIMAL / ID NUMBER	INITIALS

APPENDIX M

MODEL PROCEDURE FOR AREA SURVEYS

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix M to the Veterinary Licensing Guide, Revision 3".

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features of the model procedure and carefully review the requirements of Rule .05(7)(j). Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.9", and append your survey procedures.

A sample survey form is on Page M-3.

MODEL PROCEDURE

AMBIENT DOSE RATE SURVEYS

1. Survey Areas

    a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter, using a thin end window probe (or a probe sensitive enough to detect 2000 dpm/cm^2). If diagnostic administrations are occasionally made in an animal's private room and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

    b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

    c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

    d. In sealed source storage areas, survey quarterly with a radiation measurement survey meter.

    e. For c and d above, radiation surveys will be conducted to show that adequate steps have been taken to ensure radiation levels in unrestricted areas do not exceed the limits specified in Rule .03. This could be done by showing expected radiation levels in unrestricted areas next to the restricted areas. This survey is important if a radiation storage area is away from the main area of use and surrounded by an area occupied by non-radiation workers or members of the public.

2. Notify the Radiation Safety Officer (RSO) if you find unexpectedly high or low levels.

REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas

    a. In radiopharmaceutical elution, preparation, and administration areas, wipe daily for removable contamination. If diagnostic administrations are occasionally made in an animal's private room and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100cm^2 of removable contamination (200 dpm/100cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Notify the RSO if you find unexpectedly high or low levels.

RECORDS

1. Keep a record of dose rate and contamination survey results. This record will be kept for a minimum of three years (Rule .05(7)(j)8). It must include the following information:

a. The date, area surveyed, and equipment used.

b. The name or initials of the person who made the survey.

c. A drawing of the areas surveyed with contamination and dose rate action levels for each area as established by the RSO. (See Table M-1 below for guidance in establishing your action levels.)

d. Measured dose rates in mR/hr or contamination levels in dpm/100cm^2, as appropriate.

e. Actions taken in the case of excessive dose rates or contamination and FOLLOW-UP survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

TABLE M-1

RECOMMENDED ACTION LEVELS IN dpm/100 cm^2
FOR SURFACE CONTAMINATION BY RADIOPHARMACEUTICALS

	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
1. Unrestricted Areas	200	2,000
2. Restricted Areas, Protective Clothing Used Only in Restricted Areas, Skin	2,000	20,000

RADIATION SURVEY FOR THE MONTH OF _____, YEAR _____

MAKE A SKETCH OF THE AREAS TO BE SURVEYED BELOW. NUMBER THE AREAS TO BE SURVEYED AND MATCH THE SURVEY AREAS TO THE CHART BELOW:

	mR/hr at location													
DATE	1	2	3	4	5	6	7	8	9	10	11	12		INITIALS
TRIGGER LEVEL														

APPENDIX N

MODEL PROCEDURES FOR RADIATION SAFETY DURING IODINE THERAPY

You may use the following procedures for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure you may say on your application, "We will establish and implement the model procedure for radiation safety during iodine therapy over 30 millicuries that was published in Appendix N to the Veterinary Licensing Guide, Revision 3."

If you prefer, you may develop you own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rule .03(5), .05(7)(k), .05(12), and .07(3). Say on your application, "We have developed a procedure for radiation safety during therapeutic use of iodine for your review that is appended as ATT 10.10", and append your procedure.

"Radiation Safety Checklist for Iodine Therapy", Page N-3 may be helpful to you.

MODEL PROCEDURE

1. The animal's containment room will be as far away from the reception station and heavy traffic hallways as is consistent with good veterinary medical care. It will be an isolated room and should be without carpet.

2. Prepare the room for the procedure as follows:

a. Use leak-proof absorbent paper to cover large surfaces (the cages or stocks, and the floor around the cages or stocks) that are likely to be contaminated. Small items may be covered with absorbent paper or plastic bags

b. Prepare separate boxes for disposable waste and non-disposable contaminated items. Place a single large re-closable plastic bag in each box, or supply several small plastic bags.

c. Prepare a special collection container for the animal's urine and fecal wastes.

(1) Containers should be unbreakable and non-leaking.

(2) Litter boxes should be designed to prevent the litter from being scattered out of the box, to avoid room contamination.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by veterinary technicians and radiation safety personnel.

3. Inform the housekeeping staff that personnel should stay out of the room until otherwise notified.

4. Supply the handlers/technicians with film badges, TLDs, pocket ionization chambers, or other personnel monitoring devices.

5. Brief the veterinary technicians on radiation safety precautions. Use the sample form, "Animal Handler Instructions for Animals Treated with Iodine-131 (Page N-4), or your own instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the receptionist's station.

6. Brief the veterinary staff on radiation safety procedures for the dosage administration, prohibition of visitors, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Following administration of the dosage, measure the exposure rate in mR/hr at the animal's throat, at the sides of the cage or stock, at 1 meter from the cage or stock, at the employees' "safe line", and in the surrounding hallways and rooms (the rates in hallways and rooms must conform to requirements in Rule .03(5)(i)). Record this and any other necessary information on the veterinary technician's instructions form or the veterinary technician's dosimeter sign out form. Post the room with a "Caution - Radioactive Materials" sign.

9. For patients treated with liquid or capsules of I-131, within three (3) days after the dosage administration, measure the thyroid burden of all personnel who were present during the administration. Also consider a thyroid burden assay for animal-care personnel two (2) days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

10. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

11. Animals dosed with radioiodine must not be released before 72 hours after dosing, **and** not until radiation levels at one meter from the animal's throat are less than or equal to 0.5 mR/hour.

12. Before using the room for general occupancy, it must be decontaminated and released before admitting new animals.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter with an appropriate probe to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm^2.

    d. Inform the Housekeeping staff that cleaning restrictions are removed.

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY

PATIENT:_____ ROOM:_____ DATE:

PREPARATION:

___ Schedule an area private from non-treated animals and non-authorized personnel.

___ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.

___ Prepare labeled boxes for used linen, disposable waste, and non-disposable contaminated items.

___ Prepare urine and feces collection containers.

___ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.

___ Order disposable table service.

___ Notify housekeeping to not clean the room until further notice.

___ Brief the staff on radiation safety measures.

___ Supply the staff with personnel radiation dosimeters.

ADMINISTRATION:

___ Clear the room of unneeded personnel.

___ Administer the dosage.

___ Measure dose rates at the sides of the cage, 1 meter from the sides of the cage, and surrounding hallways and rooms.

___ Post the room with a "Caution-Radioactive Materials" sign.

FOLLOW-UP:

___ Measure the thyroid burden of all personnel who were present during the administration.

___ Pick up waste for decay-in-storage or decontamination.

___ Release the animal.

___ Decontaminate and survey the cage, area, and room. Remove the "Caution-Radioactive Materials" sign.

IN CASE OF EMERGENCY, OR IF YOU HAVE A QUESTION CALL:

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING VETERINARIAN			

ANIMAL HANDLER/TECHNICIAN INSTRUCTIONS FOR ANIMALS TREATED WITH IODINE-131

ANIMAL:_____ ID NUMBER _____ROOM:_____ DATE: _____

Attending:_____Phone:_____Pager: _____

Dose:_____mCi of _____as_____was administered at ____:___ am/pm

Signature:_____ Date: _____

RADIATION EXPOSURE RATES

Animal Orientation: Supine or Standing

UNRESTRICTED AREAS

DATE	TIME	ROOM (mR/hr)	ROOM (mR/hr)	DOOR (mR/hr)	OTHER (mR/hr)

RESTRICTED AREAS

DATE	TIME	CAGE-SIDE (mR/hr)	3' FROM CAGE (mR/hr)	DOOR (mR/hr)	OTHER (mR/hr)

INSTRUCTIONS

___ No visitors.

HANDLING RESTRICTIONS:

___ Animal restricted to area.

___ ____ Minutes each day per handler in the room.

ANIMAL CARE:

___ Wear disposable gloves. Wash your hands after caring for the patient.

___ Discard dressings, etc., in boxes in the room.

___ Collect urine and feces for authorized disposal.

___ Housekeeping personnel are <u>not</u> permitted in the room.

___ Only the Radiation Safety Officer (RSO) may release the area.

___ Wear your radiation monitor when caring for the animal. Leave it at a designated location at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO if additional monitors are needed.

IN CASE OF EMERGENCY, OR IF YOU HAVE A QUESTION CALL:

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING VETERINARIAN			

APPENDIX O

MODEL PROCEDURE FOR ANIMAL RELEASE AND OWNER SAFETY

The following general guidance and procedure may be used for releasing animal patients and ensuring owner safety after therapy. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures that were published in Appendix O to the Veterinary Licensing Guide, Revision 3", and ***submit only the methods and calculations which you will use to determine that the radiation levels at one meter from the animal's throat are less than or equal to 0.5 milliroentgen per hour.***

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of Rule .03(13), .03(14)(i), and .05(7)(n). Say on your application, "We have developed a procedure for patient-release and owner-safety for your review that is appended as ATT 10.11", and attach your procedure.

I OWNER COMPLIANCE

Before beginning therapy treatment on an animal, the following will be used to ensure that its owner will comply with all instructions for the animal's care:

(1) An authorized user will give the owner a copy of the care instructions that will be explained to the owner, who will then sign it. A copy will be made of this form with the owner's signature, and will be kept on file with the animal's records.

(2) The owner will explain the housing arrangements for the animal, including how it will be kept from escaping.

(3) The owner will explain who will have access to the animal, giving the ages of those individuals and stating whether or not they are pregnant or nursing.

(4) A record will be made of all of the above information, and kept on file with the animal's records.

(5) If the authorized user feels that the owner will not comply, information furnished is false, or the animal poses a radiological danger to any individual, the procedure will not be performed.

II RELEASE PROCEDURES

(1) It has been determined that the owner will follow all instructions for the animal's care, and that no danger is posed to members of the public from the release of the animal from this veterinary institution. The owner has a written copy of the care instructions, and a signed copy of them is on file with the animal's treatment records.

(2) The animal has been held for 72 hours after the dosing.

(3) The radiation level at one meter from the animal's throat is measured to be less than or equal to 0.5 milliroentgen per hour.

III ANIMAL CARE INSTRUCTIONS

Your pet has been given radioiodine (I-131) for the treatment of hyperthyroidism. The pet has been isolated while most of the radioiodine has been excreted from his body. A level of radioiodine still exists in your pet, but this level is below that which the State of Georgia considers necessary for complete isolation from humans. However, because some radioactivity will be present in your pet for the next few weeks, it is REQUIRED that you abide by the following precautions.

FOR THE NEXT TWO WEEKS, YOU MUST:

(1) NOT hold the pet, NOT allow the pet to sit on your lap or next to you, NOT allow the pet to sleep in the room with you.

(2) Provide a letter pan for the pet's urination and defecation. Use only disposable litter and flush the urine and feces if your pet was released to you less than 5 days after being dosed. Otherwise, you may dispose of the litter daily in an outside receptacle. Wear disposable rubber gloves when handling the litter, and dispose of the gloves daily and in the outside receptacle, as well. Hold the receptacle for an additional 2 weeks before disposing of its contents as regular trash.

(3) ALWAYS wash your hands immediately after contact with your pet or your pet's litter.

(4) Confine the pet in the home at all times.

(5) Keep the pet from all food preparation areas.

(6) NOT allow any person under 18 years of age any contact with your pet.

(7) NOT allow any pregnant female any contact with your pet.

(8) If you have any questions, please immediately call this office at: _____ (telephone number).

NOTE

Radiation exposure has been found to increase the likelihood of cancer in many studies of adult human and animal groups. At doses below the limit allowed for persons whose occupations involve using radioactive materials - 5,000 millirems per year - an increase in cancer incidence has not been proven, but is presumed by some health physicists to exist even if it is too small to be measured.

I understand and consent to abide by all of the above instructions.

_____ (Signature of Pet Owner) _____ (Date)

_____ (Signature of Authorized User) _____ (Date)

APPENDIX P

MODEL PROCEDURE FOR WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix P to the Veterinary Licensing Guide, Revision 3".

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of Rule .03(13), .03(14)(i), and 05(7)(n). Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11", and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a licensed burial site or back to the manufacturer; and release to in-house waste. With the exception of generally-licensed in-vitro kit exemptions (See Rule .02(6)(g)6.), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See Rules .03(14)(i) and .05(7)(n)).

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal as in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Animal carcasses, urine, feces, and objects contaminated with such are also radioactive wastes and must be handled and disposed of accordingly.

3. Remind employees that non-radioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

4. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

5. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in Rule .03(13)(c). Material must be readily soluble or dispersible in water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Rule .03, Table II of Appendix B of 10 CFR 20.10001 - 20.2401. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (Rule .03(13)(e)). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 120 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs or gauze in another, and unused dosages in a third container. Small departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

    a. Check your radiation detection survey meter for proper operation;

    b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

    c. Remove any shielding from around the container;

    d. Monitor all surfaces of each individual container;

    e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g. paraphernalia, unused dosages). Check to be sure no radiation labels are visible.

    f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial).

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS, solids must be transferred to a licensed burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in-vitro kits that are generally licensed pursuant to Rule .02(6)(g) is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

APPENDIX Q

RECOMMENDED SUPPORT EQUIPMENT AND SERVICES

This list is not all-inclusive, nor is every item required for every program. Descriptions of some of the items are at the end of the list.

.05(8) FOR UPTAKE, DILUTION, AND EXCRETION STUDIES

1. Portable radiation detection survey meter
2. Dose calibrator
3. Constancy check source
4. Sealed sources for dose calibrator accuracy test
5. Constancy check source for uptake, dilution, and excretion equipment
6. Syringe shield
7. Vial shield
8. Personnel shield
9. Leak-test service for sealed sources
10. Survey meter calibration service

.05(9) FOR IMAGING AND LOCALIZATION STUDIES

1. Portable radiation detection survey meter
2. Portable radiation measurement survey meter
3. Dose calibrator
4. Constancy check
5. Sealed sources for dose calibrator accuracy test
6. Syringe shield
7. Hot lab area monitor
8. Lead L-block
9. Vial shield
10. Personnel shield
11. Survey meter calibration service
12. Personnel monitoring service
13. Leak-test service for sealed sources
14. Gamma camera

.05(12) FOR RADIOPHARMACEUTICAL THERAPY

1. Portable radiation detection survey meter
2. Portable radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Syringe shield
7. Fume hood
8. Vial shields
9. Personnel shields
10. Hot lab area monitor
11. Lead L-block
12. Leak-test service for sealed sources
13. Personnel monitoring service
14. Survey meter calibration service

DESCRIPTIONS

1. A **radiation detection survey meter** usually has a GM tube or NaI(Tl) crystal detector. The scale may be labeled in cpm or mR/hr. It is useful for detecting microcurie amounts of radioactivity and indicating approximate exposure levels. If it is calibrated in mR/hr, the most sensitive scale will probably have a full-scale deflection between 0.1 and 1.0 mR/hr. It can be used for measuring small amounts of radioactivity if the user has measured its detection efficiency (cpm $\rightarrow$ dpm) for the radionuclide being measured.

2. A **radiation measurement survey meter** can actually measure mR/hr. The detector is an ionization chamber, which is usually much larger than a GM tube. The scale is labeled in mR/hr, and the most sensitive scale will usually have a full-scale deflection between 1 and 10 mR/hr.

3. A **dose calibrator** uses an ionization chamber or a GM detector to determine the amount of radiation given off by a syringe or vial containing radioactive material. The logic system within the calibrator can then calculate the amount of radioactivity in the sample. Most dose calibrators have a digital display with either a "select range" switch or an automatic range-switching circuit. The final display is in microcuries, millicuries, or curies. A dose calibrator can measure over a range of a few microcuries to a few curies. It is not sensitive enough to measure contamination wipe samples.

4. A **constancy check source** is a sealed source with the date of manufacture, the radioisotope, and the approximate activity noted.

5. A **dedicated check source** is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The same ("dedicated") source must be used every day so that the user knows what reading to expect from the instrument, in order to know if the instrument is responding properly. The source may also be used for other purposes.

6. The **sealed sources for dose calibrator accuracy** are also sealed sources with the date of manufacture and the radioisotope noted. However, the activity must be certified to within +/- 5 percent by the manufacturer. These sources do not need to be on hand if the dose calibrator accuracy test is done by a contract service.

7. The **leak-test service** may be done in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually, a well-type NaI(Tl) crystal with a ratemeter is necessary to assay gamma-emitting leak-test wipes.

8. A **hot lab area monitor** usually has a GM detector, and the scale may be labeled in cpm or mR/hr. It should be sufficiently sensitive to detect an unshielded patient dose left lying unshielded anywhere in the hot lab.

9. **Personnel shields** are used to shield workers from radioactive animals. They may be mobile upright shields in the nuclear medicine clinic or in an animal's area when a technician or nurse must stay beside an animal, or they may be lead sheets used to shield transporters from animals on transport carts.

APPENDIX R

TRAINING REQUIRED FOR AUTHORIZED USERS AND RADIATION SAFETY OFFICERS

The following training must have been obtained within the seven years preceding the date of the application to be an authorized user or a Radiation Safety Officer (RSO), or the individual must have had related continuing education and experience since the required training and experience was completed.

DIAGNOSTIC RADIOACTIVE MATERIALS

A. Training for Authorized Users

To be an authorized user, a veterinarian must have a license from the State of Georgia to practice veterinary medicine, AND EITHER:

(1) Be an authorized user for the veterinary diagnostic use of radioactive material under a Department, Agreement State, or U. S. Nuclear Regulatory Commission (NRC) license;

OR

(2) Be certified in Radiology or Radiation Oncology by the American College of Veterinary Radiology;

OR

(3) (a) Have completed a 40-hour radiation safety course that included:
- (i) Radiation protection,
- (ii) Mathematics and instrumentation pertaining to the use and measurement of radioactivity, and
- (iii) Radiation biology pertaining to both humans and animals; AND

(b) Have worked with an authorized user, who meets the requirements of A, in the hands-on treatment and follow-up of 20 cases involving the diagnostic use of radioactive materials. In those 20 cases, the training must include the diagnosis, the administration of the radioactive material, and the disposal of the radioactive waste materials.

B. Training for RSO

To be an RSO, an individual must:

(1) Be an authorized user for the veterinary diagnostic use of radioactive material under a Department, Agreement State, or NRC license;

OR

(2) Be certified in Radiology or Radiation Oncology by the American College of Veterinary Radiology;

OR

(3) Have completed a 40-hour radiation safety course that included:
   (i) Radiation protection,
   (ii) Mathematics and instrumentation pertaining to the use and measurement of radioactivity, and
   (iii) Radiation biology pertaining to both humans and animals.

I-131 RADIOPHARMACEUTICAL THERAPY FOR FELINES

A. Training for Authorized Users

To be an authorized user, a veterinarian must have a license from the State of Georgia to practice veterinary medicine, AND EITHER:

(1) Be an authorized user for the therapeutical use of I-131 for felines under a Department, Agreement State, or NRC license;

OR

(2) Be certified in Radiology or Radiation Oncology by the American College of Veterinary Radiology;

OR

(3) (a) Have completed a 40-hour radiation safety course that included:
   (i) Radiation physics,
   (i) Radiation protection,
   (ii) Mathematics and instrumentation pertaining to the use and measurement of radioactivity and I-131 administration, and
   (iii) radiation biology pertaining to both humans and animals; AND

(b) Have worked with an authorized user, who meets the requirements of A, in the hands-on treatment and follow-up of 20 I-131 feline radiopharmaceutical therapy cases. In those cases, the training must include the diagnosis, the administration of the I-131, and the disposal of the radioactive waste materials.

B. Training for RSO

To be an RSO, an individual must:

(1) Be an authorized user for the therapeutical use of I-131 for felines under a Department, Agreement State, or NRC license;

OR

(2) Be certified in Radiology or Radiation Oncology by the American College of Veterinary Radiology;

OR

(3) (a) Have completed a 40-hour radiation safety course that included:
(i) Radiation physics,
(ii) Radiation protection,
(iii) Mathematics and instrumentation pertaining to the use and measurement of radioactivity and I-131 administration, and
(iv) radiation biology pertaining to both humans and animals; AND

(b) Have worked with an authorized user, who meets the requirements of A, in the treatment of 2 I-131 feline radiopharmaceutical therapy cases. In those cases the training must include the oversight and observance of the administration of I-131 and of the disposal of the radioactive waste materials.

APPENDIX S

TRAINING REQUIRED FOR THERAPY NUCLEAR MEDICINE TECHNOLOGISTS

Nuclear medicine technologists using therapeutic doses of unsealed radioactive materials under the supervision of an authorized user must EITHER:

(1) Be certified in Nuclear Medicine by the Nuclear Medicine Technology Certification Board, or in Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine

OR

(2) Be board-eligible to take the CNMT or ARRT(N) examination

OR

(3) Have successfully completed a training program in nuclear medicine that has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution

OR

(4) Have performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing

OR

(5) (a) Have completed a 40-hour radiation safety course that included:
- (i) Radiation physics,
- (i) Radiation protection,
- (ii) Mathematics and instrumentation pertaining to the use and measurement of radioactivity and I-131 administration, and
- (iii) radiation biology pertaining to both humans and animals; AND

(b) Have work experience, under the supervision of an authorized user who meets the requirements of A, in the hands-on treatment of I-131 feline radiopharmaceutical therapy cases. In those cases, the experience must include:
- (i) Ordering, receiving, and unpacking safely the radioactive material and performing the related radiation surveys;
- (ii) Quality control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey instruments;
- (iii) Calculating, measuring, and safely preparing doses;
- (iv) Using administrative controls to insure that the use of radioactive material is in accordance with the authorized user's directions and the licensee's procedures;
- (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- (vi) Administering the doses to the animals;
- (vii) Caring for the animal safely after dosing;
- (viii) Disposing safely of radioactive waste materials, including the animals' excreta; AND

(c) Have completed the licensee's training program specified in Item 8 of this guide.