RADIOACTIVE MATERIALS PROGRAM

VETERINARY LICENSING GUIDE

REVISION 4

State of Georgia Radioactive Materials Program
Dept. Of Natural Resources 4244 International Parkway
Environmental Protection Division. Atlanta, GA 30354

Date: 10/2020 Telephone (404) 362-2675

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PART 1

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.

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 391-3-1702	Licensing of Radioactive Materials. Amended.					
Rule 391-3-1703	Standards for Protection Against Radiation. Amended.					
Rule 391-3-1705	Use of Radionuclides in the Healing Arts. Amended.					
Rule 391-3-1706	Transportation of Radioactive Material. Amended.					
Rule 391-3-1707	Notices, Instructions and Reports to Workers; Inspections. Amended.					
Rule 391-3-1710	Administration					
Rule 391-3-1711	Enforcements					

Official copies of our Rules can be obtained from Secretary of State website: http://rules.sos.ga.gov/gac/391-3-17. An unofficial pdf of the rule book can be found at: https://epd.georgia.gov/documents/radioactive-materials-rulebook-effective-02-17-2019.

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 SPECIFIC LICENSE

1.4.1 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(9). 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 $8-1/2 \times 11$ inch paper to ease handling and review. If larger drawings are necessary, fold them to $8-1/2 \times 11$ 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. 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.

Submitting trade secrets, proprietary information, or personnel information that you want withheld from public disclosure 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. 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

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

or changed, submit an application for an amendment. <u>Meanwhile, you must comply with the terms and conditions of your license until it is actually amended.</u> 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 or in a letter. 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(10(a) through (h). Contrary to how Rule .05(10)(b) is read, a license amendment <u>is</u> required prior to permitting qualified individuals to work as authorized users under a veterinary-use license.

Notifications listed under Rule .05(11) will be handled as an amendment to the license and/or as a tiedown in the license.

4. 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 12 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.

5. TERMINATION OF A LICENSE

You may request termination of your license at any time. In accordance with .05(18)(d) 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.

PART 2

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 or (404) 363-7000.

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.

Note: Our office must be notified <u>and the transfer approved</u> before control of the license is transferred. See Transfer of Ownership or Control of Licensed Activities Guide on our website. Our office must also be notified when bankruptcy proceedings have been initiated.

ITEM 3 LOCATIONS OF USE

You should specify each location of use by the street address, city, and county 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. In items 5 through 11 of the application, describe the intended use and the facilities and equipment at each location.

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	CHEMICAL/PHYSICAL FORM	AMOUNT	PURPOSE
5.a. I-131	Liquid/capsule	X mCi maximum (should not exceed more than 900 mCi). No single source to exceed X mCi	In the practice of veterinary medicine only for the treatment of hyperthyroidism in cats
Any radioactive material permitted by (41) of Rule 391-3-1705	Any form: Any radiopharmaceutical permitted by (41) of Rule 391-3-1705	As Needed	Uptake, dilution, or excretion studies as permitted by (41) of Rule 391-3-1705 for veterinary use
Any radioactive material permitted by (44) of Rule 391-3-1705(including PET and excluding generators and gases.)Edit inclusion & exclusion statement to fit licensee's needs	Any form: Any radiopharmaceutical permitted by (44) of Rule 391-3-1705	As needed	Imaging and localization studies as permitted by (44(of Rule 391-3-1705

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, security and storage procedures.

If you will be utilizing a mobile medical service, or a PET mobile, you must indicate this in your application and In your diagram in item 9.1, indicate where the mobile will be stationed by your building,

<u>ITEM 7</u> <u>INDIVIDUALS RESPONSIBLE FOR RADIATION PROTECTION PROGRAM</u>

"Responsible individuals" are the authorized users and the Radiation Safety Officer (RSO). Rule .05(10) requires that 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. Rule .05 was designed for medical practice with humans; the Department will consider individuals qualified if they meet the following criteria in Appendix R.

Note: Do not submit a Curricula vitae (CV) CV's do not supply all the information needed to evaluate an individual's training and experience.

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 above 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.
- 4. Documentation for training and experience must have been obtained within 7 years preceding the date of the application.

7.2 RADIATION SAFETY OFFICER (RSO)

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.

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. 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

Appendix A covers Guidance for Laboratory Animal and Veterinary Medicine Uses. This section discusses additional information on the use of materials in laboratory animals, in animals used for research in the environment, and by veterinarians. Incorporate these handling practices in your training procedures, written procedures and to the animal caretakers.

Your responses to these items should consist of one statement either that you will follow the model procedure in **Appendix B through S** in the Veterinary Licensing Guide Revision 4 or that you have enclosed your procedure for review, or simply the initials "NA" for "not applicable". Before you respond to an item, read the introductory paragraphs of that referenced appendix. Responses should be appended as attachments.

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. **Refer to Appendix A and B.**

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, storage, radioactive-waste storage, 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).
- 4. Security of radioactive materials.
- 5. Identify on the drawing the areas where routine wipes will be taken.
- 6. Isolation kennels housing cats administered with radioactive material should have hand and feet monitors at exits.

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. **Refer to Appendix C**.

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 or capsule form from a radiopharmacy. **Refer to Appendix D.**

9.4 PERSONNEL MONITORING PROGRAM

Describe your monitoring program for occupationally-exposed personnel and attach it as ATT 9.4. 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

<u>likely</u> 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 <u>likely</u> 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 <u>not likely</u> 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). **Refer to Appendix E**.

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. **Refer to Appendix F**.

10.2 LEAK-TEST

Submit a copy of your rules/procedures for leak-testing and attach it as ATT 10.2. **Refer to 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. **Refer to Appendix H**.

10.4 SPILL CONTROL PROCEDURES

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

10.5 ORDERING AND RECEIVING DOSES

Submit a copy of your ordering and receiving procedures and attach it as ATT 10.5. **Refer to Appendix J.**

10.6 OPENING PACKAGES

Submit a copy of your opening packages procedures and attach it as ATT 10.6. **Refer to Appendix K.**

10.7 UNIT and MULTI - DOSE RECORDS

Submit a copy of your unit and multi -dose record procedures and attach it as ATT 10.7. **Refer to Appendix L.**

10.8 AREA SURVEY PROCEDURES

Submit your area survey procedures and attach it as ATT 10.8. Refer to Appendix M.

10.9 RADIOPHARMACEUTICAL THERAPY (I-131)

Submit your procedure for radiation safety during radiopharmaceutical therapy and attach it as ATT 10.9. **Refer to 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.

10.10 ANIMAL RELEASE AND OWNER SAFETY PROCEDURES

Submit all safety procedures for the release of the animals to their owners. Append them as ATT 10.10. **Refer to 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</u> animal.
- 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.

10.11 SEALED SOURCE INVENTORY

In accordance to .05(33)(d), licensee must conduct a semi-annual physical inventory of all sealed sources in its possession.

ITEM 11 WASTE DISPOSAL

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

ITEM 12 LICENSE FEES

The applicant should contact the Department or go to https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or <a href="https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or https://epd.georgia.gov/documents/fee-table-radioactive-materials-licenses-revised-june-2019 or https://epd.georgia.gov/GAC/391-3-1710 or https://epd.georgia.gov/GAC/391-3-1710 or https://epd.georgia.gov/GAC/391-3-1710 or https://epd.gov/GAC/39

Checks for the fees should be made payable to the <u>Department of Natural Resources</u>, <u>Radioactive Materials Program</u>, 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:

Georgia Department of Natural Resources
Radioactive Materials Program
4244 International Parkway
Atlanta Tradeport, Suite 120
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.

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. Refer to the Guide for your applicable modality for detailed explanations pertaining to your application. 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, 4244 International Parkway, Suite 120, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Once a New License is issued a Prorated Annual Fees invoice will be invoiced the following quarter. 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.

orgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17	·-	
1.This is an Application for: (Check appropriate item) A. New License	B. Amendment to License C. Renewal of If B or C, Please indicate current GA. License N	
2.a. Name and Mailing Address of Applicant Name: Address: City, State, Zip Code: County: Telephone Number: () - E-mail address:	A. Permanent (list main here, include additional on S B. Additional Temporary sites throughout Georgia? (Include addresses, if known, on Supplemental S)	Supplemental Sheet) Yes
3.a Person to Contact Regarding this Application Name: Title: Telephone Number: () - Email:	3. c. Annual Fee contact and billing address (if different from Name: Address: City, State, Zip Code: Telephone Number: () - E-mail address:	rom Item 2.a.)
3.b Radiation Safety Officer: Telephone Number () - Email:	Locations where records will be kept: (note: records should be accessible at all locations of use)	
SUBMIT ITEMS 5 THROUGH 11 ON SUPPLEMENTAL SHEE SEE THE APROPRIATE LICENSE APPLICATION GUIDE		
5. RADIOACTIVE MATERIAL (see attached SUPPLEMENTAL SHEET) 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 (list on SUPPLEMENTAL SHE	
7. INDIVIDUAL(S) RESONSIBLE FOR RADIATION PROTECTION PROGRAM AND THEIR TRAINING & EXPERIENCE (if different or in addition to RSO listed in 3.b)	8. TRAINING FOR INDIVIDUALS WORKING IN OR RESTRICTED AREAS (ATTACH TO APPLICATIO No response required for medical licen	N)
9. FACILITIES AND EQUIPMENT Please include a brief business description of licensed locations. (list on SUPPLEMENTAL SHEET) Does the applicant possess any Radioactive Material Licenses from other states or the NRC? YES \(\sqrt{YES} \sqrt{\sqrt{NO}} \sqrt{\sqrt{NO}} \sqrt{\sqrt{SIS}} \) If so, please list on the SUPPLEMENTAL SHEET	10. RADIATION PROTECTION PROGRAM (ATTACH TO APPLICATIO	N)
11. WASTE MANAGEMENT and OFFSITE TRANSFER of RADIOACTIVE MATERIAL (ATTACH TO APPLICATION)	12. LICENSEE FEES (SEE DEPARTMENT'S FEE SO FEE CATEGORY: AMOUNT: \$	CHEDULE)
MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM	MAIL FEES TO: RADIOACTIVE MATERI P.O. BOX 101161 ATLAN	
13. CERTIFICATION (Must be completed by the applicant) THE APPLIC MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICATION ARE BINDING UPON THE APPLICATION THE APPLICATION AND ANY OFFICIAL EXECUTING THIS CERTITHIS APPLICATION IS PREPARED IN CONFORMITY WITH GEODESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATIC HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOW	CANT. IFICATE ON BEHALF OF THE APPLICANT NAMED IN IRGIA DEPARTMENT OF NATURAL RESOURCES RUL DN CONTAINED HEREIN, INCLUDING ANY SUPPLEM	ITEM 1, CERTIFY THAT ES AND REGULATIONS,
CERTIFYING OFFICER TYPED PRINTED NAME AND TITLE (Must be Senior Management Level for New Applications and Renewals)	SIGNATURE	DATE
		Form Povision June 2010

Georgia Department of Natural Resources

Environmental Protection Division Radioactive Materials Program

APPLICATION SUPPLEMENTAL SHEET

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

A. Permanent:

	B. Temporary Site Addresses (if known):									
5.	RADIOACTI	VE M	ATERIAL 6	& 6.	PURPOSE O	F USE	E			
	a. Element and mass number		emical and/or cal form		c. Maximum an be possessed at			6. Purpose	for which eleme	ent will be used
	FACILITIES A									
Br	rief business descr	iption (of licensed loc	ation	IS.					
_					1					
Ka	adioactive Materia	I Licen	b. License		es or the NRC: xpiration date		a. Jurisdic	tion	b. License	c. expiration date
	(State name or N	IRC)	number	С. е.	xpiration date			ne or NRC)	number	c. expiration date
							_			

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

icens	see Name		2.	License Number
Addre	ss Street No.	City	State	Zip Code
^onta	ct Person	•	5.	Telephone Number
	est is hereby made that the Radioactive			•
	<u> </u>			
Radio	active Material possessed under this lic	ense has been disp	osed of as indicate	ed below:
	No materials have been possessed of	or procured by the lic	ensee under this li	icensee.
	All material was used for the licensed	d purposes; none rei	mains.	
	All material was leased, and has bee	n returned to lessor.		
	Name of lessor		License Numbe	er
	Copy notice of receipt attached			
	Material has been transferred to the	following licensee:		
	Licensee Name		License Numbe	er
	AddressStreet 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 contamination remains at the facility			naterial and to determine
	Copy of survey results attached.			
Mana	gement Official or Radiation Safety Offi	cer		
	Signature of certifying officer			Date
	Print name			Title

Keep one copy for your records and send original to:

GEORGIA DEPT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM 4224 INTERNATIONAL PKWY, STE 120 ATLANTA, GEORGIA 30354

APPENDIX A

Guidance for Laboratory Animal and Veterinary Medicine Uses

This appendix provides additional information on the use of byproduct materials in laboratory animals, in animals used for research in the environment, and by veterinarians.

Applicants should note that authorization from the U.S. Nuclear Regulatory Commission (NRC) to use licensed material in animal studies does not relieve them of their responsibilities to comply with any other applicable Federal, State, or local regulatory

Use of Licensed Materials in Animals for Research

Many animal studies are performed with radioactive materials used as tracers in pharmaceutical research, metabolism studies, and other areas of scientific research. Many tracer studies use low-energy beta-emitters such as tritium or carbon-14, but pharmaceutical studies may be performed with gamma-emitters, such as technetium-99m, fluorine-18, and other radioactive materials typically found in nuclear medicine. In addition to the typical laboratory animals, such as mice, rats, and rabbits, animal use may involve insects, fish, birds, or large animals, such as dogs, pigs, or cows. Licensed materials typically are administered to animals by injection, but other methods may be used. The type, form, and quantity of licensed material used in the study, and the types of animals in which they will be used, will determine which radiation safety procedures will be implemented. If a researcher wants to use radioactive material as a tracer or as part of a field study involving the release of the animals into the environment, the researcher may be required to perform an assessment of the effect the byproduct material will have on the environment. See Section 8.6, "Purpose(s) for Which Licensed Material Will Be Used."

Use of Licensed Materials in Veterinary Treatment for Diagnosis or Therapy

The use of licensed materials in animals for diagnosis and therapy is similar in many ways to medical use of licensed materials in humans. The most common veterinary uses of licensed material in animals are the administration of iodine-131 for therapeutic treatment of cats and the administration of technetium-99m for diagnostic studies in horses. Although 391-3-.17(05) establishes the requirements and provisions for the medical use of byproduct material for humans, the regulations in.05 are not applicable to veterinary use of licensed materials. However, many veterinary applicants use safety equipment and procedures similar to those used in treating patients under.05. Also, many veterinarians obtain radioactive compounds, radiopharmaceuticals, or sealed sources for diagnosis and therapy of animals from the same suppliers as do medical facilities licensed under .05.

The applicant should describe how licensed materials will be obtained, such as in unit doses from a radiopharmacy. The requirements for training veterinary staff, and the procedures for contamination control and waste disposal for diagnosis and therapy, are the same as for laboratory use in research studies on animals. Note that veterinary treatment of animals must be performed under the direction of a licensed veterinarian, in accordance with State regulations, so that the applicant should include at least one veterinarian in its list of proposed Authorized Users (AUs). Most animals that veterinarians treat are pets that will be returned to their owners, and special care must be taken to ensure that doses to the owners, who are members of the public, will be as low as is reasonably achievable (ALARA). Therefore, the veterinary facility must also provide instructions to the pet owner on the care and handling of the animal when it is released.

Training for Staff Using Radionuclides in Animals

Before allowing an individual to care for animals that are used in studies or treated with licensed material, the radiation safety officer or AU must ensure that he or she has sufficient training and experience to, among other things, maintain doses ALARA, control contamination, and handle waste appropriately. AUs may be, for example, veterinarians, researchers, other laboratory staff, and animal handlers. **Refer to Appendix B.**

Contamination Control

To minimize the spread of contamination, the animals administered licensed material should be housed in cages or stalls separate from other animals. The facilities, stalls, or cages should be secured to prevent unauthorized access to the animals. Animal housing should be clearly posted or labeled so that caretakers know which animals have been involved in radioactive material studies. Care should be taken when posting/labeling cages to ensure that the posting or labeling does not become an ingestion or choking hazard to the animal. Individuals caring for these animals should reduce the chance of personal contamination by wearing gloves, lab coat, eye protection, or other protective clothing, as appropriate.

Special care should be observed when cleaning a cage or stall that may contain radioactive material in the bedding and waste (excreta) from the animal. Any radioactive material should be properly disposed of as described in Item 11, Appendix P.

The use of some compounds in animals may require special procedures, equipment, or facilities. For example, carbon-14 labeled compounds used in animals may be eliminated as carbon dioxide in the animals' breath, and the animals may need to be contained in a facility with special ventilation and air-handling capabilities. Studies of fish with licensed materials may require separate water handling and testing. Special precautions also may be needed for handling of animals and performing surveys if alpha-emitting radionuclides are used.

Waste Handling

Disposal of animal carcasses that contain radioactive material may require special procedures. Animal carcasses that contain less than 1.85 kilobecquerels [0.05 microcuries] of carbon-14 or hydrogen-3 per gram of animal tissue, averaged over the weight of the entire animal, may be disposed of by the same method as nonradioactive animal carcasses. Animal carcasses that contain byproduct material with a half-life of less than 120 days may be allowed to decay-in- storage (DIS). The DIS animal carcasses may be disposed of as nonradioactive, if radiation surveys (performed with an appropriate radiation survey instrument, in a low background area, and without any interposed shielding) of the carcasses at the end of the holding period indicate that radiation levels are indistinguishable from background. Animal carcasses containing other long-lived radioactive materials must be disposed of as radioactive waste.

Disposal of contaminated items such as animal bedding, syringes, protective gloves, booties, and paper coverings may be by DIS if the licensed materials have half-lives of 120 days or less, or by transfer to a licensed waste broker for long-lived radioactive materials. Some wastes may be suitable for disposal to the sanitary sewer, such as animal excreta, which is readily dispersible biological material and could meet the criteria in Rule .03(13)2(c). See Item11, Appendix P of this guide.

Release of Animals for Unrestricted Use

Cats can be released after treatment with I-131 when:

Any animal that has been injected with a radioactive compound or has had radioactive sources implanted cannot be released until the researcher or veterinarian ensures that the dose that members of the public will receive from the animal is within limits of Rule .03(5)i , "Dose limits for individual members of the public." require that the total effective dose equivalent to an individual member of the public from the licensed operation does not exceed 1 millisievert (mSv) [0.1 rem or 100 millirem (mrem)] in a year and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv [0.002 rem or 2 mrem] in any 1 hour. A member of the public is any individual, except when that individual is receiving an occupational dose. Members of the public, therefore, include bystanders, pet owners, family members, or other caretakers of the animal after the researcher or veterinarian has released it.

Scientists or veterinarians may release animals that received radioactive material for diagnostic, therapeutic, or research purposes to animal caretakers after treatment. These animals are considered "radioactive" and placed in cages and rooms that are posted/labeled with appropriate warning signs until the animals can be released to the "uncontrolled" population or their owners. Criteria should be developed by the licensee for assessing this release. Items to be considered for release of the animals include the type of radionuclide and concentration in the urine and/or feces; and the dose rate on contact (or at some distance from) the accessible side of the cage.

The most common example of a situation in which animals are treated with licensed materials and then released is the administration of iodine-131 (I-131) to cats for the treatment of hyperthyroidism. Therefore, this treatment will be used as an example for release of animals following administration of licensed material.

□ cats are held not less than 4 complete days [96 hours] after administration

AND

the dose rate is less than 0.01 mSv per hour (mSv/h) [1 milliroentgen (mR)/hour (h)] at 6 inches {or 0.0025 mSv/h [0.25 mR/h] at 1 foot}

AND

written instructions are provided to the owners

AND

the licensee can demonstrate that a member of the public would not receive a dose from the cat that would exceed 0.02 mSv [0.002 rem or 2 mrem] in any one hour or 1 mSv

The licensee must ensure that the dose from a cat treated with I-131 to individual members of the public (including members of the family) does not exceed the 0.02 mSv [0.002 rem or 2 mrem] in any one hour, and 1 mSv [0.1 rem or 100 mrem] annual public dose limit specified in Rule .03(5)i. The licensee should provide the owner with written instructions (to avoid confusion) to reduce the dose to members of the public. The instructions should provide a margin for dose reduction but should not be relied upon as the primary way of keeping the dose to members of the public below the 1 mSv [0.1 rem or 100 mrem] public dose limit.

[0.1 rem or 100 mrem] in a year (the limits of 10 CFR 20.1301)

In applying the above criteria for release of cats, patient-specific information and radiation data should also be considered. The dose rate of 0.0025 mSv/h [0.25 mR/h] at 1 foot is a conservative release criteria. If the owner follows instructions to limit interaction with the cat for the first few days, it is unlikely that a person would receive a 1 mSv [0.1 rem or 100 mrem] dose. The applicant must include criteria for release of cats treated with licensed materials from veterinary or laboratory activities in its application for review and approval, before implementation. Our office may accept alternate proposed criteria for veterinary cat release if

(i) the instructions pertaining to the extent and duration of contact permitted with the cat are easy for the owner to comply with, and (ii) the potential dose would be well below 0.02 mSv [0.002 rem or 2 mrem] in any one hour and 1 mSv [0.1 rem or 100 mrem] in a year. Such proposals will be reviewed on a case-by-case basis. Additional consideration may be necessary when establishing the date for release of a cat treated with I-131 to a home with small children.

For cats, release criteria above 0.5 mR/h at 1 foot are not recommended because it is unlikely that, if release criteria is less restrictive, doses to members of the public will be less than 0.02 mSv [0.002 rem or 2 mrem] in any one hour, and less than 1 mSv [0.1 rem or 100 mrem] in a year. In addition, cats released at higher radiation levels also may contain enough radioactive material that I-131 contamination of the owner and home from saliva, urine, and feces may be of concern.

Criteria for release of cats and other animals treated with licensed materials from veterinary or laboratory activities must be included in the application for review and approval, before implementation. Regardless of the release level used, the licensee should have records to document that the veterinary patient release criterion used for an individual veterinary patient will result in compliance with Rule .03(5)i. **Refer to Appendix O-1**

Instructions to Animal Caretaker upon Release

Once the veterinarian determines that the animal meets the dose criteria for release, instructions should be given to the animal's caretaker. Written instructions should address, at a minimum: (i) waste handling, (ii) contamination, and (iii) human interaction with instructions for isolation of the animal. **Refer to Appendix O-2**

These instructions should be specific to the type of treatment given, such as permanent implants, or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. The instructions should not, however, interfere with or contradict the best medical judgment of the veterinarian. The instructions should include the name of a knowledgeable person to contact and that person's telephone number, in case the caretaker has any questions.

Although it is acceptable to immediately dispose of nonradioactive animal excreta in a landfill, radioactive waste may <u>not</u> be disposed of in this way. For animals treated with short-lived radioactive materials, instructions to caretakers should include storing animal excreta in an appropriate location for a designated period of time to allow the radioactive material to decay. Many solid waste disposal facilities have installed radiation detectors to prevent the disposal of radioactive material at landfills. If the detectors indicate that there is radioactive material in the waste truck, the waste disposal facility staff or a contractor must search the truck and remove the radioactive material, which is a hazardous, costly, and time-consuming process.

tems to consid	der including in the instructions are
	$\square\square$ the regulatory limits and the need to keep doses ALARA
	$\hfill\square$ the potential radiation fields surrounding the animal and potential dose with time at various distances
	$\hfill\square$ maintaining distance from people in public places and the home
	$\hfill\Box$ minimizing time in public places (e.g., walks on public sidewalks, parks, beaches, grooming salons)
	$\hfill\Box$ precautions to reduce the spread of radioactive contamination
	$\hfill\Box$ the handling and storage of animal excreta, and the duration of storage if held for decay
	\Box the permitted extent and duration of contact by individuals with the animal, and handling of contaminated bedding and other objects with which the animal comes into contact.
	□□ the length of time each of these precautions should be in effect

APPENDIX B

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 4."

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.

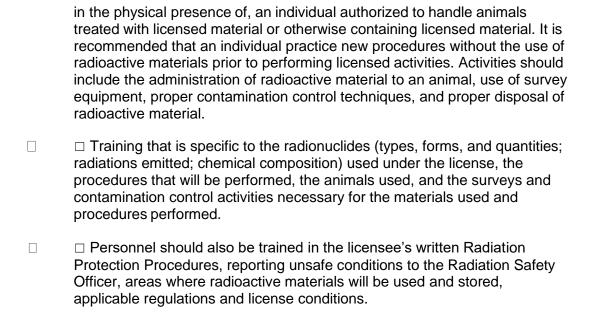
MODEL PROGRAM

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.

Classroom training may be by traditional lecture, online or recorded presentations, self-study, or other appropriate forms, and should cover the following subject areas: П □ principles and practices of radiation protection □ radioactivity measurements, monitoring techniques, and using instruments ☐ mathematics and calculations basic to using and measuring radioactivity □ biological effects of radiation Appropriate on-the-job-training should consist of □ Observing authorized personnel perform licensed activities with animals, including administration of the radioactive material to the animal, using survey equipment, proper contamination control techniques, proper personnel protection clothing and proper methods for disposal of contaminated material and radioactive material.

☐ Performing licensed activities with animals under the supervision of, and



APPENDIX C

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 C to the Veterinary Licensing Guide, Revision 4."

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(3). 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.

APPENDIX D

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 D in the Veterinary Licensing Guide, Revision 4."

If you develop your own dose calibrator procedure for review, you should carefully review Rule .05(29) 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 tests should be performed at the indicated frequency:

- constancy, at least once each day prior to assay of patient dosages (+/- 10%)
- linearity, at installation and at least annually thereafter (+/- 10%)
- geometry dependence, at installation (+/- 10%)
- accuracy, at installation and at least annually thereafter (+/- 10%)

The dose calibrator will be repaired, replaced, or corrected arithmetically if the dose calibrator falls outside the suggested tolerances. For example, a licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent and shall mathematically correct dosage readings [for dosages greater than 1.11 megabecquerels (MBq) or 30 microcurie (μ Ci)] if the geometry or linearity error exceeds 10 percent. In addition, after repair, adjustment, or relocation to another building, the dose calibrator tests will be repeated before use.

<u>Constancy</u> means reproducibility in measuring a constant source over a long period of time. At least one relatively long-lived source, such as cesium-137 (Cs-137), cobalt-60, cobalt-57

(Co-57), or radium-226 will be assayed using reproducible geometry each day before using the calibrator. The source activity will normally be in the low millicurie to hundreds of microcuries range. Two sources with different photon energies and activities may also be used to ensure the photon energy range for radionuclides used is covered.

- 1. Assay each reference source using the appropriate dose calibrator setting (e.g., use the Cs-137 setting to assay Cs-137).
- Measure background at the same setting and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
- 3. For each source used, record (e.g., plot, log) the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the name of the individual who performed the test.

- 4. Using one of the sources, repeat the above procedure for all commonly used radionuclide settings. Record (e.g., plot, log) the results.
- 5. Notify the radiation safety officer (RSO) or the authorized user if the test results fall outside +/- 10% of the expected results. For instance, the Cs-137 value should be compared to the reference activity, corrected for decay. Other radionuclides (e.g., Tc-99m) should be compared to the value determined during the last accuracy test, corrected for the reference standard's decay.

Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator will be ascertained over the range of its use between the maximum activity administered and 1.11 MBq [30 μ Ci]. This test will be performed using a vial or syringe of technetium-99m (Tc-99m) or other readily available radionuclide whose activity is at least as large as the maximum activity normally assayed for administration. Tc-99m is routinely used due to its ready availability and lower energy, and therefore lower exposure to licensee personnel, as compared to higher energy radionuclides like those used in Positron Emission Tomography and Iodine-131.

Time Decay Method

- Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the next activity in millicuries. Record the date, time to the nearest minute, and net activity on the dose calibrator linearity test form.
- 2. Repeat the assay at approximately 4-hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 1.11 MBq [30 μ Ci]. For dose calibrators on which the range is selected with a switch, select the range that would normally be used for the measurement.
- 3. Convert the time and date information that was recorded to hours elapsed since the first assay.
- 4. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.
- 5. Notify the RSO, if the deviation is more than $\pm 10\%$.

Shield Method

"Sleeves" of various thicknesses are used to test for linearity. However, they must first be calibrated. The applicant should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to

achieve a desired attenuation. The following procedure should be modified to allow for stacking of sleeves:

- 1. Begin the linearity test as described in the decay method described above. Aftermaking the first assay, the sleeves can be calibrated as follows. Steps 2 through 4 below must be completed within 6 minutes (i.e., approximately 1 percent of decay of Tc-99m).
- 2. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 3. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4. Continue for all sleeves.
- 5. Complete the decay method linearity test Steps 2 through 5 above.
- 6. From the data recorded in step 4 of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step 2.
- 7. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step 3.
- 8. Continue for all sleeves.
- 9. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

- 1. Assay the Tc-99m syringe or vial in the dose calibrator and subtract background to obtain the net activity. Record the net activity.
- 2. Steps 3 through 5 below must be completed within 6 minutes.
- 3. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 5. Continue for all sleeves.
- 6. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, the date(s) of the test, and the name of the individual who performed the test.
- 7. Notify the RSO if the greatest deviation is more than +/- 10%.

Geometry independence means that the indicated activity does not change with volume or configuration. The test for geometry independence will be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections or administrations, and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3 cubic centimeter (cc) plastic syringes and that radiopharmaceutical kits are made in 30 cc glass vials and the predetermined safety margin is +/-10%. If 5 cc syringes, 10 cc glass vials, or any other geometric variations are used, the geometry testing will include these.

Note: If these volumes are not used, change the procedure so that the syringes and vials are tested throughout the range of volumes commonly used.

- In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 millicuries (mCi)/milliliter. Set out a second small beaker or vial with water.
- 2. To test the geometry dependence for a 3 cc syringe, draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (e.g., mCi) indicated.
- 3. Remove the syringe from the calibrator, draw an additional 0.5 cc of water and assay again. Record the volume and activity indicated.
- 4. Repeat the process until a 2.0 cc volume has been assayed.
- 5. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."
- Record the model number and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
- 7. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.
- 8. To test the geometry dependence for a 30 cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.
- 9. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water and assay again. Record the volume and activity indicated.
- 10. Repeat the process until a 19.0 cc volume has been assayed. The

entire process must be completed within 10 minutes.

- 11. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal 10% error lines above and below the chosen "standard volume."
- 12. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the name of the individual who performed the test.
- 13. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% error lines.

Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from the NIST and from many radionuclide suppliers. At least one source with a principal photon energy between 100 kiloelectron-volts (keV) and 500 keV (e.g., Co-57 or barium-133) will be used. At least one reference source whose activity is within the range of activities normally assayed will be used.

- 1. Assay a calibrated reference source at the appropriate settings (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 the net activity.
- 2. The measurement should be within +/- 10% of the certified activity of the reference source, mathematically corrected for decay.
- 3. Repeat the procedure for any other calibrated reference sources possessed.
- 4. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the name of the individual who performed the test.
- 5. Notify the RSO if the test results do not agree, within +/- 10%, with the certified value of the reference source(s).
- 6. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radionuclide settings.

APPENDIX E

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 E to the Veterinary Licensing Guide. Revision 4."

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.
- 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)4.
- 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)4.
- 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).
- 7. The applicant described in its procedure, the criteria used to determine the type of bioassay and the frequencies at which it will be performed to evaluate intakes. The procedures should provide for baseline, routine emergency, and follow-up. Acceptable criteria that applicants may use in developing their bioassay programs are outlined in Regulatory Guide 8.9, Rev 1, "Acceptable Concepts, Models, Equations, and Assumptions for Bioassay Program."

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 4."

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;
- 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

<u>MEMORANDUM</u>

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 4."

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, 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(33(c)1 and 2.
 - g. The leak test record will contain the information required in Rule .05(117).

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 4."

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. 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 4."

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 oi	າ	in roon	n (location)	
	(time)	(date)		(location)	
Instrument used to ch	eck for personnel	contamina	tion:		
Meter Model:	Meter S/N:	Pro	obe Model:	Probe S/N:	
PERSONNEL PRE	SENT		PERSONNEL (CONTAMINATION RESULTS*	
					_
*On the back of the sl instituted.	neet, indicate any	personnel	decontamination	n, additional monitoring, or care	 e
Survey the spill area to contamination wipe to		ts, then beg	gin decontamina	tion. When finished, conduct a	a post cleaning
R	ADIOISOTOPES	PRESENT	OR SUSPECTE	ED IN THE SPILL	_
Millicuries Isotop	e Form				
GIVE A BRIEF DESC	RIPTION OF THE	E ACCIDEN	IT:		
GIVE A BRIEF DESC	RIPTION OF FOI	LOW UP A	ACTIONS TAKE	N TO PREVENT RECURREN	CE:
NAME				DATE	

RADIOACTIVE SPILL CONTAMINATION SURVEY

The spill occurred at:		_ am/pm on		in room
	(time)		(date)	(location)
Decontamination com	pleted at:	(time)	am/pm on	(date)

Location	Pre-clean	Post Clean		Location	Pre- clean	Р	ost 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 4".

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

- 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

MEMORANDUM										
То:	Chief of Security									
From:	Radiation Safety Of	fficer								
Subject: Rec	eipt of Packages Cor	ntaining Radioactive	e Material							
that arrive du Nuclear Medi	ring other than norma	al working hours. Pom Unlo	y packages containing ackages will be taken i ck the door and place t	mmediately to the						
	ain at the facility until		of the individuals identi neither the driver nor t							
If you have a (name)	ny questions concern	ing this memorand	um call our Radiation S	Safety Officer,						
Name Office Phone Home Phone Pager Radiation Safety Officer:										
	Nuclear Medicine Veterinarian on Call: Name Phone Phone Phone Pager									
		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 K to the Veterinary Licensing Guide, Revision 4."

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 or email at rad.materials@dnr.ga.gov when the removable radioactive surface contamination exceeds the limits of Rule .06(16)(i) or when the external radiation levels exceed the limits of Rule .06(16)(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 <u>not</u> 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 4."

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(36)(e). 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;
- 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(36)(e). 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	СС	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 4".

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(36). 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/cm²). 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

- 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/100cm² of removable contamination (200 dpm/100cm² 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(36)(i). 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/100cm², 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 cm² 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

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:

<u> </u>														
		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 4."

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. 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:
- 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, <u>and</u> 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.
 - 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 cm².
 - d. Inform the Housekeeping staff that cleaning restrictions are removed.

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY

PATII	ENT:	ROOM:	DATE:							
PREP	PARATION:									
	Schedule an area private from non-treated animals and non-authorized personnel.									
	Cover large room surfaces	with absorbent paper and sma	Il surfaces with absorbent	paper or plastic bags.						
	Prepare labeled boxes for u	used linen, disposable waste, a	and non-disposable contar	minated items.						
	Prepare urine and feces col	lection containers.								
	Stock room with disposable	gloves, absorbent paper, and	"radioactive waste" labels	3.						
	Order disposable table serv	rice.								
	Notify housekeeping to not	clean the room until further not	tice.							
	Brief the staff on radiation s	afety measures.								
	Supply the staff with person	nel radiation dosimeters.								
ADMI	NISTRATION:									
_	Clear the room of unneeded	d personnel.								
	Administer the dosage.									
_	Measure dose rates at the srooms.	sides of the cage, 1 meter from	the sides of the cage, and	d surrounding hallways and						
	Post the room with a "Cauti	on-Radioactive Materials" sign	ı .							
FOLL	OW-UP:									
	Measure the thyroid burden	of all personnel who were pre	sent during the administra	ation.						
	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:										
NA	ME	WORK TELEPHONE	HOME TELEPHONE	PAGER						
RS	0									
ΔΤ	TENDING VETERINARIAN			ļ						

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

ANIMAL:			ID NUMBE	ER	ROOM	Λ:	_ DA	TE: _				
Attending:			Phone:_			Pager:	:					
Dose:	mCi of		as	W	as admin	istered a	t	:	_am/p	m		
Signature:			Date	e:								
			F	RADIATIO	N EXPOSU	RE RATES	S					
Animal Orient	tation: Supine or	Standi	ng									
				UNRES	TRICTED A	AREAS						
DATE	TIME		ROOM (mR/hr)		ROOM (n	nR/hr)		DOOF	R (mR/h	r)	OTHER (mR/hr)	
			<u> </u>	RES ⁻	TRICTED A	REAS					<u>I</u>	
DATE	TIME	CAGI	E-SIDE (mR/hr)	3' FROM	/I CAGE (ml	₹/hr)	DO	OR (mF	R/hr)		OTHER (mR/hr)	
											_	
											+	
ANIMAL CA — Wea — Disc — Colle — Hous — Only — your	risitors. RESTRICTION RESTRICTION ARE: ARE: Ar disposable Eard dressings Ect urine and sekeeping per The Radiation Ar your radiation Shift. You me	gloves, etc. feces ersonn n Safe on mo	s. Wash your, in boxes in to for authorized are not perety Officer (RS) onitor when care	r hands he roon d dispo mitted i SO) ma aring foi	after can n. sal. in the roo by release r the anir	om. e the are nal. Lea	ea. ave	it at a	a desiç		I location at the o	
	itors are need EMERGENCY, C		OU HAVE A QU	JESTION	CALL:							
NAME			WORK TELEP	PHONE	HC	ME TELE	PHO	ONE		PAGE	R	
RSO												
ATTENDIN	C VETERINIARI	ΛNI			I							

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 4", 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)and .03(14)(i). 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.

Ш **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.

Sample Instructions to Caretakers of Animals Administered Radionharmaceuticals or Other Unsealed Radionuclides

	itat	dopilarinaceuticals of Other Oriscaled Na	dionaciacs
radioad the ani	ctivity. T mal fro	is been treated with radioactive material [Insert is The present level of radioactivity is below the reg in humans. Because some radioactivity will be pro- ing safety precautions be exercised for the next	ulatory agency level necessary for isolating resent for the next few days, it is necessary
		Avoid public transportation; avoid staying in public accor your animal in its carrier as far from passengers as is re-	
		The animal should be kept inside or in his cage or stall for	ollowing hospital discharge.
		The animal should not be permitted to have prolonged c 12 fordays following hospital discharge. (less thanminutes per day.	
		Pregnant women should avoid ANY contact with the aniidays after discharge.	mal or its urine and feces for at least
		Family members should not be permitted to sleep with the discharge. They also should limit close contact with the feet of the animal) for the next XX day(s) to no more the contact with the animal should be kept to a distance of period.	e animal (being within 1 meter or 3 an XX minutes a day. Preferably,
		Use plastic litter pan liners and scoopable litter (for cats)	
		Disposable gloves should be worn whenever handling a litter box for the next XXdays after discharge. Use only and feces if your pet was released to you less than 5 d	disposable litter and flush the urine
		Wash hands after contact with the animal or the litter.	
		Callto radiation safety concerns. NOT hold the pet,	discuss any other
		NOT allow the pet to sit on your lap or next to you, NOT sleep in the room with you for XX days.	allow the pet to
		Keep the pet from all food preparation areas for XX da	ays
l und	ersta	nd and consent to abide by all of the	e above instructions.
		(Signature of Pet Owner)	(Date)
		(Signature of Authorized Hear)	(Data)

•	
 (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 4".

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). 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)).

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 inRule .03 and 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 H-3, C-14 or I-125 per gram of: medium used for liquid scintillation counting and animal tissue, averaged over the weight of the entire animal 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.

- 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.

<u>.05(8)</u>	FOR UPTAKE, DILUTION, AND EXCRETION STUDIES
1.	Portable radiation detection survey meter
2.	Dose calibrator or a decay chart
3.	Constancy check source - if a dose calibratior will be used
4.	Sealed sources for dose calibrator accuracy test - if a dose calibrator will be used
5.	Constancy check source for uptake, dilution, and excretion equipment- if a dose calibrator will be used
6.	Syringe shield
7.	Vial shield
8.	Personnel shield
9.	Leak-test service for sealed sources
10.	Survey meter calibration service
<u>.05(9)</u>	FOR IMAGING AND LOCALIZATION STUDIES
1.	Portable radiation detection survey meter
2.	Portable radiation measurement survey meter
3.	Dose calibrator or a decay chart
4.	Constancy check - if a dose calibrator will be used
5.	Sealed sources for dose calibrator accuracy test – if a dose calibrator will be used
6.	Syringe shield
7.	Hot lab area monitor
8.	Lead L-block
9.	Vial shield
10.	Personnel shield
11.	Survey meter calibration service
12. 13.	Personnel monitoring service Leak-test service for sealed sources
13. 14.	Gamma camera
14.	Gamma camera
<u>.05(12)</u>	FOR RADIOPHARMACEUTICAL THERAPY Destable rediction detection curvey mater
1. 2.	Portable radiation detection survey meter 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

- A <u>radiation detection survey meter</u> usually has a GM tube or Nal(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 → dpm) for the radionuclide being measured.
- 2. A <u>radiation measurement survey meter</u> 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 <u>dose calibrator</u> 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 <u>constancy check source</u> is a sealed source with the date of manufacture, the radioisotope, and the approximate activity noted.
- 5. A <u>dedicated check source</u> is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The <u>same</u> ("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 <u>sealed sources for dose calibrator accuracy</u> 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 <u>leak-test service</u> 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(TI) crystal with a ratemeter is necessary to assay gamma-emitting leak-test wipes.
- 8. A <u>hot lab area monitor</u> 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. <u>Personnel shields</u> 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,
 - (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 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.
- C. Training for Staff using Radionuclides in Animals

Refer to Appendix A

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,
 - (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 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.