
RADIOACTIVE MATERIALS PROGRAM**MEDICAL LICENSING GUIDE (Revision 6, November 4, 2002)**State of Georgia
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1. INTRODUCTION

1.1 GENERAL

The Georgia Department of Natural Resources, Radioactive Materials Program (Department) regulates the intentional internal or external administration of radioactive material, or the radiation from it, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Rule .05, "Use of Radionuclides in the Healing Arts. Amended," of the Rules and Regulations for Radioactive Materials, Chapter 391-3-17.

The Department usually issues a single radioactive materials license to cover an institution's entire radioisotope program. Separate licenses, except teletherapy, are not normally issued to different departments of a 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 medical use license and to describe the medical 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 medical use programs. The information contained in this guide does not cover the use of remote afterloaders, teletherapy or stereotactic radiosurgery. You will need to refer to those licensing guides for information needed to support those uses.

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. Part 1, Appendices A through T to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for their specific radiation safety needs. In the application, applicants may certify that they will follow model procedure (appropriate certification language is given at the beginning of each Appendix). Or the licensee may say that they have developed a procedure enclosed for review (appropriate reference language is given at the beginning of each Appendix). Part 2, Appendices U through W to this guide provide additional information for managing radiation protection programs for medical use licenses.

1.2 APPLICABLE REGULATIONS

The following Georgia regulations apply 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 medical use:

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

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

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

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

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

You may request copies of the above documents from the Radioactive Materials Program (RMP) at: Atlanta Tradeport Suite 114, 4244 International Parkway, Atlanta, Georgia 30354 or from our website: http://www.ganet.org/dnr/environ/aboutepd_files/branches_files/rmprogram/default.htm

The applicant should carefully study the Regulations and this guide and should submit all information requested. The Department 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 that "each licensee shall develop, document, and implement a Radiation Protection Program sufficient to ensure compliance with the provisions of this Rule" . . . and "the licensee shall use, to the extent practical, 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)." Additionally, this Rule requires that licensees periodically review the Radiation Protection Program content and its accomplishments. Rule .05(6)(d) also outlines the requirements for an ALARA program for medical use.

A model ALARA management program is contained in Appendix G to this guide. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

1.4 TYPES OF LICENSES

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

1.4.1 General License

Rule .02(6)(g), "General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing," establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use certain small quantities of radioactive material for in vitro clinical or laboratory tests not involving administering radioactive material to humans. The rule explains the requirements for using materials outlined in that section and the possession limits for a general license. If the general license alone meets the applicant's needs, only the Department form, "Certificate - In Vitro Testing with Radioactive Material Under General License" needs to be filed. Medical use licensees do not need to file the form.

If you need more material than allowed by the general license, you may request an increased inventory limit as a separate line item on your "Application for Medical Use of Radioactive Materials" application. If you request an increased inventory limit, you will be subject to the requirements of the rules and regulations, including waste disposal.

1.4.2 Specific Licenses

Specific licenses for physicians in private practice are generally limited to physicians who are

located in private offices and not on hospital premises. A radiation safety committee is not required. Use of radioactive materials that require hospitalization of the patient are not permitted under a private practice license.

Specific licenses are also issued to medical institutions. A medical institution is an organization in which several medical disciplines are practiced. These licenses allow radioactive material for medical uses by physicians named on the institution's license. Rule .05(6)(f) requires a medical institution, except those medical institution licensees authorized to use only radiopharmaceuticals described in .05(8) and .05(9), to have a Radiation Safety Committee to oversee the use of licensed material throughout the institution and review the institution's radiation protection program. The physicians named on the institution's license conduct their programs with the approval of the Radiation Safety Committee.

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

1.4.3 Specific License of Broad Scope

Some medical institutions provide patient care and conduct research that use radioisotopes for in vitro, animal, and medical procedures. In these cases the Department may issue a license of broad scope as discussed in Rule .02(10), "Special Requirements for Specific Licenses of Broad Scope." Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of radioactive material for unspecified uses, are issued to institutions that (1) have had experience operating under a specific institutional license of limited scope, (2) are engaged in medical research and routine diagnosis and therapy using radioisotopes, and (3) have a good inspection history. A broad scope license is not appropriate for most institutions performing routine medical procedures with radioactive material. An applicant will need to reference the "Licensing Guide for Broad Scope Licenses" in addition to this guide if the broad scope license is for medical use.

2. FILING AN APPLICATION

A license application for a specific license for human use will be submitted on Form 1, "Application for Radioactive Materials License." Rule .02 (9)(b), (c), (d), and (e), "Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material," outline the requirements for a medical use license. More specific requirements regarding medical use are detailed in Rule .05, "Use of Radionuclides in the Healing Arts, Amended."

An application form, Form 1, is located in Part 1 of this guide. You should complete items 1 through 4, 7, 12, and 13 on the form itself. For items 5 through 11, submit the required information on supplementary pages. You should identify and key each separate sheet or document submitted with the application to the item number of the application to which it refers. All of the information, including drawings, should be on 8-1/2 x 11 inch paper to ease handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

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

License applications are available for review by the general public under the Georgia Open Records Act. Do not submit proprietary information unless absolutely necessary. Do not submit personal information

about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to show their ability to manage radiation protection programs or to work safely with radioactive materials. Home address and telephone numbers should be submitted only if they are a part of an emergency response plan. Dates of birth, Social Security numbers, and radiation dose information should be submitted only if specifically requested by the Department.

The regulations require that the licensee develop and carry out procedures that will ensure compliance with the regulations. Appendices A through T to this guide describe model radiation safety procedures. Each applicant should carefully review the applicable regulations and the model procedures and then decide if the model procedures are appropriate for their specific radiation safety needs.

You should prepare your application in duplicate and retain one copy for yourself. The license will be issued based on the statements and representations in your application and any supplements to it. The license is also issued based on the requirements in the regulations.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on "Application for Radioactive Materials License." The appendices to this guide serve several different purposes, i.e., 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, or to provide an outline the applicant may use to develop a procedure for Department review. The forms are included in the appendices.

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

ITEM 1 LICENSE INFORMATION

Check subitem A for a new license. For an amendment to an existing license, check subitem B. Check subitem C for renewal of an existing license. If you check B or C, provide the license number.

ITEM 2 APPLICANT'S NAME AND MAILING ADDRESS

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

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

ITEM 3 LOCATIONS OF USE

3.1 LOCATIONS OF USE

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

If you desire multiple job sites give the location where a complete set of records will be maintained for the license.

If you will be utilizing a mobile medical service, such as a mobile Positron Emission Tomography (PET) service, submit a diagram of your facility identifying the location of the mobile service unit and adjacent areas. The mobile service must be parked on the licensee's property.

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

3.2 PRIVATE PRACTICE APPLICANTS OUTSIDE OF HOSPITALS

State the name and address of the hospital that has agreed to admit patients that have been administered radioactive material and submit a letter from the hospital administrator stating their agreement to admit patients containing radioactive material. If outpatient therapy procedures are requested then submit a copy of the radiation safety precautions to be taken and list radiation survey instruments that will be available for use at the hospital.

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 medical use into five types of use. Using the table format of Table 1 as a guide, list only the types of use you want and the maximum activity. You may say "As needed" in the "Activity" column as shown. For material authorized by Rule .05(14), brachytherapy material, express the total amount in millicuries (mCi)

TABLE 1

RADIOACTIVE MATERIAL	ACTIVITY	PURPOSE
5.a. Material authorized in Rule .05(8)(a)	As Needed	6.a. Medical use
5.b. Material authorized in Rule .05(9)	As Needed	6.b. Medical use
5.c. Material authorized in Rule .05(12)	As Needed	6.c. Medical use
5.d. Material listed in Rule .05(13)(a)	As Needed	6.d. Medical use
5.e. Material listed in Rule .05(14)(a)	_____mCi	6.e. Medical use
5.f. Material listed in Rule .02(6)(g)	As Needed	6.f. In Vitro Studies

(NOTE: Broad scope medical use applicants may request "Any radioactive material with atomic numbers 1 through 83 for medical use.")

If you need generators and/or xenon 133 for medical use in Rule .05(9) specifically list those items with the

Rule [i.e. Material authorized in Rule .05(9) (including generators and xenon 133)]. You have to request generators and xenon 133 to be authorized for their use. Rule .02(6)(g), "General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing," lists the quantities of radioactive material that may be possessed under a general license. If you need to possess quantities of radioactive material for in-vitro studies greater than those listed in Rule .02(6)(g) then request in vitro material as listed in the table above.

If you need other items (for example, a survey meter calibration source, constancy check source, or material for in vivo, animal, or human studies; or authorization to participate in a protocol approved by a Radioactive Drug Research Committee approved by the Food and Drug Administration), make a separate line entry for each item. (You do not need to list sources authorized in Rule .05(7)(f).) Each line entry must identify the radionuclide, the physical form, maximum activity to be possessed expressed in mCi, and the purpose for which the material will be used.

If you will be utilizing a mobile medical service, the sources used by the mobile medical service must be on your license. This is because the mobile medical service becomes a place of use on your license. For example, if you are using a mobile PET service the transmission and calibration sources in the PET unit must be submitted for inclusion on your license. You will need to submit the Sealed Source and Device (SS&D) registry information as well as the maximum activity. This information may be provided by the mobile PET service.

If you do not want all of the material listed in each section of Rule .05 identified in Table 1, you must identify, line by line, the material that you want from the section (for example, thallium 201, 50 millicuries, for cardiac studies).

ITEM 7 **INDIVIDUALS RESPONSIBLE FOR RADIATION PROTECTION PROGRAMS - THEIR TRAINING AND EXPERIENCE**

Responsible individuals are the authorized users and the RSO. Rule .05(16) requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in a way that protects health and reduces danger to life or property. The Rule provides specific criteria for acceptable training and experience for authorized users for medical use, and for the RSO. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

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

1. Examination of patients and medical records to decide if a radiation procedure is appropriate,
2. Prescription of the radiation dosage or dose and how it is to be administered,
3. Actual use of, or direction of technologists or other paramedical personnel in the use of radioactive material, and
4. Interpretation of results of diagnostic procedures and evaluation of results in therapy procedures.

Technologists or other personnel may use material under an authorized user's supervision as defined in Rule .05(6)(i).

7.1 **AUTHORIZED USERS FOR MEDICAL USE**

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 note, which proposed uses are requested for the individual, by reference to Items 5.a, 5.b, etc.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you need only submit a current copy of the license on which the physician was specifically named an authorized user.
3. If a physician is certified by an organization listed in the appropriate section of Rule .05(16), submit Supplement A (Form 2) with Items 1, 2, and 3 completed. The physician also needs to submit a copy of their board certification and evidence that they are licensed to practice medicine in the State of Georgia.
4. Physicians not previously authorized by the Department, an Agreement State or the US Nuclear Regulatory Commission (NRC) **and** not certified by an appropriate organization must submit a letter. This letter should be on the training institution's letterhead, signed by an appropriate official, certifying that the doctor, "has successfully completed a 6-month training program in nuclear medicine as a part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience". Review .05(16)(c)2., (d)2., (e)2., (f)2 or (h)2. for specific requirements.
5. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. Rule .05(16) may be used as a guide.

7.2 RADIATION SAFETY OFFICER (RSO)

State the name and title of the person appointed by, and responsible to, the applicant's management as RSO. The RSO must agree in writing to be responsible for implementing the radiation protection program. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A. The RSO should be a full-time 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 physician is named as the RSO as allowed by Rule .05(16)(a)3 but is not licensed to use all material on the license. Therefore, an additional RSO will need to be named on the license to cover the use of radioactive material not covered by the other RSO. However, if a person is named as the RSO and meets the requirements of Rule .05(16)(a)1 or 2, then they can be the RSO for everything listed on the license.

ITEMS 8 THROUGH 11

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

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

TABLE 2
APPLICABILITY TABLE

To decide those items to which you must respond, “highlight” the columns under the categories of material you requested in Item 5. If any “✓” beside an item is highlighted, you must provide information in response to the item. If the letters “NA” (not applicable) are highlighted, you may respond “NA” in your application.

Material in Rule .05 Sections									
Item	Topic	(8)	(9)	(12)	(13)	(14)	Other	Appendix	
8.1	Training Program	✓	✓	✓	✓	✓	NA	A	
8.2	Other Training Program	NA	NA	NA	NA	NA	✓	--	
9.1	Annotated Drawing	✓	✓	✓	✓	✓	✓	FORM 4	
9.2	Survey Meter Calibration	✓	✓	✓	✓	✓	✓	B	
9.3	Dose Calibrator Calibration	✓	✓	✓	NA	NA	NA	C	
9.4	Personnel Monitor Program	✓	✓	✓	NA	✓	✓	D	
9.5	Mobile Imaging	See Special Instruction 9.5 in the Text					E or T		
9.6	Other Equipment and Facilities	NA	NA	NA	NA	NA	✓	--	
10.1	Radiation Safety Committee/Radiation Safety Officer	See Special Instruction 10.1 in the Text						F	
10.2	ALARA Program	See Special Instruction 10.2 in the Text						G	
10.3	Leak Test	✓	✓	✓	✓	✓	NA	H	
10.4	Safe Use of Radiopharmaceuticals	✓	✓	✓	NA	NA	NA	I	
10.5	Spill Control Procedures	✓	✓	✓	NA	NA	NA	J	
10.6	Ordering and Receiving	✓	✓	✓	✓	✓	✓	K	
10.7	Opening Packages	✓	✓	✓	✓	✓	✓	L	
10.8	Unit Dose Records	✓	✓	✓	NA	NA	NA	M	
10.9	Multi-dose Vial Records	✓	✓	✓	NA	NA	NA	M	
10.10	Generator Contaminants Concentration Records	NA	✓	NA	NA	NA	NA	M	
10.11	Brachytherapy (Implant) Source Use Records	NA	NA	NA	NA	✓	NA	M	
10.12	Area Survey Procedure	✓	✓	✓	NA	✓	✓	N	
10.13	Air Concentration Control	NA	✓	NA	NA	NA	NA	O	
10.14	Radiopharmaceutical Therapy	NA	NA	✓	NA	NA	NA	P	
10.15	Brachytherapy (implant Therapy)	NA	NA	NA	NA	✓	NA	Q	
10.16	Quality Management Program	✓	✓	✓	NA	✓	NA	R	
10.17	Other Safety Procedures	NA	NA	NA	NA	NA	✓	---	
11.0	Waste Disposal	✓	✓	✓	✓	✓	✓	S	

ITEM 8 TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.1 TRAINING PROGRAM

Describe your training program for individuals who work with or in the vicinity of radioactive material described in Rule .05. Append it as ATT 8.1. See Appendix A of this guide.

8.2 OTHER TRAINING PROGRAM

Describe your training program for individuals who handle radioactive material other than material authorized for medical use in Rule .05 (i.e., animal use; or in vitro use for greater than generally licensed quantities described in Rule .02(6)(g)) that you listed in Item 5 of this application. Append it as ATT 8.2.

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. (See Form 4). Note the following:

1. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials, storage, radioactive waste storage, film processor, toilet, closet, hallway).
2. Any shielding available.
3. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

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

9.2 SURVEY METER CALIBRATION

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

9.3 DOSE CALIBRATOR CALIBRATION

Submit your procedure for calibrating the dose calibrator and attach it as ATT 9.3. See Appendix C.

9.4 PERSONNEL MONITOR PROGRAM

Describe your personnel occupational exposure monitor program and attach it as ATT 9.4. See Appendix D of this guide.

9.5 MOBILE IMAGING

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. Attach it as ATT 9.5.1. See Appendix E. If you are not going to provide mobile nuclear medicine service, say "NA" in the addendum to the application. In addition, call the Georgia Department of Motor Vehicle Safety [(404)675-6171] to apply for Hazardous Material Permit for intrastate transportation of radioactive materials.

If you are utilizing a mobile medical service as part of your license, describe your procedures for this service. Attach it as ATT 9.5.2. See Appendix T for a model program. If you are not utilizing this service, say "NA" in the addendum to the application.

9.6 OTHER EQUIPMENT AND FACILITIES

Describe other equipment and facilities available for the use and storage of materials described in Item 5 of this application other than material described in Rule .05. Discuss security of storage area. Append it as ATT 9.6.

ITEM 10 RADIATION PROTECTION PROGRAM

10.1 RADIATION SAFETY COMMITTEE (RSC) /RADIATION SAFETY OFFICER (RSO)

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority and attach it as ATT 10.1. A RSC must be established by each medical licensee except those authorized for .05(8) and .05(9) only (see Rule .05(2)(l) and Rule .05(6)(g)). If you are not an institution, you will only need to submit the Radiation Safety Officer delegation of authority. See Appendix F.

10.2 ALARA PROGRAM

Submit your ALARA program and attach it as ATT 10.2. Each medical licensee must have an ALARA program (see Rule .05(6)(d)), see Appendix G.

10.3 LEAK TEST

Submit your procedure for leak-testing sealed sources and attach it as ATT 10.3. See Appendix H.

10.4 SAFE USE OF RADIOPHARMACEUTICALS

Submit a copy of your rules for the safe use of Radiopharmaceuticals and attach it as ATT 10.4. See Appendix I.

10.5 SPILL CONTROL PROCEDURES

Submit a copy of your spill control procedure and attach it as ATT 10.5. See Appendix J.

10.6 ORDERING AND RECEIVING

Submit a copy of your procedure for ordering and receiving radioactive material and attach it as ATT 10.6. See Appendix K.

10.7 OPENING PACKAGES

Submit a copy of your procedure for opening packages that contain radioactive material and attach it as ATT 10.7. See Appendix L.

10.8 UNIT DOSE RECORDS

Submit your procedure for keeping records of unit dosage use and attach it as ATT 10.8. See Appendix M.1.

10.9 MULTI-DOSE VIAL RECORDS

Submit your procedure for keeping records of multidose vial use and attach it as ATT 10.9. See Appendix M.2.

10.10 GENERATOR CONTAMINANTS CONCENTRATION RECORDS

Submit your procedure for measuring and recording generator contaminants concentration and attach it as ATT 10.10. See Appendix M.3.

10.11 BRACHYTHERAPY (IMPLANT) SOURCE USE RECORDS

Submit your procedure for keeping an inventory of implant sources and attach it as ATT 10.11. See Appendix M.4.

10.12 AREA SURVEY PROCEDURES

Submit your area survey procedures and attach it as ATT 10.12. See Appendix N.

10.13 AIR CONCENTRATION CONTROL

1. Submit your procedure for estimating worker dose from submersion in noble gases (i.e. Xenon-133). See Appendix O.
2. Submit your procedure for estimating worker dose from aerosol concentrations. See Appendix O.
3. Submit your procedure for estimating aerosol and gas concentration in effluents. See Appendix O.
4. Submit your procedure for calculating spilled gas clearance times. See Appendix O.
5. All procedures should be attached as ATT 10.13.

10.14 RADIOPHARMACEUTICAL THERAPY

Submit your procedure for radiation safety during radiopharmaceutical therapy and attach it as ATT 10.14. See Appendix P.

10.15 BRACHYTHERAPY (IMPLANT THERAPY)

Submit your procedure for radiation safety during implant therapy and attach it as ATT 10.15. See Appendix Q.

10.16 QUALITY MANAGEMENT PROGRAM

Quality Management Program (QMP), Rule .05(6)(k), requires that each licensee write a quality management program to provide documentation that radioactive material or radiation there from is administered as directed by the authorized user. The quality management program must include the policies and procedures to meet the specific objectives outlined in Rule .05(6)(k).

Appendix R can be used as a guide for preparing your QMP, which should be submitted as a part of the application as ATT 10.16.

10.17 OTHER SAFETY PROCEDURES

Submit safety procedures followed by individuals who handle radioactive material described in Item 5 of the application other than material described in Rule .05. Append them as ATT 10.17.

ITEM 11 WASTE DISPOSAL

Submit your procedures for waste disposal and attach it as ATT 11. See Appendix S.

ITEM 12 LICENSE FEES

The applicant should refer to the Radioactive Materials License Fee Schedule (Form 5) to determine the appropriate licensing fee and category. Note that, in addition to licensing fees for a new, renewed or amended license, licensees are required to pay inspection fees and annual fees. No action will be taken on applications filed without the proper fee. Checks for the fees should be made payable to the **Department of Natural Resources, Radioactive Materials Program**, and mailed to the following address:

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

Mail license applications, amendment, renewal requests, and terminations of license including a copy of the check for the appropriate fee to the following address:

**Radioactive Materials Program
4244 International Parkway
Atlanta Tradeport, Suite 114
Atlanta, GA 30354**

ITEM 13 CERTIFICATION

If the application is for a private practice, it should be signed by a senior partner or the president. If the application is for an institution, hospital, or medical center, it must be signed by its administrator, president or chief executive officer. Identify the title of the office held by the individual who signs the application. Unsigned applications will not be reviewed and will be returned for proper signature.

4. AMENDMENTS AND NOTIFICATIONS 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 or notification as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. Meanwhile, you must comply with the terms and conditions of your license until it is actually amended. Department regulations do not allow you to implement changes based on a submission requesting an amendment to your license, except as allowed by notification.

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

The appropriate fee for a license amendment should be sent to the address listed in Item 12 for **Radioactive Materials Fees**. A copy of the check should be included with the amendment and sent to the **Radioactive Materials Program** address as listed in Item 12. The Department will not issue the amendment prior to receipt of the proper fee as specified in the Fee Schedule, Form 5.

Your application should state your license 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 Item 7 of this guide.

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

In accordance with .05(5)(b) a license amendment is not required prior to permitting qualified individuals to work as authorized users. However, the licensee is required to notify the Department within 30 days and provide a copy of the board certification, the Department, Agreement State, or NRC license or permit issued by a license of broad scope. Qualifications should be reviewed and approved by the RSC, if applicable, or by the RSO with the advice and consent of management, and must be in accordance with the provisions of .05(16)(c)1., (d)1., (e)1., (f)1., (g)1., or (h)1.

5. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. Send an application for renewal, to the address specified in Item 12 of this guide. Retain a copy of the renewal because the license requires that you possess and use licensed material in accordance with the statements and representations in your renewal request and any supplements to it.

You should submit an entirely new application for 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 reevaluate 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.

The appropriate fee for a license renewal should be sent to the address listed in Item 12 for Radioactive Materials Fees. A copy of the check should be included with the renewal application and sent to the Radioactive Materials Program address as listed in Item 12. The Department will not issue the renewal prior to receipt of the proper fee as specified in the Fee Schedule, Form 5.

In accordance with .02(15) you should file your application for license renewal at least 30 days before the expiration date of your license and include the appropriate 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, see Section 6 below.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal. The renewal is necessary to avoid violating the Department's regulations that do not allow possession of licensed material without a valid license.

6. TERMINATION OF A LICENSE

You may request termination of your license at any time. This request should include a completed Department form, "Request to Terminate Radioactive Materials License" (Form 3), with appropriate documentation certifying that all sources have been disposed of in a manner authorized by .02(19). 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 no fee for licensees who request to terminate their license.

PART 1

MODEL PROCEDURES THAT APPLICANTS MAY USE TO PLAN RADIATION PROTECTION PROGRAMS

**Supplement A
TRAINING AND EXPERIENCE
AUTHORIZED USER/RADIATION SAFETY OFFICER**

1. APPLICANT AUTHORIZED USER/RADIATION SAFETY OFFICER NAME AND ADDRESS (use separate form for each user or RSO)	
FULL NAME: _____ ADDRESS: _____ CITY: _____ STATE: _____ ZIP: _____ DAYTIME TELEPHONE# _____	2.a. Radiation Safety Officer or Authorized User at other Medical Facility within last 5 years? ___ Yes License #: _____ (Attach Copy of License if Out-of-State) ___ No 2.b. GEORGIA LICENSED PHYSICIAN? ___ Yes (Submit Copy of Current License to Practice Medicine in the State of Georgia) ___ No

3. CERTIFICATION

Yes / No (If No, Complete Blocks 4 and 5)

Type of Certification (Attach Copy of Certification to Application)	DATE CERTIFIED
Refer to Rule 391-3-17-.05(16) to review the "Specific Requirements for Training". Complete the line below with the name of the board from which you received certification.	

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

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

5. EXPERIENCE WITH RADIATION

TYPE OF EXPERIENCE	PLACE OF EXPERIENCE	DURATION OF EXPERIENCE

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

1. Licensee Name _____ 2. License Number _____

3. Address _____
No. Street/ P. O. Box No. City, State Zip code

4. Contact Person _____ 5. Telephone Number _____

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

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

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

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

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

Name of lessor: _____ License No. _____

Lessor acknowledgement of receipt attached.

Material has been transferred to the following licensee:

Licensee Name _____ License No. _____

Address _____
No. Street/ P. O. Box No. City, State Zip code

Date of transfer: _____

Transferee acknowledgement of receipt attached.

Material has been disposed of in the following manner:

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

Copy of survey results attached.

8. Management Official or Radiation Safety Officer

Signature of certifying officer

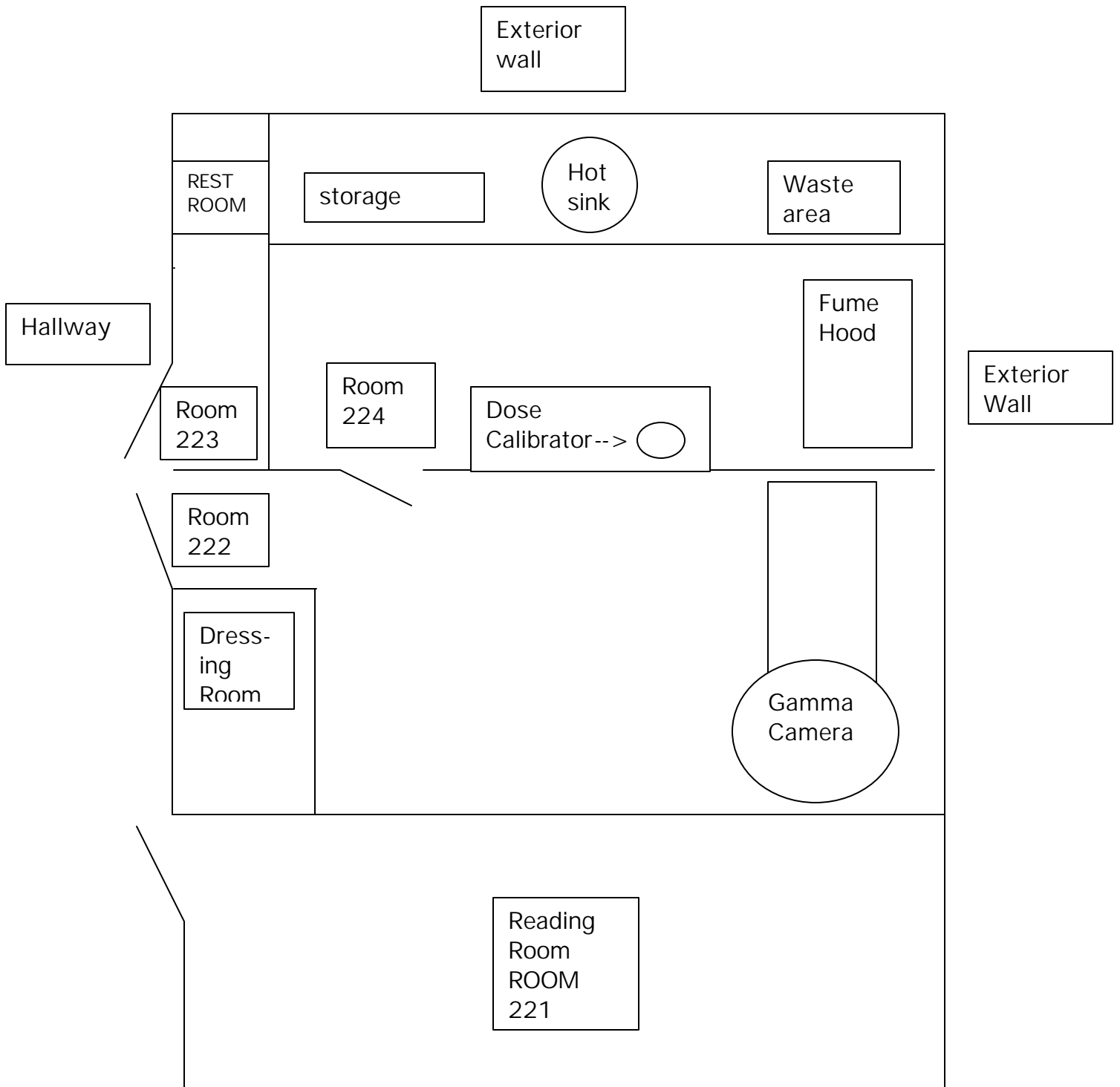
Date

Print name

Title

Keep one copy for your records and send original to:

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
4244 INTERNATIONAL PARKWAY, SUITE 114
ATLANTA, GEORGIA, 30354



LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION

FORM 5 DNR Radioactive Materials Licensee Fee Schedule License Category	Licensing Fees				Inspection Fees		Annual Fees		
	Code	Application	Renewal	Amendment	Routine	Non-Routine	Nominal	Small Entity	Lower Tier
Medical Teletherapy	A.1	3,400	790	430	1,200	1,900	3,200	600	135
Institutional Medical-Mult. Use	A.2	710	1,000	430	1,000	1,500	1,200	600	135
Institutional Medical-Single Use	A.3								
Private Practice	A.4								
In-Vitro Studies Only	A.5	500	500	380	1,200	1,200	500	500	135
In-Vitro General Licenses	A.6	0	0	0	0	0	100	100	100
Bone Mineral Analyzers	A.7	710	1,000	430	1,000	1,500	1,200	600	135
Medical Manufacturer for Distribution	A.8.a.	3,400	1,400	460	1,400	1,900	2,900	600	135
Medical Distribution or Redistribution Only	A.8.b.	1,100	500	310	800	1,200	900	600	135
Mobile Nuclear Medicine	A.9	710	1,000	430	1,000	1,500	1,200	600	135
Broad Medical	A.10	2,300	2,000	360	1,600	1,800	3,300	600	135
Eye Applicators	A.11	710	1,000	430	1,000	1,500	1,200	600	135
Depleted Uranium	A.12	110	110	110	290	350	130	130	130
Special Nuclear Material(sealed sources in devices)	B.1	500	500	380	460	1,300	400	400	135
Special Nuclear Material(other)	B.2	690	690	230	690	800	1,000	600	135
Industrial Mfg. for Distribution	C.1	1,300	2,300	550	1,000	2,000	1,500	600	135
In-house Industrial Radiography	C.2	3,000	1,800	490	1,200	2,500	2,600	600	135
Multiple Job-Site Industrial Radiography	C.3								
Gamma Irradiators (Self-Shielded)	C.4.a.								
Gamma Irradiators (<10K Ci)	C.4.b.1.	1,000	750	250	500	1,000	1,000	600	135
Gamma Irradiators (>10K<100K Ci)	C.4.b.2.	5,000	3,750	1,250	1,200	2,400	5,000	600	135
Gamma Irradiators (>100K<1M Ci)	C.4.b.3.	10,000	7,500	2,500	2,500	5,000	10,000	600	135
Gamma Irradiators (>1M Ci)	C.4.b.4.	30,000	22,500	7,500	5,000	10,000	30,000	600	135
Broad Scope Distribution, Specific	C.5.a.	2,300	1,400	230	2,100	2,100	2,100	600	135
GL Distribution (source and/or device evaluation)	C.5.b.	2,500	580	390	690	690	1,700	600	135
GL Distribution (no source and/or device evaluation)	C.5.c.	1,900	940	290	690	690	1,400	600	135
NARM Exempt Distribution (device evaluation)	C.6.a.	2,100	1,100	250	690	690	1,500	600	135
NARM Exempt Distribution (no device evaluation)	C.6.b.	2,600	1,200	350	460	690	1,700	600	135
Well Logging/Tracers	C.7	3,400	2,000	540	800	800	2,300	600	135
Nuclear Laundries	C.8	1,400	1,400	350	1,200	1,900	1,600	600	135
Industrial Research & Development	C.9	1,100	1,100	630	800	930	1,300	600	135
Gas Chromatograph, Installed Gauges, etc.	C.10	500	500	380	1,200	1,200	500	500	135
Portable Moisture Density Gauges, Pb analyzers, etc.	C.11								
Calibration Sources	C.12								
Industrial (other)	C.13	500	500	380	1,200	1,200	500	500	135
Broad Scope (Academic)	D.1	2,300	2,000	500	930	1,200	2,100	600	135
Broad Scope (Industrial R&D)	D.2								
Civil Defense	E.	580	400	310	690	690	500	500	135
Teletherapy Service Co.	F.	1,400	1,100	630	800	690	1,500	600	135
Consultants (Leak Testing Service)	G.	500	500	380	1,200	1,200	500	500	135
Storage Only	H.								
Academic (Non-Broad)	I.								
Device Evaluation	J.1	3,300	0	1,200	0	0	2,100	600	135
Source Evaluation	J.2	690	0	230	0	0	500	500	135
Reciprocity	K.	0	0	0	0	0	Appropriate License Renewal Fee		
Radioactive Waste Disposal-Burial	L.1	50,000	50,000	5,000	12,000	24,000	30,900	600	135
Radioactive Waste Disposal-Incineration	L.2								
Radioactive Waste-Storage, Packaging or Transfer	L.3								
G L Devices(except tritium safety signs)	GL	0	0	0	0	0	100	100	100

APPENDIX A

MODEL TRAINING PROGRAM

This Appendix describes information that you should know about developing a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to the Medical Licensing Guide, Revision 6."

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, board certification, etc. Site-specific training should be provided for all workers. As a minimum, training shall be provided to authorized users, nuclear medicine technologists 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., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

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

Instruction for individuals in attendance will include the following subjects:

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

APPENDIX B

MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to the Medical Licensing Guide, Revision 6."

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

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

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated before first use, annually and following any repair that will affect the calibration.

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 at midrange of each decade and at two points on at least 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 two 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 which includes the manufacturer, model number, serial number and type of detector;
 - c. Calibration source description which 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. Rates indicated by the instrument being calibrated;
 - c. The correction factor deduced from the calibration data;
 - d. The signature of the individual who performed the calibration and the date of calibration.
13. One word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.
14. The form on Page B-4 is an example of a form that can be used for the Survey Meter Calibration Form and Calibration Sticker.

APPENDIX C

MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C in the Medical Licensing Guide, Revision 6."

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

MODEL PROCEDURE

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

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

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerance.
 - a. Constancy at least once each day prior to assay of patient dosages. A tolerance of $\pm 5\%$ of the stated activity is recommended. This recommended tolerance is more restrictive than the regulation to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.
 - b. Linearity at installation and at intervals not to exceed three months after that. Linearity error may not exceed $\pm 10\%$.
 - c. Geometry dependence at installation and after repair. Geometry error may not exceed $\pm 10\%$.
 - d. Accuracy at installation, and at least annually after that. Accuracy error may not exceed $\pm 10\%$.
2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.
3. Constancy means reproducibility by measuring a constant source over a long period. Assay at least one relatively long-lived source such as Cs-137, Co-60, or Co-57 using a reproducible geometry each day before using the calibrator. The source must meet the requirements described in Rule 391-3-17-.05(7)(b)2(i). Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

- a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
 - b. Measure background at the same setting. Subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
 - c. For each source used, record the readings for each setting, the background level and the net activity of each constancy source.
 - d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Record the results.
 - e. Establish an action level or tolerance for each recorded measurement to notify the user of a suspected malfunction of the calibrator. These action levels should be recorded or posted on the calibrator.
4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and the instrument is zeroed according to the manufacturer's instructions.
5. Linearity means that the dose calibrator is able to show the correct activity over the range of use of the calibrator. This test is done using a vial or syringe of Tc-99m whose activity is equal to the highest dosage that will be administered. Two different methods can measure linearity: (1) the Decay Method and (2) the Shield Method.

Decay Method

- a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time, for example, 8:00 a.m.
- b. Repeat the assay about every four hours until the end of the work day. Continue the assay each day until the activity is less than the lowest activity used. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.
- c. Convert the time and date information you recorded to hours elapsed since the first assay.
- d. On a sheet of semilog graph paper label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.
- e. Draw a "best fit" straight line through the data points. For the point furthest from the line, calculate the deviation from the value on the line.

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

Where:

$$A_o = \text{Activity Observed}$$

$$A_l = \text{Activity Read from Line}$$

- f. If the worst deviation is more than +/-10 percent, the dose calibrator will be repaired or replaced.
- g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

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

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

Syringe Procedure

- a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.
- b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated.
- c. Remove the syringe from the calibrator, draw an additional 0.5cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- d. Repeat the process until you have assayed a 2.0-cc volume.
- e. Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is the volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."
- f. If any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

Vial Procedure

- a. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- b. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- c. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

- d. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 percent error lines above and below the chosen "standard volume."
 - e. If any correction factors are greater than 1.1 or less than 0.9 or if any data points lie outside the 10 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.
7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by NIST or equivalent. The activity of the calibrated reference sources will be within +/- 5% of their stated activity. At least two sources with different principle photon energies (such as cobalt 57, cesium 137, cobalt 60) will be used. The sources will have a minimum activity of 50 microcuries. At least one reference source whose activity is within the range of activities normally assayed will be used.
- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.
 - b. Average the three determinations. The average value should be within five percent of the certified activity of the reference source, mathematically corrected for decay.
 - c. Repeat the procedure for other calibrated reference sources.
 - d. If the average value does not agree, within five percent, with the certified value of the reference source, the dose calibrator needs to be removed from service for repair or adjustment.
 - e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.
 - f. Put a sticker on the dose calibrator that says when the next accuracy test is due.
8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

APPENDIX D

MODEL PERSONNEL EXTERNAL EXPOSURE MONITORING PROGRAM

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to the Medical Licensing Guide, Revision 6."

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, thermoluminescent dosimeter (TLD) or optically stimulated luminescent device (OSL).
2. All individuals who are occupationally exposed, as defined in Rule .01(2)(ppp) and .03(8)(b), to radiation will be issued a film badge, TLD, or OSL whole body monitor. The film badge, TLD, or OSL will be processed monthly by a dosimetry processor who meets the requirements of Rule .03(8)(a)3.
3. All individuals who regularly handle radioactive material will be issued a film or TLD finger monitor that will be processed monthly by a dosimetry processor who meets the requirements of Rule .03(8)(a)3.
4. All individuals who are occupationally exposed to radiation on an occasional basis, such as nurses caring for radiopharmaceutical therapy or implant patients, 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, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages, will not normally be issued exposure monitors.
6. All individuals who have been issued personnel monitoring will be given a written annual report of their exposure as required by Rule .07(4).

APPENDIX E

MODEL PROCEDURE FOR CHECKING EQUIPMENT USED BY A MOBILE NUCLEAR MEDICINE SERVICE PROVIDER

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

You may use the following procedures to ensure the proper operation of imaging equipment that has been transported. If you will follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix E to the Medical Licensing Guide, Revision 6".

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model procedure and the procedure recommended by the manufacturer and carefully review the requirements of Rule .05(6)(j) and .05(7)(l). Say on your application, "We have developed a procedure for ensuring equipment performance for your review that is appended as ATT.9.5.1," and append your imaging equipment quality assurance procedure.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source for consistent response before each use, at each clients address. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Dose Calibrator

Check dose calibrator for proper function, at a minimum a constancy check, before use at each clients address, or on each day of use, whichever is more frequent.

Camera

1. Perform the following checks daily at each location of use before administering radioactive material:
 - a. Peak each camera according to the manufacturer's instructions.
 - b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of the patient.
 - c. Do not administer material until an authorized user or a designated technologist approves the camera for use.
 - d. You do not have to make a permanent record of these checks.
2. Perform the following checks weekly:

- a. With the same frequently used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH), or resolution-quadrant phantom with the flood field as a source.
 - b. If a PLES or bar phantom is used, rotate it 90° so that the camera is tested for both vertical and horizontal geometric linearity.
 - c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.
 - d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.
 - e. Retain the images for two years.
3. Perform the following safety checks after repairs and quarterly:
- a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.
 - b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone should disable the camera motion. If this is not the case, repair the camera before clinical use.
4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for three years.
5. Prior to leaving a clients' address:
- a. Survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceutical and associated radioactive waste has been removed.
 - b. Retain a record of the survey for three years containing information as defined in .05(7)(l)8.

Ventilation

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

APPENDIX F

MODEL RADIATION SAFETY COMMITTEE CHARTER AND RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to the Medical Licensing Guide, Revision 6".

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 (f). Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee 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 radioactive materials license;
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;
4. Establish a table of investigational levels for occupational dose; and
5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent Department regulations, the license application, the license, and amendments;
2. Review the training and experience of the proposed authorized users, authorized nuclear pharmacists, Radiation Safety Officer (RSO), and the medical physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;
3. 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 under the license;
4. 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;
5. Review with the assistance of the RSO reports of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. 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., nursing, security, housekeeping, physical plant) are appropriately instructed as required in Rule .07(3);
7. Review at least annually the RSO's summary report of 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;
8. Review at least annually, the ALARA program according to Rule .05(6)(d)3.
9. Recommend remedial action to correct any deficiencies identified in the radiation protection program;
10. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussion, actions, recommendations, decisions, and numerical results of all votes taken; and
11. Ensure that the radioactive material license is amended prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once every six months.
2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may designate alternate members to participate in meetings in the case of absence of principal members except in the case of the RSO, Deputy RSO, or other RSO's named in the license. Management should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.) If an alternate is used, the minutes shall reflect who the alternate is substituting for on the committee. The alternate will hold a similar position within the institution as the regular member (i.e. a member of nursing will be an alternate for another member of nursing).
3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.
4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

MEMORANDUM

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.

The Radiation Safety Officer(s) is(are) also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

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) will be responsible for implementing the radiation protection program. This individual:

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 PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to the Medical Licensing Guide, Revision 6."

If you prefer, you may develop your own ALARA program for Department review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule .05(6)(d). Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

(Licensee's Name)

(Date)

1. MANAGEMENT COMMITMENT

- a. The management of this facility is committed to the program described in this document for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). We have developed an administrative organization for radiation safety and have and will develop and update the necessary written policy, procedures, and instructions to foster the ALARA concept within our organization. The organization will include a Radiation Safety Officer (RSO) and a Radiation Safety Committee (RSC)¹.
- b. We will perform a formal annual review of the radiation protection program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to show, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. We will be prepared to describe the reasons for not carrying out all of the recommendations.
- d. Besides maintaining doses to individuals as far below ALARA limits, as practicable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It is not desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involves exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

¹ Only medical institutions (other than those authorized for 8 and 9 only) are required to have an RSC.

2. RADIATION SAFETY OFFICER

a. Annual and Quarterly Review

- (1) The RSO will conduct an annual review of the radiation protection program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- (2) The RSO will conduct a quarterly review of the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of this program.
- (3) The RSO will review radiation level surveys of unrestricted and restricted areas to decide if they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

- (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
- (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. These persons will also be informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be encouraged to participate in deciding the procedures that they will be required to follow.

- (1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
- (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will find out the cause(s). When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

e. Reporting to Management

The RSO will brief management annually on the radiation protection program.

3. RADIATION SAFETY COMMITTEE²

a. Review of Proposed Users and Uses

² If there is no RSC then the RSO will assume these responsibilities outlined in this Section.

- (1) The RSC will thoroughly review each applicant's qualifications with respect to the types and quantities of materials and uses for which he has applied. This will ensure that the applicant can act appropriately to maintain exposure ALARA.
- (2) When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment which may be necessary to support the new use of material. If necessary, the special equipment will be in addition to equipment already required to maintain exposures ALARA.
- (3) The RSC will ensure that the user justifies his procedures and that doses will be ALARA (individual and collective).

b. Delegation of Authority

(The careful delegation of RSC authority is essential to the enforcement of an ALARA program.)

- (1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.
- (2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the RSC will record the basis for its action in the minutes of the committee meetings.

c. Annual Review of ALARA Program

- (1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to carry out the ALARA concept.
- (2) The RSC will perform a review of occupational radiation exposure with particular attention to instances where Investigation Levels in Table G-1 in this document are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigation Levels are exceeded (see Section 5).
- (3) The RSC will evaluate the combined efforts of the RSO, authorized users, workers and those of management to maintain the ALARA concept.

4. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

- a. Workers will be instructed in the ALARA concept and its relationship to work procedures and conditions.
- b. Workers will be instructed about what recourse is available if they feel that ALARA is not being promoted on the job.

5. ESTABLISHMENT OF INVESTIGATION LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This organization establishes the following Investigation Levels for occupational external radiation exposures that, when exceeded, will initiate review or investigation by the RSC and/or the RSO. We have adopted the Investigation Levels listed in Table G-1. These levels apply to the exposure of individual workers.

TABLE G-1

	Investigation Levels ³ (mrem per calendar quarter)	
	Level I	Level II
1. Total Effective Dose Equivalent (TEDE)	125	375
2. Sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye	1250	3750
3. Shallow dose equivalent to the skin or any extremity	1250	3750
4. Eye dose equivalent to the lens of the eye	750	2250

³ Emphasis on the Investigation Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations. The limits in this table are for guidance only. You may need to lower the investigational limits based on the work load and type of material being used. For example: a nuclear medicine lab using only material authorized by Rule .05(8) and (9) and no generators may want to set the investigational limits in this table much lower. An active brachytherapy therapy program may want to keep the levels shown in the table.

The Radiation Safety Officer will review and record results of personnel monitoring not less than once in any calendar quarter. We will take the following actions for the Investigation Levels as stated in Table G-1:

- a. Quarterly exposure of individuals to less than Investigation Level I.

No action will be taken in those cases where an individual's exposure is less than Table G-1 values for Investigation Level I, unless the RSO finds reason to question the exposure.

- b. Personnel exposures equal to or greater than Investigation Level I, but less than Investigation Level II.

The RSO will review the exposure of individuals whose quarterly exposures equal or exceed Investigation Level I. The results are reported at the first RSC meeting following the quarter of the recorded exposure. The RSC will compare the exposure with those of others performing similar tasks as an index of ALARA program quality. The RSC may take actions to prevent similar exposures in the future. Their review and recommended actions will be recorded in the RSC minutes.

- c. Exposure equal to or greater than Investigation Level II.

The RSO will quickly investigate the cause(s) of all personnel exposures equaling or exceeding Investigation Level II. The RSO will take appropriate action based on the outcome of the investigation. A report of the investigation, actions taken, and a copy of the individual's radiation exposure record will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. The RSC minutes will be made available to Georgia Department of Natural Resources, Radioactive Materials Program for review during their inspection.

- d. Reestablishment of an individual occupational worker's Investigation Level II to a level above that listed in Table G-1.

If a worker's or a group of worker's exposures need to exceed Investigation Level II, a new, higher Investigation Level II may be established. The new, higher level will be consistent with good ALARA practices for that individual or group. Justification for a new Investigation Level II will be documented.

The RSC will review the justification for, and will approve, all revisions of Investigation Level II. In such cases, when the exposure equals or exceeds the newly established Investigation Level II, those actions listed in 5.c. above will be followed.

7. SIGNATURE OF CERTIFYING OFFICIAL⁴

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

Signature: _____

Name (print or type): _____

Title: _____

Licensee Name and Address:

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

⁴ The person who is authorized to make commitments for the organization (i.e. president, owner, hospital administrator).

APPENDIX H

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 H to the Medical Licensing Guide, Revision 6."

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

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule .05(7)(g). Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 10.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at a minimum 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 a beta applicator.
 - b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
 - c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor cross hairs. Also wipe the primary and secondary collimators and trimmers.
 - d. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.
4. The samples will be analyzed as follows:
 - a. Select an instrument that is sufficiently sensitive to detect 0.005 microcurie. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a rate meter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

- b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcurie, a different instrument must be used.
- c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
- d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
- e. Continue the same analysis procedure for all wipe samples.
- f. If any wipe samples activity is 0.005 microcurie or greater, notify the RSO. Follow the procedures required by Rule .05(7)(g)5.
- g. The leak test record will contain the information required in rule .05(7)(g)4.

APPENDIX I

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 I of the Medical Licensing Guide, Revision 6."

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 10.4," 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 patients, except in circumstances when their use would compromise the patient's well-being (i.e., recessed veins, infants). In these exceptional cases, use other protective methods such as remote delivery of the dose (i.e., through use of a butterfly valve).
5.
 - a. Always use vial shields when preparing or handling a vial that contains a radiopharmaceutical.
 - b. Always store syringes that contain radioactive material in a radiation shield.
6.
 - a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
 - b. Do not store food, drink, or personal effects in areas where radioactive material is used or stored.
7.
 - a. Assay each patient dose in the dose calibrator before administration. 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 patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
 - b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity versus the order written by the physician who will perform the procedure.
8. Always wear personnel monitoring devices (film badge, OSL or TLD) 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., HP260). 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.

APPENDIX J

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 J to the Medical Licensing Guide, Revision 6."

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 10.5," 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 J-3 and J-4 of this appendix.

SPILL KIT

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

- 6 pairs disposable 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
- "Radioactive Material" labeling tape
- 1 china pencil or marking pen
- 3 prestrung "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 J-3) and the Radioactive Spill Contamination Survey (Page J-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 CONTAMINATION SURVEY

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

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

Location	Preclean	Post Clean		Location	Preclean	Post Clean	
	mR/hr	mR/hr	dpm/100cm ²		mR/hr	mR/hr	dpm/100cm ²

dpm = cpm/instrument efficiency
SKETCH OF CONTAMINATED AREA:

NAME: _____

DATE: _____

APPENDIX K

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 K to the Medical Licensing Guide, Revision 6."

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 10.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a person designated by the RSO must authorize each order for radioactive materials. The RSO must ensure that the license authorizes the requested materials and quantities for use by the requesting authorized user. The person ordering material will ensure that possession limits are not exceeded.
2. The Radiation Safety Officer will establish and maintain a system for ordering and receiving radioactive material. The system will contain the following information:
 - a. For ordering routinely used materials
 - (1) Written records that identifies 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 physician who will perform the procedure. The request must show the isotope, radiopharmaceutical, activity and supplier.
 - (2) Persons receiving the material will check the physician'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:

SAMPLE MEMORANDUM

MEMORANDUM

To: Chief of Security
From: Radiation Safety Officer
Subject: Receipt of Packages Containing Radioactive Material

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

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

If you have any questions concerning this memorandum call our Radiation Safety Officer (RSO), _____, at extension _____.
(name)

	Name	Office Phone	Home Phone	Pager
Radiation Safety Officer:	_____			

Chief of Nuclear Medicine: _____

Nuclear Medicine Technologist on Call:
(Call Page Operator at extension _____)

Nuclear Medicine Physician on Call:
(Call Page Operator at extension _____)

APPENDIX L

MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

You may use the following procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to the Medical Licensing Guide, Revision 6."

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 10.7," 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)(u). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours according to Rule .03(12)(f)3. The licensee shall immediately notify the final delivery carrier and the Department by telephone, telegram, mailgram, or facsimile, when the removable radioactive surface contamination exceeds the limits of Rule .06(15)(h) or when the external radiation levels exceed the limits of Rule .06(15)(j) 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 millirem per hour, at 1 meter from the package surface. The surface dose rate for such packages should not exceed 200 millirem 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 M

MODEL PROCEDURE FOR RECORDS OF RADIOACTIVE MATERIAL USE

GENERAL

Many suppliers include pressure sensitive stickers or forms, or bar codes that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to enter whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dose from it; if you take 30 Ir-92 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.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 M.1 to the Medical Licensing Guide, Revision 6."

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

See Page M-5 for a Unit Dosage Receipt and Use Log Form you may want to use.

MODEL PROCEDURE

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

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual);

- b. Measured activity in millicuries or microcuries and date and time of measurement;
 - c. Patient name and identification number if one has been assigned;
 - d. Time of measurement;
9. If discarded, the date and method of disposal; and
 10. Initials of the individual who made the record.

M.2 RECORDS OF MULTIDOSE VIAL USE

You may use the following model procedure to keep a record of multidose 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 multidose vial record system that was published in Appendix M.2 to the Medical Licensing Guide, Revision 6."

If you prefer, you may develop your own multidose vial record system for review. If you do so, you should carefully consider for inclusion all the features in the model system and carefully review the requirements of Rule .03(14); and .05(7)(d). Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 10.9," and append your unit dosage record procedure.

See Page M-6 for a Multi-dose Vial Preparation and Use Log Form you may want to use.

MODEL PROCEDURE

For each multidose 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.

M.3. MEASURING AND RECORDING GENERATOR CONTAMINANTS CONCENTRATION

The regulations require that each licensee who uses a generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum or strontium concentration, depending on the type of generator being used. (This does not have to be done when using radiopharmaceuticals from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain contaminants from generators in excess of those allowed by Rule .05(10)(a).

The model procedure for measuring contaminants is based on the use of a “breakthrough pig.” Your dose calibrator manufacturer will usually supply, as an option, a breakthrough pig made of lead. The pig is usually thick enough to shield all the radiopharmaceutical photons but only a fraction of the contaminant photons. The manufacturer will specify the contaminant correction factor to convert from measured to total contaminant.

The following model procedure may be used to measure the generator contaminant concentration in the generator elution. If you will follow the model procedure, you may say on your application, “We will establish and implement the model procedure for measuring and recording generator contaminant concentration that was published in Appendix M.3 of the Medical Licensing Guide, Revision 6.”

If you prefer, you may develop your own contamination concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rule .05(10). Say on your application, “We have developed a procedure for measuring and recording generator contaminant concentration for your review that is appended as ATT 10.10,” and append your procedure for measuring and recording contaminant concentration.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;
2. Date and time of elution;
3. Measured contaminant activity in microcuries;
4. Product of the measured contaminant activity and the correction factor noted by the breakthrough pig manufacturer;
5. Measured radiopharmaceutical activity in millicuries;
6. Ratio of the total contaminant in microcuries per milliliter of radiopharmaceutical. Check that the amount of the contaminant is less than allowed by Rule .05(10)(a). (If it isn't, stop and notify the RSO.)
7. Initials of the person who made the record.

M.4

KEEPING AN INVENTORY OF IMPLANT SOURCES

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 of the Medical Licensing Guide, Revision 6."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule .03(14); and .05(14)(d). Say on your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as ATT 10.11," and append your procedure for keeping an inventory and use record for implant sources.

See the forms on Pages M-7 and M-8 as samples you may want to use.

MODEL PROCEDURE

1. Use a locking closet, room, installed cabinet, or safe to store all implant sources.
2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use and the patient's name, the time and date they were removed from storage, and the number and activity of sources in storage after the removal; initial the record.
6. Each time you return the sources to storage, make a record of the number and activity of sources returned, the room number of use and the patient's name, and the time and date they were returned to storage and the number and activity of sources in storage after the return; initial the record.
7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX N

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 N to the Medical Licensing Guide, Revision 6."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features of the model procedure and carefully review the requirements of Rule .05(7)(j). Say on your application, "We have developed survey procedures for your review that are appended as ATT 10.12," and append your survey procedures.

A sample survey form is on Page N-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/100cm²). If diagnostic administrations are occasionally made in patient's rooms 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 and brachytherapy 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 RSO if you find unexpectedly high or low levels.

REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas
 - a. In radiopharmaceutical elution, preparation, and administration areas, wipe daily for removable contamination. If diagnostic administrations are occasionally made in patient's rooms 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(7)(j)8). It must include the following information:
 - a. The date, area surveyed, and equipment used.
 - b. The name or initials of the person who made the survey.
 - c. A drawing of the areas surveyed with contamination and dose rate action levels for each area as established by the RSO. (See table N-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 N-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

APPENDIX O

MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

WORKER DOSE FROM NOBLE GASES (Item 10.13.1)

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

If you will collect spent gas in a shielded trap with an effluent air contamination monitor and will follow the monitor manufacturer's instructions for checking its accuracy and constancy, you may respond to item 10.13.1 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 10.13.1 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix O.3 to the Medical Licensing Guide, Revision 6."

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for Department review during inspections.) If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item 10.13.1 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix O.1 to the Medical Licensing Guide, Revision 6."

If none of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of Rules .03(5), .03(10), .05(7)(m), and .05(11). Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as ATT 10.13.1," and append your procedure for monitoring worker dose from noble gases.

WORKER DOSE FROM AEROSOLS (Item 10.13.2)

If you will only be using single use devices such as "Aerovent" for administering Tc-99m DTPA aerosol, you do not have to monitor the trap effluent. You may respond to Item 10.13.2 by saying, "We will only use single use devices for administering aerosols and we do not monitor the effluents from these devices."

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturer's instructions for checking for accuracy and constancy, you may respond to Item 10.13.2 by saying, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring reusable effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for Department review during inspections.) If you will follow the model procedure below for calculating worker dose from aerosols, you may respond to Item 10.13.2 by saying, "We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix O.1 to the Medical Licensing Guide, Revision 6."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of Rules .03(5), .03(10), .05(7)(m), and .05(11). Say on your application, "We have developed a procedure for monitoring worker dose due to aerosol concentrations that is appended as ATT 10.13.2," and append your procedure for monitoring worker dose from aerosols.

O.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Collect the following data:
 - a. Estimated number of studies per week;
 - b. Activity to be administered per study;
 - c. Estimated activity lost to the work areas per study (you may assume a 20% loss);
 - d. Measured airflow supplied by each vent in the imaging room (if different during heating and cooling seasons, use the lesser value);
 - e. Measured airflow exhausted by each vent in the imaging room (the exhaust should be vented and not recirculated within the facility);
 - f. Measured airflow exhaust at the storage site (e.g., fume hood); and
 - g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} Ci/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For soluble Tc-99m, the maximum permissible values are 6×10^{-5} uCi/ml in restricted areas, and 2×10^{-7} Ci/ml in unrestricted areas. For other gases or aerosols, see Rule .03, Appendix B of 10 CFR Part 20.
2. The following calculations will be made:
 - a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the exhaust rate is larger than the supply rate, this ensures that the imaging room is at negative pressure.
 - b. The estimated average concentration in restricted areas.
 - (1) The total activity released to the restricted area (activity used each week multiplied by estimated fractional loss per study) divided by the total air exhausted (sum of all exhaust rates multiplied by the length of the work week) must be less than the applicable maximum permissible value for a restricted area.
 - (2) If this is not the case, plan for fewer studies. (An increase in the ventilation rate will not significantly reduce the down-wind effluent concentration, because it is primarily a function of the natural dispersion in the atmosphere.)

O.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable maximum permissible value for an unrestricted area.
2. If this is not the case plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

O.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

Charcoal traps can significantly reduce air contamination. They can also become saturated, or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

1. If the trap effluent is monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions and keep a record of the checks.
2. If the trap effluent is not monitored, check it on receipt and once each month. During one patient study collect the effluent from the trap in a plastic bag. Then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas. Compare its counts per minute (cpm) to background cpm without any other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.
3. The Radiation Safety Officer will establish an action level based on cpm or on a multiple of the background cpm. If a significant increase in the bag cpm is measured, the trap is breaking down and must be replaced.
4. Follow the trap manufacturer's instructions for replacing the trap.

PUBLIC DOSE FROM AIRBORNE EFFLUENT (Item 10.13.3)

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value of Rule .03, Table II of Appendix B to 10 CFR Part 20.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item 10.13.3 by saying, "We will not directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for Department review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond to Item 10.13.3 by saying, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix O.2 to The Medical Licensing Guide, Revision 6."

If neither of the above apply, you may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of Rules .03(5), .03(10), .05(7)(m), and .05(11). Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as ATT 10.13.3," and append your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME (Item 10.13.4)

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix O.4 should be done to determine how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 10.13.4 by saying, "We will calculate spilled gas clearance times according to the procedure that was published in Appendix O.4 to the Medical Licensing Guide, Revision 6."

You may develop your own procedure for review. If you do so, you should consider all the above information and carefully review the requirements of Rule .05(11). Say on your application, "We have developed a procedure for calculating spilled gas clearance times that is appended as ATT 10.13.4," and append your procedure.

O.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:
 - a. "A", the highest activity of gas in a single container, in microcuries;
 - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;
 - c. "Q", the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially-installed gas exhaust system;
 - d. "C", the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} Ci/ml in restricted areas and 5×10^{-7} Ci/ml in unrestricted areas. For other gases, see Rule .03, Appendix B to 10 CFR Part 20; and
 - e. "V", the volume of the room in milliliters.
2. For each room the following calculations will be made
 - a. The airflow supply must be less than the airflow exhaust to ensure that the room is at negative pressure.
 - b. The evacuation time, $t = (-V/Q) \times (\ln (CV/ A))$, where ln is the natural logarithm.
3. The clearance time will be posted in the room.

APPENDIX P

MODEL PROCEDURES FOR RADIATION SAFETY DURING IODINE THERAPY OVER 30 MILLICURIES

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 P to the Medical Licensing Guide, Revision 6."

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 model procedure and carefully review the requirements of Rule .03(5), .05(7)(k), .05(12), and .07(3). Say on your application, "We have developed a procedure for radiation safety during therapeutic use of iodine over 30 millicuries for your review that is appended as ATT 10.14," and append your procedure.

"Radiation Safety Checklist for Iodine Therapy over 30 Millicuries", Page P-3 may be helpful to you.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.
2. Prepare the room for the procedure as follows:
 - a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
 - b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.
 - c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
 - (1) Containers should be unbreakable and closable.
 - (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
 - (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
 - (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm lead.)
 - (5) Supply a wide-mouth antispash funnel.
 - d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Supply the nurses with film badges, OSL's, TLD's, or pocket ionization chambers.
5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Iodine-131" (Page P-4), or your own nursing 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 nurses' station.
6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, 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. Mark a visitor's "safe line" on the floor with tape as far from the patient as possible.
9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitor's "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 nursing instructions form or the nurses' dosimeter sign out form. Post the room with a "Caution - Radioactive Materials" sign.
10. For patients treated with liquid or capsule I-131, within three (3) days after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden assay for patient 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.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until either the exposure rate from the patient is less than 5 millirem per hour at 1 meter or the retained radioactivity is less than 30 millicuries (see Rule .05(7)(k)). If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
 - a. Remove all absorbent paper, and place it in the appropriate container.
 - b. Transfer all containers to a decay-in-storage or decontamination area.
 - c. Use a radiation detection survey meter with an appropriate probe to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100 cm².
 - d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list

RADIATION SAFETY CHECKLIST FOR IODINE THERAPY OVER 30 MILLICURIES

PATIENT: _____ ROOM: _____ DATE: _____

PREPARATION:

- ___ Schedule a private room, with private sanitary facilities and without carpet, in a low traffic area.
- ___ Cover large room surfaces with absorbent paper and small surfaces with absorbent paper or plastic bags.
- ___ Prepare labeled boxes for used linen, disposable waste, and nondisposable contaminated items.
- ___ Prepare urine collection containers if urine will be collected.
- ___ Stock room with disposable gloves, absorbent paper, and "radioactive waste" labels.
- ___ Mark a visitors' "safe line" on the floor.
- ___ Order disposable table service.
- ___ Notify housekeeping to not clean the room until further notice.
- ___ Brief the nursing staff on radiation safety measures.
- ___ Supply the nursing staff with personnel radiation dosimeters.

ADMINISTRATION:

- ___ Clear the room of unneeded personnel.
- ___ Brief the patient on the clinical procedure.
- ___ Administer the dosage.
- ___ Measure dose rates at bedside, 1 meter from bedside, visitors' "safe line", and surrounding hallways and rooms.
- ___ Post the room with a "Caution-Radioactive Materials" sign.

FOLLOW-UP:

- ___ Measure the thyroid burden of all personnel who were present for the administration.
- ___ Pick up waste for decay-in-storage or decontamination.
- ___ Release the patient.
- ___ Decontaminate and survey the room. Remove the "Caution-Radioactive Materials" sign.
- ___ Call the Housekeeping Office to clean the room.

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

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING PHYSICIAN			

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH IODINE-131, PHOSPHORUS-32, OR GOLD-198

PATIENT: _____ ID NUMBER _____ ROOM: _____ DATE: _____

Attending: _____ Phone: _____ Pager: _____

Dose: _____ mCi of _____ as _____ was administered at _____ am/pm

Signature: _____ Date: _____

RADIATION EXPOSURE RATES

Patient Orientation: Supine in bed or:

UNRESTRICTED AREAS

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

RESTRICTED AREAS

DATE	TIME	BEDSIDE (mR/hr)	3' FROM BED (mR/hr)	DOOR (mR/hr)	OTHER (mR/hr)

INSTRUCTIONS

VISITOR RESTRICTIONS:

- ___ No visitors.
- ___ No visitors under 18 or pregnant.
- ___ _____ Minutes each day maximum for each visitor. Visitors must stay behind line on floor at all times.

NURSING RESTRICTIONS:

- ___ Patient restricted to room.
- ___ _____ Minutes each day per nurse in the room.

PATIENT CARE:

- ___ Wear disposable gloves. Wash your hands after caring for the patient.
- ___ Discard linen, bedclothes, plates, utensils, dressings, etc., in boxes in the room.
- ___ Collect urine in containers provided. Discard feces in toilet.
- ___ Discard urine and feces in toilet. Flush 3 times.
- ___ Housekeeping personnel are not permitted in the room.
- ___ Only the Radiation Safety Officer (RSO) may release the room to Admitting Office.
- ___ Wear your radiation monitor when caring for the patient. Leave it at the nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share. Call RSO if additional monitors are needed.

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

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING PHYSICIAN			

APPENDIX Q

MODEL PROCEDURE FOR RADIATION SAFETY DURING BRACHYTHERAPY (IMPLANT THERAPY)

You may use the following procedure to reduce worker and public dose during implant 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 implant therapy that was published in Appendix Q to the Medical Licensing Guide, Revision 6."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all of the features of the model procedure and carefully review the requirements of Rule .03(5), .05(7)(k), .05(14), and .07(3). Say on your application, "We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 10.15," and append your procedure.

You may want to use the sample forms, "Radiation Safety Checklist for Temporary Implant Therapy", Page Q-3; and "Nursing Instructions for Patients Treated with Temporary Implant Sources", Page Q-4.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room.
2. Supply the nurses with film badges, OSL's, TLD's, or pocket ionization chambers.
3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Temporary Implant Sources," or a similar instruction form as an outline. Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items necessary as consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line" and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign out form. Post the room with a "Caution - Radioactive Materials" sign.
8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient and accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.
9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than 5 mR/hr at 1 meter. Measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

10. For implant procedures involving unsealed radioactive material:
 - a. Care should be taken during the insertion and removal of unsealed radioactive material to minimize the potential of contamination of the patient.
 - b. All items that come in contact with bodily fluids should be surveyed for contamination.
 - c. Consider the location of the patient's bed during these procedures to minimize exposure to workers and unrestricted areas.
 - d. A radioactive spill kit should be available in the patient's room and personnel should be trained in its use.

RADIATION SAFETY CHECKLIST FOR TEMPORARY IMPLANT THERAPY

PATIENT: _____ ROOM: _____ DATE: _____

PREPARATION:

- ___ Schedule a private room in a low traffic area.
- ___ Mark a visitor's "safe-line" on the floor.
- ___ Brief the nursing staff on radiation safety measures.
- ___ Supply the nursing staff with personnel radiation dosimeters.

IMPLANT:

- ___ Clear the room of unneeded personnel.
- ___ Brief the patient on the clinical procedure.
- ___ Insert the implant.
- ___ Measure dose rates at bedside, 1 meter from bedside, visitor's "safe-line", and surrounding hallways and rooms.
- ___ Post the room with a "Caution-Radioactive Materials" sign.

FOLLOW-UP:

- ___ Make a radiation survey of the patient to assure that all sources have been removed, or no contamination is present.
- ___ Count the number of sources removed from the patient to assure that all sources have been removed. (N/A, if unsealed source)
- ___ Decontaminate and survey room (N/A, if sealed source)
- ___ Remove the "Caution-Radioactive Materials" sign.

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

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING PHYSICIAN			

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH TEMPORARY IMPLANT SOURCES

PATIENT: _____ ID NUMBER _____ ROOM: _____ DATE: _____
 Attending: _____ Phone: _____ Pager: _____
 Dose: _____ mCi of _____ as _____ source(s) loaded on _____, 20 @ _____: _____ am/pm
 Signature: _____ Date: _____

RADIATION EXPOSURE RATES

UNRESTRICTED AREAS					
Patient Orientation: Supine in bed or:					
DATE	TIME	ROOM (mR/hr)	ROOM (mR/hr)	OTHER (mR/hr)	OTHER (mR/hr)
RESTRICTED AREAS					
DATE	TIME	BEDSIDE (mR/hr)	3' FROM BED (mR/hr)	DOOR (mR/hr)	OTHER (mR/hr)

RELEASE CERTIFICATION: Patient may not be released from the hospital until the following certification is signed and dated by the Radiation Safety Officer (RSO) or the attending physician.

___ (sealed source) I have removed and counted ___ individual sources from this patient. A low-range GM survey of the patient failed to indicate any remaining sources in the patient.

___ (unsealed source) Radioactive material has been removed from this patient. A low-range GM survey of the patient failed to indicate any contamination of the patient.

SIGNATURE: _____ **DATE:** _____

INSTRUCTIONS

VISITOR RESTRICTIONS:

- ___ No visitors.
- ___ No visitors under 18 or pregnant.
- ___ Minutes each day maximum for each visitor. Visitors must stay behind line on floor at all times.

NURSING RESTRICTIONS

- ___ Patient is restricted to room.
- ___ Patient is restricted to bed.
- ___ Patient must not move.
- ___ ___ minutes each day per nurse in the room.

PATIENT CARE:

- ___ Wear your radiation monitor when caring for the patient. Leave the monitor at the nursing station at the end of your shift. You may use the same monitor on your next shift. Do not share monitors with other staff members. Call RSO for additional monitors, if needed.
- ___ If a source appears dislodged, call the attending physician and the RSO immediately.
- ___ Omit bed bath.
- ___ No perineal care. Pad may be changed as necessary.
- ___ Save surgical dressings for disposal by attending physician or RSO.
- ___ See special oral hygiene care instructions.

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

NAME	WORK TELEPHONE	HOME TELEPHONE	PAGER
RSO			
ATTENDING PHYSICIAN			

APPENDIX R

MODEL PROCEDURE FOR QUALITY MANAGEMENT PROGRAM

The purpose of a quality management program (QMP) is to provide documentation that radioactive material or radiation from it is administered as directed by the authorized user.

The administration of radioactive material or radiation from it can involve many modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, or gamma stereotactic radiosurgery. Specific policies and procedures will be established for each modality, as needed, to ensure that the objectives of the QMP as outlined in Rule .05(6)(k) are met.

You may use the following procedure for your QMP. If you follow the model procedure, you may say on your application, "We will establish the model procedure for a quality management program that was published as Appendix R to the Medical Licensing Guide, Revision 6. We will follow the procedures listed in parts R.1, R.3, and R.4. We will also follow the procedures listed in R. 2 if appropriate."

If you develop your own QMP for review, you should consider for inclusion all the features of the model and the requirements of Rule .05(6)(k). Say on your application, "We have developed a quality management program for your review that is appended as ATT 10.16," and append your quality management program.

MODEL PROCEDURE

GENERAL

1. Before administration, a written directive as defined in Rule .05(2)(aa) is prepared for any teletherapy, remote afterloader, stereotactic radiosurgery or brachytherapy radiation dose; any therapeutic administration of a radiopharmaceutical; or any administration of I-125 or I-131 more than 30 microcuries.
2. Verify the patient's identity by more than one method before administering a therapeutic dose or a dose of I-125 or I-131 more than 30 microcuries. Different methods of identification include: confirm the patient's name by comparison with a picture ID card, information in the patient's record such as, birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.
3. All workers will seek guidance from the Radiation Safety Officer (RSO), authorized user, or medical physicist, if they do not understand how to carry out the written directive. Workers will ask questions if they are unsure of any part of the written directive.
4. Periodic reviews will be conducted of the QMP. The review will include an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with the QMP. The reviews will be conducted from the previous review forward and at intervals not to exceed 12 months.

R.1 POLICIES AND PROCEDURES FOR RADIOPHARMACEUTICAL USES

1. The authorized user shall date and sign a written directive before the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities of I-125 or I-131 greater than 30 microcuries.
2. Verify, before administering the radioactive material, that the specific details of the administration are according to the written directive. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive. The dosage will be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive.

3. After administering a radiopharmaceutical, the authorized user or someone under their supervision (e.g., a nuclear medicine physician, medical physicist, or technologist), will make, date and sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

R.2 POLICIES AND PROCEDURES FOR BRACHYTHERAPY (INCLUDING AFTER LOADING DEVICES)

1. The authorized user will date and sign a written directive before the administration of any brachytherapy dose. A written directive is required by Rule .05(6)(k). See Section R.3 for procedures for oral directives and revisions to written directives.
2. Verify, before administering the brachytherapy dose, that the specific details of the brachytherapy administration are according to the written directive and plan of treatment. In particular, the radioisotope, treatment site, and dose should be confirmed to verify agreement with the written directive and plan of treatment.
3. The authorized user or a person under their supervision (e.g., a medical physicist, oncology physician, dosimetrist, or radiation therapy technologist) will verify that the radioisotope, number of sources, source strengths, and, if applicable, loading sequence of the sources to be used agrees with the written directive and plan of treatment before implanting the radioactive sealed sources. The term sealed sources includes wires, balloon catheters and encapsulated sources. The licensee may use any appropriate verification method, such as checking the serial number of the sealed sources behind an appropriate shield, using a radiation detector, using a dose calibrator, using color-coded sealed sources, or using clearly marked storage locations, i. e., one location for each source strength.
4. For temporary brachytherapy implants, radiographs or other comparable images (e.g., computerized tomography) will be used to show brachytherapy radioactive sources or nonradioactive "dummy" sources in place as the basis for verifying the position of the sources and calculating the exposure time (or, equivalently, the total dose). Whenever possible, nonradioactive "dummy" sources should be used before inserting the radioactive sealed sources (e.g., cesium-137 sealed sources used for intracavitary applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary provided the position of the sources is known before inserting the radioactive sources and calculating the exposure time (or, equivalently, the total dose).
5. For permanent brachytherapy implants, radiographs or other comparable images (e.g., computerized tomography) will be used to show brachytherapy radioactive sources in place as the basis for verifying the position of the sources and calculating the total dose, if applicable, after inserting the sources (e.g., iodine-125 sealed sources used for interstitial applications). However, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., templates) to establish the location of the sources and calculate the total dose, if applicable. In these cases, radiographs or other comparable images may not be necessary.
6. After insertion of the temporary implant brachytherapy sources, the authorized user will promptly record the actual loading sequence of the radioactive sources implanted (e.g., location of each source in a tube, tandem, balloon catheter or cylinder) and sign or initial the patient's chart or other appropriate record.
7. After insertion of the permanent implant brachytherapy sources, the authorized user will promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.
8. Check the dose calculations before the total prescribed brachytherapy dose has been administered.

An authorized user or a person under their supervision, who did not make the original calculations, should cross check the dose calculations, whenever possible.

- a. Manual dose calculations should be checked for:
 - (1) Arithmetic errors,
 - (2) Appropriate transfer of data from the written directive, plan of treatment, tables, and graphs,
 - (3) Appropriate use of all pertinent data in the calculations.
 - b. Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient was used in the calculations (e.g., position of the applicator or sealed sources, number of sources, total source strength, or source loading sequence). Alternatively, the brachytherapy dose should be manually calculated to a single key point and the results compared with the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).
9. Before completion of the procedure, the authorized user will date and sign or initial a written record in the patient's chart or in another appropriate record after insertion of the brachytherapy sources. The written record should include the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose).
 10. If the authorized user determines that delaying treatment to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations should be done within two working days of completion of the brachytherapy treatment.
 11. Acceptance testing will be done by a qualified person on each treatment planning or dose calculating computer program that could be used for brachytherapy dose calculations. Acceptance testing should be done before the first use of a treatment planning or dose calculation computer program for brachytherapy dose calculations.

R.3 ORAL DIRECTIVES AND REVISIONS TO WRITTEN DIRECTIVES

1. A delay to provide a written revision to an existing order may be necessary because of the patient's medical condition. In this case, an oral revision to an existing written directive will be acceptable, if the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.
2.
 - a. A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure if the revision is dated and signed by an authorized user before the administration of the radiopharmaceutical dosage, the brachytherapy dose, or the stereotactic radiosurgery dose.
 - b. If a delay to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, if the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

R.4 PERIODIC REVIEWS

1. Periodic reviews will be conducted of each applicable program area, e.g., radiopharmaceuticals, brachytherapy, stereotactic radiosurgery. The review will include, from the previous 12 months (or

since the last review), a representative sample of patient administrations, all recordable events, and all misadministrations. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each therapy treatment modality done in the institution.

2. These periodic reviews may be conducted weekly, monthly, or quarterly if one of these periods is more compatible with current operations.
3. If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The RSO or designee should regularly review the findings of the periodic reviews to ensure that the QMP is effective.
4. For each patient case reviewed, determine if the administered radiopharmaceutical dosage or radiation dose was according to the written directive or plan of treatment as applicable. For example, determine if the following are correct:
 - a. For radiopharmaceutical therapy: the radiopharmaceutical, dosage, and route of administration;
 - b. For teletherapy: the total dose, dose per fraction, number of fraction and treatment site;
 - c. For remote after loading devices: the radioisotope, treatment site, and total dose, dose per fraction and number of fractions;
 - d. For all other brachytherapy before implantation: the radioisotope, treatment site, and dose; after implantation but before completion of the procedure: the radioisotope, treatment site, number of sources and total source strength and exposure time (or, equivalently, total dose);
 - e. For stereotactic radiosurgery: treatment site, number of target coordinates, settings per treatment for each anatomically distinct treatment site, and total dose.
5. For each patient case reviewed, identify deviations from the written directive, the cause of each deviation, and the action required to prevent recurrence. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work. Reevaluate the QMP policies and procedures after each annual review to decide whether the program is still effective or to identify actions required making the program more effective.
6. Program review results will be documented and made available for Department review during inspections. To obtain the maximum results from the lessons learned from each review, the program review reports should be distributed within the facility to appropriate management and departments. Corrective actions for deficient conditions will be carried out within a reasonable time after identification of the deficiency.

APPENDIX S

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 S to the Medical Licensing Guide, Revision 6."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of Rule .03(13), .03(14)(i), and .05(7)(n). Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 11.0," 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 burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta (See Rule .03(13)(c)2.) and generally licensed in-vitro kit exemptions (See Rule .02(6)(g)6.), nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See Rules .03(14)(i) and .05(7)(n)).

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal as in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.
3. 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.
4. 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., volatility, toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

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. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see Rule .03(13)(c)2). Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and the sink or toilet at which the material was released.
2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Rule .03(5)(j)2, Table II of Appendix B of 10 CFR 20. 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 media or animal tissue containing H-3, I-125 or C-14 may be disposed of as if it were non radioactive if it meets the criteria outlined in 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 and keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs or gauze in another, and unused dosages in a third container. Small departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed 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 as low level radioactive waste.
5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator

first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a low level radioactive waste burial site. Follow the packaging instructions you received from the transfer agent and the low level radioactive waste 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.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Rule .06 and the applicable Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (See DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination measurements required by paragraph of 173.475(i) of 49 CFR Part 173.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

APPENDIX T

MODEL PROCEDURE FOR UTILIZING A MOBILE MEDICAL SERVICE PROVIDER

When your license is issued to include this service, the mobile unit becomes a place of use at your facility. This means you as the licensee are responsible for procedures and records just as if the mobile unit were an in-house area.

You may use the following model program for mobile medical service. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model mobile medical service program published in Appendix T to the Medical Licensing Guide, Revision 6."

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 .05. Say on your application, "We have developed a mobile medical service program for your review that is appended as ATT 9.5.2," and append your program.

MODEL PROGRAM

1. An authorized user at your facility must give authorization to inject to the technologist on the mobile unit, and this record must be maintained at your facility. Ensure that the authorized user is aware of and fulfills his/her responsibility with respect to this use location. The mobile service technologist, if provided, will work under the supervision of the authorized user.
2. Provide for source accountability (scanner, dose calibrator, and survey instrument calibration sources) by performing an inventory on arrival, and prior to scanning van departure. Provide for the security of radioactive sources on the van if it is left unattended.
3. Maintain copies of the following records for the dose calibrator, which include the constancy for the day the mobile unit is at your facility, linearity for the quarter, yearly accuracy test and the current geometry test.
4. Maintain procedures for the QA /QC on the mobile service camera. The authorized user will ensure that the recommended scanner QC is performed and reviewed prior to the first patient study.
5. Provide and maintain documentation of the training provided to the mobile service technologist of your in-house radiation safety procedures. Additional radiation safety training is provided on handling high energy radiopharmaceuticals.
6. Maintain records of pharmaceutical ordering, receipt, use, and waste. Doses may be delivered directly to the facility nuclear medicine department and secured pending use. Doses may be delivered directly to the scanning van if onsite and, if that is the intended injection location and personnel are present to receive the shipment.
7. Records of personnel monitoring for the mobile medical service technologist, either provided by your facility or the mobile medical service, should be available and maintained
8. Ensure that the use location is free of radioactive contamination before releasing the mobile unit from your custody and maintain records of these surveys.
9. If high energy radiopharmaceuticals are utilized, ensure that shielding needs for receipt, use, storage, and waste handling as well as updated general safety procedures that address these uses are available. (e.g. remote handling, additional shielding and dose calibrator shielding)

10. Maintain a copy of the survey instrument calibration, if an in-house survey meter is not used.
11. Documentation of events or incidents must be maintained.
12. Perform and document the monthly RSO audits that should include staff safety practices, record keeping and adequate posting and security of the restricted area. The RSO should also determine that contamination surveys of the van are properly documented.
13. If high energy radiopharmaceuticals are utilized, provide separate patient injection/quiet room with private toilet to reduce potential radiological exposures to other patients and staff to maintain ALARA.
14. These records should be kept in a permanent location at your facility such as the nuclear medicine department unless otherwise specified in the application.

PART 2

ADDITIONAL INFORMATION FOR MANAGING RADIATION PROTECTION PROGRAMS FOR MEDICAL USE LICENSEES

APPENDIX U

CONSIDERATIONS IN MAKING RADIATION PROTECTION PROGRAM CHANGES

This appendix describes information that you should know about making changes to your Radiation Protection Program. When making changes, it is the licensee's responsibility to ensure that the result will be according to the regulations and license conditions. The Radiation Safety Officer must review changes for radiation safety considerations before approving them. (See Rule .05(4) and .05(5) for required amendments and notifications.)

Consider the following questions before making an application for a license amendment or making changes. Not all the questions apply to all changes, and you may want to consider other questions before making changes.

GENERAL

1. Proposed changes should be fully explained.
2. Clearly define all acronyms, abbreviations, or undefined words.
3. Spell out units of measure such as millicurie, microcurie, and millirem per hour, use these abbreviations only in calculations or log sheets.
4. Identify, by name or office, who is responsible for doing each task.

ROOM CHANGES

1. Why is the change needed?
2. What materials, and how much of each, will be used in the room?
3. How will the room be secured? How will the room be secured in case of spills?
4. Can the room surfaces be cleaned?
5. Is the room adequately ventilated?
6. Does the room provide radiation shielding?
7. What are the anticipated doses each week in the room and in the surrounding areas?
8. What are surrounding areas used for? What might they be used for in the future?
9. Can the old room be cleaned, surveyed, and released for unrestricted use?

EQUIPMENT CHANGES

1. Why is the change needed?
2. Was the equipment designed for the intended purpose?
3. For detection and measuring equipment:
 - a. What is the lowest level of detection for the equipment?
 - b. What is the level of detection required?
 - c. Will the instrument be compromised by ambient radiation, light, temperature, humidity, or chemicals in the area?
 - d. If it fails is backup equipment available, and can it be quickly repaired and returned to service?
4. For protection equipment:
 - a. What level of protection does it provide?
 - b. What is the required level of protection?
 - c. If it fails, is backup equipment available, and can it be quickly repaired and returned to service?

PROCEDURE CHANGES

1. Why is the change needed?
2. Does the change affect any individual's dose or dose rate?
3. For each step in the procedure, what things are likely to go wrong either because of equipment failure or human error?
4. What are the likely consequences of problems noted in Questions 3?
5. What steps can be taken to mitigate the consequences noted in Question 4?

APPENDIX V

RECOMMENDED SUPPORT EQUIPMENT AND SERVICES FOR MEDICAL PROGRAMS

Depending upon the type and size of your medical program, you will need various types of equipment and services to support your Radiation Protection Program. The following list does not include the many disposable or reusable items that are also necessary. The list is not all-inclusive, and not all items are absolutely necessary.

The list has been divided to correspond to the sections of Rule .05 that describe different types of medical uses of radioactive material. While instrumentation overlaps among sections, duplication of equipment is generally not necessary unless an instrument is to be dedicated to a single area of use or to a single user. Descriptions of some items are at the end of this list.

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

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

.05(9) FOR IMAGING AND LOCALIZATION STUDIES

1. Portable radiation detection survey meter
2. Portable radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Syringe shield
7. Hot lab area monitor
8. Flood source for gamma cameras
9. PLES, bar, orthogonal-hole, or quadrant phantom for gamma cameras
10. Lead L-block
11. Fume hood
12. Radioactive aerosol and gas administration system and trap
13. Vial shields
14. Personnel shields
15. Survey meter calibration service
16. Personnel monitoring service
17. Leak-test service for sealed sources

.05(12) FOR RADIOPHARMACEUTICAL THERAPY

1. Portable radiation detection survey meter
2. Portable radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Syringe shield
7. Fume hood

8. Vial shields
9. Personnel shields
10. Hot lab area monitor
11. Lead L-block
12. Leak-test service for sealed sources
13. Personnel monitoring service
14. Survey meter calibration service

.05(13) FOR SEALED SOURCES FOR DIAGNOSIS

1. Secure storage area
2. Leak-test service for sealed sources
3. Personnel monitoring service
4. Radiation monitoring service for measuring dose rates from packages with replacement sources and decayed sources

.05(14) FOR BRACHYTHERAPY

1. Portable radiation detection survey meter
2. Portable radiation measurement survey meter
3. Lead L-block
4. Remote handling tools
5. Shielded transport cart
6. Shielded storage safe
7. Leak-test service for sealed sources
8. Survey meter calibration service
9. Personnel monitoring service
10. Personnel shields

NOTE: If a Sr-90 ophthalmic applicator is the only brachytherapy source on your license, you will only need a storage safe, or a built-in and locked storage cabinet, and leak-test service.

DESCRIPTIONS

1. A **radiation detection survey meter** usually has a GM tube or NaI(Tl) crystal detector. The scale may be labeled in counts per minute (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 for the radionuclide being measured.
2. A **radiation measurement survey meter** has a detector known as an ionization chamber which actually measures mR/hr. The most sensitive scale usually has a full-scale deflection between 1 and 10 mR/hr but can make measurements up to 1000R/hr. This type is most commonly used in determining radiation exposure rates for patients receiving radiation therapy.
3. A **dose calibrator** uses an ionization chamber or a GM detector to determine the amount of radiation given off by a syringe or vial containing radioactive material. The logic system within the calibrator can then calculate the amount of radioactivity in the sample. Most dose calibrators have a digital display with either a "select range" switch or an automatic range-switching circuit. The final display is in microcuries, millicuries, or curies. A dose calibrator can measure over a range of a few microcuries to a few curies. It is not sensitive enough to measure contamination wipe samples.
4. A **constancy check source** is a sealed source with the date of manufacture, the radioisotope, and the approximate activity noted.

5. A **dedicated check source** is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The same ("dedicated") source must be used every day so that the user knows what reading to expect from the instrument, in order to know if the instrument is responding properly. The source may also be used for other purposes.
6. The **sealed sources for dose calibrator accuracy** are also sealed sources with the date of manufacture and the radioisotope noted. However, the activity must be certified to within +/- 5 percent by the manufacturer. These sources do not need to be on hand if the dose calibrator accuracy test is performed by a contract service.
7. The **leak-test service** may be performed in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually, a well-type NaI(Tl) crystal with a ratemeter is necessary to assay gamma-emitting leak-test wipes.
8. A **hot lab area monitor** usually has a GM detector, and the scale may be labeled in cpm or mR/hr. It should be sufficiently sensitive to detect an unshielded patient dose left lying unshielded anywhere in the hot lab.
9. A **flood source** for gamma cameras may be either one that is sealed or one that is filled by the user. The sealed sources usually contain about 5 to 15 millicuries of Co-57. The sources that can be filled by the user usually have a removable screw in a port through which radioactive material can be injected each morning.
10. **PLES, bar, orthogonal-hole, and quadrant phantoms** are used to monitor geometric linearity and the resolution capability of gamma cameras. This type of test should be run weekly, following the instructions supplied by the manufacturer, or the instructions in Appendix E in this guide.
11. A **fume hood** should have an adjustable sash. It should be directly vented to the outside air. The face velocity should be approximately 100 linear feet per minute, with the sash at its normal location. This should be measured with a velometer. If one is not available, you can hang a strip of tissue paper about 1 inch wide and 3 inches long from the bottom of the sash - at the proper face velocity, it will be gently deflected into the hood.
12. **Personnel shields** are used to shield workers from radioactive patients. They may be mobile upright shields in the nuclear medicine clinic or in a patient's room when a technician or nurse must stay beside a patient, or they may be lead sheets used to shield transporters from patients in wheelchairs.

APPENDIX W

FILING SYSTEM

The purpose of a filing system is to allow for the quick access of records. Construct the system to allow a person who is not familiar with the system to use it with minimal training. If you have not established a system, the one below may be helpful.

The filing system described contains two parts: Part one is for small or occasionally accessed files. The second part consists of five loose-leaf notebooks used to file records that are large, frequently accessed, or easily filed in alphabetical or chronological order.

PART ONE

SECTION A ACTIVE PROJECTS

Set up an individual file for each project, e.g., planning a new radioisotope lab or a research project. Label each file with a short title. File chronologically with new material in front. For example:

Shielding calculations for a new room
TLD project
Registration and travel to summer meeting

SECTION B FORMS

Set up a file for master copies of the forms you use in your facility and a file for copies of each form. Label the files as suggested.

- 0.1 Masters
- 0.2 Personal Exposure Monitor Application
- 0.3 Exposure History Request
- 0.4 Exposure History Report
- 0.5 Teletherapy Monthly Check
- 0.6 Nuclear Medicine Daily Survey
- 0.7 Survey Meter Calibration
- 0.8 Sink Disposal Log
- 0.9 Vented Release Log
- 0.10 Decay-In-Storage Release Record
- 0.11 Room Survey Master Form,

SECTION C COMMITTEES

Each subsection of this section is devoted to a single committee. In some cases, the file will contain only meeting minutes. In other cases, the file may also include a committee charter, curricula vitae of members, and topical reports.

- 1.1 Radioactive Drug Research Committee
- 1.2 Hospital Safety Committee
- 1.3 Research Safety Committee
- 1.4 Research Review Committee
- 1.5 Radiation Safety Committee

SECTION D GEORGIA RADIOACTIVE MATERIALS LICENSE

- 2.1 License Applications, License
- 2.2 Amendment Requests, Amendments
- 2.3 Records of Minor Changes
- 2.4 Inspection Reports and Replies
- 2.5 Authorized User Credentials
- 2.6 Misadministration Reports
- 2.7 Other Correspondence

SECTION E INVENTORIES, SURVEYS, AND WASTE

- 3.0 Inventory Summary Sheet
- 3.1 Nuclear Medicine Surveys and Inventory Summaries
- 3.2 Research Lab Surveys and Inventory Summaries
- 3.3 I 131-Therapy Room Release Surveys
- 3.4 Brachytherapy/Sealed Source Quarterly Inventory and Survey
- 3.5 Leak-Test Records
- 3.6 Room Survey Sets for Future Use
- 3.7 Annual Sink Disposal Summary
- 3.8 Annual Vent Disposal Summary
- 3.9 Hot Lab Sink Disposal Logs
- 3.10 Research Lab Sink Disposal Logs
- 3.11 Decay-In-Storage Release Logs

SECTION F CONTRACT SERVICES

- 4.1 Personal Dosimetry Service Contract
- 4.2 Change Forms
- 4.3 Monthly Exposure Reports
- 4.4 Waste Shipment Contract
- 4.5 Transfers of Radioactive Material

SECTION G TRAINING LECTURES OUTLINES, HANDOUTS, AND ATTENDANCE LOGS

- 5.1 Non-radiology Physicians
- 5.2 Non-radiology Technologists
- 5.3 Radiology Physicians
- 5.4 Radiology Technologists
- 5.5 Administrators
- 5.6 Security
- 5.7 Physical Plant
- 5.8 Housekeeping
- 5.9 Animal Research Facility
- 5.10 Nursing - General Radiation Safety
- 5.11 Nursing for Brachytherapy
- 5.12 Nursing for Iodine Therapy
- 5.13 Brachytherapy Team
- 5.14 Diagnostic Nuclear Medicine Personnel
- 5.15 Therapeutic Nuclear Medicine Personnel
- 5.16 In Vitro Users

SECTION H RADIATION SAFETY EQUIPMENT ON HAND

Set up an individual file for each piece of equipment. The file should contain the user's manual, guarantee, service reports, and calibration reports. File alphabetically by manufacturer.

SECTION I INCIDENTS

- 7.1 Personnel Exposures
- 7.2 Spills or Losses with No Personnel Exposure
- 7.3 Procedural Incidents

SECTION J FACILITY DESCRIPTION

Set up files for blueprints, drawings, and permanently installed equipment such as incinerators, fume hoods, and walk-in boxes.

PART TWO

LOOSE-LEAF NOTEBOOKS

1. Dosimetry Service Monthly Packing Slips. Check off each name when the monitor is returned at the end of the monitor period. This will highlight persons who are not returning monitors promptly for processing.
2. Personnel Dosimetry Individual Applications. Behind each individual's application form, file copies of previous employment exposure, incidents, requests for previous employment exposure, and bioassay results.
3. Budget and Purchase Orders
4. Georgia Radioactive Materials Medical Licensing Guide
5. Standard Operating Procedures
6. Georgia Rules and Regulations for Radioactive Material "Chapter 391-3-17"