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# MEDICAL LICENSING GUIDE

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Environmental Protection Division

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## **PART 1**

### **1. INTRODUCTION**

#### **1.1 GENERAL**

The Georgia Department of Natural Resources, Radioactive Materials Program (Department) regulates the intentional internal or external administration of radioactive material, or the radiation from it, to 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. 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 ensure an adequate radiation protection program.

##### **1.11 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.

##### **1.12 Purpose of Appendices to Guide**

The regulations require that the licensee develop and carry out procedures that will ensure compliance with the regulations. Part 4, Appendices A through R 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 one or more model procedure(s) (appropriate certification language is given at the beginning of each Appendix). Or the licensee may say that they have developed their own procedure(s) which are enclosed for review (appropriate reference language is given at the beginning of each Appendix).

#### **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 obtain copies of the above documents from our website:

[http://rules.sos.state.ga.us/cgi-bin/page.cgi?q=GEORGIA\\_DEPARTMENT\\_OF\\_NATURAL\\_RESOURCES%2FENVIRONMENTAL\\_PROTECTION%2FRADIOACTIVE\\_MATERIALS%2Findex.html&d=1](http://rules.sos.state.ga.us/cgi-bin/page.cgi?q=GEORGIA_DEPARTMENT_OF_NATURAL_RESOURCES%2FENVIRONMENTAL_PROTECTION%2FRADIOACTIVE_MATERIALS%2Findex.html&d=1)

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 may 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.

The licensee shall ensure annual occupational dose limits and dose limits for individual members of the public are not exceeded (Rule .03(5)). Quarterly investigational levels are one way to monitor individual occupational exposures to identify issues long before an annual limit is reached (this is not required but it is included in **Appendix S** as a model procedure).

**Appendix K** provides a model program that provides one way to help maintain ALARA. 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.

#### 1.41 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.

#### **1.42 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 (15)(f) requires a medical institution that are authorized for two or more different types of radioactive material use under Rule .05(48), (55), (67), and (85), or two or more types of units under Rule .05(67) 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.

Describe your Radiation Safety Committee Charter and include it in your application. See **Appendix B**.

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(9) and .05(38). Both private practitioners and institutions may apply for authorization to use radioactive material in a mobile service.

#### **1.43 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 4 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 requested 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. AMENDMENTS TO A LICENSE**

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

It is your obligation to keep your license current. Anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit an application or a letter 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, or in a letter. The application should be prepared in duplicate. Retain one copy because the license requires that you possess and use licensed material according to the statements and representations in your amendment request and in any supplements to it.

Your application or letter 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, paragraph, or letter. For example, if you wish authorized users, previously approved through a notification, to be added to the license at the time of amendment, your request must be at the time of the license amendment and submit a copy of the Department's letter approving them as an authorized user, or to change the RSO, specify the proposed RSO's name, training, and experience. The qualifications of the proposed RSO should be equivalent to those specified in Item 7.3 of this guide. You may refer to Rule .05(10)(a)

through (h) for a listing of Items requiring an amendment.

#### **4. NOTIFICATION TO A LICENSE**

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 their training documentation (refer to 7.1 – 7.5). Examples of items not requiring an amendment, but requiring written notification to the Department of the change are listed in Rule .05(11). Anticipate the need for a license notification as far in advance as possible. Qualifications should be reviewed and approved by the RSC, if applicable, or by the RSO with the advice and consent of management. These individuals, however, are not permitted to work until the licensee has received a formal response from the Department approving them as authorized users.

Notification letters expire at the time when licenses are renewed.

#### **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.

In accordance with .02(15) you should file your application for license renewal at least 30 days before the expiration date of your license. 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 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 2), with appropriate documentation certifying that all sources have been disposed of in a manner authorized by .02(18). 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 2

**\*\*Items in this part must be submitted to complete new or renewing license applications.\*\***

### **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 "A" for a new license. For an amendment to an existing license, check "B." Check "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 General**

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. In Items 5 – 7 and 9 – 11 of the application, describe the intended use, 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.

##### **3.2 Mobile Medical Services**

The general types of services provided as mobile medical services are:

- Mobile medical services (radioactive material, trained personnel, and facility) that provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the

client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

- Mobile medical service providers (radioactive material and trained personnel) that provide transportation to and use of the radioactive material within the client's facility. These mobile medical service providers are also responsible for all aspects of byproduct material use and authorized patient treatments (or administrations).

In addition to the requirements in Rule .05(9), .05(38) and Rule .05(79), mobile medical service licenses must comply with all other applicable regulations. Applicants should review Items 9 - 11 for information to be submitted as part of their applications. Mobile medical service licensees may transport licensed material and equipment **into a client's building, or may bring patients into the transport (e.g. van)**. In either case, the van should be located on the client's property that is under the client's control. If the service is provided **into the client's building**, submit a diagram of their facility identifying the areas of use. If the service is **on the transport vehicle**, provide a diagram where the mobile service will be parked. Mobile PET medical service licensee must consider a "quiet room" as an area of use if the patients in the "quiet room" cannot be released under Rule .05(37).

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready to deliver mobile medical services on arrival at a client's site. Companies providing transportation only will not be licensed for medical use. Before using a remote afterloader for this type of service, the device should be installed in an appropriately shielded treatment room.

**Appendix N** provides a model program that provides one way to satisfy the requirements referenced above.

### 3.3 Private Practice Applicants Outside Of Hospitals

State if the applicant has access to a hospital that possesses adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable per Rule (.02(9)(c)1(iii). 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.

You may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. Regardless of the role of the consultant in the radiation protection program, the licensee remains responsible for all aspects of the licensed

program, including services performed by the consultant.

## ITEM 5 RADIOACTIVE MATERIAL

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(55), brachytherapy material, express the total amount in millicuries (mCi).

**TABLE 1**

| <b>RADIOACTIVE MATERIAL</b>                                  | <b>FORM</b>                                                 | <b>ACTIVITY</b>                                                                              |
|--------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| <b>5.a.</b> Material listed in Rule .02(6)(g)                | In vitro test kits permitted in (6)(g) of Rule 391-3-17-.02 | As Needed                                                                                    |
| <b>5.b.</b> Material authorized in Rule .05(41)              | Any                                                         | As Needed                                                                                    |
| <b>5.c.</b> Material authorized in Rule .05(44)              | Any                                                         | As Needed                                                                                    |
| <b>5.d.</b> Material authorized in Rule .05(48)              | Any                                                         | 900 millicuries (For Hospitals)<br>Or No single dose to exceed 33 mCi (For private practice) |
| <b>5.e.</b> Material listed in Rule .05(55)                  | Any                                                         | _____ mCi                                                                                    |
| <b>5.f.</b> Iridium 192                                      | Sealed Source<br>(Manufacture Name and Model)               | 21.9 Curies maximum, no single source to exceed 12 Curies per installed source               |
| <b>5.g.</b> PET Radionuclides for noncommercial distribution | Any                                                         | _____ Ci                                                                                     |

(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(44) specifically list those items with the Rule [i.e. Material authorized in Rule .05(44) (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.

Sealed sources of Ra-226 may be used in Rule .05(55), (65), (67), and (85). Unsealed Ra-226 can only be used for medical use in Rule .05(85).

For the production of PET Radionuclides for noncommercial distribution to medical use licensee

within a consortium, the licensee should identify the PET radionuclides, the proposed use of the material, and maximum activity. The applicant should also review **Appendix E**.

For .05(55), .05(65), .05(67), and .05(85) Use: the radionuclide, the chemical/physical form (e.g., sealed source or device identified by manufacturer and model number), the total amount in microcuries ( $\mu\text{Ci}$ ), millicuries ( $\text{mCi}$ ), or curies ( $\text{Ci}$ ), and the maximum number of sources or activity possessed at any one time must be specified.

For sealed sources used in devices, an applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee's possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registry (SSDR) certificate.

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(32). Each line entry must identify the radionuclide, the physical form, maximum activity to be possessed, expressed in  $\text{mCi}$ , 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).

## **RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE**

All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in Rule .02(8)(g) must provide evidence of financial assurance for decommissioning.

### **ITEM 6 PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED**

- 391-3-17-.05.02(6)(g) - In vitro testing procedures as listed in (6)(g) of Rule 391-3-17-.02.
- 391-3-17-.05(41) - Uptake, dilution, or excretion studies as permitted by (41) of Rule 391-3-17-.05.
- 391-3-17-.05(44) - Imaging and localization studies as permitted by (44) of Rule 391-3-17-.05.
- 391-3-17-.05(48) - Therapeutic procedures as permitted by (48) of Rule 391-3-17-.05.
- 391-3-17-.05(55) - Brachytherapy procedures as permitted by (55) of Rule 391-3-17-.05.

- Iridium 192 - One source for medical use described in 391-3-.05(67) in a \_\_\_\_\_HDR Model \_\_\_\_\_Remote Afterloader Brachytherapy Unit. One source in its shipping container for source replacement in the remote afterloader unit.
- Cobalt 60 - One set of sources for use in a \_\_\_\_\_Model \_\_\_\_\_gamma knife stereotactic radiosurgery for the therapeutic treatment of humans. One set of sources in their shipping container to be in the possession of the licensee as necessary for the replacement of the sources in the gamma stereotactic radiosurgery unit.

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

Responsible individuals are the authorized users and the RSO. Rule .05(10)(b) 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:** Curriculum vitae and resumes do not supply the information needed to evaluate an individual's training and experience.

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

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

Nuclear Medicine Technologists or other personnel may use material under an authorized user's supervision as defined in Rule .05(18). The technologist using radioactive material shall meet the training and technical requirements outlined in .05(25).

### 7.1       **Authorized Users for Medical Use**

**7.11**   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.

**7.12**   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, or a copy of a Departmental letter previously authorizing the individual as an authorized user (notification letter), **and** a copy of their Georgia Composite Medical Board License.

**7.13**   If a physician is certified by a specialty board recognized by NRC under 10 CFR Part 35, the physician shall submit a copy of their board certification **and** a preceptor attestation letter signed by an authorized user currently approved for the sought usages **and** a copy of their Georgia Composite Medical Board License. The letter must attest to a level of competency sufficient to function independently as an authorized user of desired usage.

**7.14** 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 recentness of training on the training institution's letterhead signed by a preceptor authorized user attesting that the individual has satisfactorily completed the training requirements (see **Appendix A**) as well as their competency to function independently **and** a copy of their Georgia Composite Medical Board License.

**7.15** Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users.

## **7.2 Recentness of Training**

Recentness of training must have been obtained within the 7 years preceding the date of the application or the individual must have had related continuing education and experience since the required training and experience was completed. Refer to .05(27).

## **7.3 Radiation Safety Officer (RSO)**

State the name and title of the person appointed by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience in accordance with .05(22)(a), (b), (c)1, (d), and (e). 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 (22). 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.

The RSO must agree in writing to be responsible for implementing the radiation protection program. Submit the Radiation Safety Officer Delegation of Authority and the Radiation Safety Officer Certification. See **Appendix B**.

## **7.4 Authorized Nuclear Pharmacist**

Submit training and experience demonstrating that the proposed Nuclear Pharmacist is qualified by training and experience identified in .05(24).

## **7.5 Authorized Medical Physicist**

Submit training and experience demonstrating that the proposed Medical Physicist is qualified by training and experience identified in .05(23).

## **7.6 Nuclear Medical Technologist and Radiation Therapist**

Training and technical requirements for nuclear technologist and radiation therapist shall meet the requirements outlined in .05(25).

## ITEM 8 SAFETY INSTRUCTIONS FOR INDIVIDUALS

This is not actually required for license submission; see Element 1.

**Note:** For **Items 9-11**, your response may consist of one sentence that says you will follow the model procedure in Appendix \_\_\_\_ in the Medical Licensing Guide, your own procedure to be reviewed, or simply the notation “NA” for “not applicable.” Use the Applicability Table listed next to each item to determine if you must respond or if “NA” is acceptable. Before you respond to an item, read the introductory paragraphs of the referenced **appendix**. Responses should be appended as attachments.

## ITEM 9 FACILITIES AND EQUIPMENT

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Facilities and equipment must be adequate to protect health and minimize danger to life and property. These requirements depend on the scope of the licensee’s operations (e.g., planned use of the material, types of radioactive emissions, quantity and form of radioactive materials possessed, and the production of PET).

For PET consortium refer to **Appendix E**.

### 9.1 Annotated Drawing

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

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 3). Note the following:

**9.11** Room numbers and principal use of each room or area (for example, in vitro, hot lab, quiet room, waiting, examining, imaging, reading, office, file, fresh materials, storage, radioactive waste storage, film processor, toilet, closet, hallway, including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area).

**9.12** Shielding calculations, including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields.

**9.13** Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors, shielded traps for aerosols and gases and xenon vents).

**9.14** Security of radioactive materials. If radioactive materials cannot be secured in a hot lab, you must explain how materials will be secured if stored in another room, such as the imaging room.

**9.15** Identify on the drawing the areas where routine wipes will be taken.

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 Radiation Monitoring Instruments

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

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

**Appendix C** provides a model program that provides one way to satisfy the requirements referenced above.

## 9.3 Dose Calibrator Calibration

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  |               |
| 65  |               |
| 67  |               |
| 85  | •             |

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

**Appendix D** provides a model program that provides one way to satisfy the requirements referenced above.

## 9.4 Therapy Unit - Calibration and Use

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  |               |
| 55  | •             |
| 65  |               |
| 67  | •             |
| 85  | •             |

Submit your procedures as required by Rule .05(76), (77), and (78) for performing periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units, and attach it as ATT 9.4

## 9.5 Other Equipment and Facilities (Radiopharmaceutical Therapy, PET, Remote Afterloader Units, Manual Brachytherapy, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units)

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Facilities and equipment must be adequate to protect health and minimize danger to life or property and in keeping exposures as low as reasonably achievable (ALARA). Describe other equipment and facilities available for the use and storage of materials described in Item 5 of this application. Discuss security of storage area. Append it as ATT 9.5.

### 9.51 Radiopharmaceutical Therapy

Provide a description for additional facilities and equipment for the radiopharmaceutical therapy program to safely receive, use, store, and dispose of radioactive material. The licensee should focus on facilities to be used for radioactive drug therapy administration and patient accommodations. I-131 is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (e.g. fume hood). Note the hazards associated with volatile iodine in pill form, applicants should consider this in establishing their radiological controls. When patients are treated with I-131, sources of contamination include



airborne I-131, urine, perspiration, saliva, and other secretions.

### 9.52 PET Radionuclide

Provide a description for need for extra shielding, hot cells containing remote handling devices, special delivery system if the applicant prepares its own PET radionuclides or has them delivered by a direct transfer tube or system from a PET radionuclide producer

### 9.53 Manual Brachytherapy

Provide a description of the emergency response equipment

### 9.54 Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

Provide a description of the following:

- warning systems and restricted controls, such as locks, signs, warning lights and alarms;
- area radiation monitoring systems;
- viewing and intercom systems;
- steps that will be taken to ensure that no two units can be operating simultaneously, if another radiation-producing equipment (linear accelerator, x-ray machines) is in the treatment room;
- console keys are inaccessible to unauthorized persons when the device is not in use; and
- emergency response equipment.

## ITEM 10 RADIATION PROTECTION PROGRAM

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

In accordance with Rule .03(4), each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program should include procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are ALARA. The program must be sufficient to ensure compliance with the provisions of Rule .03 and .05(15). The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material.

Respond to the following sections of this document regarding Item 10.

### 10.1 Safety Procedures and Instructions For HDR, Teletherapy, and GSR

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  |               |
| 55  |               |
| 65  |               |
| 67  | •             |
| 85  | •             |

The applicant must develop, document, submit, and implement written safety procedures for emergency response for high dose afterloaders, teletherapy units, and Gamma Stereotactic Radiosurgery. Rule .05(70) and (71) requires that written procedures be developed, implemented, and maintained for responding to an abnormal situations, and attach it as ATT 10.1.

The procedures must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- The process for restricting access to and posting of the treatment area to

- minimize the risk of inadvertent exposure; and
- The names and telephone numbers of AU's, AMP's, and the RSO to contact if the unit or console operates abnormally.

## 10.2 Occupational Dose

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Describe your personnel **external and internal** exposure monitor program and attach it as ATT 10.2.

**Appendix F** provides a model program that provides one way to satisfy the requirements referenced above.

For estimating worker dose from submersion in noble gases (xenon), aerosol concentrations, aerosol and gas concentration in effluents, and calculating spilled gas clearance times refer to **Appendix T**.

## 10.3 Area Survey Procedures

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Submit your area survey procedures and attach it as ATT 10.3.

**Appendix G** provides a model program that provides one way to satisfy the requirements referenced above.

## 10.4 Safe Use of Unsealed Licensed Material

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  |               |
| 65  |               |
| 67  |               |
| 85  | •             |

The licensee must include in their Radiation Protection Program a procedure that includes safe use of unsealed licensed material. The licensee is responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facility until it is used, transferred, and/or disposed. The procedures should include assurance that only trained personnel will handle and use licensed material without hazard to themselves, other workers, or the public.

The licensee must include procedures for protective measures to be taken by occupational workers to keep their exposure ALARA. This may include using syringe and/or vial shields, tongs, lab coats and gloves, and monitoring hands.

When producing PET radioactive drugs, protective measures may include remote manipulation of material in a shielded hot cell and the use of remote handling tools. Attach it as ATT 10. 4.

**Appendix H** provides a model program that provides one way to satisfy the requirements referenced above.

## 10.5 Spill/Contamination Procedures

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  |               |
| 85  | •             |

The licensee must develop, document, and implement a Radiation Protection Program that includes proper response to spills of licensed material in order to prevent the spread of radioactive material. Append it as ATT 10.5.

**Appendix I** provides a model program that provides one way to satisfy the requirements referenced above.

## 10.6 Installation, Maintenance, Adjustment, Repair, Devices Containing Sealed Sources

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  |               |
| 55  |               |
| 65  |               |
| 67  | •             |
| 85  | •             |

In accordance with Rule .05(69) and .05(81), licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities should be conducted according to the manufacturer's written recommendations and instructions and according to the SSDR. In addition, .05(81) requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first. Append it as ATT 10.6.

If the licensee requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the licensee must provide sufficient information to allow the Agreement State to evaluate and approve such authorization.

**Note:** No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement state to install, maintain, adjust, repair, and inspect the specific therapy device possessed by the license.

## 10.7 Minimization of Contamination

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Licensees must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

**Note:** A response from the licensee is not required if the above criteria is addressed in the information provided by the licensee's responses to Sections 9, 9.1, 10, and 11.

## ITEM 11 WASTE MANAGEMENT

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Licensed material must be disposed in accordance with the following regulation:

- Transfer to an authorized recipient (Rule (.02(19)(b))
- Decay-in-storage
- Release in effluents within the limits in Rule .03(13)
- As authorized under Rule .03(13)(b), (c), (d), and (e)

Append it as ATT 11.

**Appendix J** provides a model program that provides one way to satisfy the requirements referenced above.

## **ITEM 12      LICENSE FEES**

The applicant should refer to the Radioactive Materials License Fee Schedule (Form 4) to determine the appropriate licensing fee and annual fee. Amendment fees are no longer required for amendment requests. Note that, in addition to licensing fees for a new license, licensees are required to pay 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, Suite 120  
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 the applicant will be asked to resubmit for proper signature.

## PART 3

### PROGRAM-RELATED GUIDANCE

The information provided in this section is included because it is a key element of the licensee's program and will be subject to evaluation for adequacy during inspections. The following information is provided as guidance to applicants in setting up their programs to satisfy regulatory requirements.

#### **ELEMENT 1 SAFETY INSTRUCTION FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Individuals working with or in the vicinity of licensed material must have adequate safety instructions. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 100 millirem, the licensee must provide safety instructions as required by Rule .07(3). Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in Rule .05(49), Rule .05(58), and Rule .05(70). Rule.05(18) requires the licensee's AU's and ANP's to provide safety instructions to all personnel using radioactive material under their supervision.

**Appendix K** provides a model program that provides one way to satisfy the requirements referenced above.

#### **ELEMENT 2 PUBLIC DOSE**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Ensure that licensed material will be used, transported, and stored in such a way that any individual member of the public will not receive more than 100 mrem (1 mSv) in 1 year, and the dose in any unrestricted area will not exceed 2 mrem (.02 mSv) in any one hour from licensed operations. Unrestricted area may include offices, shops, laboratories, and areas outside the buildings.

For areas adjacent to facilities where licensed material is used or stored, calculations and/or measurements (TLD) can be used to show compliance.

Ensure air emission of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 10 mrem (.01 mSv) in one year from these emissions.

Control and maintain constant surveillance of licensed material that is not in storage, and secure stored licensed material from unauthorized access, removal, or use.

#### **ELEMENT 3 OPENING PACKAGES**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements Rule .03(12)(f) are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA. Licensees must retain records of package surveys in accordance with Rule .03(14)(c).

**Appendix L** contains model procedures that represent one method for safely opening packages containing radioactive material.

## ELEMENT 4 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  | •             |
| 55  | •             |
| 65  |               |
| 67  | •             |
| 85  | •             |

Rule .05(19) sets forth the requirements for written directives. Rule .05(20) requires medical use licenses to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users.

**Appendix M** provides a model program that provides one way to satisfy the requirements referenced above.

## ELEMENT 5 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  | •             |
| 55  | •             |
| 65  |               |
| 67  |               |
| 85  | •             |

Licensees may release from confinement patients or human research subjects who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 0.5 rem (5 mSv). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with Rule .05(37). Refer to NRC Regulatory Guide 8.39 Release of Patients Administered Radioactive Materials for additional information on release

criteria.

## ELEMENT 6 AUDIT PROGRAM

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Under Rule .03(4)(c), all licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with the Georgia Rules and Regulations for Radioactive Materials and applicable DOT regulations and the terms and conditions of the license; and
- Occupational doses and doses to members of the public are ALARA.

The applicant should develop and implement procedures for the required review or audit of the program's content and implementation.

**Appendix L** in the NUREG - 1556, Vol. 9, Rev. 2 provides a model audit program.

## ELEMENT 7 OPERATING AND EMERGENCY PROCEDURES

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

The licensee must develop, implement, and maintain specific operating and emergency procedures containing the following instructions for:

- Opening packages;
- Using licensed material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources in accordance to the manufacturer's written recommendations and instructions;
- Conducting area radiation level and contamination surveys;
- Administering licensed material requiring a written directive;
- Ensuring patient release is in accordance with Rule .05(37);
- Calibration of survey and dosage measuring instruments;
- Periodic spot checks of therapy devices units, sources, and treatment facilities;
- Radioactive waste management;
- Steps to take, and whom to contact when the following has occurred: leaking or

- damaged sources, device malfunction and/or damage, spills, theft or loss of licensed material, or incidents involving licensed material;
- Steps for source retrieval;
- Steps to take if a therapy patient goes under emergency surgery or dies.

## ELEMENT 8 MATERIAL RECEIPT AND ACCOUNTABILITY

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

To maintain accountability of licensed material, licensees must do the following:

- secure licensed material;
- maintain records of receipt, transfer, and disposal of licensed material; and
- conduct physical inventory at required frequencies to account for licensed material.

Licensed material must be traced from receipt to disposal to ensure accountability, identify when material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded.

## ELEMENT 9 ORDERING AND RECEIVING

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Rule 391-3-17-.03(12)(f) contains the requirements for receiving packages containing licensed material. Additionally, security of licensed material, required by .03(11)(a) and (b), must be considered for all receiving areas.

**Appendix O** contains model procedures for ordering and receiving licensed material.

## ELEMENT 10 SEALED SOURCE INVENTORY

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

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

## ELEMENT 11 RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  |               |
| 67  |               |
| 85  | •             |

The licensee must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.

**ELEMENT 12            RECORDKEEPING**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

In accordance with .05(86) through .05(114) licensee must maintain records to comply with the Georgia Regulations.

A table of recordkeeping requirements appears in **Appendix P**.

**ELEMENT 13            REPORTING**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

In accordance with .05(115) through .05(119), the licensee is required to report to the Department via telephone, written report, or both in the event that the safety or security of radioactive material may be compromised.

A table of reporting requirements appears in **Appendix Q**.

**ELEMENT 14            LEAK TESTS**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

In accordance with Rule .03(6), licensees must perform leak testing of sealed sources, such as, calibration sources, transmission, and reference sources, or brachytherapy sources.

**Appendix R** provides a model program that provides one way to satisfy the requirements referenced above.

**ELEMENT 15            SAFETY PROCEDURES FOR TREATMENTS WHEN PATIENTS ARE HOSPITALIZED**

| .05 | Applicability |
|-----|---------------|
| 41  |               |
| 44  |               |
| 48  | •             |
| 55  | •             |
| 65  |               |
| 67  | •             |
| 85  | •             |

Licensee must develop and implement procedures to ensure that access to therapy treatment room, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public within regulatory limits.

**ELEMENT 16            TRANSPORTATION**

| .05 | Applicability |
|-----|---------------|
| 41  | •             |
| 44  | •             |
| 48  | •             |
| 55  | •             |
| 65  | •             |
| 67  | •             |
| 85  | •             |

Licensees who will prepare for shipment, ship or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material. Refer to Rule .06.

The hazardous material training must be provided initially and every three years thereafter. Refer to Rule 06(5)

Most packages of licensed material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g. unused radiopharmaceutical dosages) frequently meet the “limited Quantity” criteria and are exempted from certain DOT requirements.



Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. Rule .06(8) sets forth the Type B package requirements for transporting the package to a carrier for transport. These include registration as a user of the package and having an NRC-approved quality assurance plan.

Some medical use licenses that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

Licensees who do this must ensure that the manufacturer (or service licensee):

- is authorized to possess the licensed material; and
- actually takes possession of the licensed material under its license.

Licensee should also ensure that the manufacturer (or service licensee) is authorized to possess the material at temporary job sites (e.g. the licensee's facilities).

## **PART 4**

### **FORMS, EXAMPLES, AND MODEL PROCEDURES THAT APPLICANTS MAY USE TO ESTABLISH RADIATION PROTECTION PROGRAMS.**



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

1. Licensee Name \_\_\_\_\_ 2. License Number \_\_\_\_\_

3. Address \_\_\_\_\_ Street No./ P. O. Box \_\_\_\_\_

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 (mark all that apply):

☐ 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 \_\_\_\_\_ Street No./ P. O. Box \_\_\_\_\_

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

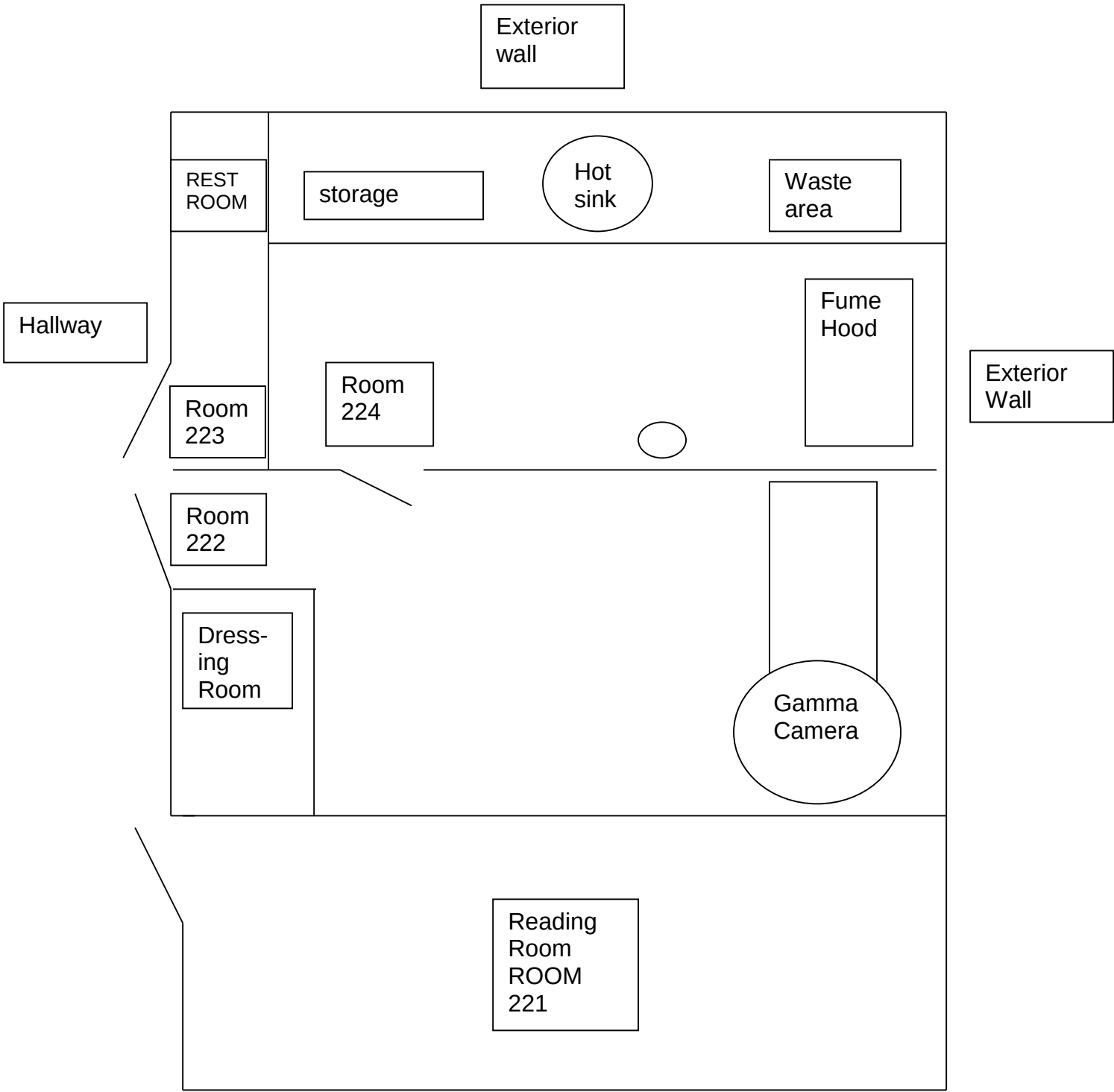
\_\_\_\_\_  
Date

\_\_\_\_\_  
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 120  
ATLANTA, GEORGIA, 30354



LAYOUT DIAGRAM FOR A FACILITY DESCRIPTION

**LICENSE FEES**

| <b>License Category</b>                              | <b>Fee Category</b> | <b>New License Application Fee</b> | <b>Annual Fee, Nominal</b> | <b>Annual Fee, Small Entity</b> | <b>Annual Fee, Lower Tier</b> |
|------------------------------------------------------|---------------------|------------------------------------|----------------------------|---------------------------------|-------------------------------|
| Medical Teletherapy                                  | A.1.a               | \$3,256.00                         | \$6,623.00                 | \$2,026.50                      | \$1,212.75                    |
| Stereotactic Radiosurgery (i.e., Gamma Knife)        | A.1.b               | \$3,256.00                         | \$6,623.00                 | \$2,026.50                      | \$1,212.75                    |
| Broad Medical                                        | A.10                | \$3,145.00                         | \$17,057.00                | \$4,550.00                      | \$3,736.25                    |
| Eye Applicators                                      | A.11                | \$999.00                           | \$3,182.00                 | \$1,982.75                      | \$1,169.00                    |
| Source Material                                      | A.12                | \$1,998.00                         | \$4,588.00                 | \$435.75                        | \$435.75                      |
| Depleted Uranium                                     | A.12                | \$222.00                           | \$666.00                   | \$266.00                        | \$266.00                      |
| Institutional Medical-Mult. Use (Including HDR)      | A.2.a               | \$999.00                           | \$3,182.00                 | \$3,150.00                      | \$2,336.25                    |
| Institutional Medical-Mult. Use                      | A.2.b               | \$999.00                           | \$3,182.00                 | \$1,982.75                      | \$1,169.00                    |
| Institutional Medical-Mult. Use (diagnostic only)    | A.2.c               | \$999.00                           | \$3,182.00                 | \$1,750.00                      | \$936.25                      |
| Institutional Medical-Single Use (therapy only)      | A.3                 | \$999.00                           | \$3,182.00                 | \$1,982.75                      | \$1,169.00                    |
| Private Practice (Therapy-HDR)                       | A.4.a               | \$999.00                           | \$3,182.00                 | \$3,150.00                      | \$2,336.25                    |
| Private Practice (Limited Therapy)                   | A.4.b               | \$999.00                           | \$3,182.00                 | \$1,982.75                      | \$1,169.00                    |
| Private Practice (Diagnostic Only)                   | A.4.c               | \$999.00                           | \$3,182.00                 | \$1,837.50                      | \$1,023.75                    |
| Private Practice (Veterinary)                        | A.4.d               | \$555.00                           | \$1,813.00                 | \$1,750.00                      | \$936.25                      |
| In-Vitro Specific Licenses                           | A.5                 | \$555.00                           | \$1,813.00                 | \$1,470.00                      | \$831.25                      |
| In-Vitro General Licenses                            | A.6                 | \$0.00                             | \$100.00                   | \$100.00                        | \$100.00                      |
| Bone Mineral Analyzers                               | A.7                 | \$999.00                           | \$3,182.00                 | \$1,750.00                      | \$936.25                      |
| Nuclear Pharmacy                                     | A.8.a.1             | \$2,405.00                         | \$6,253.00                 | \$3,990.00                      | \$3,176.25                    |
| Medical Manufacturer for Distribution                | A.8.a.2             | \$2,405.00                         | \$6,253.00                 | \$2,357.25                      | \$1,543.50                    |
| Medical Distribution or Redistribution Only (sealed) | A.8.b.1             | \$1,885.72                         | \$3,717.19                 | \$1,692.25                      | \$878.50                      |
| Medical Distribution or Redistribution Only (GL)     | A.8.b.2             | \$407.00                           | \$1,184.00                 | \$1,184.00                      | \$691.25                      |
| Mobile Nuclear Medicine                              | A.9.a               | \$999.00                           | \$3,182.00                 | \$2,275.00                      | \$1,461.25                    |
| Mobile HDR                                           | A.9.b               | \$999.00                           | \$3,182.00                 | \$2,275.00                      | \$1,461.25                    |
| Special Nuclear Material (sealed sources in devices) | B.1.a               | \$481.00                           | \$1,332.00                 | \$1,036.00                      | \$572.25                      |
| Special Nuclear Material (power sources in devices)  | B.1.b               | \$925.00                           | \$2,701.00                 | \$990.50                        | \$526.75                      |
| Special Nuclear Material (other)                     | B.2                 | \$925.00                           | \$2,701.00                 | \$1,895.25                      | \$1,081.50                    |
| Pacemaker, Byproduct or SNM -- Medical Inst          | B.3                 | \$999.00                           | \$3,182.00                 | \$1,895.25                      | \$1,081.50                    |
| Industrial Mfg. for Distribution                     | C.1                 | \$1,628.00                         | \$4,588.00                 | \$2,437.75                      | \$1,624.00                    |
| Installed Gauges                                     | C.10.a              | \$555.00                           | \$1,813.00                 | \$1,470.00                      | \$831.25                      |
| Gas Chromatograph, etc.                              | C.10.b              | \$555.00                           | \$1,813.00                 | \$1,400.00                      | \$761.25                      |

|                                                           |         |             |             |             |             |
|-----------------------------------------------------------|---------|-------------|-------------|-------------|-------------|
| Portable Moisture Density Gauges, Pb analyzers, etc.      | C.11    | \$555.00    | \$1,813.00  | \$1,750.00  | \$1,111.25  |
| Calibration Sources                                       | C.12.a  | \$555.00    | \$1,813.00  | \$1,750.00  | \$1,111.25  |
| Calibration Sources (Radium)                              | C.12.b  | \$555.00    | \$1,813.00  | \$1,349.25  | \$710.50    |
| Decontamination Services                                  | C.13.a  | \$2,368.00  | \$5,513.00  | \$2,100.00  | \$1,461.25  |
| Industrial (other) (NORM)(Gauge Service)                  | C.13.b  | \$2,368.00  | \$5,513.00  | \$1,750.00  | \$1,111.25  |
| Contaminated Equipment                                    | C.14    | \$555.00    | \$1,813.00  | \$1,349.25  | \$710.50    |
| In-house Industrial Radiography                           | C.2     | \$1,480.00  | \$9,583.00  | \$3,780.00  | \$2,966.25  |
| Multiple Job-Site Industrial Radiography                  | C.3     | \$1,480.00  | \$9,583.00  | \$3,780.00  | \$2,966.25  |
| Gamma Irradiators (Self-Shielded)                         | C.4.a   | \$1,184.00  | \$3,367.00  | \$1,135.75  | \$672.00    |
| Gamma Irradiators (<10K Ci)                               | C.4.b.1 | \$2,368.00  | \$5,735.00  | \$1,750.00  | \$936.25    |
| Gamma Irradiators (>10K<100K Ci)                          | C.4.b.2 | \$22,644.00 | \$52,133.00 | \$4,462.50  | \$3,648.75  |
| Gamma Irradiators (>100K<1M Ci)                           | C.4.b.3 | \$22,644.00 | \$52,133.00 | \$8,050.00  | \$7,236.25  |
| Gamma Irradiators (>1M Ci)                                | C.4.b.4 | \$22,644.00 | \$52,133.00 | \$17,675.00 | \$16,861.25 |
| Broad Scope Distribution, Specific (Type A)               | C.5.a.1 | \$4,736.00  | \$16,095.00 | \$5,215.00  | \$4,401.25  |
| Broad Scope Distribution, Specific (Type B)               | C.5.a.2 | \$4,736.00  | \$16,095.00 | \$2,765.00  | \$1,951.25  |
| Broad Scope Distribution, Specific (Type C)               | C.5.a.3 | \$4,736.00  | \$16,095.00 | \$2,275.00  | \$1,461.25  |
| GL Distribution (source and / or device evaluation)       | C.5.b   | \$740.00    | \$1,776.00  | \$1,655.50  | \$841.75    |
| GL Distribution (no source and /or device evaluation)     | C.5.c   | \$407.00    | \$1,184.00  | \$1,184.00  | \$967.75    |
| Possession Incident to NRC Exempt Distribution            | C.6.c   | \$555.00    | \$1,813.00  | \$1,739.50  | \$925.75    |
| Well Logging /Tracers                                     | C.7.a   | \$1,221.00  | \$3,774.00  | \$2,217.25  | \$1,403.50  |
| Field Flooding Studies                                    | C.7.b   | \$857.15    | \$2,933.85  | \$1,750.00  | \$1,111.25  |
| Nuclear Laundries                                         | C.8     | \$8,066.00  | \$17,057.00 | \$2,590.00  | \$1,776.25  |
| Industrial Research & Development                         | C.9     | \$1,295.00  | \$3,219.00  | \$1,902.25  | \$1,088.50  |
| Broad Scope (Academic) (Type A & B)                       | D.1.a   | \$1,998.00  | \$5,439.00  | \$2,563.75  | \$1,750.00  |
| Broad Scope (Academic) (Type C)                           | D.1.b   | \$1,998.00  | \$5,439.00  | \$2,075.50  | \$1,261.75  |
| Broad Scope (Industrial R&D) (Type A)                     | D.2.a   | \$1,998.00  | \$5,439.00  | \$2,563.75  | \$1,750.00  |
| Broad Scope (Industrial R&D) (Type B)                     | D.2.b   | \$1,998.00  | \$5,439.00  | \$2,292.50  | \$1,478.75  |
| Broad Scope (Industrial R&D) (Type C)                     | D.2.c   | \$1,998.00  | \$5,439.00  | \$2,075.50  | \$1,261.75  |
| Broad Scope (Medical Manufacturer for Distribution) (R&D) | D.3     | \$2,405.00  | \$5,735.00  | \$2,765.00  | \$1,951.25  |
| Civil Defense (Emergency Management)                      | E.1     | \$925.00    | \$3,330.00  | \$1,256.50  | \$617.75    |
| Civil Defense (Emergency Response)                        | E.2     | \$925.00    | \$3,330.00  | \$1,188.25  | \$549.50    |

|                                             |       |                                |              |             |             |
|---------------------------------------------|-------|--------------------------------|--------------|-------------|-------------|
| Teletherapy Service Co.                     | F     | \$2,368.00                     | \$5,513.00   | \$1,902.25  | \$1,088.50  |
| Consultants(Leak Testing Service)           | G     | \$555.00                       | \$1,813.00   | \$1,349.25  | \$411.25    |
| G L Devices (except tritium safety signs)   | GL    | \$0.00                         | \$100.00     | \$100.00    | \$100.00    |
| Academic (Non-Broad)                        | I     | \$1,295.00                     | \$3,219.00   | \$1,400.00  | \$761.25    |
| Device Evaluation                           | J.1   | \$4,595.40                     | \$5,350.20   | \$1,050.00  | \$236.25    |
| Source Evaluation                           | J.2   | \$1,709.40                     | \$2,319.90   | \$875.00    | \$236.25    |
| Radioactive Waste Disposal-Burial           | L.1   | \$154,286.53                   | \$155,200.77 | \$39,550.00 | \$38,736.25 |
| Radioactive Waste Disposal-Incineration     | L.2   | \$154,286.53                   | \$155,200.77 | \$39,550.00 | \$38,736.25 |
| Radioactive Waste, Processing & Repackaging | L.3.a | \$3,108.00                     | \$11,840.00  | \$5,390.00  | \$4,576.25  |
| Radioactive Waste, Prepackaged              | L.3.b | \$1,813.00                     | \$5,513.00   | \$3,552.50  | \$2,738.75  |
| Reciprocity                                 | K.    | appropriate nominal annual fee |              |             |             |



## APPENDIX A

### NRC Form 313A Series

#### “Medical Use Training and Experience and Preceptor Attestation”

**NRC Form 313 A - (RSO) Radiation Safety Officer Training And Experience and Preceptor Attestation**

**NRC Form 313 A - (AMP) Medical Physicist Training and Experience and Preceptor Attestation**

**NRC Form 313 A - (ANP) Nuclear Pharmacist Training and Experience and Preceptor Attestation**

**NRC Form 313 A - (AUD) Authorized User Training and Experience and Preceptor Attestation**

**NRC Form 313 A - (AUT) Authorized User Training and Experience and Preceptor Attestation**

**NRC Form 313 A – (AUS) Authorized User Training and Experience and Preceptor Attestation**

**Note:** The most current versions of these forms are found on NRC’s public Web site at <http://www.nrc.gov/materials/miau/med-use-toolkit.html> (Medical Uses Toolkit).

| TRAINING RULE CONVERSIONS |                   |
|---------------------------|-------------------|
| NRC, 10 CFR 35:           | GA, 391-3-17-.05: |
| 50                        | (22)              |
| 51                        | (23)              |
| 55                        | (24)              |
| 190                       | (43)              |
| 290                       | (47)              |
| 390                       | (52)              |
| 392                       | (53)              |
| 394                       | (54)              |
| 396                       | (54.1)            |
| 490                       | (63)              |
| 491                       | (64)              |
| 590                       | (66)              |
| 690                       | (84)              |

**APPENDIX B****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 B to the Medical Licensing Guide, Revision 9”.

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(22). Say on your application, “We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 7.3,” 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 **Radiation Protection Program** according to Rule .03(4)(c).
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 (or “and \_\_\_\_\_ have been appointed as Radiation Safety Officers”) and is(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 C

### MODEL PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, “We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix C to the Medical Licensing Guide, Revision 9.”

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 follow the nationally recognized standards or the manufacturer’s instructions (Rule .05(29)(b)). 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.

**SURVEY METER CALIBRATION REPORT****Facility**

Owner/User:

Department:

**Instrument**

Manufacturer:

Type: ☐ Ion Chamber ☐ GM ☐ NaI(Tl) ☐ Other (Describe) \_\_\_\_\_.

Meter Model Number: \_\_\_\_\_ Serial Number: \_\_\_\_\_.

Probe Model Number: \_\_\_\_\_ Serial Number: \_\_\_\_\_.

Calibration Source: \_\_\_\_\_ mCi of \_\_\_\_\_. \_\_\_\_\_ mR/hr at \_\_\_\_\_ inches on \_\_\_\_\_, 20 \_\_\_\_\_.

Instrument Checks: Battery Check: \_\_\_\_\_ mR/hr or \_\_\_\_\_.

Constancy Check: \_\_\_\_\_ integral check source indicates \_\_\_\_\_ mR/hr.

\_\_\_\_\_ mCi of \_\_\_\_\_ indicates \_\_\_\_\_ mR/hr.

Calibration Geometry:

Window: ☐ Open ☐ Closed ☐ Fixed**Calibration Data**

| DISTANCE<br>(ft.) | SOURCE (mR/hr) | AS FOUND<br>SCALE READING | SCALE READING | CORRECTION<br>FACTOR |
|-------------------|----------------|---------------------------|---------------|----------------------|
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |
|                   |                |                           |               |                      |

**CALIBRATION STICKER**

Cal. date \_\_\_\_\_, 20 \_\_\_\_

|       |            |                  |
|-------|------------|------------------|
| Scale | Corr. Fac. | Bat: _____ mR/hr |
| _____ | _____      | Chk: _____ mR/hr |
| _____ | _____      |                  |
| _____ | _____      |                  |



## APPENDIX D

### MODEL PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, “We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix D in the Medical Licensing Guide, Revision 9.”

If you develop your own dose calibrator procedure for review, you should refer to Rule .05(29)(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(29), titled “Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.” 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(29)(b). Record keeping requirements of these tests are described in Rule 391-3-17-.05(29)(d). 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. 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:

$A_o$  = Activity Observed

$A_l$  = Activity Read from Line

- f. If the worst deviation is more than +/-10 percent, the dose calibrator must 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 E**

### **Production & Noncommercial Distribution by the Medical Facility of PET Radioactive Drugs to Consortium Members**

The purpose of this Appendix is to provide guidance to the medical use applicant, in a "consortium" as defined in Rule .01(2)(u), that is requesting authority under Rule .02(7)(j) for the production and noncommercial distribution of PET radioactive drugs to other medical use licensees within the consortium. The information required by the regulations and addressed in this Appendix is specific to this authorization and supplements information required for other uses of radioactive material provided in the applicant's medical use radioactive materials license application.

Section Rule .01(2)(u) states: "Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility."

The regulatory requirements for what an application from educational institutions and medical facilities must include for authorization to produce PET radioactive drugs for noncommercial distribution to licensees in a consortium are found in Rule .02(7)(j). Regulatory requirements for licensees with this specific authorization are found in Rule .02(13)(i). The noncommercial distribution of PET radioactive drugs can be requested as an additional authorization on a licensee's current radioactive material possession license (e.g., educational institution or broad-scope or limited specific license).

It should be noted that, to produce PET radioactive drugs for noncommercial distribution to medical use licensees in a consortium does not relieve the applicant or licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

#### **CONSORTIUM CRITERIA**

This Appendix addresses only the authorization in Rule .02(7)(j) for medical facilities to noncommercially transfer (distribute) PET radioactive drugs to medical use licensees in the medical facility's consortium. Therefore, the staff must have sufficient information to make the necessary determination that the licensee is a member of a consortium that meets the definition in Rule .01(2)(u), and that the applicant will distribute the PET radioactive drugs only to medical use licensees in its consortium.

The applicant for authorization under Rule .02(7)(j) for the production of PET radioactive drugs is required to be a consortium member but is not required to be the consortium member that has the PET radionuclide production facility. The applicant is required to either request authorization for the production of PET radionuclides, if the applicant has the PET radionuclide production facility and does not have a license for it, or provide evidence of an existing license issued by an Agreement State for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

**Response from the Applicant:**

- Identify the radionuclide, including the chemical and physical form, for each PET radioactive drug produced under this authorization.
- Request authorization to receive potentially contaminated “empty” radiation transport shields back from consortium members.
- Identify the medical use members of the consortium or provide a description of the criteria for consortium membership.
- Describe the geographical area in which the members are located.
- Provide documentation of the terms of the association, demonstrating the joint ownership or sharing of the operation and the maintenance cost of the PET radionuclide production facility.
- Request authorization for the production of PET radionuclides, if the applicant has the PET radionuclide production facility but does not have a license for it.
- Provide evidence of an existing license issued under an Agreement State for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

**QUALIFICATION TO PRODUCE PET RADIOACTIVE DRUGS**

Section Rule .02(7)(j)(2) requires that the applicant be qualified to produce PET radioactive drugs for medical use by providing evidence that meets one of the following criteria:

- Provide documentation of registration with the U.S. Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); or
- Provide a copy of a State agency registration or license as a drug manufacturer; or
- Provide a copy of the State Board of Pharmacy license; or
- Provide evidence of operation as a nuclear pharmacy within a Federal medical institution; or
- Provide a copy of a State agency registration as a PET drug production facility.

Document if the material includes security-related information.

**RADIOACTIVE MATERIALS AND USES****The Applicant Should:**

- Identify the radionuclide, including the chemical and physical form, for each PET radioactive drug produced under this authorization.
- Request authorization to receive potentially contaminated “empty” radiation transport shields back from consortium members.

**INDIVIDUALS RESPONSIBLE FOR RADIOACTIVE SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE**

Individuals responsible for the Radiation Safety Program for the production of PET radioactive drugs and their transfer are the applicant’s (or licensee’s) Radiation Safety Officer (RSO) and the authorized individual(s) responsible during the processing of the PET radionuclides into PET radioactive drugs. The applicant’s RSO and authorized individuals must be qualified to use the material as required by Rule .02(8)(a). If these individuals are already identified on an NRC or Agreement State license for similar materials and uses, they may already be qualified to use the quantities, materials, and uses by experience with radiation safety practices similar to those associated with the process of producing PET radioactive drugs.

**Response from the applicant:**

- Identify the individuals responsible for the Radiation Safety Program and describe their training and experience using similar quantities, materials, and uses of radioactive materials.
- Describe the RSO's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- Describe the authorized individual's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- If producing the PET radioactive drugs in a pharmacy, identify at least one individual who meets the requirements of an ANP.

**TRAINING FOR INDIVIDUAL WORKING IN OR FREQUENTING RESTRICTED AREAS**

Individual working with licensed material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. Refer to **Element 1** and **Appendix K** of this guide.

**FACILITIES AND EQUIPMENT****Response from the applicant:**

- Descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of produced PET radioactive drugs and the location(s) for radioactive waste storage;
- Sufficient detail in the diagram to indicate locations of shielding and/or shielding equipment (e.g., hot cells for positron-emitting radionuclides), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety, such as remote handling equipment and area monitors;
- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the production, use, or storage of radioactive drugs; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose Limits of Rule .03(5)(i), and are within the ALARA constraints for air emissions established under Rule .03(4)(d).

**RADIATION SAFETY PROGRAM**

To receive authorization for the PET radioactive drug production and noncommercial transfer operations, applicants must provide sufficient information that the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property. Applicant should refer to the Radiation Safety Program described in Item 10, **and Element 1 thru Element 16 of this medical guide.**

**DOSAGE MEASUREMENT SYSTEM**

Rule .02(13)(i)2(ii) requires a licensee to possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and have procedures for use of the instrumentation.

**Response from the Applicant:**

- Describe instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium.
- Describe the types of systems (measurement or combination of measurement and calculation) intended for the measurement of PET radioactive drugs.
- For each dose measurement system used to measure the amount of radioactivity in PET radioactive drugs, state: “We have developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in Rule .02(13)(i)2(ii).”

**RADIOACTIVE DRUG LABELING FOR DISTRIBUTION**

Rule .02(13)(i)2(i) requires the licensee for noncommercial transfer of PET radioactive drugs to label each transport radiation shield, syringe, vial or syringe or vial shield with the words “CAUTION, RADIOACTIVE MATERIAL” OR “DANGER, RADIOACTIVE MATERIAL”

**Response from the Applicant:**

- Describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the transport radiation shield or the container used to hold the radioactive drug).
- Confirm that the required labels will be affixed to all transport radiation shields and each container used to hold the radioactive drugs.

**RADIO DRUG SHIELDING FOR NONCOMMERCIAL TRANSFER**

The applicant must provide information to demonstrate that shielding provided for each radioactive drug to be noncommercially distributed is appropriate for safe handling and storage by the consortium members.

**Response from the Applicant:**

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe),
- Describe the type and thickness of the “transport radiation shield” provided for each type of container, and
- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.

**TRANSPORTATION**

The types and quantities of PET radionuclides in PET radioactive drugs shipped by noncommercial transfer to other medical use licensees in the consortium will usually meet the criteria for shipment in a “Type A” package, as defined by the DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling, and radiation and contamination level limits. For applicants who transport their own packages, the packages must be secured to prevent shifting (e.g., blocked and braced), and shipping papers must be used and located properly in the driver's compartment. Refer to Element 17 of this guide.

**WASTE MANAGEMENT**

Refer to Item 11 of this guide.



## APPENDIX F

### MODEL PROCEDURE FOR PERSONNEL EXTERNAL and INTERNAL EXPOSURE MONITORING PROGRAM

Applicants must do either of the following:

1. Demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in Rule .03(5)(a), or
2. Monitor external and/or internal occupational radiation exposure, if required by .03(8)(b).

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 F to the Medical Licensing Guide, Revision 9."

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 10.2," 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)(rrr) 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).
7. The applicant describe in its procedure the criteria used to determine the type of bioassay and the frequencies at which it will be performed to evaluate intakes. The procedures should provide for baseline, routine emergency, and follow-up. Acceptable criteria that applicants may use in developing their bioassay programs are outlined in Regulatory Guide 8.9, Rev 1, "Acceptable Concepts, Models, Equations, and Assumptions for Bioassay Program."
8. Estimating worker dose exposure from aerosols and gases, refer to Appendix T.

## APPENDIX G

### MODEL PRODECURE FOR AREA SURVEYS

This model provides acceptable procedures for medical use area surveys. This model addresses some, but not all, area survey procedures associated with the production of PET radioactive drugs and their transfer or with other nonmedical uses. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Rule .03(4), Rule .03(8), and Rule .05(36). A medical use applicant that will produce or transfer PET radioactive drugs or have other nonmedical uses may need to supplement the model procedures for those activities to meet the requirements of Rule .03(4) and Rule .03(8)a. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

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 G to the Medical Licensing Guide, Revision 9.”

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features of the model procedure and carefully review the requirements of Rule .05(36). Say on your application, “We have developed survey procedures for your review that are appended as ATT 10.3,” and attach your survey procedures.

#### Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys:

- Perform surveys of dose rates in locations where:
  - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
  - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- Section Rule .03(5)(i) requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour. Appropriate surveys will be conducted to ensure that the requirements of Rule .03(5)(i) are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
  - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30  $\mu$ Ci).
  - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200  $\mu$ Ci at a time).
  - Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
  - Survey quarterly all sealed-source and brachytherapy-source storage areas.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what

caused the trigger to be tripped. Examples of trigger levels for restricted and unrestricted areas are presented in Table G.1.

| <b>Table G.1 Ambient Dose Rate Trigger Levels</b> |                      |                      |
|---------------------------------------------------|----------------------|----------------------|
| <b>Type of Survey</b>                             | <b>Area Surveyed</b> | <b>Trigger Level</b> |
| Ambient Dose Rate                                 | Unrestricted         | 0.1 mR/hr            |
| Ambient Dose Rate                                 | Restricted           | 5.0 mR/hr            |

## Contamination Surveys

Facilities and equipment for contamination surveys:

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials are used:
  - To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
  - After any spill or contamination event;
  - When procedures or processes have changed;
  - To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
  - In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly; and
  - In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables G.2 for restricted areas and G.3 for unrestricted areas (e.g., 200 dpm/100 cm<sup>2</sup> for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:
  - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents), with special care taken to remove all paraphernalia, those rooms need not be surveyed.
  - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).
  - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.

- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Examples of trigger levels for restricted areas are presented in Table G.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

| <b>Table G.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm<sup>2</sup>)</b> |                |                                                                                                            |                                             |
|--------------------------------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Area, clothing                                                                             | alpha emitters | P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198 | Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201 |
| Restricted areas, protective clothing used only in restricted areas                        | 200            | 2000                                                                                                       | 20000                                       |

| <b>Table G.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm<sup>2</sup>)</b>                                          |                            |                            |                              |
|---------------------------------------------------------------------------------------------------------------------------------------|----------------------------|----------------------------|------------------------------|
| Nuclide <sup>1</sup>                                                                                                                  | Average <sup>2, 3, 6</sup> | Maximum <sup>2, 4, 6</sup> | Removable <sup>2, 5, 6</sup> |
| I-125, I-126, I-131, I-133, Sr-90                                                                                                     | 1000                       | 3000                       | 200                          |
| Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above. | 5000                       | 15000                      | 1000                         |
| Ra-226                                                                                                                                | 100                        | 300                        | 20                           |

- <sup>1</sup> Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.
- <sup>2</sup> As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- <sup>3</sup> Measurements of average contaminants should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.
- <sup>4</sup> The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.
- <sup>5</sup> The amount of removable radioactive material per 100 cm<sup>2</sup> of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
- <sup>6</sup> The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

## Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables G.1 and G.2:

Alternate action levels for cleanup of contamination in restricted areas may be developed without prior NRC approval if:

- acceptable unrestricted area trigger levels are implemented (e.g., Tables G.1 and G.3);
- the action levels maintain occupational doses ALARA; and
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

## Alternate Survey Frequency

A sample alternate survey frequency is described below using Tables G.4, G.5, and G.6. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

| <b>Table G.4 Isotope Groups</b> |               |        |         |         |         |        |        |         |        |        |
|---------------------------------|---------------|--------|---------|---------|---------|--------|--------|---------|--------|--------|
| Group 1                         | Pb-210        | Po-210 | Ra-223  | Ra-226  | Ra-228  | Ac-227 | Th-230 | Pa-231  | Pu-238 |        |
|                                 | Am-241        | Am-243 | Cm-242  | Cm-243  | Cm-244  | Cm-245 | Cm-246 | Cf-249  |        |        |
|                                 | Cf-250        | Cf-252 | Ra-226  |         |         |        |        |         |        |        |
| Group 2                         | Na-22         | Cl-36  | Ca-45   | Sc-46   | Mn-54   | Co-56  | Co-60  | Sr-89   | Sr-90  | Y-91   |
|                                 | Zr-95         | Ru-106 | Ag-110m | Cd-115m | In-114m | Sb-124 | Sb-125 | Te-127m |        |        |
|                                 | Te-129m       | I-124  | I-125   | I-126   | I-131   | I-133  | Cs-134 | Cs-137  | Ba-140 | Ce-144 |
|                                 | Eu-152 (13 y) | Eu-154 | Tb-160  | Tm-170  | Hf-181  | Ta-182 | Ir-192 | Tl-204  |        |        |
|                                 | Bi-207        | Bi-210 | At-211  | Pb-212  | Ra-224  | Ac-228 | Pa-230 |         |        |        |

|         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Group 3 | Be-7 C-14 F-18 Na-24 C1-38 Si-31 P-32 S-35 Ar-41 K-42 K-43 Ca-47<br>Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58<br>Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77<br>Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97<br>Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103<br>Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m<br>Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-31m Te-132 I-130<br>I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-31 La-140 Ce-141 Ce-143<br>Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152<br>Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr)<br>Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188<br>Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-191 Pt-193 Pt-197 Au-196<br>Au-198 Au-199 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203<br>Bi-206 Bi-212 Rn-220 Rn-222 |
| Group 4 | H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87<br>Y-91m Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m<br>Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

| Table G.5 Classification of Laboratories for Alternate Survey Frequency |          |                  |         |
|-------------------------------------------------------------------------|----------|------------------|---------|
| Survey Frequency Category                                               |          |                  |         |
| Group                                                                   | Low      | Medium           | High    |
| 1                                                                       | <0.1 mCi | 0.1 mCi to 1 mCi | >1 mCi  |
| 2                                                                       | <1 mCi   | 1 mCi to 10 mCi  | >10 mCi |
| 3                                                                       | <100 mCi | 100 mCi to 1 Ci  | >1 Ci   |
| 4                                                                       | <10 Ci   | 10 Ci to 100 Ci  | >100 Ci |

#### Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day. Proportional fractions are to be used for more than one isotope.

| Table G.6 Modifying Factors for Alternate Survey Frequency                                         |         |
|----------------------------------------------------------------------------------------------------|---------|
| Modifying Factors                                                                                  | Factors |
| Simple storage                                                                                     | x 100   |
| Very simple wet operations (e.g., preparation of aliquots of stock solutions)                      | x 10    |
| Normal chemical operations (e.g., analysis, simple chemical preparations)                          | x 1     |
| Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)     | x 0.1   |
| Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds | x 0.1   |
| Exposure of nonoccupational persons (including patients)                                           | x 0.1   |
| Dry and dusty operations (e.g., grinding)                                                          | x 0.01  |

## **Contents of Survey Records**

- A diagram of the area surveyed,
- A list of items and equipment surveyed,
- Specific locations on the survey diagram where wipe tests were taken,
- Ambient radiation levels with appropriate units,
- Contamination levels with appropriate units,
- Make and model number of instruments used,
- Background levels, and
- Name of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

## APPENDIX H

### MODEL RULES FOR SAFE USE OF RADIOPHARMACEUTICALS

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix H of the Medical Licensing Guide, Revision 9."

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

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).
- Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of licensed material use including the generator storage, preparation locations, and injection areas, daily for contamination. If necessary, decontaminate the area.
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled
- Syringes and unit dosages must be labeled. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in Appendix C to Part 20, the syringe or vial need only be labeled to identify the radioactive drug. To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it.
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than  $\pm 20\%$  from the prescribed dosage, except as approved by an AU.
- When measuring the dosage, licensees 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. If the prescribed dosage requires a WD, the patient's identity must be verified and the administration must be in accordance with the WD.
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the Georgia license (or such individual's designee)

## APPENDIX I

### MODEL SPILL CONTROL PROCEDURES

You may use the following model spill control procedures as they appear here, saying on your application, “We will establish and implement the model spill control procedures published in Appendix I to the Medical Licensing Guide, Revision 9.”

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 attach your spill control procedures.

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

#### FORMS

You may want to use, Radioactive Spill Report and Radioactive Spill Contamination Survey Forms on Pages I-4 and I-5 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 I-4) and the Radioactive Spill Contamination Survey (Page I-5).

#### 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.

The decision to implement a major spill/contamination procedure instead of a minor spill/contamination procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated, and radiotoxicity of the spilled material.

#### **Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides**

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The radiation safety staff will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

## **Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides**

The following procedures should be followed:

1. Immediately notify the AU in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eye wear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high-energy beta rays in cases involving therapy with P-32 and Y-90.
4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.





## APPENDIX J

### 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 J to the Medical Licensing Guide, Revision 9.”

#### **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(40).

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(40). 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.

#### **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(13)(c), 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 the container which 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 K

### MODEL PROCEDURE FOR SAFETY INSTRUCTIONS FOR INDIVIDUALS WORKING IN OR FREQUENTLY RESTRICTED AREA

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet NRC requirements. Guidance on requirements for training and experience for AMPs and AUs for medical use who engage in certain specialized practices is also included.

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

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 attached as ATT 11.0."

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, presentations, professional conferences, demonstrations, or any combination of these.

#### **MODEL TRAINING PROGRAM**

##### **Training for Individuals Involved in the Medical Usage of Radioactive material:**

Training for professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, commensurate with their duties:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA
- Risk estimates, including comparison with other health risks;
- Posting requirements
- Proper use of personnel dosimetry
- Access control procedures
- Proper use of radiation shielding, if used;
- Patient release procedures
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of

- appropriate patient care
- Occupational dose limits and their significance
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy
- Worker's right to be informed of occupational radiation exposure
- Each individual's obligation to report unsafe conditions to the RSO
- Applicable regulations, license conditions, information notices, bulletins, etc.
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination
- Proper recordkeeping
- Appropriate surveys to be conducted
- Proper calibration of required survey instruments
- Emergency procedures
- Decontamination and release of facilities and equipment
- Dose to individual members of the public
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing)

### **Training for Individuals Involved in Nonmedical Usage of Byproduct Material**

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide training on the production of PET radioactive drugs and special requirements in Rule .02(7)(h)(1) and (2) and Rule .02(13)(e) for this activity. All training should be commensurate with the individual's duties.

### **Training for the Staff Directly Involved in Administration to or Care of Patients Administered Radioactive material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131), or Therapeutic Treatment Planning:**

- Leak testing of sealed sources
- Emergency procedures (including emergency response drills)
- Operating instructions
- Computerized treatment planning system
- Dosimetry protocol
- Detailed pretreatment quality assurance checks
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources
- Patient control procedures
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room)
- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet)
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources)
- Size and appearance of different types of sources and applicators
- Previous incidents, events, and/or accidents; and

For remote afterloaders, teletherapy units, and GSR units, initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:

- Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
- Hands-on training in actual operation of the device under the direct supervision of an experienced user, including “dry runs” (using dummy sources) of routine patient setup and treatment and implementation of the licensee’s emergency procedures;
- A method, such as practical examinations, to determine each trainee’s competency to use the device for each type of proposed use.

#### **Additional Training for Authorized Medical Physicists:**

Applicants for licenses to include AMPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in **Rule .05(23)(b)(1)**. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of Sr-90 sources used for ophthalmic treatments (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

#### **Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required**

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, and 10 CFR 35.690, attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in Sections 35.390, 35.490, 35.491, and 35.690 of 10 CFR Part 35.

#### **Ancillary personnel:**

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.

#### **Training for Individuals Involved in Nonmedical Usage of Byproduct Material**

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide training on the production of PET radioactive drugs and special requirements in 10 CFR 30.32(j) and 10 CFR 30.34(j) for this activity. All training should be commensurate with the individual’s duties.

## APPENDIX L

### MODEL PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

You may use the following procedure for opening packages. 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(16)(j).

#### **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)(x). 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(16)(i) or when the external radiation levels exceed the limits of Rule .06(16)(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.
- 4. For “empty” transport radiation shields being returned from consortium members, implement the following procedure for opening each package:
  - a. Monitor the package for radioactive contamination.
  - b. Visually inspect the contents to ensure that the transport radiation shield is empty. Notify the RSO if the transport radiation shield is not empty.

## **APPENDIX M**

### **MODEL PROCEDURE FOR DEVELOPING, MAINTAINING, and IMPLEMENTING WRITTEN DIRECTIVES**

The purpose of a Written Directive 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., therapeutic dose, teletherapy, brachytherapy, high dose afterloader, or gamma stereotactic radiosurgery. Specific policies and procedures will be established for each modality, as needed, to ensure that the objectives of the Written Directive as outlined in Rule .05(19) and (20) are met.

You may use the following procedure for your program, or you may develop your own program.

If you develop your own program for review, you should consider for inclusion all the features of the model and the requirements of Rule .05(19) and .05(20). 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)(ww) 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 program. The review will include an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with the program. The reviews will be conducted from the previous review forward and at intervals not to exceed 12 months.

##### **M.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. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed source behind an appropriate shield, and using clearly marked storage locations.

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.

## **M.2 PROCEDURES FOR SEALED THERAPEUTIC SOURCES AND DEVICES CONTAINING SEALED THERAPEUTIC SOURCES)**

1. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
2. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to 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 prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).
3. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
  - a. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
  - b. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
  - c. For manually-generated dose calculations, verifying:
    - (1) No arithmetical errors;
    - (2) Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
    - (3) Appropriate use of nomograms (when applicable); and
    - (4) Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify 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). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.



4. After implantation but before completion of the procedure: record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by .05(19)(b)5(ii). For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The WD may be maintained in the patient's chart.
5. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.
6. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
  - a. An individual who did not perform the full calibration (the individual will meet the requirements specified in .05(23) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in .05(72); or
  - b. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
7. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
8. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
9. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.
10. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

### **M.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.
  - 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.

### **M.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 afterloading 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 N

### 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 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(9) and .05(38).

#### **MODEL PROCEDURE**

##### **Survey Meter**

Check the survey meter with the dedicated check source for consistent response before each use, at each client's 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 client's address, or on each day of use, whichever is more frequent.

#### **Type and Location of Use**

In general, there are two types of mobile medical service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

Whether a PET mobile medical service provider that uses a "quiet room" in the client's facility is authorized for "in-van use" or "transport and use" depends on whether the PET patients meet the criteria for release in .05(37) while they are in the "quiet room." If they do not, then the "quiet room" is an area of use for the mobile service licensee.

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to the client's possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with .05(9), which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service. Additionally, as required by .05(38)(f) the licensee must survey to ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes, have been removed) before leaving a client's address.

## Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. Applicants should specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital).

Submit a description and diagram(s) of the proposed base facility and associated equipment, location of the licensed material receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. The description and diagram of the proposed facility should demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with .03(5)i. **Include a diagram showing the storage locations within the van, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with .03(5), "Occupational dose limits for adults."**

- Applicants may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the radioactive material storage, provide for the following:
  1. Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
  2. Secured storage facilities available for storage of radioactive material and radioactive waste if the van is disabled; and
  3. Radioactive material delivered directly to the van only if the van is occupied by licensee personnel at the time of delivery.
- If a base facility is located in a residential area, provide the following information:
  1. Justification of the need for a private residence location rather than for a commercial location.
  2. Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
  3. A description of the program demonstrating compliance with .03(5), "Dose limits for individual members of the public."
  4. Verification that restricted areas do not contain residential quarters.

- Perform surveys necessary to show that exposure rates do not exceed 2 mrem in any 1 hour nor 100 mrem per year.

### **Client Site**

This section applies only to therapeutic uses of radioactive material. For all types of therapy uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

#### **For self-contained radioactive material services (e.g., in-van), the following additional facility information should be provided:**

- For therapy treatments with radioactive material (e.g., high dose-rate remote afterloader), a separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public;
- A signed agreement, as delineated in the letter required by .05(9)(b), that location of the device/vehicle will be on client-owned or controlled property;
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

#### **If transportable services will be provided to the client's site for use within the client's facility by the mobile medical service's employees, the following client facility information and commitment should be provided:**

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment, receipt, and use areas, and identify all areas adjacent to restricted areas. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with .03(5)(i).
- A commitment, as delineated in the letter that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.
- The initial installation records and function checks of a remote afterloader device for each site of use, as required by .05(74), .05(77), and .05(79)

#### **For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, ensure the following:**

- Each client is properly licensed for medical use of radioactive material. If applicable, licensees should ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This

includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in .05(18), transfer to the client's AUs upon transfer of the device to the client by the mobile medical service provider.

- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- A formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

### **Training for Individuals Working in or Frequenting Restricted Areas**

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of Rule .07(3) .05(18), .05(58), and .05(70) (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

### **Order and Receipt of Radioactive Material**

Radioactive material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. Delivery of radioactive material to a van that is not occupied by the mobile medical service personnel will not be permitted. Alternatively, licensees may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

## APPENDIX O

### MODEL GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

You may use the following guidance to control the ordering and receipt of radioactive material; or you may develop your own procedure. 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).

#### 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 on the next page.



**SAMPLE MEMORANDUM****M E M O R A N D U M**

To: Chief of Security

From: Radiation Safety Officer

Subject: Receipt of Packages Containing Radioactive Material

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

### Recordkeeping Requirement

| Record                                                                                                            | Recordkeeping Requirement | Retention Period                                  |
|-------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------------------------------|
| Results of surveys and calibrations                                                                               | .03(14)(c)1               | 3 years                                           |
| Results of surveys to determine dose from external sources                                                        | .03(14)(c)2(i)            | 3 years                                           |
| Results of measurements and calculations used to determine individual intakes                                     | .03(14)(c)2(ii)           | 3 years                                           |
| Results of air samplings, surveys, and bioassays                                                                  | .03(14)(c)2(iii)          | 3 years                                           |
| Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment | .03(14)(c)2(iv)           | 3 years                                           |
| Determination of prior occupational dose                                                                          | .03(14)(e)                | 3 years                                           |
| Occupational radiation exposure history                                                                           | .03(14)(e)                | permanently                                       |
| Planned special exposure                                                                                          | .03(14)(f)                | 3 years                                           |
| Individual monitoring results                                                                                     | .03(14)(g)                | 3 years                                           |
| Dose to individual members of the public                                                                          | .03(14)(h)                | 3 years                                           |
| Waste disposal                                                                                                    | .03(14)(i)                | 3 years                                           |
| Records of receipt of radioactive material                                                                        |                           | duration of possession and 3 years after transfer |
| Records of transfer of radioactive material                                                                       | .02(19)                   | 3 years after transfer                            |
| Records of disposal of radioactive material                                                                       | .03(14)(i)                | duration of license                               |
| Authority and responsibilities of Radiation Protection Program                                                    | .05(86)                   | 5 years                                           |
| Radiation Protection Program changes                                                                              | .05(87)                   | 5 years                                           |
| Written directives                                                                                                | .05(88)                   | 3 years                                           |
| Calibrations of instruments used to measure activity of unsealed radioactive material                             | .05(91)                   | 3 years                                           |
| Radiation survey instrument calibrations                                                                          | .05(92)                   | 3 years                                           |
| Dosages of unsealed radioactive material for medical use                                                          | .05(93)                   | 3 years                                           |
| Leak tests and inventory of sealed sources and brachytherapy sources                                              | .05(94)                   | 3 years                                           |
| Surveys for ambient radiation exposure rate                                                                       | .05(95)                   | 3 years                                           |

| <b>Record</b>                                                                                                                               | <b>Recordkeeping</b> | <b>Retention Period</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------|
| Release of individuals containing unsealed radioactive material or implants containing radioactive material                                 | .05(96)              | 3 years                 |
| Mobile medical services                                                                                                                     | .05(97)              | 3 years                 |
| Decay-in-storage                                                                                                                            | .05(98)              | 3 years                 |
| Molybdenum-99 or strontium-82 or strontium-85 concentrations                                                                                | .05(45)              | 3 years                 |
| Safety instruction                                                                                                                          | .05(101)             | 3 years                 |
| Surveys after source implant and removal                                                                                                    | .05(102)             | 3 years                 |
| Brachytherapy source accountability                                                                                                         | .05(103)             | 3 years                 |
| Calibration measurements of brachytherapy sources                                                                                           | .05(104)             | 3 years                 |
| Decay of strontium-90 sources for ophthalmic treatments                                                                                     | .05(105)             | life of source          |
| Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units | .05(106)             | 3 years                 |
| Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units                        | .05(107)             | duration of license     |
| Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations                                                      | .05(108)             | 3 years                 |
| Periodic spot-checks of teletherapy units                                                                                                   | .05(109)             | 3 years                 |
| Periodic spot-checks of remote afterloader units                                                                                            | .05(110)             | 3 years                 |
| Periodic spot-checks of gamma stereotactic radiosurgery units                                                                               | .05(111)             | 3 years                 |
| Additional technical requirements for mobile remote afterloader units                                                                       | .05(112)             | 3 years                 |
| Surveys of therapeutic treatment units                                                                                                      | .05(113)             | duration of use of unit |
| 5-year inspection for teletherapy and gamma stereotactic radiosurgery units                                                                 | .05(114)             | duration of use of unit |

## APPENDIX Q

| <b>Typical NRC Notifications and/or Reports</b>                                                                                           |                               |                       |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------|-------------------------------|
| <b>Event</b>                                                                                                                              | <b>Telephone Notification</b> | <b>Written Report</b> | <b>Regulatory Requirement</b> |
| Reports to individual workers                                                                                                             | none                          | annually              | .07(4)(b)                     |
| Reports to former individual workers                                                                                                      | none                          | upon request          | .07(4)(c)                     |
| Notification of special circumstances to individuals                                                                                      | none                          | 30 days               | .07(4)(d)                     |
| Reports to worker terminating employment                                                                                                  | none                          | upon request          | .07(4)(e)                     |
| Theft or loss of material                                                                                                                 | immediate                     | 30 days               | .03(15)(a)                    |
| Whole body dose greater than 0.25 Sv (25 rems)                                                                                            | immediate                     | 30 days               | .03(15)(b)1(ii)(I)            |
| Extremity dose greater than 2.5 Sv (250 rems)                                                                                             | immediate                     | 30 days               | .03(15)(b)1(ii)(I)(III)       |
| Whole body dose greater than 0.05 Sv (5 rems) in 24 hours                                                                                 | 24 hours                      | 30 days               | .03(15)(b)2(v)(a)             |
| Extremity dose greater than 0.5 Sv (50 rems) in 24 hours                                                                                  | 24 hours                      | 30 days               | .03(15)(b)2(v)(I)(c)          |
| Doses in excess of specified criteria                                                                                                     | none                          | 30 days               | .03(15)(c)1(ii)               |
| Levels of radiation or concentrations of radioactive material in excess of specified criteria                                             | none                          | 30 days               | .03(15)(c)1(iii)              |
| Planned special exposures                                                                                                                 | none                          | 30 days               | .03(15)(d)                    |
| Report to individuals of exceeding dose limits                                                                                            | none                          | 30 days               | .03(15)(e)                    |
| Report of individual monitoring                                                                                                           | none                          | annually              | .07(4)(b)                     |
| Defect in equipment that could create a substantial safety hazard                                                                         | 24 hours                      | 30 days               | .05(15)(b)2(ii)               |
| Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits | immediate                     | 30 days               | .03(15)(b)1(i)                |
| Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits         | 24 hours                      | 30 days               | .03(15)(b)2(ii)               |
| Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material | 24 hours                      | 30 days               | .03(15)(b)2(iv)               |

| <b>Event</b>                                                                                                                                                                                                                                                                         | <b>Telephone Notification</b> | <b>Written Report</b> | <b>Regulatory Requirement</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------|-------------------------------|
| AU, ANP, or AMP discontinues performance of duties under license or has a name change                                                                                                                                                                                                | none                          | 30 days               | .05(11)(b)(1)                 |
| Licensee's mailing address changes                                                                                                                                                                                                                                                   | none                          | 30 days               | .05(11)(b)(2)                 |
| Licensee's name changes without constituting a transfer of control                                                                                                                                                                                                                   | none                          | 30 days               | .05(11)(b)(3))                |
| Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of radioactive material identified in application or license if the change or addition did not involve movement of a PET radionuclide production facility or transfer line from a PET radionuclide production facility | none                          | 30 days               | .05(11)(b)(4)                 |
| Medical event                                                                                                                                                                                                                                                                        | 1 day                         | 15 days               | .05(115)                      |
| Dose to embryo or nursing child                                                                                                                                                                                                                                                      | 1 day                         | 15 days               | .05(116)                      |
| Leaking source                                                                                                                                                                                                                                                                       | none                          | 5 days                | .05(117)                      |

## APPENDIX R

### MODEL PROCEDURE FOR LEAK-TESTING SEALED SOURCES

You may use the following model procedure to leak-test sealed sources; or you may choose to use an outside contractor.

If you choose to have leak-testing performed by an outside contractor, document the name of the company and their Radioactive Materials 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 .03(6) and Rule .05(33).

#### **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 microcuries or greater, notify the RSO. Follow the procedures required by Rule .05(33)(c).
- g. The leak test record will contain the information required in rule .03(14)(d).

## APPENDIX S

### MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS (ALARA)

You may use the text as it appears here. 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 .03(4)(d).

#### ALARA PROGRAM

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(Licensee's Name)

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(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)<sup>1</sup>.
- 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.

#### 2. RADIATION SAFETY OFFICER

- a. Annual and Quarterly Review

(1) The RSO will conduct an annual review of the radiation protection program for

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



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 COMMITTEE<sup>2</sup>

a. Review of Proposed Users and Uses

- (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.

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

- (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 R-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 S-1. These levels apply to the exposure of individual workers.

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 S-1:

- a. Personnel dose less than Investigation Level I.

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

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

When the dose of an individual equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements or additional safety measures are needed to reduce exposures. Evaluate, in the context of ALARA program quality, and record the results of investigations and evaluations.

- c. Personnel dose equal to or greater than Investigation Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. The RSO should consider actions to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

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

TABLE S-1

|                                                                                             | Investigation Levels<br>(mrem per year) |          |
|---------------------------------------------------------------------------------------------|-----------------------------------------|----------|
|                                                                                             | Level I                                 | Level II |
| Part of Body                                                                                |                                         |          |
| whole body, head, trunk including male gonads, arms above the elbow, or legs above the knee | 500                                     | 1500     |
| hands, elbows, arms below the elbow, feet, knees, legs below the knee, or skin              | 5000                                    | 15000    |
| lens of the eye                                                                             | 1500                                    | 4500     |

6. SIGNATURE OF CERTIFYING OFFICIAL<sup>4</sup>

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: \_\_\_\_\_

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

## APPENDIX T

### MODEL PROCEDURE FOR MONITORING, CALCULATING, AND CONTROLLING AIR CONCENTRATIONS

#### **WORKER DOSE FROM NOBLE GASES**

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 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 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 T.3 to the Medical Licensing Guide, Revision 9."

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 by saying, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix T.1 to the Medical Licensing Guide, Revision 9."

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), and .05(39)**. Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases" and append your procedure for monitoring worker dose from noble gases.

#### **WORKER DOSE FROM AEROSOLS**

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 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 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 by saying, “We will follow the model procedure for calculating worker dose from aerosols that was published in Appendix T.1 to the Medical Licensing Guide, Revision 9.”

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)**, and **05(39)**. Say on your application, “We have developed a procedure for monitoring worker dose due to aerosol concentrations,” and append your procedure for monitoring worker dose from aerosols.

### **T.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  $1 \times 10^{-4}$   $\mu\text{Ci/ml}$  in restricted areas and  $5 \times 10^{-7}$   $\text{uCi/ml}$  in unrestricted areas. For soluble Tc-99m, the maximum permissible values are  $6 \times 10^{-5}$   $\text{uCi/ml}$  in restricted areas, and  $2 \times 10^{-7}$   $\mu\text{Ci/ml}$  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.)

### **T.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.

### **T.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**

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 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 by saying, "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix T.2 to The Medical Licensing Guide, Revision 9."

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)**, and **.05(39)**. Say on your application, "We have developed a procedure for monitoring



airborne effluent concentration,” and append your procedure for monitoring airborne effluent concentration.

### **SPIILLED GAS CLEARANCE TIME**

Because normal room ventilation is usually not sufficient to ensure timely clearance of spilled gas, the calculations described in Appendix T.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 by saying, “We will calculate spilled gas clearance times according to the procedure that was published in Appendix T.4 to the Medical Licensing Guide, Revision 9.”

You may develop your own procedure for review. If you do so, you should consider all the above information. Say on your application, “We have developed a procedure for calculating spilled gas clearance times” and append your procedure.

### **T.4 MODEL PROCEDURE FOR CALCULATING SPIILLED 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  $1 \times 10^{-4}$   $\mu\text{Ci/ml}$  in restricted areas and  $5 \times 10^{-7}$   $\mu\text{Ci/ml}$  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.