CONSOLIDATED GUIDANCE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL USE LICENSEES

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DIVISION OF RADIOLOGICAL HEALTH
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July 2013

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APPENDICES

INTRODUCTION

1.1 Purpose of the Guide

The purpose of this guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals that authorize possession of licensed material for medical use. This guide is intended to provide the applicant or licensee with information that will provide an understanding of specific regulatory requirements and licensing policies as they apply to medical licenses.

1.2 Purpose of Appendices to the Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through O 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 procedure appropriately addresses specific radiation safety program needs. In the application, applicants may certify that they will follow a model procedure, or that they have developed a procedure that is analogous and is enclosed for review.

1.3 Applicable Regulations

Regulations that apply to medical programs and should be used in conjunction with this guide are the Mississippi State Board of Health Regulations for Control of Radiation, Subchapter 1, "General Provisions", Subchapter 3, "Licensing of Radioactive Material", Subchapter 4, "Standards for Protection Against Radiation", Subchapter 7, "Use of Radionuclides in the Healing Arts", and Subchapter 10, "Notices, Instructions and Reports to Workers; Inspections", and Subchapter 13 “Transportation”. As a licensee, you are subject to all applicable provisions of the regulations as they pertain to medical use.

1.4 Authority and Responsibilities for the Radiation Protection Program

1.4.1 General ALARA Considerations

Each individual who is authorized to use licensed material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material and should ensure that the facility and equipment are adequate for safe use. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or radiation safety officer (RSO).

1.4.2 ALARA in Medical Institutions

Each medical licensee must have a formal written ALARA program. The success of an ALARA program depends on the cooperation of each person who works at the licensed facility. Management should make a commitment to the ALARA philosophy and implement that commitment with adequate resources. A radiation safety committee (RSC) composed of individuals who have special expertise in the safe use of licensed material is required by Rule 1.7.13(6) to review uses for safety and ALARA considerations. The RSC, RSO, and management should audit the program to ensure the continued safe use of licensed material. In addition to being a member of the committee, the RSO serves as a technical consultant to the committee and is also responsible for the day-to-day operation of the radiation safety program. A model ALARA program is contained in Appendix N of this guide. Applicants should consider the ALARA philosophy in the development of plans for work with radioactive materials.

1.5 Written Directives

Rule 1.7.16 of the regulations requires that a written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 uCi), any therapeutic dosage of radioactive material or any therapeutic dosage of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in the patient's record and a written directive is prepared within 48 hours of the oral directive. A model Written Directive Program is contained in Appendix O of this guide for your convenience.

1.6 Types of Licenses

The Division of Radiological Health (DRH) issues two (2) types of licenses for the medical use of radioactive material. 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 safety program.

01.6.1 Specific License

Specific licenses for physicians in private practice are generally limited to physicians who are located in a private office, practice a limited number of medical disciplines, and whose practice is not sited within a licensed medical institution. For this group of licensees, a RSC is not required and procedures requiring hospitalization of the patient are not authorized to be performed.

Specific licenses are also issued to medical institutions for human use of radioactive material. A medical institution is an organization in which several medical disciplines are practiced. Licenses authorizing multiple quantities and types of radioactive material for human use will be issued if (1) the applicant has appointed a radiation safety officer/committee (Appendix A to this guide) to oversee the safe use of licensed material throughout the institution and to review the institution's radiation safety program, (2) the applicant possesses adequate facilities for the clinical care patients, (3) the physician designated on the application as the authorized user has substantial experience in the proposed use, handling, and administration of radioactive material and, where applicable, the clinical management of radioactive patients, and (4) if the application is for a license to use unspecified quantities of multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

A specific license may also be issued for a mobile nuclear medicine service (Rule 1.7.11). Both private practice physicians and medical institutions may apply for authorization to use radioactive material in conjunction with a mobile nuclear medicine service.

1.6.2 Specific License of Broad Scope

Some medical institutions provide patient care and conduct research programs that use radioisotopes for in vitro, animal, and medical procedures. In these cases, the DRH may issue a specific license 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 previous experience successfully operating under a specific institutional license of limited scope; and 2) are engaged in medical research as well as routine diagnostic and therapy using radioactive material.

2. FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Agency Form 707E, "Application For Materials License-Medical". The applicant must complete all items on the application form in sufficient detail for the DRH staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form 707E is limited, the applicant should append separate sheets of paper for Items 7-25 listed on the form. Each separate sheet should contain the item number and the applicable date in the lower right corner.

One copy of the application with all attachments should be retained by the applicant, since the license will require as a condition that the licensee follow the statements and representations set forth in the application and any supplement to it. The original should be mailed to the Mississippi State Department of Health, Division of Radiological Health, P. O. Box 1700, Jackson, Mississippi 39215.

3. CONTENTS OF AN APPLICATION

This portion of the guide explains, item by item, the information requested on Form 707E. This guide contains several appendices that present sample procedures or sample programs. You may wish to adopt one or more of these samples as part of your program. In your application, if you refer to a section of this guide, that section or appendix will be incorporated as a part of the terms and conditions of your license. You will be inspected against the commitments contained in the referenced section, appendix, or document, just as you will be inspected against your more detailed responses. Therefore, you must keep a copy of the referenced guide on hand at all times so that you can review your commitments as necessary.

Item 1.a. - Name and Mailing Address of Applicant

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive materials 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 legal name of the corporation or other legal entity applying for the license should be provided. The address specified here should be the complete mailing address for correspondence and may contain a post office box number, a department name, a mailing code, or other information that will assist in getting mail to the applicant. This may or may not be the same as the address at which licensed material will be used, as specified in Item 1.b. In general, an "attention" line should be included in the address, but that line should specify a title rather than a particular person's name.

Item 1.b. - Street Address(es) At Which Radioactive Material Will Be Used

Specify each proposed location of use by the physical address (including building name and other locating information, if appropriate), city, and state or other descriptive address to allow the DRH to locate the facility. A post office box address is not acceptable. If radioactive material is to be used at more than one location under the license, the specific address (e.g., street, building) must be provided. If you are applying for a license for a mobile service (diagnostic or therapy), identify the name and location of each client where mobile services are proposed.

Item 2 - Person to Contact Regarding This Application

Provide the name of the individual who is cognizant of the proposed radiation safety program and can answer questions about the application. Provide the individual's work phone number in the event that the DRH needs to contact the individual with questions about the application. If the contact person changes, notify the DRH. The individual named in Item 2 may or may not be the same individual who signs the application as the "certifying official" on behalf of the licensee and has the authority to make commitments to DRH. Any commitments made by the applicant should be signed by the individual named in Item 26 since only that individual is considered by the DRH to have the authority to make commitments on behalf of the applicant.

Item 3 - Application for:

Indicate whether this is an application for a new license or an amendment in its entirety. If the application is for an amendment in its entirety, indicate the license number.

Item 4 - Individual Users

List the full names of all physicians who will use or directly supervise the use of radioactive material and include copies of board certificates and/or preceptors.

Item 5 - Radiation Safety Officer

State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation safety program. If the RSO is not one of the proposed authorized users, documentation of the individual's training and experience must be submitted with the application. The training requirements for the RSO are specified in Rule 1.7.19 of the regulations. It is recognized that licensees may use a consultant, or consultant group, to assist in preparation of the license application, provide support to the radiation safety program, or to augment the role of the RSO. If a consultant is used, specify the name of the individual or consultant group. Licensees are reminded that regardless of the role of the consultant in radiation safety program management, the licensee remains ultimately responsible for all aspects of the licensed program, including the services performed by the consultant.

Item 6.a.- Radioactive Material for Medical Use

Subchapter 7 of the Mississippi State Board of Health Regulations for Control of Radiation divides radioactive material for medical use into five (5) types (Rules 1.7.37, 1.7.40, 1.7.44, 1.7.49, 1.7.59, and 1.7.61). Indicate the types of use and maximum quantity of radioactive material requested. You may indicate "As needed" in the "Maximum Possession Limits" column as shown. For Rule 1.7.49 brachytherapy sources, 1.7.59 sealed sources, and 1.7.61 sources, express the total amount in millicuries (mCi) or curies (Ci) depending upon the type of procedures performed. If you intend to possess an eye applicator, list it as a separate line item on the application. Sources for a high-dose-rate remote afterloading device should be listed separately. List the manufacturer's name, model number, and activity (in millicuries) for all sealed sources.

A specific authorization must be obtained from the DRH to perform studies involving the use of radioactive materials in animals.

Item 6.b.- Radioactive Material for Uses not listed in Item 6.a.

Describe the intended use for each radionuclide and form listed in Item 6.b. If the radioactive material has not been approved for routine human use by the Food and Drug Administration (FDA), submit evidence that procurement, preparation, and use of the material will be in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. If the study is under a "Notice of Claimed Investigational Exemption for a New Drug" (IND) sponsored by the physician or institution, state the radionuclide, chemical form, possession limit, and use, and submit a copy of the IND acceptance letter from the FDA.

If you need other items (e.g., more radioactive material for in vitro testing than is allowed under Rule 1.3.6(9)(a), a survey meter calibration source, or human studies), make a separate line entry for each item. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in millicuries, and the purpose for which the material will be used. If you do not want all the material listed in a section, you must identify, line by line, the material that you do want from that section. When determining both individual nuclide and total quantities, all materials to be possessed at any one time under the license should be included, i.e., materials received awaiting use (new brachytherapy source for exchange); materials in use or possessed; and those materials classified as waste awaiting disposal or being held for decay-in-storage. For further discussion on the purposes for which licensed material will be used for each type of medical use currently authorized, e.g., manual brachytherapy, refer to the appropriate licensing guidance module of this guide.

Item 6.c. - Alpha and/or Beta - Emitting Radiopharmaceuticals

Licensees who wish to utilize alpha and/or beta - emitting radiopharmaceuticals must obtain them in unit dose form, calibrated by the supplier for individual patients. The supplier must participate in a measurement quality assurance program with the National Institute of Standards and Technology which ensures that the unit doses have a calibration traceable to a national standard.

Item 7 - Radiation Safety Committee

In accordance with Rule 1.7.13(6), **unless exempted,** of the Mississippi State Board of Health Regulations for Control of Radiation, an institution applying for a radioactive material license is required to establish a radiation safety committee. This committee evaluates all proposals for research, diagnostic, and therapeutic use of radioisotopes. Membership of the committee should include an authorized user of each type of use permitted by the license; the Radiation Safety Officer; a representative of the nursing service; and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

Submit the following information:

a. The responsibility and duties of the committee in accordance with Rule 1.7.13(6)

b. The meeting frequency of the committee (at intervals not to exceed six (6) months).

c. The name and specialty of each member of the committee.

The DRH considers the RSC to be a key focal point for effective management of the licensed program. The RSC acts as the administrative arm of executive management and the communication link between radiation safety staff, authorized users, supervised individuals and RSO with facility executive management. Although the RSO is typically responsible for the day-to-day operations of a radiation safety program, the RSC must maintain a constant pulse on licensed activities. The RSC is also responsible for authorizing physician users and approving qualified physicists and RSOs prior to seeking an amendment to recognize this group of individuals.

Appendix A to this guide contains an example of typical responsibilities and duties for a radiation safety committee. Indicate, by checking the appropriate box in Item 7, that the responsibilities, duties, and meeting frequency will be as described in Appendix A, or propose alternatives. If the responsibilities, duties, or meeting frequency will be different from those described, submit a complete description.

Item 8 - Training and Experience

Individuals responsible for the radiation safety program include licensee senior management, the authorized users, RSO, RSC, and physicists.

Senior Management

If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply. DRH holds the licensee responsible for the radiation safety program; therefore, it is essential for those activities licensed within a medical institution that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability is sometimes underemphasized or not addressed in applications and often poorly understood by licensee employees and managers. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative, to communicate with and direct personnel regarding the regulations and/or license provisions. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities and for the acts and omissions of individuals handling licensed material. Licensees may contract for patient services for which they do not have in-house expertise. In those instances where the contracted service is regulated by the DRH, the licensee should be aware that the licensee remains responsible for regulatory compliance and implementation of the radiation safety program. The licensee should not assume that by hiring a consultant to perform certain tasks that it has fully satisfied all regulatory requirements or that it has somehow transferred responsibility for the licensed program to a consultant. Licensee management should ensure that adequate mechanisms for oversight are in place to determine that the radiation safety program are effectively implemented by the appropriate individuals, to provide high confidence that licensed material is administered as directed by the authorized user.

Authorized Users for Medical Use

1. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, it is necessary to submit only the previous license number (if issued by the Mississippi State Department of Health, Division of Radiological Health) on which the physician was specifically named as an authorized user.
2. If a physician is certified by an organization approved by the Agency, (or NRC), it is necessary to submit only a copy of the certification.

3. Physicians not previously authorized to use radioactive material must state where they are licensed to practice medicine and must submit a complete description of their training and experience using Supplements A and B to Form 707. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Appendix A are met. If the training and experience does not appear to meet the criteria, DRH may request the assistance of its Radiation Advisory Council.
4. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. The criteria may include a provision that allows the applicant's Radiation Safety Committee to grant case-by-case exceptions.

Authorized Users for Nonmedical Use

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person's training and experience using Supplement A. For uses that do not involve the intentional exposure of humans (e.g., in vitro, calibration, dosimetry research, etc.), the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the licensed material for the requested use.

Physicists

Responsibilities of physicists with regard to brachytherapy procedures at medical facilities are described in Subchapter 7 of the regulations. For brachytherapy, Rule 1.7.20 on necessary training and experience for the medical physics staff is described.

Item 9 - Instrumentation

Instruments required in a typical nuclear medicine laboratory are:

a. Survey Instruments
b. Dose Calibrators (to assay radiopharmaceuticals)
c. Diagnostic Instruments (e.g., gamma camera, well counter, thyroid probe, etc.)
d. Other Instrumentation (e.g., liquid scintillation counter, area monitor, etc.)

Appendix B to this guide contains a form that may be used to describe the instruments. Complete this form by listing the instruments to be used. If this form will not be not used, attach equivalent information. Check the appropriate box in Item 9 of Form 707.

Item 10 - Calibration of Instruments

a. Survey Instrument Calibration

An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Rule 1.7.26 of the regulations provides the required minimum procedure for calibrating and checking survey instruments. Submit your procedures for survey instrument calibration. Provide the activity (in millicuries), manufacturer's name and model number, identity, and accuracy of the source(s) used for survey meter calibrations. Submit step-by-step procedures, including associated radiation safety

procedures. Section 1 of Appendix C of this guide contains a model procedure for calibrating survey instruments and a form that may be used to supply the information required in Item 10 of the application. Indicate, by checking the appropriate box in Item 10 of Form 707, if the procedure in Appendix C will be followed; or submit equivalent procedures.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, specify the name, address, and the license number. Contact the firm or consultant that will provide the calibration to determine if information concerning calibration services and procedures has been filed with the DRH. If this information has not been filed, submit it with your application.

If you possess only one survey instrument, describe your procedure for when the survey instrument is out for calibration or repair and either routine or emergency radiation surveys need to be performed.

b. Dose Calibrator Calibration

All radiopharmaceuticals must be assayed for activity to an accuracy of ten percent (10%) prior to being administered to patients. Upon installation and periodically thereafter, dose calibrators should be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the range of use between ten (10) microcuries and the highest dose that will be assayed, and for day-to-day constancy of operation.

Rule 1.7.25 of the regulations describes requirements for the use, possession, calibration, and check of dose calibrators used to measure patient doses. Submit procedures for calibrating the dose calibrator. These should include as a minimum:

(1) The manufacturer's name and model number of any sealed sources to be used.
(2) The nuclide and activity (in millicuries) of radioactive material in the standards.
(3) The accuracy of the standard.
(4) The step-by-step procedures used for calibration.

If an instrument other than a dose calibrator is used to assay patient doses, submit a complete description of:

(1) The assay method.
(2) The method of calibration.
(3) The frequency of calibration.
(4) The standards to be used for calibration (radionuclide, activity, accuracy).

Section 2 of Appendix C to this guide contains an acceptable procedure for calibrating dose calibrators and a form that may be used to supply the information required in Item 10 of the application. Indicate, by checking the appropriate box in Item 10 of Form 707, if the procedure in Appendix C for calibrating dose calibrators will be followed. If the procedure in Appendix C will not be followed, submit equivalent procedures. If you possess only one dose calibrator to assay patient dosages, describe your procedure for when the dose calibrator is out for calibration or repair and measurements of patient dosages are needed.

c. Diagnostic Instrument Calibration

The manufacturer's directions should be followed for calibration and maintenance of diagnostic instrumentation in accordance with Rule 1.7.24. If nuclear medicine imaging equipment will be

transported as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit from one location to another.

Item 11 - Facilities and Equipment

Describe the available facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods, etc.) at each location where radioactive material will be used. Include a description of the area(s) assigned for the receipt, storage (including waste), preparation, injection, and assay of radioactive material. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Indicate any wall shielding, special storage shielding, or movable shielding around storage areas, generators, kit preparation areas, etc.

For facilities in which radioactive material may become airborne, include schematic descriptions of the ventilation system in the diagrams with the pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Draw diagrams to a specified scale or indicate dimensions.

Item 12 - Personnel Training Program

Describe the training required for all personnel who work with or in the vicinity of radioactive materials. Include the form of training (e.g., formal course work, lectures, etc.), frequency of the training, duration of the training, and subject matter. Appendix D to this guide contains model guidance that may be used to develop a training program.

The training program should be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, house-keeping, and security personnel receive proper instruction in the items specified in Rule 1.10.3, including:

a. Areas where radioactive material is used or stored.
b. Potential hazards associated with radioactive materials.
c. Radiological safety procedures appropriate to their respective duties.
d. Pertinent Agency regulations.
e. Rules and regulations of the license.
f. Pertinent terms of the license.
g. Their obligation to report unsafe conditions.
h. Appropriate response to emergencies or unsafe conditions.
i. Their right to be informed of their radiation exposure and bioassay results.
j. Locations where the licensee has posted or made available notices, copies of the pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by Subchapter 10.

Verify that personnel will be properly instructed 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, or terms of the license.

Item 13 - Procedures for Ordering and Receiving Radioactive Material

Describe procedures for ordering radioactive materials, for receiving radioactive materials during off-duty

hours, and for notifying responsible persons upon receipt of radioactive materials. These procedures must be adequate to ensure that possession limits are not exceeded, that radioactive materials are secured at all times against unauthorized removal, and that radiation levels in unrestricted areas do not exceed the limits specified in Rule 1.4.15(2)(b)(ii). Rule 1.4.33 of the regulations requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within three (3) hours of receipt if it is received during normal working hours, or not later than three (3) hours from the beginning of the next working day, if it is received during non-working hours. Security personnel, nursing personnel, or anyone else who receives packages during off-duty hours must be issued written instructions as to procedures to be followed for receiving and securing the package; for notification procedures if the package is found or suspected to be leaking; and the steps to be taken to prevent the spread of contamination. Appendix E to this guide contains sample procedures and instructions for ordering and receiving packages containing radioactive material, a sample memo to personnel regarding the off-duty delivery of packages containing radioactive material, and a radioactive shipment receipt report which may be used to supplement your facility's procedures.

Item 14 - Procedures for Safely Opening Packages Containing Radioactive Materials

Describe your procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages in accordance with Rule 1.4.33 of the regulations. Perform the monitoring as soon as practicable after receipt of the package of radioactive material. The procedures may vary depending on the quantity of radioactive material received but should, as a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination after opening. Appendix F to this guide contains a description of an acceptable procedure for safely opening packages containing radioactive material. Indicate, by checking the appropriate box in Item 14 of Form 707, that the procedure in Appendix F will be followed. If the procedure in Appendix F will not be followed, submit equivalent procedures.

Item 15 - General Rules for the Safe Use of Radioactive Material

Describe the general instructions to be followed by physicians and technologists while working with radioactive materials. Appendix G to this guide contains an acceptable set of laboratory rules for the safe use of radioactive material. Indicate, by checking the appropriate box in Item 15 of Form 707, if Appendix G rules will be followed. If Appendix G rules will not be followed, submit equivalent procedures.

Item 16 - Emergency Procedures

Describe the emergency procedures to be posted in all laboratory areas where radioactive materials are used. Appendix H to this guide contains an acceptable set of emergency procedures. Indicate, by checking the appropriate box in Item 16 of Form 707, that the procedures in Appendix H will be followed. If the procedures in Appendix H will not be followed, submit equivalent procedures.

Item 17 - Area Survey Procedures

Describe the routine survey program, including the areas to be surveyed, dose rate and removable contamination action levels, and provisions for maintaining records of surveys. Requirements for conducting surveys for contamination and ambient radiation dose rates are found in Rule 1.7.32 of the regulations. If the application covers multiple users and areas of use, the individual users must perform surveys of their own work areas in addition to those performed by the radiation safety staff. Appendix I

to this guide contains acceptable procedures and frequencies for routine area surveys. Indicate, by checking the appropriate box in Item 17 of Form 707, that procedures in Appendix I will be followed; otherwise, if Appendix I will not be followed, submit equivalent procedures.

Item 18 - Waste Disposal

Describe specific methods used for disposal of licensed material. Appendix J to this guide contains a form that may be used to supply the information requested in Item 18 of the application form. Indicate, by checking the appropriate box in Item 18 of Form 707, that you will dispose of wastes as specified on the form in Appendix J. If the procedures in Appendix J will not be followed, submit equivalent procedures.

Item - 19 Therapeutic Use of Radiopharmaceuticals

Describe special precautions for patients treated with radiopharmaceuticals for therapeutic purposes. Appendix K of this guide contains a description of precautions to be followed for patients treated with iodine-131, gold-198, and phosphorus-32. Indicate, by checking the appropriate box in Item 19 of Form 707, that you will follow Appendix K procedures. If Appendix K will not be followed, submit equivalent procedures. In either case, attach a separate description of facilities and detailed procedures for preparation and administration of therapeutic doses.

Item - 20 Therapeutic Use of Sealed Sources

Describe special procedures for patients treated with radioactive sealed sources for therapeutic purposes. Appendix L to this guide contains a description of precautions and procedures to be followed for patients treated with sealed sources. In response to Item 20, indicate that the procedures listed in Appendix L will be followed and attach detailed information specific to the proposed use(s) at your facility. If the procedures in Appendix L will not be followed, submit equivalent procedures.

Item 21 - Procedures and Precautions for the Use of Radioactive Gases (i.e., Xenon-133)

The use of radioactive gases (e.g., xenon-133 gas or gas in saline) requires attention not only to the standard radiation safety considerations, but also to an evaluation of expected air concentrations of the radioactive gas in restricted and unrestricted areas. The DRH requires that each applicant make such determinations for their own unique situation and submit sufficient evidence to the Agency in support of their request. Rule 1.7.35 of the regulations specifies the requirements for control of aerosols and gases which must be included in your procedures.

Appendix M to this guide contains instructions for submitting an application to use xenon-133. The information requested in Appendix M should be submitted.

Item 22 - Procedures and Precautions for the Use of Radioactive Material in Animals

Describe procedures to be followed if radioisotopes will be used in animals including:

(a) A description of the animal housing facilities.
(b) A copy of instructions provided to animal caretakers for the handling of animals, animal waste, and carcasses.
(c) Instructions for cleaning and decontaminating animal cages.

(d) Procedures for ensuring that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive material.

Item 23 - Procedures and Precautions for Use of Radioactive Material Specified In Item 6.b.

Clearly state any additional radiation safety procedures to be followed while individuals are using the materials listed in Item 6.b., such as air sampling, special surveys, field uniformity tests (flood tests), bar phantoms, and bioassays.

The licensee must state that they will perform (1) as a minimum, quality control procedures and specify frequencies, as those recommended by equipment manufacturers or (2) other procedures, such as flood tests on the gamma camera prior to its use, and that bar phantoms will be performed on a weekly basis.

Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125, or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Indicate in the application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is appropriate for the intended use of radioactive material. Submit a copy of your bioassay program and all associated equipment. A sample bioassay program is located in Appendix K to this guide.

Item 24 - Personnel Monitoring Devices

The license application should include a statement regarding the establishment of a personnel monitoring program to ensure the exposure of all personnel is evaluated to determine whether monitoring is required to demonstrate compliance with the occupational dose limits described in the regulations.

State the name of the dosimetry processor who will provide film badge or thermoluminescent dosimeter (TLD) services.

NOTE: The dosimetry processor must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology and must be approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

Specify the frequency with which the badges are exchanged and evaluated, and give a description of the type (e.g., whole-body, wrist, or finger badge). State that control badges provided by the dosimetry processor will be returned at the required exchange interval with the proper set of badges. Any monitored individual who handles radioactive sources should wear extremity monitoring in addition to a whole body badge. Where wrist badges are worn to monitor extremity exposures and exposures to fingertips are likely to be greater than wrist exposures, describe how fingertip exposures will be estimated from the wrist badge data in lieu of fingertip monitors, and provide any backup data used to perform or verify these estimates.

Item - 25 (For Private Practice Applicants Only)

a. State the name and address of the hospital that has agreed to admit patients containing radioactive material.

b. Submit a copy of the letter of authorization, signed by the administrator, from the hospital that has agreed to admit patients containing radioactive material.

c. If patients treated with therapeutic quantities under the license are admitted to the hospital, describe the radiation detection instruments available at the hospital and submit a copy of the radiation safety procedures to be followed.

Item 26 - Certificate

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 director or chief executive officer. Identify the title of the office held by the individual who signs the application.

BEFORE SUBMITTING THE APPLICATION, REVIEW THE CONTENTS OF THE APPLICATION TO ENSURE THAT YOU HAVE RESPONDED TO EACH ITEM AND BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED TO PROVIDE SUPPLEMENTAL INFORMATION AS REQUESTED HAS AN ATTACHMENT NUMBER THAT CORRESPONDS TO THE CORRECT ITEM AND IS DATED.

4. LICENSE FEES

An application fee paid in full is required. You should refer to the "Schedule of Fees" to determine the amount of the fee that must accompany your application. An application received without a fee or with an inadequate fee may be returned to you without further processing. All application fees may be charged irrespective of the DRH's disposition of the application or your withdrawal of the application.

APPENDIX A

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Licensees that are only authorized for diagnostic imaging under Rules 1.7.37 and 1.7.40 are not required to have a Radiation Safety Committee; however, all licensees are required to have a Radiation Safety Officer to fulfill the duties and responsibilities listed below. In addition, each applicant must submit a written "Delegation of Authority" signed by management and the Radiation Safety Officer.

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with Mississippi Department of Health and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of Rule 1.7.13 of the Mississippi State Board of Health Regulations for Control of Radiation. Typically, these duties and responsibilities include ensuring the following:

1. Stopping unsafe activities involving licensed material;
2. Radiation exposures are ALARA;
3. Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented;
4. Possession, use, and storage of licensed material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
5. Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
6. Personnel training is conducted and is commensurate with duties regarding licensed material;
7. Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of allowable limits or that personnel monitoring devices are provided;
8. When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
9. Licensed material is properly secured;
10. Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;

11. Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
12. Medical events and precursor events are investigated and reported to the Mississippi Department of Health, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
13. Audits of the radiation protection program are performed at least annually and documented;
14. If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;

15. Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
16. Licensed material is disposed of properly;
17. Appropriate records are maintained; and
18. An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Division of Radiological Health, Mississippi State Department of Health at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

_____	_____
Signature of Management Representative	Signature of Radiation Safety Officer
_____	_____
Date	Date

cc: Affected department heads

RADIATION SAFETY COMMITTEE

Licensees that are authorized for two or more different types of radioactive material use, such as identified in Rules 1.7.44, 1.7.49, 1.7.61, and 1.7.79, or two (2) or more types under 1.7.61 must have a Radiation Safety Committee. If you prefer, you may develop your own statement of authority, duties, and administrative procedures. If you do so, you should consider for inclusion all the features in the model text and carefully review the requirements of Rule 1.7.13(6) Check on your application, "Equivalent duties attached."

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 the Mississippi State Board of Health Regulations for Control of Radiation and the radioactive material 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 individual occupational radiation exposures; and
5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent regulations, the license application, the license, and amendments;
2. Review the training and experience of the proposed authorized users, the 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 within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;
5. 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 Section 1000.03;
6. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with the 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 inspections, written safety procedures, written directives, and the adequacy of the management control system;
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program;
8. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken;
9. Ensure that the radioactive material license is amended, if required, prior to any changes in facilities, equipment, policies, procedures, and personnel.

The Committee shall meet as often as necessary to conduct its business but no less than every six (6) Months; 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 appoint alternate members to participate in meetings in the case of absence of principal members; and to establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

APPENDIX B

INSTRUMENTATION

1. Survey meter manufacturer/model #

2. Dose calibrator manufacturer/model#

3. Manufacturer/Model # of diagnostic scanning equipment (SPECT, PET, CARD)

4. Thyroid uptake/bioassay equipment manufacturer/model #

5. Shielded Xenon delivery system manufacturer/model #

6. Other(s)

APPENDIX C (Section 1)

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

____1. Survey instruments will be calibrated at intervals not to exceed 12 months and following repair in accordance with Rule 1.7.26

____2. Calibration will be performed at two points on each scale.
The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within +/-20% of the calculated or known values for each point checked.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source/activity_____

Manufacturer's/model # of calibrator_____

(2) The step-by-step procedures, including radiation safety procedures, are attached.

____ c. By a consultant or outside firm

(1) Name_____

(2) License #_____

(3) Procedures and sources_____

APPENDIX C (Section 2)

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

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, check on your application, "Appendix C procedures followed for dose calibrator." If you develop your own dose calibrator calibration procedure for review, you should carefully review Rule 1.7.25 and all the features in the model procedure. Check on your application, "Equivalent procedures attached."

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

   a. Constancy at least once each day prior to assay of patient dosages (+/-10%).
   b. Linearity at installation and at three (3) month intervals thereafter (+/-10%).
   c. Geometry dependence at installation (+/-10%).
   d. Accuracy at installation and at twelve (12) month intervals thereafter (+/-10%).

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

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 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 and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.
c. For each source used either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
e. Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation-requires repair or replacement if the error exceeds 10% .

4. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dose syringe, or in a radiopharmaceutical therapy, whichever is largest.

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 a.m.
b. Repeat the assay at about noon, and again at about 4 p.m. **Continue on subsequent days until the assayed activity is less than 10 microcuries**. 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 farthest from the line, calculate its deviation from the value on the line. (A- observed - A-line)/(A-line) = deviation.

f. If the worst deviation is more than +/- 10%, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate them.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. **Steps b through d below must be completed within 6 minutes.**
b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
d. Continue for all sleeves.
e. Complete the decay method linearity test steps b through g above.
f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.
g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with data recorded in step c.
h. Continue for all sleeves.
i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

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

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
b. **Steps c through e below must be completed within 6 minutes**.
c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
e. Continue for all sleeves.
f. 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 model number and serial number of the dose calibrator.
g. Plot the data using the equivalent decay time associated with each sleeve.
h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/A-line = deviation.
i. If the worst deviation is more than +/-10%, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."
j. Put a sticker on the dose calibrator that says when the next linearity test is due.

5. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test 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, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

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 0.5 cc 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 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 5% error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the 5% 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.

g. 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.

h. 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.

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

j. 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 5% error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5% 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.

6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries. Other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

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 5% 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 5%, with the certified value of the reference

source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10%.

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.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

____First elution from new Mo-99/Tc-99m generator

or

____Other (must be equivalent to highest activity used)

B. Sources used for accuracy

Radionuclide	Activity (mCi)	Accuracy
Co-57	_____	_____
Ba-133	_____	_____
Cs-137	_____	_____

_____C. The procedures described in Section 2 of Appendix C will be used for calibration of the dose calibrator.

or

_____ D. Equivalent procedures are attached.

APPENDIX D

Training

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, check on your application, "Description of training attached which includes Appendix D rules." You may use lectures, videotaped presentations, or demonstrations, for example, as methods of training. 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 Rule 1.10.03.

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

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations, license conditions, and radiation safety procedures.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

5. Appropriate response to emergencies or unsafe conditions.

6. Worker's right to be informed of occupational radiation exposure and bioassay results.

7. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

8. Question and answer period.

APPENDIX E

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, check on your application, "Appendix E procedures followed." If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule 1.1.4. Check on your application, "Equivalent procedures attached."

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

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

    a. For routinely used materials

        (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

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

    b. For occasionally used materials (e.g., therapeutic dosages)
        1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

        (2) The person who receives 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 in accordance with procedures outlined in the sample memorandum.

SAMPLE MEMORANDUM

MEMORANDUM FOR: **Security Personnel**

FROM: **Administrator**

SUBJECT: **RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL**

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter, and relock the door. ***Do Not Open the Container***. If the package is wet or appears to be damaged, *immediately* contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER:_____ Phone #_____

NUCLEAR MED. TECH: _____ _____ Phone #_____

EMERGENCY CONTACT/24 hour_____

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

You may use the following model procedure for opening packages. If you follow the model procedure, check on your application, "Appendix F procedures followed." If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Check on your application, "Equivalent procedures attached."

MODEL PROCEDURE

1. Visually inspect the package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer.
2. Measure the exposure rate at three (3) feet from the package surface and record. If > 10 mR/hr, stop the procedure and notify the Radiation Safety Officer.
3. Measure the surface exposure rate and record. If > 200 mR/hr, stop the procedure and notify the Radiation Safety Officer.
4. Put on gloves.
5. a. Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in Section100..02 of the regulations;
   b. Monitor the external surfaces of a labeled package for radioactive contamination unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in Appendix A of Subchapter 13 of the regulations; and
   c. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. The monitoring in Item 5 shall be performed as soon as practicable after receipt of the package, but no later than three (3) hours after the package is received, provided receipt was during normal working hours, or not later than three (3) hours from the beginning of the next working day if receipt was after working hours.
7. Open the outer package (following the manufacturer's directions, if supplied) and remove the packing slip. Open the inner package to verify the contents (compare requisition, packing slip, and label on bottle) and check integrity of the final source container (inspecting for breakage of seals or vials, loss of liquid, and/or discoloration of packaging material). Check that shipment does not exceed the possession limits of the license.
8. 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. [The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.] Take precautions against the potential spread of contamination.
9. Monitor the packing material and packages for contamination before discarding.
   a. If contaminated, treat as radioactive waste.
   b. If not contaminated, obliterate radiation labels before discarding in regular trash.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P. O. Number_____ Survey Date_____ Time_____ A.M./P.M.

   Surveyor_____

2. CONDITION OF PACKAGE:
   ____O.K. ____Punctured ____Wet ____Crushed ____Other

3. LABEL:
   ____White I ____Yellow II ____Yellow III

4. MEASURED RADIATION LEVELS:

   a. Package surface:_____ mR/hr(Notify RSO if > 200 mR/hr.)
   b. 3 feet or 1 meter from surface:_____mR/hr (Notify RSO if > 10 mR/hr.)

5. DO PACKING SLIP AND CONTENTS AGREE?

   a. Radionuclide _____Yes _____No
   Difference_____
   b. Amount _____Yes _____No
   Difference_____
   c. Chemical Form _____Yes _____No Difference_____

6. WIPE RESULTS FROM:

   Final source container _____CPM = _____DPM
   efficiency = _____

   (CPM/efficiency = DPM)

7. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS_____ mR/hr, CPM

8. DISPOSITION OF PACKAGE AFTER INSPECTION_____

9. CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

   Time:_____ A.M./P.M. Date:_____

   Persons Notified: _____
   _____
   _____
   _____
   _____

Signature & Date_____

APPENDIX G

Model Procedures for Safe Use of Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure. (Some of the health physics practices listed below may also apply to sealed sources.)

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low- background area using an appropriate survey instrument.
4. 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.
5. Do not eat, store food, drink, smoke, or apply cosmetics in any area where licensed material is stored or used.
6. 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.
7. Wear extremity dosimeters (ring badges) when handling radioactive material.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Wipe-test unsealed byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
11. Survey with a radiation detection survey meter all areas of licensed material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily (except when administering therapy dosages in patients' rooms when patients are confined).
12. Store radioactive solutions in shielded containers that are clearly labeled.
13. Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled.
14. Syringes and unit dosages must be labeled in accordance with Rule 1.7.30. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
15. For prepared dosages, **assay within 30 minutes of administration** each patient dosage in dose calibrator.
16. Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ±20% from the prescribed dosage, except as approved by an authorized user.
17. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
18. Check patient's name and identification number and prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive
19. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
20. Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the license (or such individual's designee).

APPENDIX H

EMERGENCY PROCEDURES

You may use the following model emergency procedures as they appear here, saying on your application, "Appendix H procedures followed." If you prefer, you may develop your own emergency procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Check on your application, "Equivalent procedures attached."

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste. Insert into the plastic bag all other contaminated materials such as disposable gloves.
4. SURVEY: With a low-range, thin-window, G-M survey meter, check the area around the spill, hands, and clothing for contamination.
5. REPORT: Report the incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
5. CALL FOR HELP: Notify the Radiation Safety Officer.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

EMERGENCY NOTIFICATION CONTACTS

RADIATION SAFETY OFFICER:_____ **Phone #**_____

NUCLEAR MED TECH _____ Phone #_____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY THE RSO:

_____

APPENDIX I

AREA SURVEY PROCEDURES

You may use the following model procedure to perform area surveys. If you follow the model procedure, check on your application, "Appendix I procedures followed." You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rule 1.7.32. Check on your application, "Equivalent procedures attached."

MODEL PROCEDURE

1. A survey of all areas where radiopharmaceuticals are routinely prepared for use or administered shall be made with a radiation detection instrument at the end of each day of use.

2. A survey of all areas where radiopharmaceuticals or radioactive wastes are stored shall be made with a radiation detection instrument at least once each week.

3. A survey for removable contamination shall be made each week of use in all areas where radiopharmaceuticals are routinely prepared for use or administered and where radioactive materials are stored.

4. The survey will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr, and a series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect contamination on each wipe sample of 2000 disintegrations per minute (dpm).

5. The following action levels will be established:

    a. **Dose rate** action levels for the surveys required by Rule 1.7.32(1); and

    b. **Removable contamination** action levels for the surveys required by Rule 1.7.32(2).

    Note: The individual performing the survey shall immediately notify the RSO if the dose rate or the contamination exceeds the action level

6. A permanent record will be kept of all survey results in accordance with Rule 1.7.88 of the regulations. **The record must include** (1) the name of the individual performing the survey; (2) drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.; (3) The measured dose rate at several points in each area **expressed in millirems per hour** or the removable contamination in each area **expressed in disintegrations per minute per 100 cm^2** ***Note: The removable contamination may be expressed in counts per minute provided the record contains the correct formula for converting counts per minute to disintegrations per minute. See the sample survey form. Instrument efficiency may be obtained from the manufacturer or the instrument calibration service***; and the serial number and the model number of the instrument used to make the survey or analyze the samples.

*********EXAMPLE*********

AREA WIPE TEST FOR REMOVABLE CONTAMINATION

DATE OF TEST: _____

ACTION LEVELS:

RESTRICTED AREA:_____DPM/100 cm^2

NON-RESTRICTED AREA:_____DPM/100 cm^2

SURVEY INSTRUMENT: MODEL NO.:_____

SERIAL NO.:_____

LAST CALIBRATED:_____

BACKGROUND:_____CPM

CALCULATIONS: ***GROSS SAMPLE CPM - BACKGROUND CPM / INSTRUMENT COUNTING EFFICIENCY = NET DPM***

	SURVEY AREAS	CPM-BKG CPM/EFFICIENCY =	DPM/100 cm^2
1.	DOSE CALIBRATOR	=	
2.	SINK	=	
3.	LEAD SHIELD	=	
4.	WASTE CONTAINER	=	
5.	FLOOR @ INJECTION AREA	=	
6.	INJECTION AREA	=	
7.	WORK DESK	=	
8.	RECEIPT AREA	=	
9.	DOSE PREP AREA	=	
10.	FLOOR @ DOSE PREP AREA	=	

PERFORMED BY:_____

COMMENTS_____

_____

_____

*********EXAMPLE*********

AREA SURVEY TEST

DATE OF TEST: _____

ACTION LEVELS:

RESTRICTED AREA:_____mR/HR

NON-RESTRICTED AREA:_____mR/HR

SURVEY INSTRUMENT: MODEL NO.:_____

SERIAL NO.:_____

LAST CALIBRATED:_____

BACKGROUND:_____mR/hr

	SURVEY AREAS	GROSS mR/HR-BKG mR/HR
1.	DOSE CALIBRATOR	_____mR/HR
2.	SINK	_____mR/HR
3.	LEAD SHIELD	_____mR/HR
4.	WASTE CONTAINER	_____mR/HR
5.	FLOOR @ INJECTION AREA	_____mR/HR
6.	INJECTION AREA	_____mR/HR
7.	WORK DESK	_____mR/HR
8.	RECEIPT AREA	_____mR/HR
9.	DOSE PREP AREA	_____mR/HR
10.	FLOOR @ DOSE PREP AREA	_____mR/HR

PERFORMED BY:_____

COMMENTS_____

_____

_____

_____

APPENDIX J

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, check on your application, "Appendix J form attached." 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 Rules 1.4.34 – 1.4.40 and 1.7.36. Check on your application, "Equivalent information attached."

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste, **except for material that will be handled as biomedical waste after release.** If waste is compacted, all labels that are visible 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 review 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., 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 1.4.36. Material must be readily soluble or dispersible in the 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 1.4.36(2)) Make a record of the date, radionuclide, and estimated activity that was released (in millicuries or microcuries).

2. Limits on permissible concentrations in effluent to unrestricted areas are enumerated in Table II of Appendix B to Section 400 of the regulations. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and of the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie or less per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (Rule 1.4.38). 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 of.

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

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

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

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

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

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

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

    c. Remove any shielding from around the container;

    d. Monitor all surfaces of each individual container;

    e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure that 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.

WASTE DISPOSAL FORM

(Check all that apply)

1. Liquid waste will be disposed of: (Check as appropriate.)

____ By commercial waste disposal service. (See Item 4 below.)

____ In the sanitary sewer system in accordance with Section 400.36.

____ Other (specify):_____

_____

2. Mo-99/Tc-99m generators will be: (Check as appropriate.)

____ Returned to the manufacturer for disposal.

____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

____ Disposed of by a commercial waste disposal service. (See Item 4 below.)

____ Other
(specify):_____

3. Other solid waste will be: (Check as appropriate.)

____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash. See sample decay-in-storage log.

____ Disposed of by a commercial waste disposal service. (See Item 4 below.)

____ Other
(specify):_____

4. The commercial waste disposal service used will be:

Name:_____

City:_____

State:_____

License No._____

DECAY IN STORAGE LOG

START DATE	TECH	RADIONUCLIDE	BACKGROUND DOSE RATE	CONTAINER DOSE RATE	DISPOSAL DATE

*mR/Hr

Survey Meter_____
(Model and Serial No.)

1. Monitor radioactive material at the container surface before disposal to determine that its radioactivity cannot be distinguished from the background radiation level.
2. Remove or obliterate all radiation labels, except for material that will be handled as biomedical waste.
3. Separate and monitor each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background levels.

For radioactive material disposed in accordance with Rule 1.7.36, the licensee shall retain a record of each disposal for 3 years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

APPENDIX K

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may say on your application, "Appendix K procedures followed."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rules 1.4.14, 1.7.33, 1.7.45 & 1.7.46. Check on your application, "Equivalent procedures attached."

1. For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with **Section 700.33,** quarter the patient either in a private room with a private sanitary facility, or a room with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and cannot be released in accordance with Rule 1.7.33. ***You may choose to use Appendix P Release Criteria. If you do, you must submit your procedure for release of patients and calculations used to comply with release criteria in accordance with Rule 1.7.33.***

2. Visibly post the patient's room with a "Caution-Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the room.

3. Prepare the room as follows:

    a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

    b. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

    c. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

        (i) All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

        (ii) Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar disposable waste items placed in a specially designated container will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

        (iii) Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

d. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

(i) Containers should be unbreakable and closable.

(ii) If there is no need for assay or volumetric determination, urine may be released to the sanitary sewer system.

(iii) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

(iv) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately three (3) mm of lead.)

(v) Supply a wide-mouth antisplash funnel.

4. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

5. Supply the nurses with film badges, thermoluminescent dosimeters (TLDs), or pocket ionization chambers.

6. Brief the nurses on radiation safety precautions. Use the "Instructions to Nurses" guidelines and sample form, "Nursing Instructions for Patients Treated with Therapeutic Radiopharmaceuticals", or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart **and** at the nurses' station.

7. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

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

9. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three (3) feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and door.

10. The form, "Nursing Instructions for Patients Treated with Therapeutic Radiopharmaceuticals", will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

11. Do not release any patient until either the exposure rate from the patient is less than the specified limits identified in **Table K.1**. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of one (1) meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, one (1) meter from the bedside with the patient supine.

12. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

13. In accordance with Rule 1.7.46(a)(7), within three (3) days after administration of a dose of liquid or gelatin-capsule I-131 to a patient, the thyroid burden of all personnel who helped prepare or administer the dose will be measured. Retain for the period required by Rule 1.4.47 of the regulations, a record of each thyroid burden measurement, date of the measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

Note: Bioassay procedures must be submitted with your application. You may use the "Radioiodine Bioassay Procedure" as a guideline for your procedures.

Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table K.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table K.1 for that radionuclide. In this case, however, Rule 1.7.33 requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table K.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by Rule 1.7.33. The dose rate at 1 meter may be calculated from Appendix P, Equation P.2 or P.3, as appropriate, because the dose rate at 1 meter is equal to ' Q / 10,000 cm^2.

Table K.1 Activities and Dose Rates for Authorizing Patient Release†

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**

Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table K-1

The activity values were computed based on 0.5 rem (5 millisieverts) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by Rule 1.7.33, because the measurement includes shielding by tissue.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Appendix P, Equations P.2 or P.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants. In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.
Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

INSTRUCTIONS TO NURSES ASSIGNED TO PATIENTS RECEIVING THERAPEUTIC RADIOPHARMACEUTICALS

1. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. ***CALL THE RADIATION SAFETY OFFICER OR HIS DESIGNEE WITH ANY QUESTIONS REGARDING THE CARE OF THESE PATIENTS AND/OR RADIATION SAFETY PRECAUTIONS.***

2. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

3. Patients must remain in bed while visitors are in the room and visitors should remain at least three (3) feet from the patient.

4. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

5. Visitors or attendants who are pregnant should not be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant. Declared pregnant nurses should not be assigned to the personal care of these patients. (See Rule 1.4.13)

6. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash hands after removing gloves. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

7. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

8. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

9. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

10. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

11. For iodine-131 patients:

    (a) Urine from iodine-131 patients that will be collected will be done so in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

    (b) If the nurse helps to collect the excreta, disposable gloves should be worn. Hands should be washed after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

    (c) Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.

    (d) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext._____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

    (e) Any vomitus collected must be kept in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be flushed three (3) times.

        Note: Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or his designee.

12. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

13. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

14. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department, and request that the room be surveyed for contamination before remaking the room.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH THERAPEUTIC RADIOPHARMACEUTICALS

Patient's Name:_____

Room No.:_____ Physician's Name:_____

Radioisotope Administered:_____

Date and Time of Administration:_____

Dose Received:_____ Method of Administration:_____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

____1. Visiting time permitted:
____2. Visitors must remain _____ feet from patient.
____3. Patient may *not* leave room.
____4. Visitors under 18 are not permitted.
____5. Pregnant visitors are not permitted.
____6. Film badges must be worn.
____7. Tag the following objects and fill out the tag:
____door ____bed ____chart
____8. Gloves must be worn while attending patient.
____9. Patient must use disposable utensils.
____10. All items must remain in room until approved by the Radiation Safety Officer or his designee.
____11. Smoking is not permitted.
____12. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
____13. Other instructions. (Attach as needed.)

In case of an emergency contact:

RSO: _____

Telephone: _____(On-duty)

_____(Off-duty)

RADIOIODINE BIOASSAY PROCEDURE

Calibration

This bioassay procedure uses a sodium iodide crystal and a single channel analyzer (such as an uptake probe) to determine thyroid burden. Calibration of the system will be performed annually.

A description of the equipment to be utilized including manufacturers, model numbers, and serial numbers is as follows:

Manufacturer:	Manufacturer:
Model No.:	Model No.:
Serial No.:	Serial No.:

A. Set Window or Region of Interest

The window or region of interest must be set to detect emissions for the radionuclide you are trying to detect. In the case if Iodine-131, the region of interest must be in the area of 364 keV.

B. Establish Background

Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a one minute count. Record results.

C. Count Standard

A known (measured) amount of radioactivity must be used as the standard. When assaying for I-131, an I-131 standard (or a standard source of known activity that emits photons of approximately the same energy as I-131. e.g., Barium-133) must be used. I-131 liquid or capsule may be used, and must be measured and corrected for decay. Place the standard in a thyroid phantom*. Hold probe against the phantom in an established geometry, similar to the geometry to be used when performing a bioassay on an individual, for the required amount of time (1 minute). Record results.

(*Note: Specifications for design of a neck phantom can be found in American National Standard ANSI N44.3-1973, "Thyroid Radioiodine Uptake Measurements Using a Neck Phantom".)

D. Establish System Efficiency

Standard CPM - Background CPM = Net Standard CPM

$$\frac{\text{Net Standard CPM}}{\text{Standard Activity (uCi)}} \times \frac{100}{2.2 \times 10^6 \text{ DPM/uCi}} = \text{\% Efficiency}$$

Investigation Limits

E. Establish In-House Investigation Limits*

1. The Radiation Safety Officer (RSO) shall be notified whenever the thyroid burden at the time of measurement exceeds 0.04 uCi of I-131. The RSO shall perform an investigation into the cause of the exposure and the potential for further exposure, and develop corrective actions to prevent recurrence.

2. The RSO shall be notified immediately whenever the thyroid burden at the time of measurement exceeds 0.14 uCi of I-131. The RSO must perform an investigation, as described above, and must perform weekly bioassays on the individual until the individual's thyroid burden is less than 0.04 uCi of I-131.

(*Note: In-house investigation limits are adopted from U. S. Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131".)

Measurement

F. Measure Thyroid Gland

1. Perform measurements in a low background area.

2. Hold probe on thigh (ensure thigh and/or lab coat are not contaminated) for a one minute count. Record results.

3. Hold probe in the center of the neck near Adam's apple for required amount of time (1 minute). Record results.

4. Subtract background from thyroid count to obtain net counts. Record results.

5. Calculate and record the amount of radioactivity in the thyroid by using the following equation:

$$\frac{\text{Net Counts (CPM) X 100}}{\%\ \text{Efficiency X } 2.2 \times 10^6\ \text{DPM/uCi}} = \underline{\qquad} \text{ uCi}$$

6. If the results are less than the investigation limits established in E.1. above, you are finished.

7. If results are more than the investigation limits established in E.1. above, notify the RSO immediately. The RSO may restrict the employee's further handling of I-131 until the thyroid burden is measured to be below the reporting limits established in E. above.

APPENDIX L

THERAPEUTIC USE OF SEALED SOURCES

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, check on your application, "Appendix L procedures followed", and submit detailed information in accordance with these procedures which is specific to the proposed use(s) at your facility.

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of Rules 1.7.50 through 1.7.58. Check on your application, "Equivalent procedures attached."

***NOTE: The specific items identified below should be addressed in addition to the more general items identified in the licensing guide which apply to all medical use licensees and applicants. When providing information on a particular item, reference the section indicated in this guide to facilitate the review by licensing staff.*

This appendix will provide assistance to applicants and licensees in preparing applications for new licenses, license amendments and license renewals that authorize possession of radioactive material for use as sources for manual brachytherapy procedures. This type of license is provided for in Subchapter 7 of the Mississippi State Board of Health Regulations for Control of Radiation: "Use of Radionuclides in the Healing Arts." This appendix is intended to provide you, the applicant or licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to manual brachytherapy. Specifically, guidance is provided for temporary and permanent brachytherapy implants, eye plaque brachytherapy implants, and strontium-90 eye applicators. Guidance will be provided separately for remote afterloading brachytherapy.

The specific regulations for the use of sources for brachytherapy are contained in Rules 1.7.50-58; however, licensees also must comply with the other applicable regulations of the Mississippi State Board of Health Regulations for Control of Radiation. The information provided only addresses the current state of the art for brachytherapy and may not provide specific guidance for emerging technologies. Therefore, licensees are encouraged to make modifications as necessary to accommodate new technologies. A glossary is provided at the end of this appendix to define those terms that are specific to brachytherapy.

<u>Item 6.b. - Radioactive Material for Uses Not Listed In Item 6.a.</u>

On the license application, you must specify the sealed sources you wish to appear on your license including manufacturer, model number, physical form (e.g. seeds, wire, etc.), and maximum amount.

You must specify the maximum total amount of material to be possessed at any given time and the total cumulative quantity for all materials. Sources for a high dose rate remote afterloader and eye applicator must be listed. When establishing both individual nuclide and total maximum quantities, all materials to be possessed under the license must be included, i.e., materials received awaiting use, materials in use or process, and those categorized as waste awaiting disposal.

Item 6.b. - Describe Purpose of Use

Rule 1.7.49 requires brachytherapy sources to be used in accordance and as approved in the Sealed Source and Device Registry and with the manufacturer's radiation safety and handling instructions. It is not the intent of Subchapter 7 to prohibit appropriate medical practices. One of the objectives of Rule 1.7.49 is to ensure that sealed sources used in brachytherapy procedures have undergone appropriate safety review. When the manufacturer or end user requests that a safety review be performed for a proposed type of use, the integrity of the source is tested against the criteria for the type of use requested and not against all testing criteria associated with the other types of use.

1. Interstitial Treatment of Cancer

The following sources may be used for the interstitial treatment of cancer:

a. Cesium-137 (Cs-137) and cobalt-60 (Co-60) as sealed sources in needles and applicator cells.
b. Iridium-192 (Ir-192) as seeds encased in nylon ribbon.
c. Gold-198 (Au-198), iodine-125 (I-125) and palladium-103 (Pd-103) as sealed sources in seeds.

2. Eye Plaque Brachytherapy Implants for Treatment of Cancer

The eye plaque consists of a curved soft plastic insert that has a series of grooves, molded into the rear convex surface, which are designed to hold the radioactive seeds. After the plastic insert is loaded with the seeds, a solid gold cover, matched in size to the insert, is placed over the convex surface of the insert and cemented in place to seal the seeds into a fixed array within the plaque. The insert is completely surrounded by the gold cover except for the concave surface that is placed against the eye. The gold cover provides considerable shielding of the normal tissues surrounding the eye and limits the external dose rates surrounding the patient.

The use of I-125 or Pd-103 seeds in an eye plaque is authorized. Although not implanted into the tumor, because the plaque is placed in the orbit of the eye over the tumor site and sutured to the sclera of the eye to stabilize its position on the tumor while in the orbit, this is considered interstitial, not topical, treatment. Release of patients with an eye plaque is discussed in Item 11.

3. Intracavitary Treatment of Cancer

The following sources may be used for the intracavitary treatment of cancer:

Cs-137 and Co-60 as a sealed source in needles and applicators cells.

4. Topical Applications

The following sources may be used for topical applications:

a. Cs-137 and Co-60 as sealed sources in needles and applicator cells for topical treatment of cancer.
b. Strontium-90 (Sr-90) as a sealed source in an applicator for treatment of superficial eye conditions. (Authorization for use of a Sr-90 eye applicator for patient procedures does not authorize its use on treatment sites other than the eye.)

Ir-192 and Pd-103 seeds authorized for interstitial use only, appear to have been routinely used for intracavitary use for many years with no apparent health and safety problems. The Nuclear Regulatory Commission's (NRC) Sealed Source and Device Registry concludes that registered sources which have passed the testing criteria for interstitial use could be used in intracavitary or topical applications without requiring the licensee to commit to additional administrative controls to ensure safe use of these sources. In addition, for purposes of NRC's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.

Item 11 - Facilities and Equipment

Facility Diagram

In addition to the general information described previously in this guide, provide a description of any additional shielding of proposed patient rooms used for implant therapy. Include in this description areas surrounding the patient rooms. The patient room should be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. In accordance with Rule 1.7.53(1)(a), the patient must not be quartered in the same room with a patient not receiving radiation therapy unless you demonstrate compliance with the requirements of Rule 1.4.14(1) at a distance of one meter from the implant.

Item 12 - Personnel Training Program

In addition to the general information described previously in this guide, provide a description of training which will be provided every twelve (12) months to individuals working with or near patients treated with sealed sources.

1. Training Program for Individuals Responsible for Manual Brachytherapy

Personnel must be instructed as follows:

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

(NOTE) Many of the topics listed are repeated for the different specialties. Licensees should tailor their training programs according to their specific needs.

2. Training for Nursing Staff

Individuals must be instructed in the following topics, commensurate with their duties:

a. Radiation biology, e.g., interaction of ionizing radiation with cells, tissues, and organs;
b. Radiation physics, to include concepts of time, distance, and shielding;
c. Risk estimates, including comparison with other health risks so that nurses will have an understanding of the risks involved and respond appropriately, rather than react from excessive fear or lack of concern;
d. ALARA concept;
e. Posting requirements;
f. Proper use of personnel dosimetry (when applicable);
g. Licensee's Written Directive Program - To ensure that each administration is in accordance with the written directive. Attention to correct positioning of sources and applicators to ensure that treatment is to correct site;
h. Proper use of devices and shielding to include safe handling and shielding of dislodged sources;
i. Size and appearance of different types of sources and applicators;
j. Safe handling of linens and surgical dressings;
k. Practice drills using no radioactive (dummy) sources (when possible);
l. Visitor's stay times and safe lines;
m. Patient control procedures;
n. Visitor control procedures;
o. Access control procedures;
p. Patient release criteria;
q. Instruction in procedures for reacting to medical emergencies or patient death, including notification of appropriate medical personnel and the RSO (The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care.);
r. Occupational dose limits;
s. Dose to the embryo/fetus limits including instruction about declaration of pregnancy;
t. Dose to individual members of the public;
u. Workers right to be informed of occupational radiation exposure;
v. Each individual’s obligation to report unsafe conditions to the RSO;
w. Applicable regulations, license conditions, information notices, bulletins, etc.
x. Location where copies of the applicable regulations, the license, and its application are posted or made available for examination;
y. Proper record keeping;
z. Previous incidents, events, and/or accidents; and

A question and answer period should be included.

3. Training for the Medical Physics Staff (Medical Physicist, Therapists, and Dosimetrists)

In addition to the topics identified above for nursing staff, individuals must be instructed in the following, commensurate with their duties:

a. Appropriate surveys to be conducted, and when;
b. Inventory control;
c. Leak testing (if license permits); and
d. Emergency procedures.

4. Training for Ancillary Personnel (Housekeeping, Dietary Services, Security, etc.)

Individuals must be instructed in the following topics: (Licensees may choose to prohibit ancillary personnel from entering restricted areas, and train accordingly.)

a. Posting/Labeling
b. Precautions

5. Training for Contractors

Licensees must ensure that individuals who work under a contractual arrangement will be instructed in the topics described above, as if they were employees.

6. Records

Records of worker training must include date and duration of training, topics covered, name(s) of individual(s) providing training and attendees, and should be maintained for three (3) years.

Item 18 - Waste Disposal

In addition to the general information described previously in this guide, provide a detailed description on the disposal of brachytherapy sources. Many brachytherapy sources may be reused for therapy. Whenever possible, used sources that will not be reused should be returned to the vendor for disposal as opposed to indefinite storage at the licensee's facility. In this case, the licensee must ensure that the following procedures are developed and adhered to:

1. Proper packaging.
2. Proper package surveys.
3. Proper package labeling.
4. Proper preparation of shipping papers.
5. Proper record keeping.

Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table L.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table U.1 for that radionuclide. In this case, however, Rule 1.7.33 requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table L.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 700.33. The dose rate at 1 meter may be calculated from Appendix P, Equation P.2 or P.3, as appropriate, because the dose rate at 1 meter is equal to ' $Q / 10{,}000\ cm^2$.

Table L.1 Activities and Dose Rates for Authorizing Patient Release†

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4

Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table L-1

The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by Rule 1.7.33, because the measurement includes shielding by tissue.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Appendix P, Equations P.2 or P.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants. In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

RADIATION SAFETY PROGRAM

You must submit your procedures for the radiation safety of workers, members of the public, and patients, that will be followed during any brachytherapy procedure. These should include:

Leak Tests

You must submit procedures for leak testing all sealed sources as required pursuant to Rule 1.7.29 "Requirements for Possession of Sealed Sources and Brachytherapy Sources." The leak test may be performed in house or by a consultant as long as the method is sensitive to detect 0.005 microcurie and the procedures are submitted and approved by the Agency.

Personnel Monitoring

If nurses who are handling brachytherapy patients enter a restricted area under the circumstances described in 400.18, the license must indicate that these individuals will be monitored. Any individual who handles the sources must wear extremity monitoring in addition to a whole body badge. If you use pocket dosimeters to monitor personnel exposures, you must provide the useful range of the dosimeters; procedures and frequency for calibration and maintenance of pocket dosimeters; and procedures for

maintaining records of individuals monitored (to include frequency at which exposure on dosimeter will be recorded) in accordance with 400.47.

Safe Use and Handling of Brachytherapy Sources

You must describe the shielding (specify thickness) and remote handling devices available for handling brachytherapy sources. In addition, describe the equipment and shielding available for transporting the brachytherapy sources from storage sites to the place of use. This must include the safety instructions described in Rules 1.7.52 & 1.7.53.

Implant Source Record and Inventory

You must commit to conducting a quarterly physical inventory of all sealed sources and brachytherapy sources in your possession, pursuant to Rule 1.7.29(6). The records of such an inventory must be kept for five (5) years and include the model and serial number of each source, radionuclide, nominal activity, location of each source, and signature of the RSO. You must submit your procedures for keeping an inventory and use record (log) of sources, pursuant to Rule 1.7.51. The procedure must include, as a minimum, the following items:

a. Use of a locked cabinet or safe, under licensee control, to store all implant sources.
b. List of names of those individuals permitted to handle sources to include their initials.
c. Map of storage drawers and list of individuals should be posted in a conspicuous location near the inventory log.
d. Map of the storage drawer used for long-lived isotopes with activity of each source according to its location in the source storage drawer. For short-lived sources stored in the manufacturer's shipping container, indicate the area in the safe where stored.
e. Sources are entered on the inventory log upon receipt, and source information to include the isotope, activity, and number of seeds is verified against the package shipping label.
f. Each time source is removed from storage, a record is made of the number and activity of sources removed, the room number of use and patient's name, the time and date they were removed from storage, and the number and activity of the sources in storage after the removal. This record is initialed by the individual removing the sources.
g. Upon removing sources from a patient, the sources are promptly returned to storage area and counted to ensure that every source removed has been returned. A record is made of the number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, and the number and activity of sources in storage after return. This record is initialed by the individual returning the sources.
h. If any discrepancies exist between the record and the number of sources in use and in storage, the RSO should be notified immediately.

Area Survey Procedures

You must submit your procedures for performing surveys to meet the requirements of Rules 1.7.50 and 1.7.53. Records of these surveys must be maintained for three (3) years. These surveys include:

a. Quarterly survey of ambient dose rates in all areas where sources are stored. The record must include date, plan of area surveyed, measured dose rate at several points in each area (in units of mRem/hr), survey instrument used, and the signature of the RSO.
b. Survey of patient administered a permanent implant prior to release to ensure the dose rate from

the patient is less than 5 mRem/hr at a distance of one meter.

c. Immediately after removing last temporary implant source from a patient, survey patient to confirm all sources have been removed. Record must include the date, name of the patient, dose rate from patient (mRem/hr at one meter), survey instrument used, and initials of individual who performed survey.

d. Promptly after implanting sources, survey dose rates in contiguous restricted and unrestricted areas to demonstrate compliance with Subchapter 4 of the regulations. Record must include the time and date of the survey, plan of area or list of points surveyed, measured dose rates at several points (mRem/hr), survey instrument used, and initials of individual who performed survey.

Information currently available indicates that sources (including seeds and ribbons) may become dislodged during implantation or after surgery and inadvertently lost or removed. You must submit procedures to ensure that dislodged sources are located and recovered (e.g.. a survey of the brachytherapy patient bed linens before removing them from the patient's room or a survey of the operating room and patient's room).

Implant Therapy and Release of Patients

1. Temporary Implants

Rule 1.7.50 requires licensees to survey the patient immediately after removing the last source from the patient. This is to confirm all sources have been removed before the licensee may authorize release of the patient from confinement for medical care. Before the patient is released, all sources must be removed from the patient and are accounted for. A record of the patient survey must be maintained for three (3) years.

2. Permanent Implants

A licensee may not release a patient with a permanent implant until the measured dose rate from the patient is less than the specified limit identified in Appendix P at a distance of one meter (Rule 1.7.33). If a patient is authorized for release, you must provide them with radiation safety guidance on how to maintain doses to other individuals, such as family members and members of the public, as low as reasonably achievable (1.7.33(2). This guidance may include, as appropriate, the need for:

- maintaining distance from individuals, including sleeping arrangements and avoiding public transportation;
- avoiding public places;
- avoiding close contact with children;
- action following the discovery of a dislodged source including notification of the licensee; and
- length of time precautions are necessary.

The licensee is not responsible for the radioactive material after the patient has left the hospital. The patient's home is an unrestricted area since the licensee has no control over access by other individuals. It is important, therefore, that you include instructions on how to handle dislodged sources as part of the radiation safety guidance. In addition, if you become aware a radiological problem exists, good health physics practices must be followed.

If a patient dies prior to release from confinement from medical care but the dose rate is less than the specified limit identified in Table 1 of Appendix P, and therefore could have been released for radiological considerations), the licensee may release the body. However, you must develop procedures to ensure that instructions are given for handling the body. Guidelines for autopsy or preparation of the

body for cremation or burial are outlined in the National Council on Radiation Protection Report No. 37, "Precautions in the Management of Patients who have Received Therapeutic Amounts of Radionuclides." If the body is to be autopsied, the tissue containing the implant may be removed prior to the rest of the autopsy.

Eye Plaques

Brachytherapy sources for temporary implants have high levels of radiation and remain radioactive for long periods of time. Although the eye plaque implant is temporary, in that it is removed after several days, the manner in which it is used is similar to a permanent implant. Because the implant is sutured into place, the device cannot be removed by the average patient, nor is it likely to become dislodged or lost.

If you want to release patients with an eye plaque implant, you must commit to the requirements described below to ensure adequate protection of public health and safety and meet the survey requirements for permanent implant patients specified in Rule 1.7.33. The authorization to release these patients with the implant in place will require a license amendment. Specifically, you must commit to the following provisions:

a. The measured dose rate from the patient will be less than the limit specified in Table 1 of Appendix P at a distance of 1 meter;
b. A non-hardening bonding agent will be used between the insert and the metal shield for all temporary eye plaques;
c. The patient will be provided with radiation safety guidance on how to maintain doses to other individuals as low as reasonably achievable.
d. A radiation survey of the patient will be made with a radiation detection survey instrument after removing the eye plaque, prior to release of the patient to ensure that all sources have been removed.
e. Upon removal of the eye plaque, the plaque will be disassembled and a physical inventory of the seeds will be conducted to confirm that all sources have been removed.

In addition to the above radiation safety requirements, the licensee must address any additional radiation safety precautions which will be taken and/or specific radiation safety instructions to be provided to patients.

Other Safety Procedures

If brachytherapy sources are to be used for non-human use, you should address any additional applicable radiation safety procedures to be followed.

Access Control

Rule 1.7.53 requires the licensee to take certain safety precautions to ensure compliance with the exposure limits of Subchapter 4. You must submit your procedures to meet these requirements which must include:

a. Only those persons needed for medical, safety, or training purposes will be present during the implant procedure. Access will be limited for housekeeping and dietary personnel;
b. Mark a visitor's "safe line" on the floor with tape as far from the patient as possible;
c. Authorize visits by minors only on a patient-by-patient basis with the approval of the authorized user and consultation with the RSO;
d. Note on the door, in the patient's chart, and/or on the nursing instruction form, where ("safe line") and for how long ("stay time") visitors may stay in the patient's room.

MODEL PROCEDURE FOR PATIENTS TREATED WITH BRACHYTHERAPY

1. All patients treated with brachytherapy sources will be placed as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities.

2. The patient's room will be properly posted in accordance with Rule 1.4.30.

3. Supply the nurses caring for brachytherapy patients with film badges, thermoluminescent dosimeters (TLDs), or pocket ionization chambers. TLD finger badges will also be supplied to nurses who must provide extended personal care to the patient.

4. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated With Brachytherapy Sources," or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.

5. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

6. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

7. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, three (3) feet (or one meter) from the patient, three (3) feet (or one meter) from the bed, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times and the exposure rate at three (3) feet (or one (1) meter) form the patient on the patient's chart.

8. The form "Nursing Instructions for Patients Treated With Brachytherapy Sources" will be completed immediately after the sources are implanted. A copy will be placed on the patient's chart.

9. Radiation levels in unrestricted areas will be maintained less than the limits specified in Rule 1.4.14(1).

10. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirm that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form.

11. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than the limit specified in Table 1 of Appendix P at one (1) meter. Measure this exposure rate with a radiation measurement survey meter at a distance of one (1) meter from the umbilicus with the patient standing.

INSTRUCTIONS TO NURSES ASSIGNED TO BRACHYTHERAPY PATIENTS

1. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. ***CALL THE RADIATION SAFETY OFFICER OR HIS DESIGNEE WITH ANY QUESTIONS REGARDING THE CARE OF THESE PATIENTS AND/OR RADIATION SAFETY PRECAUTIONS.***

2. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet on the patient's chart.

3. Visitors should sit at least three (3) feet (or 1 meter) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on the chart.

4. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

5. Visitors or attendants who are pregnant should not be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether or not they are pregnant. Declared pregnant nurses should not be assigned to the personal care of these patients. (See 4.13.)

6. When a nurse receives an assignment to a therapy patient, a film or TLD badge or pocket ionization chamber should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

7. Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and place it in the corner of the room or in the shielded container provided. Contact Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.

8. Bed baths should be omitted while the sources are in place.

9. Perineal care is not given during gynecological treatment. The perineal pad may be changed when necessary unless orders to the contrary have been written.

10. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist and ***MAY NOT BE DISCARDED*** until directed by the radiologist. Dressings should be kept in a basin until checked by the Radiation Safety Officer or his designee. Special orders will be written for oral hygiene for patients with oral implants.

12. No special precautions are needed for sputum, urine, vomits, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into these items.

13. All bed linens must be checked with a radiation survey meter before being removed from the patient's room to ensure that no dislodged sources are inadvertently removed.

14. *EMERGENCY PROCEDURES:*

(1) IF AN IMPLANTED SOURCE BECOMES LOOSE OR SEPARATED FROM THE PATIENT, OR

(2) IF THE PATIENT DIES, OR

(3) IF THE PATIENT REQUIRES EMERGENCY SURGERY, IMMEDIATELY CALL:

_____

_____

_____

TELEPHONE NUMBER: *DAY:*_____

*NIGHT:*_____

15. At the conclusion of the treatment, call the Radiation Safety Officer to do the following:

(1) Survey the patient and room.

(2) Count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name:_____

Room No:_____Physician's Name:_____

Isotope_____ Activity:_____

Date and Time of Administration:_____

Date and Time Sources Are To Be Removed:_____@_____a.m./p.m.

Exposure Rates in mR/hr

Bedside	3 feet from bed	10 feet from bed
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Comply with all checked items.

____1. Wear film badge.
____2. Wear rubber gloves.
____3. Place laundry in linen bag and save.
____4. Housekeeping may not enter the room.
____5. Patient may not have visitors.
____6. Patient may not have pregnant visitors.
____7. Patient may not have visitors under 18 years of age.
____8. A dismissal survey must be performed *before* patient is discharged.
____9. Patient must have a private room.
____10.Other instructions. (Attach as needed.)

In case of an emergency contact:

RSO: _____

Telephone: _____(On-duty)

_____(Off-duty)

APPENDIX M

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

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 manufacturers instructions for checking its accuracy and constancy, you may respond to Item 21 by saying, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you will collect spent gas in a shielded trap and will follow the model procedure for checking trap effluent, you may respond to Item 21 by saying, "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent in Appendix M."

If you are not monitoring trap effluent or if you exhaust spent gas to the atmosphere, you must estimate worker dose by calculation. **(Calculations must be submitted and kept for review during inspections.)** If you will follow the model procedure below for calculating worker dose from noble gases, you may respond to Item 21 by saying, "We will follow the model procedure for calculating worker dose from noble gases in Appendix M."

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 Rule 1.7.35. Say on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases" and submit your procedure for monitoring worker dose from noble gases.

WORKER DOSE FROM AEROSOLS

If you will collect spent aerosol in a shielded trap, will use an air contamination monitor for reusable traps, and will follow the monitor manufacturers instructions for checking for accuracy and constancy, you may respond to Item 21 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." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. **(Calculations must be submitted and kept for review during inspections.)** If you will follow the model procedure below for dose from aerosols, you may respond to Item 21 by saying, "We will follow the model procedure for calculating worker dose from aerosols in Appendix M."

If neither of the above applies, 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 monitoring worker dose due to aerosol concentrations" and submit your procedure for monitoring worker dose from aerosols.

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 20 percent 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., a fume hood); and

   g. Maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uCi/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For other gases or aerosols, see Appendix B to Subchapter 4.

2. The following calculations must be made:

   a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, 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 downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.)

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.

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 you do not monitor the trap effluent, check it on receipt and once each month. Collect the effluent from the trap during one patient study in a plastic bag and then monitor the activity in the bag by holding the bag against a camera, with the camera adjusted to detect the noble gas, and compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm.

3. The RSO will establish an action level based on cpm or a multiple of background cpm. If you measure a significant increase in the bag cpm, 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 Table II of Appendix B to Subchapter 4.

If you are not directly venting aerosols and gases to the atmosphere, you may respond to Item 21 by saying, "We will not directly vent spent aerosols and gases to the atmosphere; 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. **(Calculations must be submitted and kept for review during inspections.)** If you will follow the model procedure below for calculating release concentrations, you may respond to Item 21 by saying "We will follow the model procedure for calculating airborne effluent concentration in Appendix M."

If neither of the above applies, 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 monitoring airborne effluent concentration," and submit your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME

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

If you will calculate spilled gas clearance times according to the following procedure, you may respond to Item 21 by saying, "We will calculate spilled gas clearance times according to the procedure in Appendix M." If you submit different procedures for review. If you do so, you should consider all the above information, and state, "We have developed a procedure for calculating spilled gas clearance times."

MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:

   a. A, the highest activity of gas in a single container, in microcuries;

   b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser value), in milliliters per minute;

   c. Q, the total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room (the exhaust should be vented and not recirculated within the facility); this may be either the normal air exhaust or a specially installed gas exhaust system;

   d. C, the maximum permissible air concentrations in restricted and unrestricted areas. For Xe-133, the maximum permissible values are 1×10^{-4} uci/ml in restricted areas and 5×10^{-7} uCi/ml in unrestricted areas. For other gases, see Appendix B to Section 400; and

   e. V, the volume of the room in milliliters.

2. For each room make the following calculations:

   a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.

   b. The evacuation time $t = -V/Q \times \ln (C \times V/A)$.

USEFUL CONVERSIONS

1 mCi = 10^3 uCi

1 ft^3 = 2.832×10^{-2} m^3
= 2.832×10^4 ml

1 ft^3/min = 1.699×10^6 ml/hr
= 6.797×10^7 ml/40 hour week
= 1.484×10^{10} ml/year

1 week = 168 hrs

APPENDIX N

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE AT MEDICAL INSTITUTIONS ALARA

You may use the text as it appears here or you may develop your own ALARA program for Agency review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Rule 1.4.5 of the Mississippi State Board of Health Regulations for Control of Radiation.

ALARA PROGRAM

_____
(Licensee's Name)

_____
(Date)

1. Management Commitment

   a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee **(If Required)**

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of material and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures 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.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious 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 when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the RSC meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a semiannual review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 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 investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

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 and 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 given opportunities to participate in formulating 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 determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain

exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in resources available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on Form RH-6, "Occupational Exposure Record for a Monitoring Period", or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following action will be taken at the investigational levels as stated in Table 1:

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than the Table 1 values for Investigational Level I.

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

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to exposure is required unless deemed appropriate by the RSC. The RSC will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the RSC minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action to reduce the probability of recurrence. A report of the investigation, any action taken, and a copy of the individual's Form RH-6 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be

included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group or workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

Table 1

Investigational Levels

		(mrems per calendar quarter)	
		Level I	Level II
1.	Deep Dose Equivalent (Whole body)	125	375
2.	Shallow Dose Equivalent (Extremity)	1250	3750

APPENDIX O

Model Procedures for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your own procedure to meet the requirements of Rules 1.7.16 and 1.7.17.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This model does not restrict your use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in Rule 1.7.17 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in Rule 1.7.16 and be retained in accordance with Rule 1.7.81.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies. For each such modality for which Rule 1.7.16 requires, or would require, a written directive (as defined in Rule 1.7.2), the licensee should develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of Rules 1.7.16 and1.7.17 outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in Rule 1.7.17(2), including the patient or human research subject’s name;
- Verify the patient’s or human research subject’s identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and

- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 Microcurie of Sodium Iodide I-131

Develop, implement, and maintain the following procedures to meet the objectives of Rules 1.7.16 and 1.7.17:

- An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licensees are required under Rules 1.7.16 and 1.7.17 to have written directives for certain administrations of doses and to have procedures for administrations for which a written directive is required. Model procedures for meeting these requirements appear below.

A. 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.
B. 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 non-radioactive 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).
C. 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:
    1. 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).
    2. 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).
    3. For manually-generated dose calculations, verifying:

a. No arithmetic errors;
b. Appropriate transfer of data from the WD, treatment plan, tables and graphs;
c. Appropriate use of nomograms (when applicable); and
d. 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.

D. After implantation but before completion of the procedure: record in the written directive the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by Rule 1.7.16(2). 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 written directive may be maintained in the patient's chart.
E. 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.
F. 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 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%.
G. 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.
H. 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 non-recastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
I. 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., arithmetic 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.
J. 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.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high dose rate (HDR) brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

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. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by Rule 1.7.17, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Medical Events

Notify by telephone the Division of Radiological Health no later than the next calendar day after discovery of a medical event and submit a written report within 15 days after the discovery of the medical event, as required by Section 700.107. Also notify the referring physician and the patient as required by Rule 1.7.107.

I hereby certify that_____(Name of Facility) has implemented the procedures set forth above.

Signature_____ _____Date_____
Name (print or type)
Title_____

Patient Name_____ID #_____

Please show this form to every physician consulted concerning this patient until

_____.
(date)

Patient was treated on _____ with _____.
(date) (radiopharmaceutical)

No special radiation safety precautions are necessary after _____.
(date)

UNTIL THAT DATE:

A. If applicable, patient should not be pregnant, nor become pregnant for a period of six (6) months.
B. Patient should distance themselves from others whenever possible. (Do not hold babies or small children in lap.)
C. Patient should intake plenty of fluids.
D. Patient should flush the toilet twice after urinating.
E. Some patients may experience a sore throat a few days after injection. If any reactions occur, contact your physician.

If vomiting occurs within 4-6 hours after taking this dose or the patient is hospitalized, or if death of the patient occurs, please notify the following immediately:

Radiation Therapy Department

_____

Phone Number

DEPARTMENT OF Radiation Therapy
QUALITY MANAGEMENT PROGRAM

(601)_____

(601)_____ AFTER 5 P.M.

Date:_____

Radiology # :_____

Patient Name:_____ Verified by asking patient name ( )

Birth Date:_____ Verified by arm bracelet ( )

Patient Doctor:_____

Patient Dose:_____mCi / uCi

Dose calibrator reading:_____ mCi / uCi

Activity of Implants_____ mCi # of seeds_____

HDR fraction dose_____cGy

IV Administration:_____PO Administration_____

For treatment of_____

I understand that my physician has requested that I receive a therapy dose for treatment of my condition. I have been instructed about radiation safety precautions that are necessary in my case. I ***do*** *consent to this treatment. If applicable,* ***I am not pregnant nor will I become pregnant for a period of at least six (6) months****.*

Patient Signature:_____

Doctor:_____

Witness:_____

APPENDIX P

Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

****Note****

This section uses Nuclear Regulatory CommissionNUREG 1556, Volumn 9 guidance, Appendix U, for determining release of patients. You may use this guidance or other Agency approved guidance for the release of patients. Licensees must maintain records of all calculations used to release patients.

Rule 1.7.33, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Radioactive Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the "patient."

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides."

NCRP Report No. 37 uses the following equation to calculate the exposure until time *t* at a distance *r* from the patient:

Equation P.1:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_P\,(1 - e^{-0.693t/T_P})}{r^2}$$

Where:

D(t) = Accumulated exposure at time t, in roentgens

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm

Q_0 = Initial activity of the point source in millicuries, at the time of the release

T= Physical half-life in days

r = Distance from the point source to the point of interest, in centimeters

t = Exposure time in days.

This appendix uses the NCRP equation (Equation P.1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1-e^{-0.693t/Tp})$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation P.1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation P.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E, of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day: Equation P.2:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{(100\ cm)^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used: Equation P.3:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{(100\ cm)^2}$$

Equations P.2 and P.3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see “Internal Dose,”of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child

must be considered separately, as discussed in Item P.1.1, “Release of Patients Based on Administered Activity.”

P.1 Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed byproduct material or implants containing byproduct material have been administered in accordance with regulatory requirements.

P.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in Rule 1.7.33, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table P.1. The activities in Table P.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, “Internal Dose,” of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item P.3.2, “Records of Instructions for Breast-Feeding Patients.” The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.40 and 35.63.

If the activity administered exceeds the activity in Column 1 of Table P.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table P.1. In this case, 10 CFR 35.75(c) requires a record because the patient’s release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table P.1 were calculated using either Equation P.2 or P.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table P.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation P.2 or P.3 may

be used, as appropriate, to calculate the activity *Q* corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table P.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table P.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items P.2.2 and P.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

P.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table P.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table P.1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table P.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisieverts (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation P.2 or P.3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q / 10{,}000\ cm^2$.

P.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisievert (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table P.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by 10 CFR 35.75(c). If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

Table P.1 Activities and Dose Rates for Authorizing Patient Release†				
Radionuclide	**COLUMN 1 Activity at or Below Which Patients May Be Released**		**COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released***	
	(GBq)	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table P-1

The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue.

See Item P.3.1, "Records of Release," for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The millicurie values were calculated using Equations P.2 or P.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. The dose rate values are calculated using the millicurie values and the exposure rate constants. In general, the values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.
Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.
Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

P.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. You may either adopt these model instructions or develop your own instructions to meet the requirements of 10 CFR 35.75.

P.2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released.[1] Column 1 of Table P.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table P.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item P.2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table P.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation P.2 or P.3, as appropriate, may be used.

P.2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the

recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

[1] NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table P.3 was administered to the patient, the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table P.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table P.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table P.3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin.

P.2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to
P.2.3.1 and P.2.3.2).

Table P.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	**COLUMN 1 Activity Above Which Instructions Are Required**		**COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required**	
	(GBq)	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67***	1.7	47	0.04	4
I-123***	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111***	0.47	13	0.04	4

Table P.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	**COLUMN 1 Activity Above Which Instructions Are Required**		**COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required**	
	(GBq)	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**

Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201***	3.1	85	0.04	4

Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Footnotes for Table U.2

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

*** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

Notes: The values for activity were calculated using Equations P.2 or P.3 and the physical half-life. The values given in SI units (gigabecquerel values) were using conversion factors.

In general, values are rounded to two significant figures; however, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their state regulations before using these values.

Table P.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI**	20	0.5	100	3	
I-123 OIH**	100	4	700	20	

I-123 MIBG**	70	2	400	10	24 hours for 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell *In Vitro* Labeling	1000	30	6000	150	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	

Table P.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Radionuclide	**COLUMN 1 Activity Above Which Instructions Are Required**		**COLUMN 2 Activity Above Which a Record is Required**		**COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding**
	(MBq)	**(mCi)**	**(MBq)**	**(mCi)**	

Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate**	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells**	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride**	40	1	200	5	2 weeks for 110 MBq (3 mCi)

Footnotes for Table P.3

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

** These radionuclides are not byproduct material and are not regulated by the NRC. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the NRC and state requirements for non-NRC regulated material.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

P.2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements. Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 10 CFR 35.75(b), provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

P.3 Records

P.3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table P.1; however, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration.

In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation**: The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.
- For **Immediate Release of a Patient Based on Measured Dose Rate**: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation**: The time of the administration, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate**: The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

P.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d). Column 2 of Table P.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

P.4 Summary Table

Table U.4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table P.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained

Patient Group	Basis for Release	Criteria for Release	Instructions Needed?	Release Records Required?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity #Column 1 of Table P.1	Yes, if administered activity > Column 1 of Table P.2	No
Table P.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained	Patient Group	Basis for Release	Criteria for Release	Instructions needed?
Release Records required?	All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity #Column 1 of Table P.1	Yes, if administered activity > Column 1 of Table P.2
No	Table P.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained	Patient Group	Basis for Release	Criteria for Release
Instructions needed?	Release Records required?	All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity #Column 1 of Table P.1

Implementation

The purpose of this section is to provide information to licensees and applicants regarding NRC staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 10 CFR 35.75, the methods described in this appendix will be used in the evaluation of a licensee's compliance with 10 CFR 35.75.

References

National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,"

NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.

"Guidelines for Patients Receiving Radioiodine Treatment," *Society of Nuclear Medicine,* 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Table P.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide[1]	**Physical Half-Life (days)[2]**	**Exposure Rate Constant[3] (R/mCi-h at 1 cm)**
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.114
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.594
P-32	14.29	N/A[6]
Pd-103 implant	16.96	0.865
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A[6]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A[6]
Yb-169	32.01	1.83

Footnotes for Table U.5

[1] Although non-byproduct materials are not regulated by NRC, information on non-byproduct material is included for the convenience of the licensee.

[2]

K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, “Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,”

Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

[3]

Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber,
J.W. Baum, and C.B. Meinhold, “Radiation Safety Issues Related to Radiolabeled Antibodies,” NUREG/CR-4444,
.U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material,” U.S. NRC, February 1997.
.R. Nath, A.S. Meigooni, and J.A. Meli, “Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources,” Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

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A.S. Meigooni, S. Sabnis, R. Nath, “Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants,” *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an “apparent” value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

[6]

Not applicable (N/A) because the release activity is not based on bet