



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-8037

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INFORMATION RELEVANT TO ENSURING THAT OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS WILL BE AS LOW AS IS REASONABLY ACHIEVABLE

A. INTRODUCTION

This guide is directed specifically toward medical licensees and recommends methods that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable to maintain occupational exposures as low as is reasonably achievable (ALARA) in medical institutions. In a medical institution, certain persons other than employees are exposed to radiation from licensed radioactive material. These persons include visitors, as well as patients other than those being treated with radioactive material. This guide addresses the protection of these individuals. The content of this guide is also applicable to veterinary medical institutions, insofar as specific diagnostic or therapeutic procedures are performed. Similar protection practices are applicable for keeping employee and visitor exposures ALARA, whether the patients are animal or human.

Title 10, Section 20.1101(b), of the *Code of Federal Regulations* (10 CFR 20.1101(b)) (Ref. 1), states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. Regulatory Guide 8.10, Revision 1, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," issued May 1977 (Ref. 2), sets forth the philosophy and general management policies and programs that licensees should follow to maintain radiation exposures to employees ALARA. NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," issued January 2008 (Ref. 3), includes information on an acceptable management program for keeping exposures ALARA, as well as specific examples of radiation protection programs and practices acceptable to the NRC's licensing staff.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official or final NRC staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at <http://www.nrc.gov>; or faxed to (301) 492-3446. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments should be received by March 19, 2010.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>; and the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML091940170.

Specific guidance regarding radioactive materials in effluents to unrestricted areas is beyond the scope of this guide. This topic is mentioned only in connection with actions that influence both occupational exposure and effluent control. NUREG-1556, Volume 9, provides further details on this subject. In addition, this guide addresses only radioactive materials subject to licensing by the NRC. The regulations and recommendations of other agencies should be consulted in regard to controlling radiation exposures from x-ray machines, other radiation-emitting equipment, and materials not licensed by the NRC.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collection requirements covered by 10 CFR Part 20, "Standards for Protection Against Radiation," that the Office of Management and Budget (OMB) approved under OMB control number 3150-0014. The NRC may neither conduct nor sponsor, and a person is not required to respond to, any information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

A number of organizations have recommended that exposures be kept ALARA. These include the National Council on Radiation Protection and Measurements (NCRP) (Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," issued in 1990 (Ref. 4), and Report No. 116, "Limitation of Exposure to Ionizing Radiation," issued in 1993 (Ref. 5)); the National Academy of Sciences ("The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980" (Ref. 6)); the Federal Radiation Council ("Background Material for the Development of Radiation Protection Standards," Report No. 5, issued in 1964 (Ref. 7)), and other independent scientific and professional organizations (U.S. Department of Health, Education and Welfare, Publication No. (FDA) 73-8029, "Health Physics in the Healing Arts," *Proceedings of the Seventh Midyear Symposium of the Health Physics Society*, issued December 1972 (Ref. 8), and the American Conference of Governmental Industrial Hygienists Committee on Industrial Ventilation, "A Manual of Recommended Practice for Design," dated February 1, 2007 (Ref. 9)). The NRC licensing staff has incorporated the basic radiation protection philosophy of these recommendations in its regulations and guides.

The values proposed for maximum doses present a small risk when compared to the other hazards of life. Nevertheless, in view of the incomplete evidence upon which the values are based, coupled with the knowledge that certain radiation effects are irreversible and cumulative, the NRC licensing staff strongly recommends that every effort be made to reduce exposure to all types of ionizing radiation to the lowest possible level.

C. REGULATORY POSITION

The NRC licensing staff will consider a licensee's radiation protection program to be in compliance with the ALARA requirements in 10 CFR Part 20, "Standards for Protection against Radiation," if the licensee has adopted and implemented the major principles and practices identified below as part of its policies and programs.

1. Management Philosophy and Organization

The radiation protection responsibility of licensee management¹ at a medical institution is to maintain exposures ALARA for employees, visitors, students, and patients who do not receive radiation or radioactive materials as part of their hospital care. The licensee should carry out this responsibility with respect to employees and staff by the following means:

- a. information and policy statements² to the medical and hospital staff;
- b. periodic management audit of operational efforts to maintain exposures ALARA;
- c. continuing management evaluation of radiation safety staffing, program, and budget requirements;
- d. management programs to ensure that all staff and employees who may be exposed to radiation receive appropriate briefings and training in radiation safety, including ALARA concepts;
- e. delegation of sufficient authority to the Radiation Safety Officer (RSO)³ to enforce regulations and administrative policies regarding radiation safety; and
- f. administrative direction to ensure that any new hospital facilities or equipment that may affect radiation protection is planned or designed in consultation with the RSO.

Appendix M, "Model Procedures for an Occupational Dose Program," to NUREG-1556, Volume 9, presents a model program for implementing this management philosophy.

2. Radiation Safety Officer Functions

This guide uses the term RSO to indicate the individual that should be established as provided in 10 CFR 35.24(b) (Ref. 10), to direct and coordinate the administrative aspects of the radiation protection program. The extent of this program should be commensurate with potential radiation protection problems.

2.1 Staffing and Organizational Requirements

The appendix to this guide presents a sample outline of the various tasks of a typical radiation safety office. The time and effort required for each of the listed tasks vary widely depending on the size of the medical institution and the nature and extent of radioactive material usage. Management should (1) review the staffing requirements for each of these tasks and provide the necessary personnel to establish and carry out radiation protection program requirements and (2) evaluate them on an annual basis.

2.2 Radiation Safety Personnel Qualifications

¹ "Management" is defined here as those persons authorized by the charter of the medical institution to make its policies and direct its activities.

² Policy statements should include a detailed set of radiation exposure investigational levels, as presented in Appendix M to NUREG-1556, Volume 9.

Management should select a RSO who meets the requirements of 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59, and carefully review radiation protection personnel qualifications, based on the nature of the radiation safety program and the extent of effort and expertise required to carry out the tasks noted in Appendix A to this guide.

2.3 Space and Equipment

The RSO should have adequate equipment and space in appropriate locations to carry out the following functions:

- a. maintain, repair, and perform electronic calibrations on radiation safety equipment;
- b. calibrate radiation safety equipment with radioactive sources (and check the calibrations of other hospital radiation safety equipment, if radiation safety and medical physics functions are combined);
- c. stock radiation safety supplies for labeling, surveying, decontamination, and personnel protection and monitoring;
- d. conduct radiometric measurement of smear tests from contamination surveys and source leak tests;
- e. store radioactive waste and sources not in use;
- f. decontaminate personnel, clothing, and equipment;
- g. process orders for licensed radioactive materials and receive and distribute such materials;
- h. receive, process, and file regulations and licensing correspondence;
- i. prepare reports and records of surveys and personnel monitoring as required by 10 CFR Part 20; and
- j. instruct and brief personnel as required by 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations" (Ref. 11).

In addition, licensees should examine the tasks listed in the appendix to this guide for other activities that may require specific space allocations for radiation safety offices in larger hospitals.

2.4 Tasks and Procedures

The RSO and the radiation safety staff are responsible for conducting surveillance programs and investigations to ensure that occupational exposures are ALARA. In addition, they should be vigilant in searching out new and better ways to reduce doses for jobs involving radiation exposure. The appendix to this guide, as well as NUREG-1556, Volume 9, provide a list of the types of tasks carried out by a radiation safety office to ensure good radiation safety surveillance and to meet regulatory and license conditions.

For medical institutions in which a full- or part-time professional health physics staff is available, this staff should coordinate the planning of radiation safety procedures with management to ensure optimum efficiency and exposures that are ALARA. This coordination should extend to the implementation of the ongoing radiation protection program by the professional health physicists under the general supervision of the RSO.

2.5 Administrative Authority

The radiation safety office, supervised by the RSO, should carry out the radiation protection program, including the tasks listed in the appendix to this guide. In accordance with 10 CFR 35.24(e), the licensee shall establish the authority, duties, and responsibilities of the RSO in writing. The licensee's designation should include authority for the RSO to communicate directly with the level of management

that is able to take corrective action when needed to enforce rules and procedures pertaining to the institution's radiation protection program. The RSO should also be granted administrative authority to suspend certain activities temporarily when needed in emergencies to avoid immediate danger to life or health. However, the RSO should exercise his or her authority to suspend activities only when it will not interfere with life-saving medical procedures that warrant an overriding priority and that cannot await alleviation of the radiation safety problems.

2.6 Radiation Safety Committee

Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of 10 CFR Part 35, or two or more types of units under Subpart H of this part, shall, pursuant to 10 CFR 35.24(f), establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. As required by 10 CFR 35.24(f), the Committee must include an authorized user of each type of use permitted 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. The Committee may include other members the licensee considers appropriate.

3. Facility and Equipment Design

3.1 General Considerations

The design of facilities and equipment required for the medical uses of radioactive materials depends not only on hospital and medical care considerations but also on the nature and quantity of radioactive materials involved and the relative potential for external and internal radiation exposure. The following paragraphs discuss the major aspects of planning and design which the licensee should consider.

3.1.1 Space Layout

The licensee should plan the facility layout to maintain employee exposures ALARA, while at the same time ensuring that actions taken to achieve this objective do not increase exposure to other persons in restricted or unrestricted areas. Considerations should include the following:

- a. the need for access to radiation or radioactive material areas by medical staff, employees, patients, visitors, and others, while providing optimum separation between work areas with frequent occupancy and radiation sources or contamination;
- b. ventilation requirements, including whether to maintain lower pressures in rooms in which radioactive materials may possibly be spilled or volatilized;
- c. floor loading for heavily shielded sources;
- d. receipt and shipment of radioactive material, including radiation surveys of the shipping containers;
- e. ingress and egress of some radiation therapy and nuclear medicine outpatients, including parking; and
- f. the need to protect supplies of stored diagnostic films from radiation exposure.

3.1.2 Shielding

Permanent shielding may be needed in some cases for walls, floors, and ceilings to provide protection against radiation associated with radioactive materials currently housed in the institution, as well as radioactive materials that might be introduced into the area by future medical care requirements. Section 3.2 of this guide discusses permanent shielding for radiation therapy facilities. In shielding

calculations for a teletherapy facility, the licensee should take into account occupancy and use factors, as recommended in NCRP handbooks, but such factors should be chosen with the principle of ALARA in mind. The licensee should consult the NRC licensing staff during the planning and design stage to obtain guidance on acceptable use and occupancy factors in shielding design.

3.1.3 Caution Signs and Interlocks

The licensee should use caution signs, signals, and interlocks, as required by 10 CFR Part 20, to control or restrict access to certain areas.

3.1.4 Ventilation

To the extent possible, the licensee should:

- a. Provide any necessary local exhaust ventilation (such as chemical hoods) or general ventilation, as recommended by professional health physicists, for areas where breathable concentrations of radioactive material may be present.
- b. Design exhaust systems to avoid transporting contaminated air through long ductwork passing through many other hospital areas on its way to the stack on the roof.
- c. Locate exhaust vents so as to provide meteorological diffusion and dilution adequate to meet 10 CFR Part 20 requirements for effluents to unrestricted areas and ALARA exposure considerations for the public, as well as to avoid recirculating contaminated exhaust air into the building.
- d. Where appropriate, include specific types of filters or air cleaners for the exhaust air.
- e. Maintain rooms in which radioactive gases or aerosols may be released at negative pressure with respect to adjacent rooms by appropriate exhaust ventilation, as described in item a. above.

3.1.5 Fire Control

Licensees should consider the need for personnel to exit and close the facility to prevent the spread of radioactive material for areas in which laboratory procedures could result in dispersal of radioactive material in the event of a fire. Licensees should provide local showers and fire extinguishers, where necessary. For the vast majority of medical institutions, emergency procedures and training should include immediate fire control as a priority item.

3.1.6 Special Laboratory Design Features

Licensees should consider providing laboratory surfaces that may be easily cleaned and decontaminated daily to maintain minimal contamination levels and radiation exposures, as well as minimal interference with medical and clinical procedures. Laboratory needs may also include the following:

- a. provision for appropriate placement of radiation- and contamination-monitoring instruments;
- b. designated sinks for rinsing and disposing of minor quantities of radioactive wastes (within 10 CFR Part 20 limits);
- c. special plumbing and waste storage provisions; and
- d. adequate separation between areas occupied by personnel and radiation sources or contamination.

In general, no hospital procedure should use quantities of radioactive material that, because of their radiotoxicity, could result in potential air concentrations approaching the concentration values given

in 10 CFR Part 20. Licensees should design ventilation and contamination control to maintain air concentrations and contamination levels ALARA.

3.1.7 Storage, Source Control, and Inventory

In institutions ordering a number and variety of radioactive material sources, it is often easier, less costly, and more secure to provide a centralized storage room for radioactive materials not in use or used only occasionally. Such a facility is also helpful in keeping exposures ALARA, since it may result in a decrease in the amount of radioactive material stored in laboratories occupied by personnel.

3.1.8 Shipping and Receiving

Medical institutions should:

- a. Plan specific radioactive material storage areas for day, night, and weekend deliveries, so that deliveries of radioactive materials may be received at any time and placed in a secure locked location where they may not cause unnecessary exposure to personnel while awaiting survey by the RSO or the user. The licensee should ensure that a written procedure for receipt, survey, and storage of deliveries is provided to anyone responsible for the receipt or delivery of radioactive material.
- b. When packages may expose couriers to measurable radiation, provide a cart or carrier that maintains an adequate distance between the person transporting the material and the package to keep exposures ALARA.
- c. Provide space in the receiving area for an initial survey and smear test of each package, unless other means are used to avoid transporting a contaminated package through unrestricted areas of the hospital.
- d. Locate shipping and receiving areas and access to them away from areas where radioactive materials are used to (1) minimize the time required for transporting radioactive material to areas where it is to be used, and (2) avoid the need to transport radioactive materials through crowded areas or areas occupied by personnel, patients, or visitors.

3.1.9 Equipment Considerations

Licensees should employ the following general features when using equipment to handle or contain radioactive materials:

- a. Surfaces should be easy to clean and decontaminate, in case unsealed radioactive material is released.
- b. Equipment should be designed to optimize the ease of carrying out procedures where personnel are exposed to radiation, thereby minimizing working times, and to maximize distances of personnel from the radioactive materials with which they are working, to an extent consistent with the purposes of the procedure.
- c. Equipment should operate in such a fashion that it does not damage radiation sources and release radioactive materials if it were to fail.
- d. Adequate shielding should be provided as part of the equipment, where feasible, to keep exposures ALARA.
- e. Appropriate caution signs, symbols, signals, and alarms should be provided as part of the equipment to meet the requirements of 10 CFR Part 20 and recommended standards of the medical physics profession.

3.2 Radiation Therapy Equipment and Facilities

The NRC licensing staff provides specific licensing guides for licensed radiation therapy programs, and the NRC licensing staff reviews the safety aspects of facilities and equipment before issuing a license. In designing shielding for radiotherapy treatment rooms (e.g., teletherapy and gamma stereotactic radiosurgery units, high dose rate brachytherapy, and gamma knife), the medical institution should consult NCRP Report No. 151, “Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities,” issued in 2005 (Ref. 12), for recommended design details; specifications; methods of shielding against direct, scattered, and leakage radiation; and general principles of radiation safety design.

In addition, the institution should:

- a. Protect each radiotherapy treatment room from inadvertent entry by the following means:
 - (1) Provide a door interlock that allows a “Beam On” condition only when the door is closed and turns the beam off if the door is opened.
 - (2) Provide independent backup caution lights on the console, above the door, and inside the treatment room to indicate the “Beam On” condition to radiotherapy technologists and other staff members. Independent audible signals provide added safety if the caution lights fail.
 - (3) Establish a procedure for determining whether everyone except the patient is out of the treatment room before the door is closed and the beam is turned on.
 - (4) Install independent gamma-ray-sensing caution lights or signals near the entry inside the treatment rooms to provide a warning to the radiotherapy technologist or others entering the room in case the door interlock system fails when the beam is in the “on” condition.
 - (5) Provide a scram button for emergency shutdown of the source from inside the room and provide audio communication into the room from the outside control panel.
- b. Consider leakage through the radiotherapy unit with the source in the “on” position when designing shielding. Data provided by the manufacturer of the radiotherapy unit and NCRP recommendations should be used for this purpose.
- c. Design areas adjacent to the treatment room that will be occupied by personnel, patients, or visitors who are not associated with the radiation therapy department so that exposures to these areas are maintained ALARA. Reduction of occupational exposures to radiation therapy personnel should be achieved by design provisions, procedures, or beam orientations that are directed toward unoccupied or low-occupancy areas. The institution should design to ensure that dose rates will not exceed 0.002 rem (0.02 millisievert) in any single hour (see 10 CFR 20.1301, “Dose Limits for Individual Members of the Public”) in restricted or unrestricted areas adjacent to the radiotherapy treatment rooms.

3.3 Nuclear Medicine Facilities

To ensure that exposures are ALARA, the layout and design for new nuclear medicine facilities and equipment should:

- a. Allow sufficient space for personnel operating nuclear medicine equipment to be at least 1 meter, and preferably 2 meters, from any patient undergoing imaging, whenever the condition of the patient and other conditions permit, or provide adequate portable shields.
- b. Allow adequate space for stretcher patients awaiting scans, as well as for outpatients. Dosed patients awaiting scans may generate radiation levels on the order of 0.002 rem (0.02 millisievert) or more near the edge of the stretcher. These patients may need to be segregated from the general

waiting area to reduce radiation exposure to receptionists and persons passing through the area, such as technologists and aides.

- c. Locate physicians' offices and other occupied areas within easy access to needed radiopharmaceuticals, but allow enough distance (several meters is usually sufficient) to minimize exposures from stored radiopharmaceuticals and radioactive wastes.
- d. Provide adequate shielding for stored radiopharmaceuticals and adequate body shielding for employees preparing dosages for patients.
- e. Supply an adequate number of syringe shields and vial shields (as well as appropriate tongs or forceps) near the place of dosage preparation.
- f. Provide adequate exhaust ventilation (see Ref. 9) in the laboratory near or in the radiopharmaceutical storage and dose preparation areas to protect against airborne radioactive or toxic materials that might result from accidental release or spill of radiopharmaceuticals.
- g. Include a special shielded waste receptacle for used syringes and other radioactive wastes in the nuclear medicine laboratory near the dosage preparation area.
- h. Locate a permanently fixed radiation counter or rate meter near the entrance to the nuclear medicine preparation laboratory for employees to check regularly for hand or clothing contamination when leaving the department. A portable survey meter available at a convenient location should also help keep exposures ALARA.
- i. Provide individual labeled lockers and change areas for segregating laboratory coats that may be contaminated from other clothing when operations are such that contamination levels on persons or clothing may exceed the action levels of Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions" (Ref. 13).
- j. Provide finger badges or dosimeters, as well as body dosimeters, to monitor the occupational exposure of personnel involved in dose preparation and the injection and handling of patients.

3.4 In Vitro Clinical and Research Laboratories

Many of the design considerations for in vitro clinical and research laboratories are similar to those already stated for other facilities. Special considerations include the following:

- a. easily discarded bench paper, absorbent on the top surface only, for catching and easily disposing of small amounts of contamination that may drip or be removed from laboratory apparatus and glassware;
- b. suitable, easily cleaned drip trays for carrying out manipulations of radioactive materials where spillage may occur; and
- c. protective clothing, including rubber or plastic disposable gloves (which should be changed frequently), for persons working with radioactive materials.

In addition, licensee should provide equipment for monitoring clothing before laundering. Radioactive laundry and radioactive wastes should be turned over to the Radiation Safety Office for further disposition when surveys indicate contamination levels that may exceed 10^5 microcuries per square centimeter.

NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel," issued in 1989 (Ref. 14), provides additional information on carrying out in vivo experiments with animals.

4. Safe Work Practices and Procedures

4.1 General Principles

The NRC licensing staff recommends, as a minimum, the safe work practices and procedures contained in this section for handling radioactive materials in medical institutions. Regulatory Guide 8.23 and NUREG-1556, Volume 9, contain additional information.

4.1.1 Periodic Inventory and Control of All Radiation Sources

Many of the more serious occupational exposures, as well as patient exposures, have resulted from misplaced or lost radioactive material, which may inadvertently expose unsuspecting persons or may be subject to improper usage by unauthorized persons. Licensees should take the following procedures to guard against these problems:

- a. According to 10 CFR 35.67(g), a licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semiannual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with 10 CFR 35.2067(b). The inventory should be combined with an inspection to ensure proper labeling (see 10 CFR 35.69, "Labeling of Vials and Syringes," and 10 CFR 20.1902, "Posting Requirements").
- b. Sources should be secured within locked rooms or storage areas when authorized users or their responsible employees are not present (see Section C.3.1.7 of this guide). Licensees should provide special shielded vaults or containers in the storage area for sealed sources.
- c. Authorized persons should be required to sign for the removal and return of each source. The radiation safety office staff should regularly check the source log.

4.1.2 Shielding

All radioactive material not in use should be shielded so that exposure rates in any area that may be occupied by personnel should be well below (i.e., ALARA) the levels for unrestricted areas given in 10 CFR Part 20. Whenever radioactive materials are in use, the material should be unshielded only in the direction necessary for its use and to the extent that accessibility to the source is necessary.

4.1.3 Control of Contamination

Licensees should ensure that radioactive materials in unsealed form or undergoing chemical or physical processing are handled only in properly designed facilities (as described in Section C.3.3 of this guide) and with proper procedures to avoid transferring radioactive material to the air or to surfaces if inhalation or ingestion of the material by personnel is possible. Heat sterilization should be avoided if it might rupture the source. If necessary to ensure that exposures are ALARA, licensees should conduct preliminary tests of procedures with nonradioactive simulated materials or colored liquids to check provisions for containment, handling, and ventilation. The radiation safety office staff may make preliminary estimates of job exposure commitments using tracer levels of radioactive material.

Trays and absorbent materials should be used as a backup to catch and limit the spread of radioactive contamination whenever a possibility exists that planned procedures may fail to contain the radioactive material.

Personnel should wear protective clothing appropriate to the type and quantity of the radioactive material being processed whenever escape of radioactive contamination is considered possible.

4.1.4 Proper Work Habits

In general, licensees should train all personnel handling radioactive materials to use appropriate shielding materials, maintain as much distance as possible from radiation sources, and limit the time of exposure to radiation sources to the time necessary to carry out the required task or clinical procedure.

The following good work habits are particularly important in ensuring that exposures are maintained ALARA:

- a. Except for very-low-level sources, such as flood sources or other sources designed for manual use in checking instrumentation, sealed or unsealed sources should not be touched or held with the fingers, but only with tongs or tweezers appropriate to the operation.
- b. Personnel who are handling or manipulating unsealed or unshielded sources with tongs or forceps, or who are holding partially shielded containers of radioactive material with their hands should wear finger dosimeters,³ as well as body dosimeters. However, these dosimeters are not needed for personnel handling only the types of sources used for tracer-level in vitro studies or if dose rates are less than 5 millirem (0.05 millisievert) per hour at 1 centimeter.
- c. Special attention should be given to instructing all nursing staff and others coming in contact with patients who may be excreting radioactive material that they may need to follow precautions to avoid contaminating themselves and others.
- d. When working with unencapsulated radioactive materials, personnel should wear rubber or plastic gloves and other special clothing.
- e. Care should be taken to avoid needless contamination of objects such as light switches, taps, or door knobs.
- f. Radioactive solutions should never be pipetted by mouth.
- g. Eating, smoking, drinking, and application of cosmetics should be prohibited in laboratories where radioactive materials are handled.
- h. Special precautions should be taken to avoid the possibility of small amounts of radioactive material entering into cuts.
- i. The use of containers or glassware with sharp edges should be avoided. Care should be taken to avoid bites or scratches in working with animals to which radioactive materials have been administered.
- j. Food and drink should not be stored in the same place (e.g., the refrigerator) with radioactive materials.
- k. Radioactive materials should be secured (e.g., placed in a locked room) when personnel are not present.
- l. Surveillance of individual operations, such as “milking” generators, should be provided to ensure that workloads are distributed so that individual employee doses are kept ALARA.

4.1.5 Radiation or Radioactivity Monitoring

Section C.2 of this guide discusses the independent radiation surveys, inspections, inventories, and smear tests to be carried out by the radiation safety office staff. In addition, each user of radioactive materials should survey radiation and radioactivity levels daily within his or her own operations to help maintain exposures ALARA. A simple logbook of readings or general levels of radiation or contamination maintained by the user may help to indicate any changes in radiation or radioactivity levels that require modification of procedures or equipment to meet ALARA radiation exposure objectives.

³ With some finger dosimeters, labels may wash off or the badge may rip protective gloves. In these cases, wrist badges may be preferable. In any case, the user should be aware of the fact that neither of these dosimeters will measure very high finger-contact doses, and handling unshielded syringes or bottles with the fingers should absolutely be avoided.

Regulatory Guide 8.23 and NUREG-1556, Volume 9, provide further guidance on radiation surveys in medical institutions and nuclear pharmacies.

In hospital situations in which higher exposure rates may occur (e.g., in teletherapy rooms where, in an accident, the limits of 10 CFR Part 20 could be approached before an indication is provided by routine personnel-monitoring devices), self-reading devices that may be read by the wearer at least daily, as well as warning devices worn on the body, may be helpful in maintaining exposures ALARA.

4.1.6 Training

Licensees should make employees aware of the ALARA provisions of 10 CFR Part 20 and the guidance of Regulatory Guide 8.10. Employees should be instructed in the philosophy and recommendations of Regulatory Guide 8.13, “Instruction Concerning Prenatal Radiation Exposure” (Ref. 15), whenever there is a possibility that pregnant women may be exposed to radiation.

Employees should be acquainted with their institution’s own procedures for handling radioactive sources and radioactive materials and with NRC licenses and their radiation safety provisions (including license conditions incorporated from license applications and correspondence). Licensees should make copies of these procedures, licenses, and related correspondence available for review by employees as part of their orientation to radiation safety requirements. Licensees should also support professional education and development to ensure that staff members are up to date on radiation safety methods.

Licensees should consult NUREG-1556, Volume 9, for topics that are important in training radiation workers.

4.2 Radiation Therapy

This guide provides recommendations for maintaining exposures ALARA in three subdivisions of radiation therapy:

- a. Radiotherapy—the treatment of patients with high-energy beams from shielded equipment containing sources of high gamma ray emission rates.
- b. Brachytherapy—the treatment of patients by insertion of sealed sources such as needles or tubes for interstitial or intracavitary irradiation or by surface application.
- c. Radiopharmaceutical therapy—the injection or oral administration of solutions or colloids of radioactive pharmaceuticals that tend to concentrate in and irradiate the organs in which they are dispersed or absorbed.

4.2.1 Radiotherapy

Radiation protection measures in radiotherapy should rely primarily on the adequacy of facilities and equipment, since very intense radiation levels are generated (see Section C.3.2 of this guide). Nevertheless, the licensee should use the following basic and routine operating principles for maintaining occupational exposures ALARA:

- a. With the aid of the maintenance and operating manuals provided by the manufacturer of the radiotherapy unit, procedures for routine maintenance and check of safety-related features of the teletherapy unit should be established.
- b. A daily morning checkout procedure should be established and posted for the therapy technologist to carry out simple operational checks of indicator lights, caution lights and signs, key and door interlocks, gamma radiation level indicators, timer operation, and interlock function.

- c. A general safety check, including a spot or point radiation output check and check on beam alignment and confining devices, should be made and recorded at least monthly. All records of the monthly output and safety check, as well as the morning checkouts, should be signed and dated by the persons carrying out the tests.
- d. During patient treatment or operation of the radiotherapy unit for calibration or maintenance procedures, care should be taken to follow written instructions and to use installed safety devices to ensure that no personnel except the patient to be exposed are in the treatment room during the “Beam On” condition. These procedures are also important when personnel carry out test procedures with phantoms on the treatment table.
- e. During “Beam On” operation, the operator at the console should remain in a position of lowest radiation intensity, while maintaining vigilance of the console and the patient during treatment, as advised by the radiation safety office staff using the post-installation radiation survey. In a well-designed facility, the shielding provides a very high degree of protection at the location of the console. However, all persons not required to remain near the console should remain or work in areas of lower radiation intensity while the radiotherapy unit is in operation. During “Beam Off” conditions, treatment setup should be accomplished with minimum occupancy of the room and minimum time spent near the source to keep exposures from leakage radiation ALARA.
- f. Emergency procedures established as required by NRC regulations or license conditions should be tested by regular familiarization sessions or by staging mock emergencies for the training of personnel.

4.2.2 Brachytherapy

NCRP Report No. 40, “Protection Against Radiation from Brachytherapy Sources,” issued in 1972 (Ref. 16), provides detailed recommendations for reducing radiation exposures in brachytherapy, and NCRP Report No. 37, “Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides,” issued in 1970 (Ref. 17), contains additional recommendations pertinent to brachytherapy, as well as radiopharmaceutical therapy. The licensee should also consider the following important practices for maintaining exposures ALARA:

- a. Afterloading devices should be used wherever medically acceptable. Remote afterloaders are particularly effective in keeping exposures ALARA.
- b. Jigs or remote afterloaders should be prepared and tested for ease in loading sources into afterloading devices in the patient’s room.
- c. When manual afterloading is used, jigs for loading the afterloaders should be set up behind shields with lead-glass viewing windows, and auxiliary lead-brick shielding should be provided to shield the arms of the personnel loading the afterloaders for as much of the duration of the procedure as possible.
- d. When the radiation sources of afterloading sleeves or ovoids are loaded, they should be placed in adequately shielded carts or transport devices for liquid sterilization or transport to the patient’s room when the physician is ready to insert the afterloaders. These carts should be properly tagged and should, at all times, be under the supervision of the radiation physicist, the radiation safety staff, or a member of the radiotherapy staff.
- e. Similar protection should be provided for use in threading radioactive needles for implant therapy.
- f. While manipulating sources, loading the afterloaders, and threading needles, personnel should be provided with tongs and surgical clamps to maintain the distance of the fingers at least 30 centimeters from these sources.
- g. Personnel should wear finger dosimeters, as well as body dosimeters, when they are loading or preparing sources for insertion. Also, the radiation safety office staff should periodically survey the loading procedures and provide job-time and exposure information to help employees maintain exposures ALARA. Use of a gamma alarm monitor in the storage or loading area will

indicate when radiation sources are outside their shields and help to avoid inadvertent exposures resulting from lost or misplaced sources (see 10 CFR 20.1101(b) and 10 CFR 20.1601, “Control of Access to High Radiation Areas”).

- h. A continuing list and count of removals and returns of individual sources from the storage containers should be maintained to help ensure against inadvertent loss of sources and exposure of personnel.
- i. Sources maintained in fixed position for a constancy check on the operation of any intracavitary ion chambers should be kept within shielded wells in constant geometry so they can be used for a rapid and safe check on ion chamber operation before the treatment of each patient.
- j. The radiation safety staff should carry out job-time/exposure studies on typical surgical implants and typical insertions of radioactive sources—either in the operating room or by afterloading in the patient’s room. These time/exposure studies should be recorded and reported to the personnel involved to maintain an awareness of radiation exposures resulting from these procedures.
- k. The radiation safety office staff or the radiation therapy staff should directly supervise the transport of a patient containing radioactive material to areas outside the operating room and to his or her room. Also, radiation safety office staff or radiation therapy staff should check and supervise the transport of afterloading sources and supplies for the insertion of applicators, lead bedside shields for the nurses, and any other supplies and equipment required for expediting an efficient afterloading procedure. Radiation surveys should also be carried out on a sample basis and recorded to maintain an awareness of the exposures resulting from these procedures.
- l. Nursing personnel should be provided with personnel dosimeters (when required by 10 CFR Part 20) and should be trained in their use.
- m. Radiation safety staff or radiation therapy staff should survey patients after removal of brachytherapy sources and before discharge as a final step to check against incomplete removal of these sources from the patient, leakage of contamination from sources, or inadvertent loss of sources. All linens and waste should remain in the room until checked by a survey meter or until all sources are accounted for.

4.2.3 Radiopharmaceutical Therapy (Nuclear Medicine Therapy with Unsealed Radioactive Materials)

Where feasible and in the best interests of the patient, licensees should ensure that administration of millicurie quantities of the types of radioactive drugs used for therapy of specific diseases should be carried out in a specific area or room separate from other nuclear medicine or radiotherapy operations. However, this special area or room should be in the general vicinity of the laboratory where the radiopharmaceuticals are stored to eliminate the need for transporting these materials over long distances or through other areas of the institution. When these materials must be transported to a patient’s room for administration, good radiation safety practice and efficient medical procedures often dictate that the radiation safety staff or nuclear medicine therapy staff monitor and assist in the preparation of the materials and supplies, the transport of the materials to the patient’s room, and the administration of the radioactive drugs, as directed by the physician in charge. When therapy is carried out with potentially volatile radioiodine compounds, licensees should consult Regulatory Guide 8.20, “Applications of Bioassay for I-125 and I-131” (Ref. 18), to determine whether employees who have participated in the radioiodine administration should be sampled for bioassay.

After treatment, all articles, including, but not limited to bedding, clothing, food, towels, and food trays, should be surveyed for possible contamination before they are released from the room. Contaminated articles must be held for decay or disposal according to 10 CFR 35.92, “Decay-in-Storage.” The patient should be surveyed before release and should be instructed on ways to minimize contamination of the environment and exposure of other members of the public.

In supervising the administration of radiopharmaceuticals to patients, the physician in charge and the radiation safety staff may use many of the principles given for brachytherapy in Section C.4.2.2 of this guide, as well as principles and practices presented in NCRP Report No. 37. The use of these procedures should help to ensure that exposures to hospital staff and private duty nurses are ALARA, not only during the administration of the dosage to the patient but also during any hospital care of the patient, during and after discharge of the patient, and in the event of any later surgery, autopsy, or burial of the patient. NUREG-1556, Volume 9, provides additional guidance.

4.3 Diagnostic Nuclear Medicine

Previous sections on recommendations for nuclear medicine facilities and equipment (Section C.3.3 of this guide) and general principles of safe work practices in handling radioactive materials (Section C.4.1 of this guide) discussed many of the principles of radiation protection practice in diagnostic nuclear medicine. Additional recommendations include the following:

- a. Use syringe shields for administering all injections of radioactive material; only compromise this procedure on rare occasions when absolutely necessary. Use gloves to protect against possible hand contamination.
- b. Place radionuclide generators as far as possible from areas occupied by workers in other nuclear medicine operations, with adequate ventilation and additional shielding as necessary, to reduce external as well as internal exposure to personnel during elution.
- c. Use samples in shielded bottles for checking the assay of eluates in the nuclear medicine dose calibrator or other suitable assay system. Calibration procedures with a smaller quantity of radioactive material may sometimes reduce exposures.
- d. Shield chamber calibrators, where possible, to maintain employee exposures ALARA and reduce background radiation while nuclear medicine doses are being calibrated. Recalibrate refitted chambers as necessary.
- e. Use fume hoods (see Reference 9) and good contamination control principles when preparing dosages of radiopharmaceuticals that have potential volatility or a potential for release from rubber septum syringes.
- f. Keep shielded radioactive waste cans for used syringes and other radioactive wastes at the greatest distance from those areas in the laboratory most frequently occupied by personnel, consistent with ease of disposal.
- g. Use protective lead screens to protect employees and other patients during procedures using technetium-99m (Tc-99m) or other gamma emitters if the screens do not interfere with the diagnostic tests. Portable screens of lead only 2 millimeters thick will reduce Tc-99m gamma-ray exposure rates to less than 1 percent of those without the screens.
- h. In lung perfusion or ventilation studies with xenon-133 (Xe-133), use additional lead shielding 1.6 millimeters thick (or appropriate thicknesses for other radioactive gases or aerosols) around the absorber canister, oxygen bag, and waste receptacle to reduce occupational exposures when undertaking frequent procedures. Use proper equipment to prevent leakage or contamination from the radioactive material being used. Installation of a Xe-133 monitor in the room where ventilation studies are performed should warn of any leakage of Xe-133.
- i. In addition to regular nursing staff members who receive personnel monitoring, carefully monitor private duty nurses and others who may come in close contact with patients who have been administered radiopharmaceuticals for diagnostic or therapeutic purposes for exposure and contamination and provide them with appropriate instructions and briefings on radiation protection procedures.

4.4 Low-Level Clinical or Medical Research Laboratory Activities

Laboratories in medical institutions that use tracer amounts of the less radiotoxic nuclides may keep exposures ALARA by using the recommendations contained in Section C.4.1 of this guide. Many of the radionuclides used for in vitro clinical tests, such as radioimmunoassay, and other low-level in vitro or animal studies, involve pure beta emitters or weak gamma emitters, with individual personnel handling and processing only microcurie or submicrocurie quantities at any one time. External and internal radiation exposures to personnel in such laboratories should ordinarily be maintained well below 10 percent of the permissible occupational exposure limits of 10 CFR Part 20 through careful initial planning of laboratory facilities, equipment, and procedures by the laboratory supervisor, in conjunction with qualified health physics personnel.

5. Management Audit and Inspection of the Radiation Protection Program

The governing body of the hospital bears the ultimate responsibility for the establishment and continuation of an adequate radiation protection program in a medical institution. The administrator reporting to this governing body should be sufficiently informed at all times to ensure that all regulations are faithfully adhered to and that the use and safe handling of radioisotopes are properly carried out to maintain exposures ALARA.

The hospital administration should perform an annual audit of the radiation protection program in cooperation with members of the radiation safety committee and the radiation safety office. The results of this audit may then be discussed at a radiation safety committee meeting to ensure that all users and responsible staff are aware of current policies and procedures and methods for their improvement. NUREG-1556, Volume 9, contains a sample checklist of items that may be inspected by the administration during this annual audit. The radiation safety office should maintain a report of the results of the audit for possible use in expediting any inspections by regulatory or accrediting agencies, as well as for reference in further audits and for improving the ALARA program.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC licensing staff's plans for using this regulatory guide. The NRC licensing staff does not intend or approve any imposition or backfit in connection with its issuance.

The NRC licensing staff has issued this draft guide to encourage public participation in its development. The NRC licensing staff will consider all public comments received in development of the final guidance document. In some cases, applicants or licensees may propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REGULATORY ANALYSIS

This regulatory guide does not contain a separate regulatory analysis. The regulatory analysis prepared for 10 CFR Part 20 (56 Fed. Reg. 23360 (May 21, 1991)) provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. The regulatory analysis is available electronically through the Rulemaking-RuleForum on the NRC's public Web site at <http://www.nrc.gov/about-nrc/regulatory/rulemaking.html>. A copy is available for inspection and copying (for a fee) at the NRC's Public Document Room.

REFERENCES⁴

1. 10 CFR Part 20, “Standards for Protection against Radiation,” U.S. Nuclear Regulatory Commission, Washington, DC.
2. Regulatory Guide 8.10, Revision 1, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,” U.S. Nuclear Regulatory Commission, Washington, DC.
3. NUREG-1556, Volume 9, Revision 2, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” January 2008.
4. NCRP Report No. 107, “Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel,” National Council on Radiation Protection and Measurements, Bethesda, MD, 1990.⁵
5. NCRP Report No. 116, “Limitation of Exposure to Ionizing Radiation,” National Council on Radiation Protection and Measurements, Bethesda, MD, 1993.
6. “The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980,” National Academy of Sciences—National Research Council, Washington, DC, 1980.
7. Report No. 5, “Background Material for the Development of Radiation Protection Standards,” Federal Radiation Council, Washington, DC, 1964.
8. Publication No. (FDA) 73-8029, “Health Physics in the Healing Arts,” *Proceedings of the Seventh Midyear Symposium of the Health Physics Society*, San Juan, Puerto Rico, Department of Health, Education and Welfare, December 1972.
9. “Industrial Ventilation: A Manual of Recommended Practice for Design,” American Conference of Governmental Industrial Hygienists, Committee on Industrial Ventilation, February 1, 2007.
10. 10 CFR Part 35, “Medical Use of Byproduct Material,” U.S. Nuclear Regulatory Commission, Washington, DC.
11. 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” U.S. Nuclear Regulatory Commission, Washington, DC.

⁴ Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters listed herein are available electronically through the Electronic Reading Room on the NRC’s public Web site at: <http://www.nrc.gov/reading-rm/doc-collections/>. Copies are also available for inspection or copying for a fee from the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR.Resource@nrc.gov.

⁵ Copies of the non-NRC documents included in these references may be obtained directly from the publishing organization.

12. NCRP Report No. 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," 2005.
13. Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions," U.S. Nuclear Regulatory Commission, Washington, DC.
14. NCRP Report No. 105, "Radiation Protection for Medical and Allied Health Personnel," National Council on Radiation Protection and Measurements, Bethesda, MD, 1989.
15. Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," U.S. Nuclear Regulatory Commission, Washington, DC.
16. NCRP Report No. 40, "Protection Against Radiation from Brachytherapy Sources," National Council on Radiation Protection and Measurements, Washington, DC, 1972.
17. NCRP Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," National Council on Radiation Protection and Measurements, Washington, DC, 1970.
18. Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," U.S. Nuclear Regulatory Commission, Washington, DC.

APPENDIX A

RADIATION SAFETY TASKS INVOLVED IN KEEPING OCCUPATIONAL EXPOSURES ALARA

A-1 Surveys of the following radioactivity areas:

- a. nuclear medicine
- b. radiation therapy
- c. oncology
- d. nuclear cardiology
- e. radioactive waste disposal and storage
- f. other research and clinical laboratories using radioactive materials
- g. pathology
- h. operating rooms

A-2. Survey of diagnostic and therapeutic machines and generators, including the following:

- a. teletherapy sources and machines
- b. positron emission tomography cameras
- c. gamma knife
- d. gamma irradiators

A-3. Personnel monitoring:

- a. review of personnel exposure data and reports
- b. review of reports required by regulations
- c. filing, collecting, and mailing personnel monitoring devices (including late and lost)
- d. special investigations of exposure and notifications to regulatory agencies where appropriate
- e. calibration of personnel monitoring dosimeters, including commercially supplied film badge service

A-4. Radiation safety instrument calibration and maintenance

Licensees should ensure that radiation safety instruments are properly calibrated and maintained using the following methods:

- a. calibration
- b. battery replacement and adjustment
- c. pocket chamber and thermoluminescence dosimeter calibration
- d. minor repair (electronic)
- e. instrument selection and distribution
- f. check-source calibration

A-5. Decontamination and waste disposal practices:

- a. collection and packaging
- b. surveying
- c. recording
- d. shipping arrangements

- e. placarding
- f. decontamination of surgical instruments, rooms, and laboratories

A-6. Leak-testing of radioactive sources using the following techniques:

- a. wiping
- b. counting
- c. calculations
- d. recording
- e. counter calibration

A-7. Evaluation of internal exposure by the following means:

- a. collection of samples, including air samples, where applicable
- b. radiochemical or scintillation bioassay analysis
- c. counter calibration
- d. in vivo counting
- e. computer analysis of results

A-8. Special surveys of patients and rooms for implant, intracavitary, or unsealed radiopharmaceutical therapy, including the following:

- a. Room preparation and protective covering, as follows:
 - (1) labeling (bed, chart, door),
 - (2) nursing staff and housekeeping staff briefings
 - (3) background surveys
 - (4) source insertion and afterloading surveys
 - (5) surveys of patients in operating and recovery rooms
 - (6) placing of lead barriers
 - (7) recovery of sources and wastes
 - (8) survey of room cleanup and decontamination
 - (9) instructions to patient and to family of patient, as appropriate
 - (10) measurement of radiation from cadavers and briefings to pathology staff and funeral directors, where appropriate
- b. Administration and consultation, including the following:
 - (1) approval of facilities, equipment, and procedures used in areas where radioactive materials are handled
 - (2) preparation of license applications and amendments
 - (3) preparation of hazard evaluation reports for licensing
 - (4) programming of routine required surveys
 - (5) supervision of routine radiation safety operations
 - (6) revisions to radiation safety manual
 - (7) periodic radiation safety instruction for hospital staff and administration
 - (8) training of residents and medical staff
 - (9) conferences with physicians and other safety staff
 - (10) coordination of radiation safety committee meetings and minutes
 - (11) inspections and discussions with Government regulatory agency representatives
 - (12) professional meetings
 - (13) selection and ordering of equipment and supplies
 - (14) planning and budgeting

- (15) facility and shield design and meetings with architects
- (16) record maintenance and related computer programming
- (17) planning prompt effective response to incidents and emergencies involving radiation
- (18) providing instruction or direction for outside persons (e.g., firemen) who would respond to an emergency situation involving or potentially involving radiation
- (19) preparation of radiation safety office reports to hospital administration