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REGULATORY GUIDE 8.18

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

A. INTRODUCTION

Paragraph 20.1(c) of 10 CFR Part 20, "Standards for Protection Against Radiation," states that licensees should make every reasonable effort to keep radiation exposures, as well as releases of radioactive material to unrestricted areas, as far below the limits specified in that part as reasonably achievable. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," sets forth the philosophy and general management policies and programs that licensees should follow to achieve this objective of maintaining radiation exposures to employees "as low as is reasonably achievable" (ALARA). Regulatory Guide 10.8, "Guide for the Reparation of Applications for Medical Programs," includes information on an acceptable management program for keeping exposures ALARA, as well as specific examples of radiation safety programs and practices acceptable to the NRC licensing staff. These examples supplement the general outline of principles and practices contained in this guide and in an associated report, NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable" (Ref. 1).

This guide is directed specifically toward medical licensees and recommends methods acceptable to the NRC staff for maintaining occupational exposures ALARA in medical institutions. NUREG-0267 is a compendium of good practices and helpful information derived from the experience of the radiological and health physics professions and is not to be construed in any way as additional regulatory requirements of the Nuclear Regulatory Commission. In fact, many of the suggestions made in the report are based on accepted health protection practices not specifically addressed in NRC regulations. NUREG-0267 also provides a reference list that may be used for background information on radiation protection science and philosophy, radiation protection standards, and planning and design information useful for radiation protection programs in medical institutions. Sections of the report are keyed to the section numbers of this guide for the reader's convenience.

This guide is generally directed toward occupational health protection. However, in a medical institution, certain persons other than employees are exposed to radiation from NRC-licensed radioactive material. These persons include visitors as well as patients other than those being treated with radioactive material. Protection of these individuals is also addressed in this guide. 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.

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. Further details on this subject are given in Regulatory Guide 10.8. In addition, this guide and the associated report (Ref. 1) deal only with radioactive materials subject to licensing by the Nuclear Regulatory Commission. 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 NRC.

B. DISCUSSION

The principle of maintaining occupational radiation exposures ALARA is an extension of an original recommendation of the National Committee on Radiation Protection (now the National Council on Radiation Protection and Measurements (NCRP)) in its 1949 report (published in 1954 as Report No. 17 (Ref. 2)). In this early report, the NCRP introduced the philosophy of assuming that any radiation exposure may carry some risk and recommended that

radiation exposure be kept at a level "as low as is practicable" (currently referred to as "ALARA") below the recommended maximum permissible dose equivalent. Similar recommendations to keep exposures ALARA have been included in NCRP reports (Ref. 3). as well as in recommendations of the National Academy of Sciences - National Research Council (Ref. 4). the Federal Radiation Council (Ref. 5). and other independent scientific and professional organizations (Refs. 6-8). The basic radiation protection philosophy of these recommendations has been incorporated in regulations and guides of the Nuclear Regulatory Commission.

This guide and the associated report provide a supplement for medical institutions to the basic philosophy of Regulatory Guide 8.10, which lists for all specific licensees the types of management commitments and radiation protection programs that would help to achieve the objective of maintaining occupational exposures ALARA. This guide, Regulatory Guide 8.10, and Regulatory Guide 10.8 will be used as a basis for evaluating license applications and radiation safety programs of NRC-Licensed medical institutions, unless the licensee proposes an alternative method of complying with specified portions of the Commission's regulations.

C. REGULATORY POSITION

A licensee's radiation safety program will be considered in compliance with the 10 CFR Part 20 ALARA requirement and in accord with the ALARA philosophy if the major principles and practices identified below are adopted and implemented as part of the institution's policies and programs.

1. MANAGEMENT PHILOSOPHY AND ORGANIZATION

The radiation protection responsibility of licensee management[1] 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. This responsibility should be carried out by means of:

a. Information and policy statements[2] 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[3] (RSO) to enforce regulations and administrative policies regarding radiation safety; and

f. Administrative direction to ensure that any new hospital facilities or equipment may may affect radiation protection will be planned or designed in consultation with the RSO.

A model program implementing this management philosophy is presented in Appendix O to Regulatory Guide 10.8.

2. RADIATION SAFETY OFFICE FUNCTIONS

The term "Radiation Safety Office" is used here only to indicate that some entity should be established to direct and coordinate administrative aspects of the radiation safety program. The extent of this program should be commensurate with potential radiation protection problems.

2.1 Staffing and Organizational Requirements

A sample outline of the various tasks of a typical Radiation Safety Office is presented in the appendix. The time and effort required for each of the listed tasks vary widely with the size of the medical institution and the nature and extent of radioactive material usage. Management (1) should review the staffing requirements for each of these tasks and provide the necessary personnel to establish and carry out radiation safety program requirements and (2) should evaluate them on an annual basis.

2.2 Radiation Safety Personnel Qualifications

Management should select radiation safety personnel appropriate to the radiation safety program after careful review of the nature of the program and the extent of effort and expertise required to carry out the tasks noted in the appendix.

2.3 Space and Equipment

The Radiation Safety Office 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 in radiation fields radiation safety and survey equipment (and check the calibrations of other hospital radiation sources if radiation safety and medical physics functions are combined).

c. Stock radiation safety supplies for labeling. surveying. decontamination, and personnel protection and monitoring.

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

[2] Policy statements should include a detailed set of radiation exposure investigation levels as presented in Regulatory Guide 10.8, Appendix O.

[3] The title "Radiation Safety Officer." used by many medical licensees, is used in this guide to designate the qualified individual who is responsible for carrying out the institution's radiation safety program and who is listed as the Radiation Safety Officer on the institution's "Application for Materials License-Medical." Form NRC-313M (see Exhibit A of Regulatory Guide 10.8).

d. Conduct radiometric measurement of smear tests from contamination surveys and source leak tests.

e. Store radioactive wastes 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.

j. Instruct and brief personnel as required by 10 CFR Part 19.

In addition, the tasks listed in the appendix should be examined 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. A list of the types of tasks carried out by a Radiation Safety Office in order to provide good radiation safety surveillance and meet regulatory and license conditions is presented in the appendix.

For medical institutions in which a full- or part-time professional health physics staff is available, the planning of radiation safety procedures by this staff should be carried out in coordination with management to ensure optimum efficiency and exposures that are ALARA. This coordination should extend to the implementation of the ongoing radiation safety 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 have responsibility for carrying out the radiation safety program, including the tasks listed in the appendix. This responsibility should be formally delegated in writing by responsible management and should include authority for the RSO to communicate directly with the level of management that can take corrective action when needed to enforce rules and procedures pertaining to the institution's radiation safety program. Administrative authority to suspend certain activities temporarily should also be provided to the RSO when needed in emergencies to avoid immediate danger to life or health. However, the authority of the RSO to suspend activities should be exercised 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

Part 35 requires that a radiation safety committee be appointed to supervise the institution's radiation safety program. Typical functions and responsibilities of the committee are given in Regulatory Guide 10.8. The RSO, who is required to be a member of the committee, may either serve as chairman or assist the chairman in preparing for and conducting meetings and maintaining committee records.

Meetings of the committee should be held at least quarterly. Every member of the committee should be invited to each meeting.

The purposes of the meetings should include:

a. Discussing any radiation safety problems requiring a general solution;

b. Determining whether current procedures are maintaining exposures ALARA;

c. Considering new proposals for the use of radioisotopes and evaluating the safety of those uses and the qualifications of the users; and

d. Auditing the radiation safety program to ensure that it meets all the goals presented in Sections C.2.1 through C.2.5 and all pertinent regulations.

All radiation safety committee meetings should be documented by a record of minutes approved by committee members and filed as part of the radiation safety record system within 60 days following each meeting.

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. Major aspects of planning and design that should be considered art discussed below.

3.1.1 Space Layout

Facility layout should be planned to maintain employee exposures ALARA while at the same time ensuring that exposure is not thereby increased to other persons in restricted or unrestricted areas. Considerations should include:

a. The need for access to radiation or radioactive materials areas by medical staff, employees, patients,

visitors, and others, while at the same time providing optimum separation between workers' "sit down" areas of frequent occupancy and radiation sources or contamination;

b. Ventilation requirements, including whether there is a need 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 materials, 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 from radioactive materials currently housed in the institution, as well as radioactive materials that might he introduced into the area by future medical care requirements. Section 3.2 contains a discussion of permanent shielding for radiation therapy facilities. Teletherapy installations always require permanent shielding. Occupancy and use factors should be taken into account as recommended in NCRP handbooks, but such factors should be chosen with the principle of ALARA in mind. The NRC licensing staff should also be consulted during the planning and design stage to obtain licensing guidance on acceptable use and occupancy factors in shielding design.

3.1.3 Caution Signs and Interlocks

Access to certain areas should be controlled or restricted by the use of caution signs, signals. and interlocks as required by § 20.203 of 10 CFR Part 20.

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 § 20.106 of 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 cxhausr air.

c. Rooms in which radioactive gases or aerosols may be released should be maintained at negative pressure with respect to adjacent rooms by appropriate exhaust ventilation as in a.

3.1.5. Fire Control

The need for personnel exit and for closing the facility to prevent the spread of radioactive materials should be considered for areas where laboratory procedures could result in dispersal of radioactive materials in the event of a fire. Provision should be made for local showers and fire extinguishers, where necessary. For the vast majority of medical institutions, emergency procedures and training should include immediate fire contro1 as a priority item.

3.1.6 Special Laboratory Design Features

Consideration should he given to 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:

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, there is no need in hospitals for any procedures that would use quantities of radioactive material sufficiently radiotoxic that potential air concentrations may reach levels approaching the concentration values given in 10 CFR Part 20. Ventilation and contamination control should be designed to maintain air concentrations and contamination levels as low as reasonably achievable. Guidance for the use of Xe-133 in nuclear medicine is available from the Office of Nuclear Material Safety and Safeguards. U.S. Nuclear Regulatory Commission, or in Regulatory Guide 10.8.

3.1.7 Storage, Source Control, and Inventory

In institutions ordering a number and variety of sources of radioactive material, 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 will not cause unnecessary exposure to personnel while awaiting survey by the Radiation Safety Office or the user. A written procedure for receipt, survey, and storage of deliveries should be provided to anyone responsible for the receipt or delivery of radioactive material.

b. When packages may expose couriers to measurable radiation, make available a cart or carrier that will maintain 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 the access to them away from areas where radioactive materials are used so as 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

General features applicable for equipment that will be used for handling or containing radioactive materials are as follows:

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 fails.

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 § 20.203 of 10 CFR Part 20 and recommended standards of the medical physics profession.

3.2 Radiation Therapy Equipment and Facilities

Specific NRC licensing guides are provided 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 teletherapy treatment rooms, the medical institution should consult NCRP Handbook 34 or 49 (Ref. 9) 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 teletherapy 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 also provide added safety in the event the caution lights fail.

(3) Establish a procedure for checking 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 teletherapy treatment rooms to provide a warning to the therapy 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 teletherapy room and provide audio communication with the outside control panel.

b. Consider leakage through the teletherapy head with the source in the “on” position when designing shielding. Data provided by the manufacturer of the teletherapy machine 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 as as to maintain exposures 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. In no case should it be necessary to design for instantaneous rates greater than 10 mrad/week in restricted or unrestricted areas adjacent to teletherapy treatment rooms.

3.3 Nuclear Medicine Facilities

To ensure that exposures are ALARA, 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 one meter and preferably two 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 cause radiation levels on the order of 10 mR/h or more near the edge of the stretcher. They may need to be segregated from the general waiting area to reduce radiation exposure to receptionists and persons passing through the area such as orderlies 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 dosage 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 (Ref. 10) 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 will 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 action levels of Regulatory Guide 8.23, "Radiation Safety Surveys at Medical Institutions."

j. Provide finger badges or dosimeters as well as body dosimeters for monitoring occupational exposure of personnel involved in dose preparation and 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 given for other facilities. Special considerations include:

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.

h. Suitable easily cleaned drip trays for carrying out manipulations of radioactive materials where spillage may occur.

c. Protective clothing, including rubber or plastic dlsposable gloves. for persons working with radioactive materials. (Disposable gloves should be changed frequently.) Equipment should be provided 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 may exceed 10^{-5} μCi/cm^{2}.

Additional information on carrying out in vivo experiments with animals is given in Reference 11 and NUREG-0267.

4. SAFE WORK PRACTICES AND PROCEDURES

4.1 General Principles

The safe work practices and procedures contained in this section for handling radioactive materials in medical institutions are recommended as a minimum. Additional information is contained in NUREG-0267, Regulatory Guide 8.23, and Regulatory Guide 10.8.

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 then may inadvertently expose unsuspecting persons or may be subject to improper usage by unauthorized persons. The following procedures should be taken to guard against these problems:

a. Periodic inventories should be made of all radioactive sources. and a continuous record of the locations of all sources and their usage should be maintained. The inventory should be combined with an inspection to ensure proper labeling (see § 20.203 of 10 CFR Part 20). Paragraph 35.14 (b)(5)(v) of 10 CFR Part 35 requires inventories of sealed sources in Group VI and calibration sources to be conducted at least quarterly. Inventory procedures should also provide for the RSO to he alerted if all sources are not returned within a specified time in order to avoid sending patients home with brachytherapy sources; still in place (see Reference 12).

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). Special shielded vaults or containers Should be provided in the storage area for sealed sources.

c. Authorized persons should be required to sign for the removal and return of each source. The source log Should be checked regularly by the Radiation Safety Office Staff.

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 will be well below (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

Radioactive materials in unsealed form or undergoing chemical or physical processing Should be handled only in properly designed facilities (as described in Section C-3.3 above) 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 cause rupture of the Source. If necessary to ensure that exposures are ALARA, preliminary tests of procedures should be carried out 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 there is a possibility that planned procedure will fail to contain the radioactive material.

Protective clothing appropriate to the type and quantity of radioactive material being processed should be worn whenever escape of radioactive contamination is considered possible.

4.1.4 Proper Work Habits

In general, all personnel handling radioactive materials Should be trained 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:

8. Except for very-low-level sources such as flood sources or other sources designed for manual use in checking instrumentation, scaled or unsealed sources should not be touched or held with the fingers, but only with tongs or tweezers appropriate to the operation.

b. Finger dosimeters[4] as well as body dosimeters should be worn by 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. 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 mrem per hour at 1 cm.

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 also 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., 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

The independent radiation surveys, inspections, inventories, and smear tests to be carried out by the Radiation Safety Office staff were discussed in Section C.2. In addition,

[4] 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 be absolutely avoided.

each user of radioactive materials should survey radiation and radioactivity levels within his or her own operations daily to help maintain exposures ALARA. A simple logbook of readings or general levels of radiation or contamination may be helpful if maintained by the user to indicate any changes in radiation or radioactivity levels that show a need for changes in procedures or equipment to meet ALARA radiation exposure objectives. Regulatory Guide 8.23 and Regulatory Guide 10.8 give further guidance on radiation surveys in medical institutions (and nuclear pharmacies).

In hospital situations in which the 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

Employees should be made aware of the ALARA provisons of § 20.1 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," whenever there is a possibility that pregnant women may be exposed to radiation.

Each employee should be acquainted with the 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). Copies of these procedures, licenses, and related correspondence should he made available for review by employees as part of their orientation to radiation safety requirements. Professional education and development to ensure that staff members are up to date on radiation safety methods should also be supported.

Regulatory Guide 10.8 should be consulted for a list of topics important in training radiation workers.

4.2 Radiation Therapy

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

a. Teletherapy - the treatment of patients with high-energy beams from shielded irradiators 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 Teletherapy

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

a. With the aid of the maintenance and operating manuals provided by the manufacturer of the teletherapy unit, procedures should be established for routine maintenance and checkout of safety-related features of the teletherapy unit.

b. A daily morning checkout procedure should he 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 teletherapy unit for calibration or maintenance procedures, care should be taken to follow written instructions and use installed safety devices to ensure that no personnel except the patient to be exposed are in the teletherapy 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 consistent with vigilance of the console and 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 teletherapy 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

Detailed recommendations for reducing radiation exposures in brachytherapy are given in NCRP Report Number 40 (Ref. 12). and additional recommendations

pertinent to brachytherapy, as well as radiopharmaceutical therapy, are containedin NCRP Report Number 37 (Ref. 13). Some of the most important practices for maintaining exposures ALARA are:

a. Modern 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 about 30 centimeters or more from these sources.

g. Finger dosimeters as well as body dosimeters should be worn by personnel 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/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 avoid inadvertent exposures due to lost or misplaced sources.

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 maintained within shielded wells in constant geometry so they can be used for a rapid and safe check of ion chamber operation before the treatment of each patient.

j. Job-time/exposure studies should be carried out by the radiation protection staff 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. Transport of a patient containing radioactive material to areas outside the operating room and to his room should be directly supervised by the Radiation Safety Office staff or the radiation therapy staff. Also, transport of afterloading sources and supplies for insertion of applicators, lead bedside shields for the nurses, and any other supplies and equipment required for expediting an efficient afterloading procedure should be checked and supervised by the Radiation Safety Office staff or the radiation therapy staff. Radiation surveys should also be carried out on a sample basis and recorded to maintain an awareness of the exposures resulting from these procedures.

1. Nursing personnel should be provided with personnel dosimeters (when required by 10 CFR Part 20) and should be trained in their use.

m. Patients should be surveyed by the radiation safety staff 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 inadvertant loss of sources. Also. 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 Radiopharmacautical Therapy (Nuclear Medicine Therapy with Unsealed Radioactive Materials)

Where feasible and in the best interests of the patient, 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 procedure often dictate that the radiation safety staff should 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. Precalibrated contained sources (e.g., capsules) should be used whenever possible. When therapy is carried out with potentially volatile radioiodine compounds, Regulatory Guide 8.20, "Applications of Bioassay for I-125 and l-131." should be consulted to determine whether employees who have participated in the radioiodine administration should be sampled for bioassay.

After treatment, all articles should be surveyed for possible contamination before they are released from the room. Contaminated articles must be released to the Radiation Safety Officer for decay or disposal. Also, 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 above, as well as principles and practices presented in NCRP Report 37 (Ref. 13). The use of these procedures should help 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. Additional guidance is available from the Material Licensing Branch, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, and in Appendix K to Regulatory Guide 10.8.

4.3 Diagnostic Nuclear Medicine

Many of the principles of radiation protection practice in diagnostic nuclear medicine were discussed in previous sections on recommendations for nuclear medicine facilities and equipment (Section C.3.3) and general principles of safe work practices in handling radioactive materials (Section C.4.1). Additional recommendations are:

a. Use syringe shields for administering all injections of radioactive material; only compromise this procedure on rare occasions when absolutely necessary. Also, use gloves to protect against possible large doses from 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 ALARA. (See Regulatory Guide 10.8 for Procedures.)

d. Shield chamber calibrators, where possible, to maintain employee exposures ALARA while nuclear medicine doses are being calibrated. Recalibrate refitted chambers as necessary.

e. Use fume hoods (Ref. 10) 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 Tc-99m or other low-energy gamma emitters (for example. when there is a room full of patients awaiting brain scans) if the screens do not interfere with the diagnostic tests. Portable screens of Pb only 2 mm thick will reduce Tc-99m gamma-ray exposure rates to less than 0.5 percent of those without the screens.

h. In lung perfusion or ventilation studies with xenon-133, use additional lead shielding 1.6 mm thick (or appropriate thicknesses for other radioactive gases or aerosols) around the absorber canister. oxygen bag. and waste receptacle to reduce occupational exposures when frequent procedures are carried out. Also 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 will warn of any leakage of Xe-133.

i. In addition to regular nursing staff who receive personnel monitoring, private duty nurses and others who may come into close contact with patients who have been administered radiopharmaceuticals for diagnostic or therapeutic purposes should be carefully monitored for exposure and contamination and should receive 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 given in Section C.4.1. 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 only microcurie or submicrocurie quantities handled and processed by individual personnel 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 SAFETY PROGRAM

Ultimate responsibility for the establishment and continuation of an adequate radiation safety program in a medical institution has been placed with the governing body of the hospital. The administrator reporting to this governing body should be sufficiently informed at all times to be sure that all regulations are faithfully adhered to and that the use and safe handling of radioisotopes are properly carried out to maintain exposure ALARA.

The hospital administration should carry out an annual audit of the radiation safety 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 an annual 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-0267 contains an example of a checklist of items that may be inspected by the administration during this annual audit. A report containing the results of the audit should be maintained by the Radiation Safety Office for possible use in expediting any inspections by regulatoy or accrediting agencies, as well as for reference in further auditing and improving the ALARA program.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staffs plans for using this regulatory guide. This guide reflects practices currently acceptable to the NRC staff. Except in those cases in which the applicant or licensee proposes alternative practices or methods for complying with specified portions of the Commission's regulations, the practices or methods described herein together with those in other applicable regulatory guides are being and will continue to be used as a basis for the evaluation of applications for specific materials licenses for medical institutions.

APPENDIX

RADIATION SAFETY TASKS INVOLVED IN KEEPING OCCUPATIONAL EXPOSURES ALARA

1. Surveys of the following radioactivity areas:

a. Nuclear medicine
b. Radiation therapy
c. Oncology
d. Pathlology
c. Cardiology
f. Pediatrics
g. Radioactlve waste disposal and storage
h. Other research and clinical laboratories using radioactive materials

2. Surveys of diagnostic and therapeutic machines and generators, including:

a. Teletherapy sources and machines
b. Computerized axial tomography scanners
c. Interlock and safety checks
d. Calibrations
e. Fluoroscopes
f. Radiographic x-ray

3. Personnel monitoring:

a. Review of personnel exposure data and reports
b. Preparation of reports required by regulations
c. Filing, collection, and mailing of personnel monitoring devices (including late and lost)
d. Specific investigations of exposure and notifications lo regulatory agencies where appropriate
e. Calibration of personnel monitoring dosimeters, including commercially supplied film badge service

4. Radiation safety instrument calibration and maintenance:

a. Calibration
b. Battery replacement and adjustment
c. Pocket chamber and TLD calibration
d. Minor repair (electronics)
e. Instrument selection and distribution
f. Check-source calibration

5. Decontamination and waste disposal:

a. Collection and packaging
b. Surveying
c. Recording
d. Shipping arrangements
e. Placarding
f. Decontamination of surgical instruments, rooms, and laboratories

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

a. Wiping
b. Counting
c. Calculations
d. Recording
e. Counter calibration

7. Evaluation of internal exposure by means of:

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

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

a. Room preparation and protective covering
h. Labeling (bed, chart, door)
c. Nursing staff and housekeeping staff briefings
d. Background surveys
c. Source insertion and afterloading surveys
f. Surveys of patients in operating room and recovery room
g. Placing of lead barriers
h. Recovery of sources and wastes
i. Survey of room cleanup and decontamination
j. Instructions to patient and to family of patient, as appropriate
k. Measurement of radiation from cadavers, briefings to pathology staff and funeral directors, where appropriate

9. Administration and consultation, including:

a. Approval of facilities, equipment, and procedures used in areas where radioactive materials are handled
b. Preparation of license applications and amendments
c. Preparation of hazard evaluation reports for licensing
d. Programming of routine required surveys
e. Supervision of routine radiation safety operations
f. Revisions to radiation safety manual
g. Periodic radiation safety instruction for hospital staff and administration
h. Training of residents and medical staff
i. Conferences with physicians and other safety staff

j. Coordination of Radiation Safety Committee meetings and minutes
k. Inspections and discussions with government regulatory agency representatives
l. Professional meetings
m. Selection and ordering of equipment and supplies
n. Planning and budgeting
o. Facility and shield design and meetings with architects
p. Record maintenance and related computer programming
q. Planning prompt effective response to incidents and emergencies involving radiation
r. Providing instruction or direction for outside persons (for example, firemen) who would respond to an emergency situation involving or potentially involving radiation
s. Reparation of Radiation Safety Office reports to hospital administration.

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