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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

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).

This guide is directed specifically toward medical licensees and recommends methods acceptable to the NRC staff for maintaining occupational exposures ALARA in medical institutions. An associated report, NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable" (Ref. 1), provides more detailed information for controlling exposures in these institutions. It also provides a bibliography of 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 NUREG 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.

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. 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 and non-NRC licensed materials.

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 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 up to the present time (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 NUREG report provide a supplement for medical institutions of 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. Both this guide and Regulatory Guide 8.10 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

Methods or procedures given in this guide should be incorporated in appropriate sections of a license application according to the format of licensing guides provided to the applicant by the licensing staff of the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The considerations of this guide are intended to assist the applicants in preparing license applications that are acceptable to the NRC licensing staff as well as in accord with the philosophy of ALARA. Unique features not addressed here will require specific review by the NRC licensing staff.

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 following major principles and practices are adopted as part of the institution's policies and programs.

1. MANAGEMENT PHILOSOPHY AND ORGANIZATION

The radiation protection responsibility of licensee management* at a medical institution is to maintain exposures ALARA for employees, visitors, students, and patients not under medical supervision for the administration of radiation or radioactive materials for therapeutic or diagnostic purposes.

This responsibility should be carried out by means of

a. Information and policy statements 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 hospital staff and employees receive appropriate briefings and training in radiation safety, including ALARA concepts;

e. Delegation of sufficient authority to the Radiation Safety Officer ** (RSO) 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 will be planned or designed in consultation with the RSO.

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 Organization 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 hospital 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 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

The Radiation Safety Office should have adequate space to carry out the following functions:

a. Calibrate, maintain, and repair radiation safety equipment.

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

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

d. Store radioactive wastes and sources not in use.

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

** The term "Radiation Safety Officer" is used by many licensees and will be 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 Protection Officer on the institution's "Application for Byproduct Material License," Form AEC-313.

e. Calibrate radiation safety and survey equipment and check the calibrations of other hospital radiation sources.

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 the 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 perform all radiation jobs with less 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 where 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 will also provide for a smooth transition between program planning and supervision of the ongoing radiation safety program by the professional health physicist 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 delegated in the Medical Staff Bylaws 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 is consistent with non-interference with life-saving medical procedures that warrant an overriding priority and that cannot await alleviation of the radiation safety problems.

2.6 Medical Isotopes Committee

The Chairman of the Medical Isotopes Committee (required by §35.11 of 10 CFR Part 35) should prepare for and conduct Medical Isotopes Committee meetings. The RSO should be a member of the committee and may assist the Chairman in conducting meetings and maintaining committee records.

Any institution required to appoint such a committee as a condition of its license should call meetings at least quarterly. Every member of the Medical Isotopes Committee should be invited.

The purposes of the meetings should include the following:

a. To discuss any radiation safety problems requiring a general solution;

b. To determine whether current procedures are maintaining exposures ALARA; and

c. To audit the radiation safety program to ensure that it meets all the goals and requirements presented in Sections C.2.1 through C.2.5 above.

All Medical Isotopes 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 hospital 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 are 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 [illegible]iation or radioactive materials areas by medical [illegible]employees, patients, visitors, and others;

b. Ventilation requiremen[illegible]luding the need to maintain lower pressures in [illegible] in which radioactive materials are likely to be [illegible]or volatilized;

c. Floor loading in case [illegible]avily shielded sources;

d. Receipt and shipment of [illegible]tive materials; and

c. Ingress and egress of some radiation therapy and nuclear medicine outpatients, including parking.

3.1.2 Shielding

Permanent shielding may be needed in some cases for walls, floors, and ceilings to provide protection against radioactive materials currently housed in the institution, as well as radioactive materials that might be introduced into the area by future medical care requirements. 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 10 CFR Part 20, § 20.203.

3.1.4 Ventilation

As far as possible:

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 are, on its way to the stack on the roof.

c. Locate exhaust vents so as to provide adequate meteorological diffusion and dilution to meet 10 CFR Part 20, § 20.106 requirements for effluents to unrestricted areas, as well as ALARA exposure considerations for the public.

d. Where appropriate, include specific types of filters or air cleaners for the exhaust air.

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 control as a priority item.

3.1.6 Special Laboratory Design Features

Consideration should be 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. Special sinks for rinsing and disposing of minor quantities of radioactive wastes (within 10 CFR Part 20 limits); and

c. Special plumbing and waste storage provisions.

In general, there is no justification in hospitals for any procedures using quantities of radioactive material sufficiently radiotoxic that potential air concentrations may reach levels near or at 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 and requirements for the use of Xe-133 in nuclear medicine are available from the Office of Nuclear Material and Safety Safeguards, U.S. Nuclear Regulatory Commission.

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 radiation source storage areas for day, night, and weekend deliveries so that sources 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. Make available a cart or carrier that will maintain an adequate distance between the courier and the radioactive material package.

c. Provide space in the receiving area for an initial survey and smear test of each package to avoid transporting a contaminated package through unrestricted areas of the hospital.

d. Locate shipping and receiving areas 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, containing, or contacting radioactive materials are as follows:

a. Surfaces should be easily cleaned and decontaminated 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, 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 10 CFR Part 20, §20.203 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 and scattered 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.

(2) Connect this interlock in series with a green light above the door to indicate its proper connection when the door is closed.

(3) Provide independent back-up 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.

(4) Establish a procedure for checking whether everyone except the patient is out of the area before the door is closed and the beam is turned on.

(5) Install independent caution lights 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.

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 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 as to maintain exposures ALARA. Reduction of occupational exposures to radiation therapy personnel should be achieved by design provisions, procedures, or planning beam orientations that would increase exposure to persons in unrestricted areas.

3.3 Nuclear Medicine Facilities

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

a. Allow sufficient space for personnel operating nuclear medicine equipment to be at least two meters from any patient undergoing scanning whenever the condition of the patient permits.

b. Allow adequate space for stretcher patients awaiting scans, as well as outpatients. Dosed patients awaiting scans may cause radiation levels on the order of 10m R/hr or more. 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 aids.

c. Provide for easy access to physicians' offices and other occupied areas to needed radiopharmaceuticals, but allow enough distance (several meters is usually sufficient) so that exposures from stored radiopharmaceuticals and radioactive wastes will be minimized.

d. Provide adequate shielding for stored radiopharmaceuticals and partial shielding for employees preparing dosage for patients.

e. Supply an adequate number of syringe shields and bottle shields (as well as appropriate tongs or forceps) near the place of dosage preparation.

f. Provide additional exhaust ventilation in the laboratory near the radiopharmaceutical storage area to protect against any 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 and rate meter immediately outside 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 by other clothing.

j. Provide finger badges or dosimeters as well as body badges for monitoring occupational exposure of personnel.

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.

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

c. Protective clothing, including rubber or plastic disposable gloves, for persons working with radioactive materials. (Disposable gloves should be changed frequently.) Equipment should be provided for monitoring clothing before laundering. Potentially radioactive laundry and radioactive wastes should be turned over to the Radiation Safety Office for further disposition.

Additional recommendations for carrying out *in vivo* experiments with animals are given in Reference 10.

4. SAFE WORK PRACTICES AND PROCEDURES

4.1 General Principles

The following safe work practices and procedures for handling radioactive materials in medical institutions are recommended as a minimum. Additional detail is given in NUREG–0267.

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

a. A frequent inventory should be made of all radioactive sources, and a continuous record of all sources and their usage should be maintained. The inventory should be combined with an inspection to ensure proper labeling (see 10 CFR Part 20, § 20.203). Section 35.14 of 10 CFR Part 35 requires inventories to be conducted at least quarterly. Inventory procedures should also provide that the RSO will be alerted if all sources are not returned within a specified time, in order to avoid sending patients home with brachytherapy sources still in place.

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 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.

4.1.2 Shielding

All radioactive material not in use should be completely shielded so that exposure rates in any area that may be occupied by personnel will be well below the levels for unrestricted areas of 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 where inhalation or ingestion of the material by personnel is possible. Where necessary to ensure that exposures are ALARA, preliminary tests of procedures should be carried out with simulated nonradioactive 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 procedures will fail to contain the radioactive material.

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

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:

a. Sealed or unsealed sources should not be touched or held with the fingers, but only with tongs or tweezers appropriate to the operation.

b. Finger badges as well as body badges 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 badges are not needed for personnel handling only the types of sources used for tracer level *in vitro* studies, where dose rates are less than 0.1 mrem per hour at 1 cm.

c. When working with unencapsulated radioactive materials, personnel should wear rubber or plastic gloves and other special clothing.

d. Care should be taken to avoid needless contamination of objects such as light switches, taps, or door knobs.

e. Radioactive solutions should never be pipetted by mouth.

f. Eating, smoking, drinking, and application of cosmetics should be prohibited in laboratories where radioactive materials are handled.

g. Special precautions should be taken to avoid the possibility of small amounts of radioactive materials entering into cuts.

h. The use of containers or glassware with sharp edges should be avoided. Care should be taken in working with contaminated animals to avoid bites or scratches.

i. Food and drink should not be stored in the same place (e.g., refrigerator) with radioactive materials.

j. Radioactive materials should be secured (e.g., placed in a locked room) when personnel are not present.

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 earlier in Section C.2. In addition, 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 daily readings should be 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.

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

4.1.6 Training

Employees should be made aware of the ALARA provisions of 10 CFR Part 20, § 20.1 as well as those of Regulatory Guide 8.10. Employees should be instructed in the philosophy and provisions of Regulatory Guide 8.13, "Instructions 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 be made available to the employees as part of their orientation to radiation safety requirements.

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.

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 be posted and established 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, and timer operation and interlock function.

c. A general safety check, including a spot or point calibration check and check on beam alignment and confining devices, should be made and recorded at least monthly. All records of the monthly calibration 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 or phantom to be exposed is in the teletherapy treatment room during the "Beam On" condition.

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. All persons not required to remain near the console should remain or work in areas of lower radiation background intensity while the teletherapy unit is in operation.

f. Emergency procedures established as required by NRC 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. 11), and additional recommendations pertinent to brachytherapy, as well as radiopharmaceutical therapy, are contained in NCRP Report Number 37 (Ref. 12). Some of the most important practices for maintaining exposures ALARA are as follows:

a. Modern after-loading devices should be used wherever medically acceptable.

b. Jigs should be prepared and tested for ease in loading sources into after-loading devices in the patient's room.

c. Jigs for loading the after-loaders 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 after-loaders for as much of the duration of the procedure as possible.

d. When after-loading sleeves or ovoids are loaded, they should be placed in adequately shielded carts for sterilization and for transport to the patient's room when the physician is ready to insert the after-loaders. These carts should be properly tagged and should at all times be under the direct supervision of the radiation physicist or radiation safety staff.

e. Similar protection should be provided for use in threading radioactive needles for implant therapy.

f. While manipulating sources, loading the after-loaders, and threading needles, personnel should be provided with tongs and surgical clamps to maintain the distance of the fingers preferably 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 type ionization chamber in the storage-loading area will indicate when radiation sources are outside their shields and help avoid inadvertent exposure 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 and exposure of sources.

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. Time and 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 after-loading 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 physicist. Also, transport of after-loading sources and supplies for insertion of applicators, lead bedside shields for the nurses, and any other supplies and equipment required for expediting an efficient after-loading procedure should be checked and supervised by the Radiation Safety 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.

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

m. Patients should be surveyed in their rooms by the radiation safety staff after removal of brachytherapy sources and before discharge as a final step to check against leakage of contamination from brachytherapy sources or inadvertent loss of these sources in the patient's room.

4.2.3 Radiopharmaceutical 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 alleviate 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, 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. Precalibrated contained sources (e.g., capsules) should be used whenever possible.

After treatment, surveys of all articles should be made before release from the room to the general public. Contaminated articles must be released to the Radiation Protection 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. 12). 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 also available from the Radioisotopes Licensing Branch, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission.

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. Place radionuclide generators in an area separate from the other nuclear medicine operations, with adequate ventilation and additional shielding as necessary to reduce external as well as internal exposure to personnel during elution.

b. Use separate shielded bottles for checking the assay of eluates in the nuclear medicine dose calibrator, or other suitable assay system, to allow calibration procedures with a smaller quantity of radioactive material.

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

d. Use fume hoods and good contamination control principles when preparing dosages of radiopharmaceuticals that have potential volatility.

e. Keep shielded radioactive waste cans for used syringes and other radioactive wastes at an adequate distance from the laboratory areas most frequently occupied by personnel, to the extent possible.

f. When they do not interfere with the diagnostic tests, use protective lead screens to protect employees and other patients during procedures using Tc-99m or other low-energy gamma emitters. Portable screens of only 2 mm Pb thickness will reduce Tc-99m gamma-ray exposure rates to less than 0.5 percent.

g. In lung perfusion or ventilation studies with xenon-133 or other radioactive gases or aerosols, use additional lead shielding of 1.6 mm thickness around the absorber cannister, oxygen bag, and waste receptacle to reduce occupational exposures when frequent procedures are carried out.

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 blood volume, 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% 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 exposures ALARA.

The hospital administration should consider an annual audit of the radiation safety program in cooperation with members of the Medical Isotopes Committee and the Radiation Safety Office. The results of this audit may then be discussed at an annual Medical Isotopes Committee meeting to ensure that all users and responsible staff are aware of current policies and procedures and methods for their improvement. An inspection checklist in NUREG-0267 gives 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 regulatory or accrediting agencies.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide. This guide reflects practices currently acceptable to 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 will 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. Pathology
   e. Cardiology
   f. Pediatrics
   g. Radioactive 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. Special investigations of exposure and notifications to regulatory agencies where appropriate
4. Radiation safety instrument calibration and maintenance
   a. Calibration
   b. Battery replacement and adjustment
   c. Pocket chamber and TLD calibration
   d. Light repair (electronic)
   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
   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
   b. Labeling (bed, chart, door)
   c. Nursing staff and housekeeping staff briefings
   d. Background surveys
   e. Source insertion and after-loading 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
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

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