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Management of Radioactive Material Safety Programs at Medical Facilities

Final Report

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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ABSTRACT

A Task Force, comprising eight U.S. Nuclear Regulatory Commission and two Agreement State program staff members, developed the guidance contained in this report. This report describes a systematic approach for effectively managing radiation safety programs at medical facilities. This is accomplished by defining and emphasizing the roles of an institution's executive management, radiation safety committee, and radiation safety officer. Various aspects of program management are discussed and guidance is offered on selecting the radiation safety officer, determining adequate resources for the program, using such contractual services as consultants and service companies, conducting audits, and establishing the roles of authorized users and supervised individuals; NRC's reporting and notification requirements are discussed, and a general description is given of how NRC's licensing, inspection and enforcement programs work. The appendices present detailed guidance on specific aspects of a radiation safety program, including a glossary that defines terms used in this report and an annotated bibliography prepared by the Radiological Sciences Division of Brookhaven National Laboratory.

NRC's statutory authority is limited to byproduct material; therefore, the guidance in this report is primarily directed toward the safe use of such material in medical facilities. However, the management principles discussed could be applied to managing the safe use of other sources of radiation within a medical facility.

The guidance contained herein does not represent new or proposed regulatory requirements, and licensees will not be inspected against any portion of it. In accordance with NRC usage, the word "should" is used when discussing or referencing NRC regulations. Additionally, regulatory compliance with all applicable regulations is not assured by licensees who adopt any portion of, or apply the principles described in, this report.

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EXECUTIVE SUMMARY

This NRC publication presents guidance on mechanisms and tools proven effective for managing radiation safety programs at medical facilities licensed either by the U.S. Nuclear Regulatory Commission or by Agreement States. As discussed in the "Scope of Purpose," NRC's statutory authority is limited to the safe use of byproduct, source, and special nuclear material in 21 States, the District of Columbia, Puerto Rico, U.S. Territories, and most Federal facilities. NRC has no have jurisdiction over other types of radioactive materials, sources, or radiation devices (X-rays) used within States directly regulated by the NRC or the other 29 States, referred to as Agreement States. By formal agreement with the NRC, Agreement States regulate the safe use of all sources of radiation within Agreement State borders, except for most Federal facilities.

Regardless of which regulatory agency has jurisdiction, a license is issued to a medical facility to authorize the possession and use of radioactive material or certain sources of radiation. Executive management of the licensed facility assumes ultimate responsibility for its safe use and is required to implement an effective radiation safety program to achieve this goal. For the purposes of this report, "executive management" refers to an individual at the senior vice-president or chief executive officer level who is responsible for oversight of the facility's radiation safety program. This management representative is expected to have authority to delegate necessary resources for the program. The term "executive management" does not apply to department managers in radiology, nuclear medicine, radiation oncology, or any other facility department, regardless of its size. To assist executive management in fulfilling its responsibility for the radiation safety program, this report offers practical guidance on effective management tools for programs of various size and scope and gives less detail on the specifics of day-to-day operations.

In this report, the staff introduces the concept of the "management triangle" to emphasize that three parties are responsible for providing effective oversight of the radiation safety program. They are executive management, the radiation safety committee (RSC), and the radiation safety officer (RSO). Each element is equally important, is dependent upon the others, and has specific duties. However, regulatory agencies consider executive management of the licensed facility to have ultimate responsibility for the program regardless of how large a role the RSC or RSO plays. Three chapters have been dedicated to defining the specific role of each management component, respectively, and discussing the necessary interrelationships among them (see Chapters 1, 2, and 3).

In Chapter 1, the staff defines the role of executive management, discusses the importance of delegating authority to the other two parties, describes effective tools for assessing the performance of the RSC and RSO, and emphasizes the importance of executive management's participation as a member of the RSC. In Chapter 2, the staff defines the role of the RSC (e.g, selecting committee members and conducting meetings) and the relationship of the RSC to the other two parties. In Chapter 3, the staff defines the role of the RSO for programs of various size, describes the RSO's relationship with the other two parties, and offers more detailed guidance on management of day-to-day operations. In Chapter 4, the staff discusses management tools for selecting a qualified individual to be authorized as the RSO. The advantages and disadvantages of authorizing certain categories of individuals as RSOs, such as physicians, physicists, and pharmacists, are briefly discussed. The optimal RSO candidate for a specific program could come from any one of these categories.

In addition to the responsibilities of the three elements in the management triangle, other individuals routinely assume responsibility for the safe use of licensed material on a daily basis. These include physicians authorized to use licensed material on an NRC license, physicians under their supervision, technologists, health and

medical physicists, dosimetrists, nuclear pharmacists, nurses and other allied health personnel, and such ancillary workers as security personnel, housekeeping staff, and dieticians. In Chapter 5, the staff defines the roles of each category of worker.

Radiation safety programs require resources, whether it is space, equipment, staffing, or time. As mentioned previously, executive management is ultimately responsible for ensuring that adequate resources are provided. Typically, management consults with the RSC and the RSO, to determine necessary resources for programs under development or for existing programs undergoing change or significant growth. In Chapter 6, the staff gives general guidance on determining adequate resources for programs of various size. With respect to resources, the management team may determine that certain radiation safety support services are needed and will be provided by a consultant or a service company. Most medical use licensees rely on a service company to supply personnel dosimetry devices for radiation monitoring, to calibrate radiation survey instruments, and to perform leak testing of sealed sources of radioactive material (such as sources used in radiation oncology). In Chapter 7, the staff discusses the use of consultants or service companies; the staff neither promotes nor discourages their use.

An important task associated with managing radiation safety programs is the conduct of periodic audits of the program. Most regulatory agencies require that licensees perform periodic audits to ensure that the radiation safety program, as described to the regulatory agency in the license application or subsequent communications and as implemented, is adequate to protect public health and safety. Regulatory agencies also require that the licensee maintain records to document the audit, its findings, and corrective actions that address findings. The conduct of audits may be as formal or informal as a licensee wishes, but audits should be conducted with a constructive critical analysis approach. In Chapter 8, the staff discusses the conduct of each required audit.

With the use of radiation sources, there is always the potential for an incident that may result in the inadvertent loss or release of licensed material, failure of equipment or devices containing or designed to secure radiation sources, or unintended radiation exposure to individuals. Such incidents could include misadministrations or recordable events in which errors have occurred during the delivery of a prescribed radiation dose to a patient or patients. As a result, in Chapter 9, the staff provides a quick reference on NRC's regulatory reporting and notification requirements in the event of a radiation incident.

Finally, in Chapter 10, the staff provides a broad overview of NRC's licensing, inspection, and enforcement process. It describes the mechanisms used by NRC during licensing, inspection, and enforcement to ensure the safe use of licensed material at medical facilities, and encourages the active participation of the licensee or applicant to facilitate this process.

In 19 appendices, the staff provides more specific information to assist in day-to-day operations. The following appendices may be of particular interest to executive management: Appendix A provides information for contacting Agreement State programs. Appendices H and I describe NRC's training and experience criteria for RSOs, Appendix M is a glossary in which terms used in this report are defined, Appendices N and O contain sample licenses, and Appendix P describes NRC's enforcement program. In Appendix R, the Radiological Sciences Division of Brookhaven National Laboratory, with assistance from members of the National Council on Radiation Protection and Measurements, has provided an additional bibliography (including abstracts) to identify additional sources of information on management of radiation safety programs at medical facilities. Some reference material provides scientific or technical information on certain program areas and may be beneficial to the RSC, the RSO, or to other individuals responsible for the safe use of licensed material. Appendix S lists NRC information notices issued to medical licensees for the period of 1989–1996.

SCOPE OF PURPOSE

This report represents the collective work of some U.S. Nuclear Regulatory Commission staff (see list of authors, p. xv) with input from two representatives of the Agreement States (see Appendix A for a directory of Agreement States). Furthermore, because this report does not contain patent or copyright information, it has not been reviewed by the Office of the General Counsel. During various stages of development, the authors received significant input from professional organizations and the Agreement States through presentations and peer review. Peer comments greatly increased the utility of this document and were generally constructive and very beneficial. However, one exception needs to be noted. The American College of Nuclear Physicians/Society of Nuclear Medicine requested that the following statement be included: "We would request that in the background section of the NUREG it be noted that the ACNP/SNM had serious concerns about the development of this document and provided those comments to NRC." Specifically, ACNP/SNM was concerned that this report identified new or proposed NRC requirements.

This report presents regulatory guidance. It does not describe new or proposed regulations, and licensees are not required to adhere to its principles. Any discussion or specific information that seems to imply a new or proposed regulatory requirement does so uninten-tionally. Rather, this should be viewed as a practical guide to present a management approach and describe management tools which regulatory agencies have observed to be effective when managing a radiation safety program at a medical facility. To facilitate discussion and emphasize that there are three parties responsible for radiation safety management, this report introduces the "management triangle" concept. Each element of the management triangle is considered equally important for providing effective oversight of the licensed radiation safety program, is dependent upon the others, and has different specific duties. However, regulatory agencies consider executive management to have the ultimate responsibility for the licensed program regardless of the magnitude of the role of the radiation safety committee and radiation safety officer. Although not all licensed programs are required to have a radiation safety committee, the management philosophy reflected throughout this report may be applied to radiation safety programs of various sizes and scopes. Additionally, some licensees may find it necessary to implement additional management tools to exercise control over specific program areas.

In addition to discussing the roles of executive management, the radiation safety committee and radiation safety officer, this report provides guidance on such practical issues associated with program management as selecting the radiation safety officer, defining the roles of other individuals such as authorized users, determining adequate resources, deciding whether to utilize the services of a consultant or service company, and conducting audits and incident response. Also, the last chapter provides general information regarding NRC's licensing, inspection, and enforcement process. The appendices provide more detailed information on program management and include a sample radiation safety committee meeting agendum and minutes, sample training program outlines, sample audit outline, sample list of necessary radiation safety-related equipment for various departments, sample licenses, and a quick reference guide to NRC reporting and notification requirements for different events including misadministrations.

NRC's statutory authority is limited to the safe use of byproduct material and special nuclear material in 21 States, the District of Columbia, Puerto Rico, U.S. Territories, and most Federal facilities. NRC does not have jurisdiction over other types of radioactive materials or sources of ionizing radiation used within these "NRC or licensing" States or the other 29 States, referred to as Agreement States. Agreement States are States that have entered into a formal agreement with NRC to regulate the safe use of byproduct

material. Appendix A contains a list of Agreement States. Other sources of ionizing radiation not regulated by NRC, but which may be regulated by each State, include: X-ray machines (i.e., fluoroscopic imaging and computerized tomography equipment), positron emission tomography (PET), linear accelerators used for patient treatment, cyclotrons for radiopharmaceutical production, and naturally occurring radionuclides. Even though the radiation safety principles and practices in this report are directed toward byproduct material, they have universal applicability and may be used by the radiation safety officer and other responsible individuals to manage the safe use of other radioactive materials and radiation-producing machines not specifically addressed in this guidance. Therefore, for ease of discussion the terms "radioactive or licensed material" and "radiation safety program" are used in place of "byproduct material" and "radioactive material safety program."

Throughout this document references are made to information obtained by NRC and the Agreement States while conducting inspections or evaluating license applications. Please note that there may be significant differences between NRC and Agreement States in their regulatory approaches to program requirements (such as training and experience requirements for users, and area survey requirements). For the sake of simplicity, references are made to NRC requirements only. These requirements may not necessarily be equivalent to regulations in effect in various Agreement States. Therefore, it is important that a licensee in an Agreement State reviews and abides by the appropriate State's regulations.

This NUREG was published in draft for comment in January 1995. The availability and 12-month comment period for the draft document was announced in the *Federal Register* (60 FR 8259; February 13, 1995). The comments received are incorporated into this NUREG and/or the *Federal Register* notice announcing availability of this NUREG.

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Our appreciation is also extended to John Baum, Ph.D., and Sandra G. Sullivan of the Radiological Sciences Division, Brookhaven National Laboratory (BNL) for providing contractual support on this project. Specifically, BNL staff conducted a literature search, prepared the abstracts contained in Appendix R of this report, and reviewed technical aspects of this report in its final stages of development. BNL also solicited comments from members of the National Council on Radiation Protection and Measurements (NCRP), Medical Health Physics Section of the Health Physics Society, and American Association of Physicists in Medicine to perform technical reviews of the draft document. BNL technical experts included Dr. John Baum, Head, Radiological Sciences Division and member of the NCRP; Dr. A.L. Carsten; Darryl G.L. Kaurin; Bruce J. Dionne; Michael O'Brien; and Charles B. Meinhold who is on staff at BNL and president of the NCRP. Other NCRP members included Dr. Joel E. Gray, Professor of Radiological Physics, Mayo Clinic, Rochester, Minnesota and Kenneth R. Kase, Head, Radiation Physics Department, Stanford University, Stanford, California. Other reviewers solicited by BNL included Edward O'Connell, Health Physicist, State University of New York at Stony Brook; Jean St. Germain, Radiation Safety Officer, Memorial Sloan–Kettering Cancer Center, New York; S.Brent Colby, Radiation Physicist, MeritCare Medical Center, Fargo, North Dakota; and Dr. Jacob Shapiro, Radiation Protection Officer, Harvard University, Cambridge, Massachusetts.

ABBREVIATIONS

AAPM – American Association of Physicists in Medicine

ACMUI – Advisory Committee on the Medical Uses of Isotopes

ALARA – as low as reasonably achievable

BNL – Brookhaven National Laboratory

CFR – Code of Federal Regulations

DIS – decay-in-storage

EPA – Environmental Protection Agency

FDA – Food and Drug Administration

IRB – Institutional Review Board

JCAHO – Joint Commission on Accreditation of Healthcare Organizations

NCRP – National Council on Radiation Protection and Measurements

NOV – Notice of Violation

NRC – Nuclear Regulatory Commission

NRRPT – National Registry of Radiological Protection Technologists

OI – NRC Office of Investigations

PET – position emission tomography

QM – quality management

QMP – quality management program/plan

RAM – radioactive material

RDRC – Radioactive Drug Research Committee

REAC/TS – Radiation Emergency Assistance Center/Training Site (Oak Ridge, Tenn.)

RG – regulatory guide

RSC – radiation safety committee

RSO – radiation safety officer

TLD – thermoluminescence dosimeter

1 ROLE OF EXECUTIVE MANAGEMENT

1.1 Introduction

This chapter offers guidance to executive management of a licensed medical facility on executive management's role in effective implementation and management of the radiation safety program. For the purposes of this report, the term "executive management" refers to an individual at the senior vice-president or chief executive officer level who is responsible for oversight of the facility's radiation safety program. In a broad scope program, this individual could be a senior administrator, whereas, in a small licensed program, this individual could be the sole owner and operator. Regardless of the individual's title, the NRC expects executive management to appoint a representative who actively participates as a member of the radiation safety committee (RSC) and has the authority to delegate necessary resources to the radiation safety program, as identified by the RSC. The term "executive management" does not include department managers in radiology, nuclear medicine, radiation oncology, or any other department of the facility, regardless of department size.

Executive management should become familiar with the types of radiation sources used at the facility, and where they are used, received, and stored. This is particularly important since some medical uses pose a higher safety risk than others for occupational workers, patients, and the public. For example, radiation therapy presents a higher risk than diagnostic radiology or nuclear medicine applications. Specifically, sealed radiation sources and linear accelerators for in-patient and out-patient radiation therapy procedures pose a potentially significant safety hazard because of the higher radiation levels associated with the use of these devices. In order to fully appreciate these medical use areas, executive management should consult with individuals expert in these areas, such as authorized physician users or health or medical physicists, to ensure that adequate resources are provided for the radiation safety program, including support for the radiation safety officer (RSO) and the RSC. See Chapter 6 for further discussion on radiation safety program resources.

1.2 The Management Triangle

The "management triangle," a concept used throughout this report, comprises three elements: executive management, the RSO, and the RSC. The concept was developed for the purposes of this report to emphasize that there are three primary responsible entities for radiation safety program management. No one element is considered more important than the others; rather, the management triangle represents a team approach in which the success of the team is dependent upon the contribution of each element. Each element of the management triangle is discussed in a separate chapter to emphasize its respective role, relationship with the other elements, and the need for effective communication between elements to establish and maintain an effective management team (Chapters 1, 2, and 3). Even though all elements are considered equally important, it should be noted that NRC regulations specify that executive management of the licensed facility has ultimate responsibility for the radiation safety program, even though executive management may depend heavily upon the RSO and RSC. This means that even though the RSC and, in particular, the RSO, oversee the day-to-day operations of the program, and are the informed bodies to which executive management turns for information, the license is issued to the institution (executive management) and executive management of that institution is held responsible for implementing the licensed program.

Figure 1: Management Triangle (Emphasis on Executive Management)

In addition to the three elements of the triangle, it is recognized that other individuals augment the management triangle and are responsible for many aspects of the day-to-day operations within a radiation safety program. Among these individuals are authorized users including physicians, supervised nuclear medicine and radiation therapy technologists, pharmacists, physicists, nursing staff, radiation safety staff, other allied health care personnel, consultants, and contractual service companies. In Chapter 5, the staff discusses the role of facility personnel, and Chapter 7 discusses the use of consultants and service companies.

The Management Triangle Without the RSC

NRC requires all medical facilities that meet its definition of a "medical institution" to establish an RSC. Licensed facilities that do not meet this definition are only required to have an RSO, who assists executive management in the oversight of the licensed program. Examples of programs that may not meet the definition of medical institution include some private or group physician practices, freestanding clinics, or mobile nuclear medicine services. The national health care delivery system is evolving and the number of medical facilities and number of services offered per facility are changing. As a result, regulatory agencies should reevaluate licensed programs that grow significantly, such as an increase in the number of medical disciplines practiced or number of authorized users, to determine whether additional regulatory requirements should apply to ensure an adequate level of radiation protection for facility workers and members of the public. Therefore, a licensed program that has historically not been required to have an RSC may become subject to this requirement on the basis of growth.

In medical facilities without an RSC, the role of executive management may actually be greater on a day-to-day basis, than in programs that have an RSC, since the responsibility for oversight of the licensed program is shared only with the RSO. Also, in the practices of some private physicians, executive management may be limited to one individual who is also the sole owner, sole authorized user, and RSO. In this case, the executive management–RSO would be the sole individual responsible for the radiation safety program. Regardless of whether there is an RSC or whether another individual is authorized as RSO, executive management should be knowledgeable of its responsibilities and should support the day-to-day operations of the program.

1.3 Selecting the Executive Management Representative to the RSC

Careful consideration of who will be selected to represent executive management and oversee the radiation safety program is a high priority when developing a program, or reassigning this responsibility. This individual represents the highest level of facility management and should have authority to delegate resources for the radiation safety program, as identified by the RSC. Additionally, executive managers should become knowledgeable of their role, the roles of the RSC and RSO, and their interrelationship. The radiation safety program may have significant financial needs and the executive manager should have authority to appropriate funds in a timely manner. In addition, the radiation safety program at the facility often involves several departments; therefore, the manager should have broad responsibilities and authority, and should have the ability to negotiate the needs of various parties. Although uncommon among licensees, it may be beneficial if the executive management representative has a science background or an aptitude for radiation safety issues.

The designated management representative should be available to the RSO and RSC

chairperson and should not be buried in a chain of command that does not facilitate effective and immediate action on behalf of management or the RSO and RSC in the event of a radiation safety emergency or potential emergency. In other words, the RSC chairperson and RSO should have access to and a direct line of communication with executive management to discuss radiation safety issues that need to be brought to management's attention. Additionally, the executive management representative should have the authority to make prompt decisions on the basis of the information available without having to consult with higher management officials.

1.4 Executive Management's Relationship With the RSO and RSC

1.4.1 Management Support for the RSO's Authority

The RSO has primary responsibility for maintaining the radiation safety program on a day-to-day basis; therefore, selecting the RSO for a new program or replacing the RSO in an existing one should be carefully considered. Chapter 4 is dedicated to this issue. When establishing or redefining the role of the RSO, executive management should clearly define the authority delegated to the RSO from executive management. In 10 CFR Part 35, NRC requires its licensees to submit a written statement detailing the authorities, duties, and responsibilities of the RSO. Therefore, the delegation of authority to the RSO should be discussed with the RSC to ensure that ample authority has been bestowed, and that the RSO has the necessary latitude to ensure implementation of an effective radiation safety program. In a radiation emergency or a potential emergency during which health and safety may be jeopardized, the RSO should be given ample authority to resolve the situation immediately. Specifically, the RSO should have authority to immediately terminate an unsafe practice or work activity with unchallenged authority and without prior coordination with the RSC or licensee management. This authorization should include unhampered access to all human uses of, and research projects utilizing, radioactive material.

The RSO should also have the authority to suspend or cease operations that are not in full compliance with safety regulations or license commitments. To support the RSO in these actions, management should not create a real or implied consent which permits some individuals at the facility to circumvent radiation safety requirements. Violators of the institution's radiation safety requirements should be aware of management's support for internal enforcement, which may include suspension of user authorizations. However, an authorized user, whose authorization has been suspended or revoked, should have the opportunity to appeal to the RSC a decision made solely by the RSO.

Executive management should ensure that the RSO has adequate time to fulfill the role. Depending upon the size and scope of the licensed program, the RSO's job could be a part-time or full-time commitment. If the job of the RSO is a full-time commitment, it may be difficult if not impossible for the RSO to be involved with or responsible for patient therapy procedures, some of which demand considerable time. Therefore, management, with assistance from the RSC, should accurately estimate time requirements associated with program management, delegate the necessary authority to the RSO, and demonstrate support for the RSO to fulfill the role. Without management's support, the RSO may not be effective.

On occasion, the RSO will be absent for a period of time and there will be a need to identify a qualified individual to carry out the responsibilities of the RSO. This typically occurs when the RSO is absent because of illness, vacation, work travel, holidays, and the like. However, the substitute cannot fulfill the role of RSO for an extended period of time without seeking prior approval by the regulatory agency. Usually, the RSC, in coordination with executive management, determines who will temporarily be responsible for acting as RSO. It is important that executive management delegate an appropriate level of authority to this individual so that the person can act effectively. Also, management should ensure that the individual filling in for the RSO has adequate time to perform all the duties and tasks of the RSO. Other assigned duties may

need to be reassigned until the RSO returns and the replacement individual returns to his/her position. Generally, the practice of identifying an individual to temporarily replace the RSO is permitted by regulatory agencies; however, it should be noted that, under NRC regulations, only one person can be authorized and responsible as the RSO. Therefore, RSO *duties* can be delegated to other qualified individual(s) on a permanent or temporary basis, but the *responsibilities* of the RSO cannot be delegated. See Chapter 3, "Role of the Radiation Safety Officer," for further discussion on delegation of RSO tasks and duties.

1.4.2 Management's Support for RSC's Authority

Management should empower RSCs to conduct their official duties and responsibilities and exercise authority in accordance with regulatory requirements, including those described in the license application. Similar to what is required of RSOs, NRC requires its licensees to submit in writing the authorities, duties, and responsibilities of the RSC. Management should delegate an appropriate level of authority to the RSC to enable the committee to fulfill its role as part of the management team. After all, the RSC serves as a collegial consensus and resource for executive management and is responsible for most, if not all, decisions that affect the radiation safety program. RSC duties include, but are not limited to, the review of the licensed as low as reasonably achievable (ALARA) program to ensure radiation exposure levels at the facility are within acceptable limits; review of training and experience documentation submitted by proposed authorized users, RSOs, and medical physicists; approval of policies and procedures; review of radiation exposure dosimetry records; investigation of incidents involving licensed material; review of the annual audit of the radiation safety program; and enforcement of decisions made by the RSC. Since the RSC membership is composed of a cross-section of departments that use radioactive material, their input and decisions are valuable and serve as a collegial consensus for facility personnel and management. In Chapter 2, the staff describes the role of the RSC, its duties and responsibilities, and its relationship with executive management and the RSO.

1.4.3 Communication With the RSO and RSC

Once the radiation safety program management "triangle" has been established, effective and periodic communication between all elements in each direction is essential. Poor communication between one or more elements can lead to a weak radiation safety program and can result in an overall lack of adequate oversight. This is particularly true when one element leaves the majority of the responsibility to the other two elements, and does not routinely communicate its concerns, questions, or information regarding the program. If the RSC is not as active as it should be, executive management may not be aware of program resource needs. As a result, management may not appropriate adequate resources and the RSO could find it difficult, if not impossible, to implement and maintain the radiation safety program. Good communication among the three components of the triangle requires conversation and periodic meetings, either formal or informal, both of which may need to be followed up in writing so that agreements are confirmed and all individuals are fully aware of their responsibilities and associated time limits.

1.4.4 Management Attendance at and Participation in RSC Meetings

Under the leadership of the RSC chairperson and the RSO, RSC meetings should be conducted periodically to discuss radiation safety issues at the medical facility. It is essential that all required members attend and, in particular, that the executive management representative of NRC-licensed facilities attends. To establish a quorum, the regulations require that at least half of the members be present, including the RSO and executive management representative (10 CFR 35.22(a)(3)). If the designated executive management representative is unable to attend or to send an alternate, the meeting could be held but it should not be counted as one of the required periodic meetings. Regulatory agencies recognize that, from time to time, the executive management representative will be unavailable at

the last minute to attend, and it may be necessary to have an alternate attend in order to transmit information. This practice is considered acceptable if it occurs infrequently. However, if it becomes more frequent or routine, the RSC should bring this issue to the attention of a higher management official to ensure that the radiation safety program receives the support it needs from licensee management. This is necessary to ensure that the overall performance and effectiveness of the committee is not impaired. Additionally, executive management should be cognizant of all required RSC members and should be aware of members who are routinely absent, since this may indicate someone who is reluctant to participate. In that case, executive management may need to recommend to the RSC that such members be replaced.

Active participation in the RSC by executive management sends a strong message to the RSC, the RSO, authorized users, and other individuals involved with or responsible for the radiation safety program. In addition, management involvement is essential when the institution is undergoing rapid change, a reorganization, or restructuring. Problems can occur when executive management does not take a proactive approach until radiation safety or related administrative problems escalate. Therefore, it is in management's best interest to gather information on the magnitude of the radiation safety program and its needs because executive management is ultimately responsible and provides necessary resources for the program.

1.4.5 Assessing RSO and RSC Performance

NRC or Agreement State* inspectors perform regulatory assessments for compliance. However, executive management should not rely on regulatory inspections alone to assess overall performance of the RSC, the RSO, and the radiation safety program. Regulatory agencies expect licensees and, in particular, executive management to periodically perform self-evaluations of the radiation safety program and to take action on identified problems. Therefore, by performing the assessments discussed below and the audits described in Chapter 8 of this report, management will be able to meet this challenge.

Parts 20 and 35 of 10 CFR require NRC licensees to periodically (at least annually) review the radiation protection program content and implementation. Additionally, for NRC licensees who have committed to Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix G, executive management should evaluate the implementation of the radiation safety program annually. A meaningful evaluation to meet these commitments requires assessing RSO and RSC performance by reviewing technical program achievements, regulatory compliance, and relationships with authorized users of radioactive material. It is recognized that executive management may not have the knowledge or resources to perform this assessment; therefore, from time to time, executive management may need to rely on outside assistance or to utilize technically qualified persons within the medical institution to make this assessment. Obviously, individuals within the licensed facility may find it difficult to be completely objective or may lack sufficient knowledge to make a comprehensive assessment. Qualified health-physics consultants and RSOs from other medical facilities could perform independent assessments and may provide meaningful insight into other programs. An exchange program could be established whereby similar facilities conduct periodic audits of each program in an effort to identify deficiencies, potential violations, and health and safety issues. Peer audits can be effective when conducted in an open, non-threatening manner for the purpose of improving the program through constructive criticism. It should be emphasized that the idea of utilizing an external auditor to conduct the required management audit of the radiation safety program is not an NRC requirement; rather, the idea is presented as a possible management tool to assess the RSO's and RSC's performance.

As part of conducting a management audit of the radiation safety program, management should determine whether the RSO and RSC chairperson work well together and with others who are responsible for the safe use of licensed material.

*See Appendix A for a directory of Agreement States.

The RSO, the RSC chairperson, and authorized users should work cooperatively for the program to succeed and for the RSO to enforce radiation safety program policy. Executive management should address situations in which an authorized user is able to exert influence over radiation safety enforcement by virtue of title, rank, or reputation by demonstrating support for the RSO when the RSO is unnecessarily challenged. As a result of such support, individuals will be more likely to comply and the RSO will be more effective. For such a balance to exist, it is imperative that all three elements of the management triangle support this philosophy.

1.5 Deciding Whether To Use Consultants or Service Companies

Utilizing the services of qualified consultants and service companies (collectively, "contractors") is a decision to be made by each licensee. The practice is generally neither discouraged nor encouraged by regulatory agencies. Contractors can provide valuable services which enhance the quality of a radiation safety program. Most licensees contract for such services as survey instrument calibration, sealed source leak testing, and personnel dosimetry. In Chapter 7, "Use of Consultants and Service Companies," the staff discusses the types and roles of contractors, contractual arrangements, and issues associated with the use of contractual support. It is important that executive management note that a contractor's findings should always be reviewed by the RSO, the RSC, and executive management for completeness and accuracy. In addition, regulatory agencies hold the licensee, not the consultant, responsible in instances in which the consultant fails to identify a safety problem or regulatory violation, or when the licensee fails to follow up on an issue or violation identified by the consultant.

1.6 Conduct of Required Audits

Executive management is responsible for ensuring that the radiation safety program is audited as required by the regulatory agency. Most regulatory agencies require periodic audits of certain aspects of the program, such as personnel radiation exposure records, to ensure adequate protection of public health and safety and regulatory compliance. One type of required audit, the "management" audit was briefly discussed earlier in this chapter when describing how to assess RSO and RSC performance. Audit feedback mechanisms are an effective management tool for the radiation safety program and provide regulatory agencies with information regarding implementation of a radiation safety program. In Chapter 8, "Conduct of Audits," the staff discusses all required audits in greater detail.

1.7 Enforcing Radiation Safety Policy

Executive management should be committed to assisting the RSC and RSO in resolving cases where individuals have violated internal radiation safety polices or procedures, or regulatory commitments. In many cases, the final official decision for corrective action will require support by the RSO and RSC, and may require a final decision by executive management. This decision should be based on a fair and impartial review by the RSO and RSC where all affected and interested parties have had their opportunity to present relevant information. Executive management should never allow an individual's influence or status to overrule the RSC's or RSO's decisions, or alter the decision process. To permit this would severely compromise the radiation safety program and make a mockery out of the authority of the RSO and RSC. Also, such biased actions by management could be construed as wilfully condoning violations of radiation safety requirements.

1.8 Summary

Executive management, even though assisted by the RSO and RSC, is ultimately responsible for the radiation safety program. Executive management should delegate an appropriate level of authority to, and demonstrate support for, the RSO and RSC for decisions that affect the licensed program. The RSO and RSC may find it difficult, if not impossible, to fulfill their responsibilities in the absence of executive management support. Radiation safety programs require such resources as space, equipment, personnel, time, and possibly contractors.

Therefore, executive management should assess these needs to ensure that adequate resources are continously provided. Equally important is the need to create an environment that promotes and facilitates effective communication and oversight. Since no two facilities are exactly alike, this report cannot describe the ideal or perfect organizational chart to facilitate effective management in each licensed facility. However, the necessary tools have been briefly described. In developing a facility-specific program, it is important to be open to alternatives for establishing an effective oversight program which may include untraditional organizational charts, the use of contractors to perform radiation safety program audits, delegation of specific duties to individuals, and an "exchange" program with a facility of similar size and scope for performing independent evaluations of the radiation saety program.

2 ROLE OF THE RADIATION SAFETY COMMITTEE

2.1 Introduction

This chapter discusses the responsibilities of the RSC, including selecting committee members and conducting meetings, and the RSC's relationship to the two other elements of the management triangle: the RSO and executive management. As discussed in Chapter 1, medical facilities that constitute a medical institution should establish an RSC to oversee the radiation safety program with the assistance of the RSO. The RSC represents a cross-section of medical use areas, expertise, and management, and serves as an effective collegial group to develop and promote a quality radiation safety program.

Figure 2: Management Triangle (Emphasis on the RSC)

2.2 RSC Support to Executive Management

The RSC functions to provide guidance and information on the radiation safety program to executive management, ensure that adequate resources are provided by licensee management, and assist the RSO in the development, implementation, and maintenance of the radiation safety program. The RSC serves as a "window" to the licensed program through which management gains an overall picture of its activities, and the respective roles of the RSO, RSC, and other responsible individuals, including authorized users. The RSC should ensure that executive management is periodically given all relevant information regarding the radiation safety program, particularly when management will make decisions that may affect the program. After careful deliberation and collective decision-making between management and the RSC, the RSC (including the RSO) should support and implement the final management decision. In order for other individuals at the licensed facility to support the final decision, they must observe that the management team reviewed all relative information and arrived at a consensus. Without such support from individuals working with licensed material on a daily basis, the management team will be ineffective.

2.3 Selecting an RSC Chairperson and RSC Members

2.3.1 Selecting the RSC Chairperson

The knowledge and leadership abilities of the RSC chairperson will promote the effectiveness of the RSC. Thus, selection of the RSC chairperson is an important task for executive management and other RSC members if an RSC exists. Some qualified individuals at the facility would prefer not to assume the role for various reasons, and these people should not be coerced since a reluctant individual could presage an inactive chairperson and an inactive committee. Another important consideration is whether the prospective candidate has adequate time to devote to the RSC chairperson position in addition to other job responsibilities or assignments. An effective RSC usually has as its head someone who wants the position, is knowledgeable, and has leadership skills and adequate time to devote to accomplishing the goals of the RSC and fulfilling the role of chairperson.

Although often convenient, management should be cautious when appointing the RSO to chair the RSC for several reasons. First, the RSO is responsible for the day-to-day operations of the radiation safety program and may be too closely involved with licensed activities to be objective. Secondly, depending on the scope of the licensed program, the time necessary to carry out the responsibilities as RSO and complete other

assigned duties associated with patient care may absorb all of that individual's time. Third, the chairperson represents an extension of facility management should a disagreement arise between the RSO and an authorized user, or with any individual involved with licensed material, making such issues difficult to resolve if the RSO is the chairperson. Finally, filling the chair with the RSO is not consistent with the management triangle at medical institutions, since the role of the RSO is to provide technical expertise to the RSC and executive management. Regulatory agencies have observed difficulties in programs in which the RSO is also the RSC chairperson. The committee and its chairperson represent executive management in the formulation of policy for the radiation safety program; therefore, the chairperson is expected to guide the committee's agenda. Frequently, the best radiation safety policy for the institution is not the easiest for the RSO to implement; thus, conflicts of interest may arise when the RSO is chairperson. Also, because the committee is expected to hear users' grievances against audit findings, it is inappropriate for the RSO to be the most prominent member of the committee. Furthermore, among the responsibilities of the RSC is the auditing of the radiation safety office in the performance of its duties. Again, this makes it difficult and inappropriate for the RSO to be the most prominent member of the committee.

Some medical institutions appoint an authorized physician user as the RSC chairperson. Authorized users can effectively head the RSC since they are knowledgeable of the medical application of licensed material, have requisite authority and credibility, and access to executive management. However, problems can occur when the chairperson is an authorized user who is the principal large user, since a conflict of interest could occur in certain situations involving licensed material and the radiation safety program. The RSC could develop internal procedures to avoid this situation. Also, it could be difficult for the authorized user-chairperson to be effective since physicians are typically not employees of the medical facility and, as a result, may be limited in their authority to impart or enforce decisions. For other users, such as researchers or principal investigators, to be designated as chairperson, executive management should delegate an appropriate level of authority to the position so that the chairperson is effective, particularly in situations where decisions will affect other departments or areas in the facility.

In some licensed programs, a medical physicist assumes the role of RSC chairperson. This can be an effective choice since a qualified medical physicist has a more than adequate knowledge of radiation and issues related to radiation safety. Additionally, in many cases, the physicist has responsibility for, and hands-on involvement with, those types of radioactive material at the licensed facility that pose the greatest hazard to patients, workers, and the public, that is, sealed sources used for teletherapy and brachytherapy. Like the researcher or principal investigator, if executive management selects a physicist to head the committee, an appropriate level of authority should be delegated to, and support should be demonstrated for, the RSC head. This is particularly true since one or more members of the RSC may be authorized users who supervise the physicist's work in the radiation oncology department. Regulatory agencies have observed that medical physicists have significant time-consuming responsibilities planning therapy treatment. It then becomes important to assess whether the medical physicist will have sufficient time to devote to the RSC as chairperson.

Occasionally, the chair position will be filled by the executive management representative. The advantage of this choice is that executive management, which has ultimate responsibility for the program, would be actively involved in managing the program and would have a broader working knowledge of the program. The disadvantage of having executive management head the committee is that decisions could be made on the basis of incomplete information or financial implications alone, which adversely impact the radiation safety program.

2.3.2 Selecting Other RSC Members

When establishing a new program, the RSO and the RSC chairperson should work together to appoint other people who are interested in serving

on the RSC. The RSO should ensure that all RSC members, to be effective in their role, are adequately trained or possess an appropriate level of knowledge of radiation safety issues and the medical uses utilized at the licensed facility. NRC membership requirements for the RSC for limited scope licensees are described in 10 CFR Part 35, and guidance for broad scope licensees appears in NRC Regulatory Guide 10.5, "Applications for Type A Licensees of Broad Scope." (Note that regulatory guides contain guidance, not requirements.) NRC regulations require that the RSC for a limited specific medical license, should include, at minimum, a representative from each authorized area of medical use, the RSO, executive management, and a nursing representative. NRC regulations also stipulate that the management representative cannot be the authorized user or RSO. User group representatives, such as radiation therapy (oncology), nuclear medicine, radiology, cardiology, research, and pathology, should also be active members. Additionally, NRC regulations require that a quorum be present for each meeting of at least one-half of the RSC membership, including the RSO and executive management.

Typically, the nursing representative on the RSC is a nurse with administrative authority and responsibility to ensure that facility nurses who care for patients undergoing therapy procedures receive required radiation safety training and are aware of relevant radiation safety issues that may affect them or the patients under their care. This individual should have, or should be provided with, a general knowledge of the institution's radiation and radioactive material uses for patient procedures (e.g., diagnostic, radiopharmaceutical therapy, teletherapy, and brachytherapy uses, especially where patients are required to be confined). The RSO, with the assistance of the nursing representative, should develop a mechanism to ensure that radiation safety training, relative to nursing responsibilities, is provided to *all* nurses who will care for patients undergoing radiation therapy. This includes new and temporary nursing staff. Adequate training is particularly important since serious radiation safety incidents have occurred when improperly trained nursing staff who cared for such patients made errors involving radioactive material. Therefore, the nursing representative should be actively involved in the RSC meetings and should be proactive in obtaining information and asking questions on matters related to radiation and patient nursing care. Because of its continued and close contact with patients, the nursing staff, if properly trained, is often the first to notice a radiation safety problem involving a patient and may also be the first to take the critically important initial emergency measures to reduce unwanted radiation exposure to the patient, the nursing staff, other facility staff, and possibly visitors.

2.4 Scheduling and Conduct of RSC Meetings

NRC requires that RSCs hold regularly scheduled meetings at least quarterly. It may also be necessary for the RSC chairperson to schedule additional meetings to discuss issues that arise and demand early intervention or attention. The RSC can conduct considerable business by telephone or mail. For example, members can receive user applications or reports by mail and be ready to discuss them at an upcoming meeting. Voting is also permissible by telephone when necessary. However, NRC requires that all RSC minutes contain recommended actions and the tally of all ballots; therefore, the RSO may want to consider maintaining a telephone log to document such discussions and results.

The RSO and RSC chairperson should ensure that members receive all necessary documents and information before each meeting so that the exchange of information and deliberations reached during the meeting are well researched. Meetings may be as formal or informal as desired by the chairperson. Certain business items are usually discussed first, followed by authorized user applications, license amendment requests, modifications to the radiation safety or quality management (QM) programs, incidents, dosimetry data, and problems involving personnel, equipment, or facilities. The RSO is expected to provide considerable information at the meetings and to be responsive to questions from RSC members. The RSC depends on the RSO to be extremely knowledgeable about the details of the

licensed program and applicable regulatory requirements. If information is not known at the time of the RSC meeting, the RSO can research the issue and make the information available to members at the earliest opportunity. This could include circulating documents to RSC members for comment and discussion. The key is to follow up quickly and thoroughly on outstanding items so that no detail goes unaddressed. Appendix B contains a sample RSC agenda for a meeting.

2.5 Responsibilities

2.5.1 Review and Approval of Authorized Users, User Permits, and License Amendments

One of the RSC's most important responsibilities is to evaluate the training and experience qualifications of applicants who request authorization to use radioactive material at the licensed facility. Holders of limited specific medical licenses are required to apply for and receive an amendment to the license to authorize new individuals to use radioactive material. The exception to this requirement is for a physician who either possesses board certification, as recognized in 10 CFR Part 35, or is identified as an authorized user on another NRC or agreement state license. In this case, the licensee is required to submit notification to the NRC within a specified period of time. Before making an amendment request, the RSC should review the applicant's training and experience documentation to determine whether NRC's criteria have been met. If the documentation is found acceptable, the licensee should submit an amendment request to the NRC and, upon approval, the authorized user may begin to use licensed material. Broad scope medical use licensees have authority to authorize qualified users of licensed material without NRC review or approval. Rather, the RSC reviews the applicant's training and experience documentation to determine if the applicant meets NRC's criteria. If the applicant is deemed qualified, the licensee imparts the authority to the user and no NRC review and approval is needed at this time. The approval process employed by broad scope licensees is reviewed at the time of inspection.

Regardless of whether the facility has been issued a limited specific or a broad scope license, the RSC members should be made aware of the regulatory training and experience criteria that apply to each type of medical use at their institution to facilitate an efficient review of the application and processing of the user's application. Applications for medical use should be carefully reviewed by all RSC members, not just by the RSO. Approval of users and uses may not always go together. For example, a physician may be authorized to perform clinical procedures but may not possess the necessary qualifications to perform research work (or vice versa). The RSC members should clearly understand the applicant's proposed uses. Research involving human use, investigational radiopharmaceuticals, animal studies, or releases to the environment need to be thoroughly reviewed. Typically, the RSO presents and clarifies the information, and it is sometimes helpful to have the applicant attend the RSC meeting to respond to questions as appropriate.

When new users or new uses are authorized, either by the RSC or the regulatory agency, they should be added to the annual audit program to ensure that these new users or new areas of use are monitored for health and safety issues and regulatory compliance.

2.5.2 Review of Consultant's Reports and Findings

As discussed in Chapters 1 and 7, the institution may engage a consultant to augment the radiation safety program. The consultant could either assist the RSO, serve as the RSO, or perform periodic audits of the program. Licensees may also use service companies to provide personnel dosimetry services, leak testing services, teletherapy calibration services, survey instrument calibrations, audits, and other tasks. The reports and related information submitted by consultants and service companies should be carefully reviewed by the RSC. The RSC should not make a habit of accepting the report with no questions asked. A common error made by licensees is to accept consultants' and service companies' reports and findings without reviewing them to ensure that the services were performed in accordance

with the contractual agreement for those services. In addition, the RSC is responsible for acting on the findings identified in the report. If facility personnel take no action, based on a consultant's report that contains errors or misrepresentations of license commitments or requirements, and those actions lead to violations or other problems, regulatory agencies will typically hold the medical institution responsible and not the consultant. Additionally, regulatory agencies may utilize the consultant's report to assess the licensee's response to the findings identified in the report, and may cite the licensee for possible violations identified in the consultant's report if the licensee took no action in response to the findings in the report. Therefore, it is in the licensee's best interest to review a consultant's reports upon receipt and take appropriate action or seek clarification on the findings.

2.5.3 Required Audits and Program Reviews

The RSC, including executive management, shares responsibility with the RSO for the conduct of certain periodic audits of the radiation safety program. In Chapter 8, the staff discusses the conduct of audits and describes required audits in more detail. However, since the RSC has a significant responsibility for the conduct of required audits, the audits are briefly discussed below.

Quarterly Radiation Exposure Audit

At each RSC meeting, the RSO should summarize personnel dosimetry data gathered since the last RSC meeting and discuss the results of required periodic radiation surveys, any significant radiation incidents (including spills, contamination events, misadministrations, and recordable events) that may have occurred. These audits serve as a periodic benchmark to keep the RSC informed of all radiation exposures and incidents. As discussed in Chapter 3, licensees should continually evaluate the personnel monitoring program to ensure that all individuals are monitored as required and that appropriate methods are used, or that historical radiation dosimetry records indicate that personnel monitoring is no longer required.

Annual Audit

Generally, one of the more important RSC meetings is the one in which the RSC members review the results of the annual audit of the radiation safety program. More significant events, radiation exposure summaries, and overall compliance status achieved by authorized users should be thoroughly reviewed. Possible trends should be analyzed and suggestions for timely and effective corrective action should be made. The annual review should concentrate on critical self-analysis to ensure that aggressive and timely corrective actions have been taken throughout the year. Problems should be clearly defined and tracked as "open items" until appropriate corrective action has been taken. Additionally, an assessment of the effectiveness of the corrective actions will help the licensee deter or eliminate future problems and violations.

As Low As Reasonably Achievable (ALARA) Audit

10 CFR Parts 20 and 35 require the establishment of an ALARA program and Part 35 requires that the RSC periodically review the program. The ALARA program should be reviewed at each RSC meeting and summarized at the end of every year. The RSC should also review recommendations (e.g., from employees) on ways to maintain individual and collective doses ALARA. In addition, as part of the annual review, a determination should be made regarding whether the radiation safety program needs to be modified to keep exposures ALARA.

Quality Management Program (QMP) Audit

NRC requires its licensees to review the QMP, at least every 12 months, to determine its effectiveness. Licensees should review all misadministrations, all recordable events, and a representative sample of patient administrations. The review should also ensure that the current version of the QM plan clearly reflects all modifications made to the program to increase its effectiveness and meet the objectives of the QM rule. QMP modifications should be submitted to NRC within 30 days of implementation.

2.6 RSC Meeting Minutes

Proper documentation of the RSC meetings is essential to inform executive management,

internal or external auditors, and regulatory inspectors about oversight of the radiation safety program. Minutes of RSC meetings are especially helpful for members who were unable to attend the meeting, or other interested individuals. The RSC minutes should be written by an individual who understands the technical language used and who can comprehensively describe events to others who may not have an in-depth knowledge of radiation safety program information. The technical, narrative, and decision- making aspects of each meeting should be reflected in clear, concise minutes that convey the key meeting elements without being too lengthy. Contrarily, care should be taken to avoid minutes that are too simplistic and that omit details of key discussions and decisions.

The minutes should clearly reflect voting results and significant discussions and opinions expressed by the RSC and others in attendance. The minutes will rarely stand alone and are usually accompanied by several appended documents, such as user applications, audit reports, dosimetry data, and incident reports. NRC requires that the minutes of each RSC meeting include, at a minimum:

- date of the meeting
- names of members present
- names of members absent
- summary of deliberations and discussions
- recommended actions and the numerical results of all ballots
- ALARA program reviews described in 10 CFR 35.20(c)

Meeting minutes should be prepared and distributed in a timely manner to ensure management and RSC members not in attendance will remain updated on radiation safety issues. Minutes should also list outstanding action items and progress toward resolving these issues. Minutes should be carefully reviewed and concurred on by a qualified individual (e.g., the RSO or RSC chairperson), and the RSC should also concur by voting on the minutes at the next meeting. Appendix C contains sample minutes of an RSC meeting.

2.7 Summary

The RSC is an integral part of the management triangle necessary for effective management of the radiation safety program. The RSC depends heavily on the technical expertise of its members and a cooperative and supportive relationship with the RSO and executive management. Together with the RSO, the RSC can help to ensure that the radiation safety program receives an appropriate level of attention and resources from facility management to ensure regulatory compliance and a safe working environment. The RSC also represents various areas of authorized use at the licensed facility and medical and physics expertise that should serve as a resource for executive management and other facility personnel responsible for the safe use of licensed material.

3 ROLE OF THE RADIATION SAFETY OFFICER

3.1 Introduction

The RSO's primary responsibility is to implement the radiation safety program with the assistance and support of the RSC and executive management. Therefore, the RSO should ensure that radiation safety activities are being performed according to approved policies and procedures, and that all regulatory requirements are complied with in the daily operation of the licensed program. In this chapter, the staff outlines the general responsibilities of the RSO at a medical facility and provides guidance on customizing the role of the RSO to conform to the needs of a specific facility. The major areas of discussion are delegation of authority to the RSO, delegation of tasks, high priorities for the RSO, general duties and responsibilities of the RSO, and additional responsibilities at a broad scope program. Two duties of the RSO, the conduct of audits and incident response, are discussed in detail in Chapters 8 and 9, respectively, and only briefly in this chapter. The conduct of audits is addressed in a separate chapter since it is the most frequently used mechanism to assess the success of the program and involves numerous actions and interrelated steps. The duty of incident response is addressed in a separate chapter to provide expanded information to assist the RSO when responding to an event in a prompt and appropriate manner.

Figure 3 Management Triangle (Emphasis on Radiation Safety Officer)

3.2 Priorities

3.2.1 Health and Safety

The highest priority for the RSO is to ensure that day-to-day operations involving radioactive material are conducted according to policies and procedures designed to adequately protect public health and safety and maintain exposures ALARA. To accomplish this, the RSO should have unhampered access to all activities involving radioactive material. In addition, because of the consequences of actions taken by the RSO in response to emergency situations, the RSO should be intimately familiar with the regulations, applicable regulatory guidance, and license commitments. If the RSO discovers an activity involving radioactive material in which health and safety appear to be compromised to an unacceptable level, the RSO should have the authority to terminate the unsafe activity immediately without consulting with executive management or the RSC. However, at the next available opportunity, the RSO should brief executive management and the RSC chairperson about the event and the RSO's immediate response. These responsible parties should determine the root cause of the problem, collectively identify effective corrective actions, and document such deliberations in the minutes of the RSC meeting. It is helpful for RSOs to attend meetings of professional organizations to keep abreast of new technology, proposed regulations, and guidance developed by applicable professional organizations in order to enhance their role in ensuring public health and safety. Therefore, executive management should identify resources for the RSO, and the radiation support staff if indicated, to attend professional meetings and should secure reference material to help them perform well.

3.2.2 Implementing the Radiation Safety Program

The RSO should be delegated the authority and is responsible for establishing, maintaining, and auditing written policies and procedures to implement various aspects of the radiation safety

program. These policies and procedures should be collected in a centralized location, or close to the area of use, so that they can be easily located in response to an incident or at the time of a regulatory compliance inspection. Appendix D contains a list of minimum radiation safety procedures required by NRC. This list should not be considered all inclusive for licensees of broad scope or large limited specific programs. NRC's Regulatory Guide 10.8 (Revision 2), "Guide for the Preparation of Applications for Medical Uses Programs," contains model procedures that applicants or licensees may use to develop and describe their radiation safety program. Agreement States may have similar guidance documents describing their requirements for policies and procedures in radiation safety programs.

3.2.3 Assisting the RSC

The RSO assists the RSC in ensuring that radiation safety issues are addressed in a comprehensive and timely manner, audits are conducted as required, feedback mechanisms are in place to correct deficiencies, and that adequate resources are provided for implementing the radiation safety program or when modifications are needed. The strongest radiation safety programs are those in which the RSO works closely with the RSC chairperson and principal users on a continuing basis, rather than limiting this work to the periodic RSC meetings. The RSC should keep abreast of the status of the program through the RSO to prevent a tremendous void of information in the event that the RSO discontinues services. In some cases, licensees relied so heavily on the RSO to ensure effective oversight of the licensed program that, upon the RSO's departure, executive management and the RSC did not have adequate knowledge of basic regulatory commitments.

Typically, the RSO takes the lead in gaining first-hand knowledge on the specifics of the licensed program including license commitments, applicable regulatory requirements, and radiation safety, to ensure that adequate protection of the public, patients, and workers is maintained. Although executive management has ultimate responsibility, management typically depends heavily on the RSC and the RSO, and the RSC depends heavily on the RSO to provide complete and accurate information on the radiation safety program. Often, even though RSC members may be technically competent, they may not necessarily be well versed in the regulations or in the commitments of the license. The RSO should also assist the RSC in performing the duties described below by providing precise information on the commitments made in the license and applicable regulations. The RSO provides assistance to the RSC on a wide variety of issues that include the following:

- Reviewing and preparing a summary of the occupational radiation dose records of all personnel for RSC review on a quarterly basis to identify changes in trends and reviewing recommendations on ways to maintain individual and collective doses ALARA;
- Reviewing proposed user applications by performing the initial evaluation on all proposed uses and users and by preparing a summary of the RSO's evaluation and recommendation;
- Performing the initial review of all incidents involving radioactive material, such as major spills and overexposures;
- Reviewing a representative sample of patient administrations to identify recordable events and misadministrations;
- Reviewing all recordable events and misadministrations to verify compliance with, and to determine the effectiveness of, the quality management program.

Appendix B contains a sample agendum for an RSC meeting which should be used as a guideline for developing an agenda that reflects a licensee's specific program and areas for discussion at each meeting. In addition to the agenda, depending on the scope of the program, it may be necessary for the RSO to distribute, in advance of the meeting, additional background information on certain items for discussion.

3.3 Communications

The RSO communicates with individuals at all levels while fulfilling the role of auditor and advisor. A portion of the RSO's time should be devoted to providing consultation on health physics matters and regulatory requirements to authorized users and other persons at all levels of responsibility within the organization who may have special needs or concerns. In effect, because of the unique training and experience requirements of the RSO, RSOs should be relied upon to answer or to find the answer to most technical and regulatory questions brought to their attention. In addition, the RSO plays a key role in the conduct of various audits of the radiation safety program described in Chapter 8.

The RSO is responsible for communicating with the regulatory agency as needed to respond to inspection findings and requests for renewal or amendment of the license, or to seek clarification regarding regulatory commitments or other information. Chapter 10, "Interactions With the NRC" provides a broad overview of this subject.

3.4 General Description of Duties, Tasks, and Responsibilities

The general descriptions that follow identify duties and tasks that are common to both limited specific and broad scope medical licensees. However, this list should not be considered all inclusive since licensees may have tasks associated with special authorizations that are not addressed below. In addition, discussion of duties, tasks, and responsibilities unique to broad scope RSOs are addressed later in this chapter.

3.4.1 Training Program

NRC regulations require that licensees instruct supervised individuals in licensed activities in the principles of radiation safety appropriate to that individual's use of radioactive material, and in the licensee's quality management program (QMP), as required. Regulatory agency inspectors and some licensees often find that the root cause of an incident or misadministration is ineffective training or a lack of training. The RSO should dedicate adequate time to ensure that job-specific training and annual retraining is provided to all authorized users, physicians under the supervision of authorized users, and supervised individuals including technologists, physicists, nursing personnel, and ancillary personnel. The RSO might consider developing a brochure or other training material for employees to consolidate relevant radiation safety information. Some RSOs have found it helpful to circulate a bulletin, newsletter, or notice to inform personnel about new policies, procedures, regulations, or other information relative to their ares of use and responsibility. The RSO, with the assistance of the nursing representative, should develop a mechanism to ensure that radiation safety training, relative to their duties, is provided to all nursing staff who will care for patients undergoing radionuclide therapy. This includes new and temporary nurse employees, if such employees will be required to care for this group of patients. Adequate training for nurses is particularly important since serious radiation safety incidents have occurred when poorly trained nursing staff handle radioactive material improperly. Therefore, the nursing representative to the RSC should be actively involved in the RSC meetings and should be proactive in obtaining information and asking questions on matters related to radiation and patient nursing care. Because nurses have such continued and close contact with patients, the nursing staff, if properly trained, is often the first to notice a radiation safety problem involving a patient in its care and also the first to take the critically important initial emergency measures to reduce unwanted radiation exposure to the patient, nursing and other facility staff, and possibly visitors.

In addition, individuals who work under the supervision of authorized users, including physicians, should receive training on the importance of following instructions provided by the user, written radiation safety procedures, including the QMP, and adhering to all applicable requirements. Authorized users who supervise individuals also have the responsibility to periodically review the individual's use of licensed material and the records maintained to document this use. Appendix E contains sample training

program agenda for several groups of licensee personnel.

3.4.2 Personnel Monitoring Program

In most medical programs, personnel monitoring is required, although the criteria will vary for determining who is monitored, the frequency for exchange of monitoring devices, and the type of monitoring device. Licensees should review applicable regulations, the license application, and licensed activities to determine which categories of individuals should be monitored at any given time. As a result, the categories of personnel or individuals monitored could periodically change, depending on the types and quantities of licensed material in use, review of radiation exposure histories and exposure potential, and revised regulatory requirements. For example, as revised, 10 CFR Part 20 requires licensees to monitor both internal and external doses of individual workers and demonstrate compliance by summing internal and external doses. Personnel monitoring programs may also require that bioassays be performed on workers, depending upon the types, quantities, and use of licensed material, including where and how it is stored, handled, and administered to patients. In addition, declared pregnant occupational workers have different monitoring thresholds from other occupational workers. The RSO should calculate the worker dose from noble gases, evaluate effluent releases because of the potential exposure to the public, and calculate the spilled gas clearance time to ensure that the laboratory or patient procedure room is sufficiently free of the spilled noble gas before any personnel reenter the area.

As part of the licensee's ALARA program, the RSO should establish, with the assistance of the RSC, levels of occupational radiation exposure which, if received, will trigger an investigation. The RSC and RSO are responsible for periodically auditing the personnel monitoring program to ascertain that all persons who should be monitored are being monitored, that badges are returned promptly for processing, and that trends of radiation exposure that may indicate a health and safety problem and radiation exposures exceeding ALARA investigational levels are investigated promptly. The frequency of these audits depends on license conditions and the frequency with which personnel monitoring reports are received by the facility. It may also depend on the number of dosimeter devices. For large broad scope programs, personnel dosimetry may number in the thousands per month and just handling the devices administratively can require considerable resources. However, for most licensees, personnel monitoring audits are usually performed on a monthly or quarterly basis.

3.4.3 Facilities and Equipment

Ideally, the RSO should be involved in the early planning stages of designing new or remodeling existing facilities that will be used for patient procedures involving licensed material, and areas for possession, use, or storage of radioactive material. The RSO should evaluate the hazard associated with the use of licensed material to ensure that the facilities will have adequate shielding available and to ensure the use of any safety equipment that may be required, such as fume hoods, leaded blocks or glass, or fixed radiation area monitors. The use of such noble gases as xenon-133 presents an external source of exposure and requires that the laboratory is at negative pressure compared to the adjoining rooms. Since some licensees use volatile forms of radioiodine, special equipment such as fume hoods and containers may be required. In other cases of radionuclide use, specialized facilities, equipment, and procedures may be needed, including phosphorus-32 plexiglass shielding, brachytherapy treatment room shielding, experimental animal handling and care facilities, and waste storage, packaging, and disposal areas.

The RSO and the radiation safety staff use a variety of specialized instruments to monitor the presence of radioactive material in use. Portable survey instruments are essential, and should accurately measure (1) external radiation fields and (2) surface contamination emitted by various beta and gamma radiation energies from materials in use or storage. These instruments should be available in sufficient numbers for use by all who have survey responsibilities on the RSO's staff and in the individual research and clinical use areas. The instrument used should be correct for the

type and energy of radiation being monitored. For example, a scintillation probe designed to detect low energy gamma radiation would be unsuitable for measuring low energy beta radiation originating from tritium or carbon-14; and a thin-window Geiger- Mueller "pancake" probe would not be suitable for measuring shielding effectiveness around a teletherapy unit.

The finest radiation detection or measurement instruments will be unreliable unless they are properly calibrated for the radiation present. Calibration sources with identical or similar radiation characteristics to the radionuclide intended for measurement should be used during the calibration process. Improper or out-of-date calibrations may lead to misleading survey results, which could result in either overreacting or under-reacting to radiation exposures and contamination.

3.4.4 Incident Response

The RSO is responsible for initiating investigations into possible overexposures from, accidents with, and spills, losses, or thefts of radioactive material. In addition, the RSO is responsible for initiating investigations of deviations from approved radiation safety practice such as unauthorized receipts, uses, transfers, and disposal, as well as misadministrations and recordable events. If the cause of the accident or extent of the spill is not immediately known, it may be necessary to terminate certain activities or to close entire laboratory areas temporarily. If too much emphasis is placed on immediate cleanup of contaminated areas instead of concentrating on gathering information on the extent and cause of the contamination, valuable time may be lost in identifying possible offsite contamination that could result in unacceptable risks to public health and safety. Any of these events may trigger regulatory reporting requirements and the RSO should have a thorough understanding of these reporting requirements in order to avoid more serious enforcement action by the regulatory authority. Some reporting requirements require immediate notification or notification within 24 hours of the incident. Chapter 9 contains a thorough discussion on incident response, and Appendix F describes NRC notification and reporting requirements.

3.4.5 Security of Licensed Material

Although discussed briefly above, NRC considers the security of licensed material to be an important responsibility of the RSO. Licensed material should always be securely stored, transported, or under constant surveillance. Regulatory inspectors often observe, during routine inspections, that laboratories or storage areas containing licensed material are left unlocked, unsecured, or unattended. This creates an unnecessary potential hazard to public health and safety; the potential hazard can be easily avoided by following relatively simple measures. In developing measures to prevent such loss of control, the RSO should work with facility personnel who directly handle licensed material to identify and implement procedures that are effective and not burdensome on the responsible individuals.

On occasion, a shipment of radioactive material may be received before or after working hours. All licensees should implement procedures to ensure that personnel responsible for receiving such packages, such as security guards, receive proper training on the receipt and transport of such packages. Adequate training should include, but is not limited to, procedures for inspecting the outer package upon receipt for damage and leakage; verifying correct facility address; transporting the package to a secured radioactive material storage area; documenting its arrival, and in some cases, notifying a previously identified individual, such as the RSO or a member of the radiation safety staff.

3.4.6 Required Radiation Surveys

In order to ensure the safe use of licensed material, all licensees are required to perform radiation surveys. The RSO is responsible for conducting required radiation surveys, or ensuring that they are conducted, in accordance with license commitments and regulatory requirements. Therefore, the RSO should continually evaluate the radiation safety program and keep current with applicable regulations to determine (1) that all required surveys are being

performed and (2) if additional surveys are warranted. Most regulations for radiation surveys require that survey results be documented in a record which should be maintained for a required length of time. NRC Regulatory Guide 10.8 contains model procedures for the conduct of surveys and sample recordkeeping forms to document the survey results. Licensees may use any recordkeeping format to meet their individual needs, provided that the required information is included.

3.4.7 Radioactive Material Inventory Records

Regulatory agencies require each licensee to retain records of receipt, transferral, and disposal of all radioactive material used at medical facilities. The RSO should establish and maintain an inventory system for ordering, receiving, and properly disposing of radioactive material. Ideally, the inventory system should provide a continual tally of radioactive material possessed by the licensee to ensure and document that regulatory possession limits are not exceeded. Today, there is software available to assist in radioactive material inventory which may be of great benefit to some programs, particularly, large broad scope programs.

The RSO should develop an accounting system that suits the type of licensed program. For example, a small medical facility will generally need to maintain receipt records, disposal records, and records of any transfers to other such licensed facilities as nuclear pharmacies. On the other hand, a broad scope medical licensee will need a sophisticated accounting system which provides accurate information on the receipt of material, its location, the amount used and disposed of, the amount transferred to other laboratories operating under the license, and the amount remaining after decay. The accounting system should also consider radioactive material held for decay-in-storage, near-term disposal, or transfers to other licensees. Routine physical audits by the RSO or staff should test the accounting system to ensure that it is accurate.

3.4.8 Radioactive Waste Management

The RSO is responsible for the supervision and coordination of the radioactive waste disposal program. Medical programs, not involving the use of radioactive materials in research-related activities and not administering iodine-131, will generally not find waste disposal a serious problem. However, those licensees who are involved in research using long-lived radioactive materials and those who administer iodine-131 will need to dedicate space for storing radioactive waste generated by these activities. In some States where access has been denied to the low-level waste sites, licensees may need to provide for long-term interim storage. This will necessitate the RSO and RSC making recommendations to executive management that dedicated space be established for this purpose and submitted to the regulatory agency for approval. Such waste-reduction methods as compaction and incineration, if approved by the regulatory agency, may reduce space requirements. Regulatory agencies may allow licensees to dispose of radioactive waste containing short-lived materials (e.g., half-lives of less than 65 days) provided that certain precautionary measures are taken and records are maintained. This requires that the licensee hold the waste for a minimum of 10 half-lives to allow for an adequate level of radioactive decay. After decay, the licensee should monitor the radiation level of waste before disposal and meet specific disposal and recordkeeping requirements. Licensees are reminded to review the license document since many regulatory agencies list a specific license condition to describe authorized waste disposal methods at the facility.

3.4.9 Records and Reports

Regulations and license commitments require that licensees maintain records and reports to document certain activities of the radiation safety program for minimum periods of time. These records should be accessible to all responsible personnel and regulatory agency inspectors, and should be complete, legible, and maintained up to date in an auditable form. The licensee might consider maintaining duplicate copies of required policies and procedures in separate locations in

the facility in the event of a fire or flood, or other loss. Regulatory agencies recognize the trend for licensees to maintain records in electronic form, and it is acceptable for some records as long as they are easily retrievable and are available during the time of inspection. Therefore, licensees should ensure that, in the absence of the individual responsible for maintaining the electronic records, other individuals know how to retrieve requested records. Note that regulatory agencies may have specific requirements concerning quality assurance and, in fact, may not allow electronic storage of some records, such as those that require signatures. The licensee should be certain to check for restrictions with the appropriate regulatory agency. Appendix G contains a list of NRC notification and reporting requirements.

3.4.10 Certain Medical Devices

In those medical institutions in which other modalities, such as teletherapy, high-dose-rate and low-dose-rate remote afterloaders for brachytherapy, and gamma stereotactic radiosurgery, are used, the RSO will need to be generally familiar with the operation, various safety features, and potential hazards of each modality. All of the equipment used will have primary and ancillary safety devices, such as area monitors, alarms, and status indicators, which will require periodic checking according to instrument manufacturers' operations manuals and license commitments. The RSO should develop procedures for periodically evaluating the performance of these devices in accordance with the manufacturers' guides, regulations, and license commitments.

NRC regulations require the mobile nuclear medicine service licensee to conform to additional technical requirements. Therefore, the person named as RSO on a mobile nuclear medicine license should know about applicable transportation regulations, security requirements, special survey meter and dose calibrator requirements, and tests, as well as about recordkeeping requirements.

3.5 Delegation of Tasks

The responsibilities of the RSO, as designated in the regulations and the license, may not be transferred to other individuals without a clear statement in the license permitting such transfer and approval by the NRC. Many tasks and duties associated with management of the radiation safety program may be assigned or delegated to other qualified individuals; however, the responsibility for ensuring that these tasks and duties are performed correctly lies with the RSO and, ultimately, with the RSC and executive management. For example, the RSO should attend all RSC meetings; no substitute is allowed unless authorized by the regulatory agency. In large radiation safety programs, the delegation of radiation safety tasks becomes a necessity in order to fully implement and oversee all aspects of the radiation safety program. Large broad scope medical programs may have several health physicists who hold degrees in radiological health, physics, or a physical science, or equally trained individuals, who assist the RSO in addressing the technical aspects of the program. Trained technologists working under the direction of the RSO may be used for more routine portions of the program such as laboratory surveys, waste handling, and recordkeeping. Although the task can be delegated to other qualified individuals, the responsibility always remains with the RSO.

Often, inspectors and license reviewers are questioned about who can perform the duties of the RSO while the RSO is away. As discussed in Chapter 2, regulatory agencies expect that, from time to time, a qualified individual will need to fill the role of the RSO during short-term absences for illness, vacation, or work away from the facility. However, this privilege should not be extended indefinitely or on a long-term basis. The RSO's duties and tasks may be delegated to a qualified individual, but the responsibilities of the RSO, and the authority granted by management to the RSO, may not be shared with anyone else. Typically, the NRC does not recognize the position of assistant or alternate RSO because sharing the responsibility with someone else can dilute the RSO's authority and can lead to potential problems in managing the radiation safety

program, particularly when the other individual involved is not given clear instruction or guidance on those aspects of the program that he/she oversees. However, some Agreement States do endorse this management approach and will authorize an alternate RSO on the license. Some qualified individuals who serve as "substitute" RSOs are a health or medical physicist, a nuclear pharmacist, an authorized user, or a chief technologist in nuclear medicine or radiation therapy. The scope of the licensed program and potential problem areas, the length of time an alternate is needed, the training and experience of the individual considered, and the amount of authority delegated by management to this position will help to determine who might best serve as alternate RSO.

3.6 Additional RSO Responsibilities in a Broad Scope Program

The RSO of a broad scope medical license is responsible for more complex matters involving multiple uses and users of radioactive materials, and many broad scope programs include research activities, both medical and non-medical. The broad scope license is written to give the licensee the greatest amount of flexibility, so that research and development can proceed with the least amount of external regulatory involvement, provided that the licensee has implemented the radiation safety program as described in the license application and subsequent amendments. Specific guidance for applications for broad scope medical licenses is given in Regulatory Guide 10.5, "Applications for Licenses of Broad Scope."

Most broad scope licenses permit use of any radionuclide with atomic numbers 1 or 3 through 83, in any form, some of which may require special handling techniques not normally required in a limited specific medical program. Often, RSOs at broad scope facilities have to monitor and maintain special systems and shielding associated with the use, storage, and disposal of radioactive material. Because of the types and quantities of certain radioactive material used in research laboratories, the RSO may need to evaluate, select, design, and supervise maintenance of process control and confinement systems, such as glove boxes and hoods. In some cases, the RSO may become involved in the evaluation, selection, maintenance, and use of respiratory protective equipment. Shielding evaluations, including the determination of the type and amount of shielding needed, are very important because of the types of radiation frequently used.

Additional broad scope matters that require RSO assistance to the RSC include advice and consultation on special incident reporting requirements not normally encountered in a limited specific medical program, development and maintenance of an emergency plan for responding to release of radioactive materials, the determination of need for financial assurance for decommissioning, and development and maintenance of a decommissioning funding plan. These apply to unsealed as well as to sealed sources of radiation. Since broad scope medical licensees transfer radioactive material to other licensed facilities in research-related activities, the RSO should have a comprehensive knowledge of transportation regulations as they apply to materials shipped. Specific information about the transportation of radioactive materials can be found in NRC Information Notice 90-35 entitled, "Transportation of Type A Quantities of Non-fissile Radioactive Materials;" however, this notice should be reviewed with the understanding that changes to the Department of Transportation regulations (49 CFR) and corresponding 10 CFR Part 71 changes were recently completed.

Many broad scope programs include multiple-use locations and unique operations that impact staffing and resource requirements of the radiation safety office. The needs of broad scope programs are constantly changing, so it is important that the RSO furnish the RSC and executive management with current staffing and resource needs. With a constantly changing program, the need to train facility staff in radiation protection becomes crucial. Appendix E outlines a sample program for training medical licensees; it should be used as a guide.

Applicable regulations require that some broad scope licensees establish procedures to ensure completion of safety evaluations of proposed uses

of radioactive material that consider such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. In a medical broad scope program, the RSC, with the assistance of the RSO, uses the established procedures to review and approve authorized users, uses, and facilities as authorized by its license. The RSO often serves as a facilitator by advising the RSC on matters related to the approval of proposed authorized users.

NRC's training and experience criteria for approving medical/human use is detailed in 10 CFR Part 35, Subpart J. However, the training and experience criteria for proposed non-medical use by researchers should be developed by the RSO and RSC. A classification scheme to define minimum criteria can be developed on the basis of radiotoxicity and levels of activities used. The same scientific basis can be useful for establishing standards of design for laboratories, required equipment, personnel monitoring, and survey requirements.

In addition to the tasks and responsibilities described above, the RSO for a broad scope medical license should assist the RSC with such matters as determining compliance with other regulatory authorities. Other agencies may include the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Department of Energy (DOE), local ordinances, specific license conditions, and conditions of materials use specified by the RSC.

A broad scope medical program may be authorized to approve and conduct research involving the use of radioactive drugs or radiation-emitting devices in humans. Such research may, however, require prior FDA approval. In addition, final approval to conduct research studies involving radiation typically requires that the broad scope licensee contact an Institutional Review Board (IRB), a Radioactive Drug Research Committee (RDRC), or other appropriate committees that review and accept research studies based on patient and human research subjects safety, ethical considerations, and scientific merit. The RSO should be involved in the approval process to serve as a central institutional authority through which all applications for the human use of radioactive materials are submitted so as to ensure that the radiation safety (research subject and occupational worker) and regulatory aspects of the study are appropriately addressed.

The RDRC is an institutional committee defined under FDA regulations (21 CFR Part 361) that can approve research studies intended to obtain basic information regarding the metabolis (including kinetics, distribution, and localization) of a radioactively labeled drug, or regarding human physiology, pathology, or biochemistry. RDRC approval authority does not, however, extend to research involving the use of radioactive drugs for immediate diagnostic studies or therapeutic purposes (i.e., to carry out a clinical trial). The IRB is an institutional committee, mandated by the Department of Health and Human Services, which reviews all research studies (radioactive and nonradioactive) performed within the institution or by investigators affiliated with the institution. The principal objectives of the IRB are to ensure that the potential benefits to be gained from the research study exceed the associated risks to the subject and that the research subject is fully informed of the study procedures, potential risks and benefits, and a person's rights as a research subject.

3.7 Summary

In summary, as the focal point of any radiation safety program, the RSO may have a broad spectrum of responsibilities. The RSO's primary responsibilities are to ensure adequate protection of public health and safety, and that day-to-day operations are conducted in accordance with approved procedures and in compliance with regulatory requirements. In addition, it is typically the RSO who responds first to incidents involving licensed material and conducts required program audits. Each licensed program should be considered unique in both the scope of licensed activities and its organization. Therefore, each licensee should evaluate its own radiation safety program to determine the role of the RSO, and whether additional trained radiation safety staff

are needed to support the RSO. Each licensee should also establish a mechanism to ensure adequate involvement in the program by the RSC and executive management. Additionally, when determining how large a role the RSO will play in any licensed program, management should consider that many RSOs with clinical responsibilities are also responsible for the safe use of licensed material in such departments as radiology, nuclear medicine, and radiation therapy or in a clinical laboratory, and therefore, need adequate time to devote to the role. Although the RSO is the primary individual responsible for day-to-day operations, executive management is ultimately responsible for the program and should ensure that adequate resources are provided to the radiation safety program, including the availability of the RSO.

4 SELECTING A RADIATION SAFETY OFFICER

4.1 Introduction

The RSO is a critical component of the management triangle because the RSO, with the assistance of the RSC, is responsible for implementing and maintaining the licensed radiation safety program. Executive management is obligated to select an RSO who has sufficient training and experience to address all facets of the radiation safety program. However, compliance with the training and experience criteria described in the regulations, whether they are NRC or State criteria, may not be sufficient qualifications for the individual to be effective. For example, the RSO candidate should also possess good management skills, welcome the responsibility, and be willing to dedicate enough time to ensure that the required tasks to implement or maintain the radiation safety program are properly performed. The careful selection of the RSO is a crucial task for executive management. Therefore, to assist licensees in this selection process, this chapter discusses *minimum* RSO qualifications for different types of licenses, as well as the advantages and disadvantages of certain categories of RSO candidates, and makes suggestions for locating qualified candidates.

4.2 Qualifications

To implement the radiation safety program, the RSO is responsible for overseeing the day-to-day operations and should have unhampered access to all levels of the organization. Executive management should empower the RSO to terminate an unsafe activity immediately without being challenged and, in some cases, without prior coordination with the RSC or executive management. Therefore, executive management should select an individual in whom it has confidence to delegate this authority.

The nature of activities conducted under a limited specific versus broad scope license can be extremely different. The magnitude of potential safety-related problems requires the RSO of a broad scope license to be more knowledgeable in various aspects of health physics. Because NRC criteria for acceptable training and experience for the RSO of the two types of licensees are different, in the next two sections the staff discusses *minimum* NRC training and experience criteria for each category of licensee.

4.2.1 Limited Specific Licensee

The limited specific licensee usually performs routine diagnostic or therapeutic procedures or both with Food and Drug Administration (FDA)-approved radiopharmaceuticals and sealed sources. NRC's training and experience criteria for qualifying an RSO for a limited specific program are described in 10 CFR Part 35, Subpart J, and allow three training pathways: certification by professional boards recognized in the regulations, specific classroom training, and work and clinical experience. Being listed as an authorized user on the license is also acceptable. Additionally, individuals may qualify if they have been previously authorized as RSOs at a facility of similar size and scope. NRC requires that the training and experience be obtained within seven years preceding the date of the application, or that the applicant should have had related continuing education and experience since completing the required training. NRC's training and experience requirements for limited specific licensees are outlined in Appendix H. (Agreement State regulations have different requirements.)

Some professional boards are recognized in NRC regulations because, as part of the certification criteria, applicants have successfully completed a radiation safety component determined by NRC to be adequate. An alternate pathway consists, at a minimum, of basic classroom and laboratory training in courses related to radiation safety and direct work experience under the supervision of an RSO in a medical facility of similar or larger size and similar or broader scope. Typically, classroom and laboratory training comprises course work in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiopharmaceutical chemistry. Although appropriate classroom and laboratory training is

an important benchmark for demonstrating adequate qualifications, the practical experience gained while working under the supervision of an RSO in a medical facility cannot be overstated. It is through this practical experience that an individual learns to apply the technical knowledge gained from classroom and laboratory training. NRC regulations require a minimum of 1 year of practical experience.

4.2.2 Broad Scope Licensee

Broad scope medical licensees are authorized to use a variety of radiopharmaceuticals and sealed sources for diagnostic and therapeutic patient procedures and other human use, and for both medical and nonmedical research. Because of the nature of this varied program, broad scope licensees generally need more flexibility in managing their programs than do limited specific licensees. For example, the RSC, with the assistance of the RSO, typically approves facilities, equipment, uses, and users. For this reason, broad scope licensees should have staff including the RSC, and particularly the RSO, who are eminently qualified to review and approve these requests.

Generally, an RSO at a broad scope facility should have experience using and supervising a broad spectrum of isotopes, activities, and uses. Although this RSO is not required to have direct experience with *all* isotopes used in the broad scope facility, the RSO should know when to ask for assistance from individuals who have the appropriate expertise. Applicants for the RSO position should also have practical experience in certain tasks before being considered acceptable candidates for the position. An RSO in a broad scope facility should have experience in such areas as laboratory auditing, personnel monitoring, bioassay, contamination control, investigation of incidents, training personnel, instrumentation and calibration, material inventory and accountability, radioactive waste disposal, transportation, and the use of an RDRC and an IRB. See Section 3.6 for further discussion on RDRCs and IRBs.

Also desirable in a candidate are such management abilities as developing and administering a budget, supervising a staff, being familiar with human resource matters, and having good writing and oral communication skills. A thorough knowledge of regulatory requirements is essential to maintaining compliance for an RSO of any type of licensed program; however, this knowledge becomes critical for the more complicated program of a broad scope license.

Appendix I provides guidance on the type and length of formal education, certification, and experience that NRC staff recommends for RSOs of broad scope programs. This guidance is based on similar guidance described in NRC Draft Regulatory Guide OP 722-4, "Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program." The guidance in Appendix I can be used to determine if a candidate has sufficient practical or applied health physics experience based on education or certification. The higher the degree of formal education in health physics or radiological health, the less applied health physics experience is required. Regardless of education, however, the licensee should thoroughly review each candidate's experience. Licensees of broad scope programs should ask each potential candidate to disclose complete information about previous training and experience.

Appendix J contains a checklist that licensees of broad scope facilities can use to analyze an RSO applicant's training and experience. However, this checklist should not be considered all inclusive. Licensees are encouraged to develop criteria that address the unique needs of their facilities. The checklist is simply a tool that can be used to identify acceptable RSO candidates easily. The checklist may also be useful for preparing and submitting documentation of credentials to regulatory agencies for a candidate whom the licensee believes is qualified to act as RSO.

After establishing appropriate criteria for evaluating candidates, holders of broad scope licenses should establish and define a process to review the training and experience of each applicant. The selection process can be time intensive; therefore, if the RSC has been established, it may consider setting up a subcommittee to review the credentials of all

applicants and to prepare a preferred candidates list. The credentials of these selected candidates can then be carefully reviewed by the entire membership of the RSC. The RSC can rate the candidates and recommend the most qualified individual to executive management. Several other methods have also proved to be equally effective, but the actual selection process is left to the discretion of executive management. Although the licensee is obligated to select the RSC's candidate, the final approval of an RSO for a facility is the authority and responsibility of the regulatory agency.

4.3 Interpersonal Skills

In addition to finding an individual who is technically competent, not unlike any other personnel selection, the licensee should attempt to find one who works well with other people. After all, an RSO depends on other individuals to follow procedures and complete tasks, and should interact with them as needed to ensure an effective radiation safety program. An RSO's effectiveness in managing the program is often dependent on the ability to convey important regulatory and technical information from one group to another, and the rapport established with members of the organization.

The RSO should convey information to all levels of the organization, from the executive management of the facility to the laboratory staff. Additionally, the RSO should convey licensee policy and regulatory requirements for the use of radioactive material to primary users and laboratory staff; should work with the RSC to identify failures or weaknesses in the radiation safety program; should recommend corrective actions to avoid health and safety problems and noncompliance; and should counsel executive management so it can make informed decisions regarding appropriate disciplinary actions for infractions against a licensee's policy or violation of regulatory requirements. Also, from time to time, it will be necessary for the RSO to convey licensing requests and inspection responses to regulatory agencies. Therefore, it is imperative that the RSO's communication skills, written and verbal, be effective.

Good interpersonal skills are important to facilitate management of the radiation safety program. Problems can occur when technically qualified RSOs become ineffective because they become involved with personality conflicts or power struggles within the organization. The RSO cannot perform all the tasks required for implementing the program without the cooperation of other qualified individuals. Therefore, the RSO should be skilled in delegating tasks and negotiating issues with staff on behalf of the institution. The RSO should never hesitate to aggressively pursue issues related to health and safety, and regulatory compliance. In other words, the RSO should be assertive, but diplomatic, and should be willing to participate actively in auditing and, in some cases, supervising the use of radioactive material in the facility by conducting both announced and unannounced audits. The RSO should be "comfortable" with exercising authority when addressing and following up on safety or compliance offenders. For licensees who use consultants to augment their radiation safety programs, the RSO should be knowledgeable of the defined role of the consultant and should work effectively to ensure that all aspects of the license program are audited and that findings are addressed with appropriate followup action.

4.4 Advantages and Disadvantages of Certain Categories of Individuals as RSO

The discussion that follows highlights the advantages and disadvantages observed by regulators when licensees select certain categories of individuals to fill the role of RSO. Generally, the category of individual selected and authorized as RSO is dependent upon the size and scope of the program; any of the individual categories discussed below could ultimately be the best RSO for a particular licensed program.

4.4.1 Health and Medical Physicist

Health and medical physicists represent two categories of professionals that may have varied responsibilities in a medical facility; however, there is usually a distinct difference between the two groups with respect to their roles. For

example, health physicists employed in the medical arena are typically involved with such radiation program issues as radioactive waste processing, personnel dosimetry, equipment quality control and acceptance testing, and radiation monitoring. Medical physicists are typically responsible for treatment planning for brachytherapy, teletherapy, linear accelerators, or gamma stereotactic radiosurgery patient procedures. Both categories of individuals routinely work with and are responsible for the safe use of radiation sources which pose the greatest potential for harm to facility patients and workers. As a result, these individuals possess a great deal of practical knowledge and are adept at emergency response in the event of a radiation incident. Furthermore, their academic or technical training typically prepares them thoroughly for dealing with many of the complex technical issues associated with radiation safety program management.

Unfortunately, on occasion, health or medical physicists, in response to job assignments, may focus almost all of their attention on a single area of the radiation safety program, leaving other areas virtually unattended. For example, the medical physicist–RSO who works in an institution that has an active nuclear medicine program, as well as a therapy program, may become so involved with the therapy program that very little time is devoted to diagnostic nuclear medicine activities. Therefore, if executive management selects a health/medical physicist to serve as RSO and also to function in other capacities, it should ensure that the health/medical physicist–RSO is provided with, and dedicates adequate time to, the program and has an interest in exercising oversight of each area of responsibility. Generally speaking, because of their relevant education and hands-on responsibility with licensed material, health or medical physicists should, in most cases, be considered serious contenders for the position of RSO.

4.4.2 Physician

Physicians are frequently designated as RSOs for limited specific licensed programs because of their direct involvement with licensed material, notable stature and influence in the organization, and the fact that authorized physician users meet NRC's training and experience criteria. Physicians who are interested in the role can be very effective RSOs in some programs. Unfortunately, regulatory agencies have observed many cases in which physicians failed to fulfill the RSO role and discharge RSO duties properly. On several occasions, physician–RSOs have delegated duties to other individuals and failed to follow up on tasks to ensure they were performed as required. Often, physicians are so busy practicing medicine that they do not have sufficient time to fill the role of RSO. In some cases, physicians were simply not interested in performing RSO duties, and only agreed to perform them thinking that the position should be filled by a physician, or that the RSO position provided a professional credential. Some physicians were not accurately informed by executive management of the RSO's responsibilities, and accepted the position with little or no background information. If licensee management selects a physician user as RSO, it should ensure that the physician welcomes the responsibility and understands the obligation and time commitment. It may be necessary to provide the physician–RSO with radiation safety training specific to the licensed program, since each program has different needs, uses, and license commitments. Training may include formal courses offered by professional organizations, universities, or consultant services, and on-the-job training at other licensed medical institutions or facilities of similar size and scope.

Additionally, regulatory agencies recognize that it is no longer common practice for physicians to be employed directly by medical institutions. Instead, most physicians work out of private or group practices under contract to the medical institution; therefore, a physician–RSO's line of authority within the licensed facility could be neither clear

nor strong. Therefore, it may be appropriate in some cases to consider establishing a contractual agreement between the physician–RSO and executive management regarding the licensee's expectations of the physician as RSO.

4.4.3 Technologist

Technologists are usually detail oriented because of their technical training and work experience. They are familiar with the hands-on use of the radioactive material in day-to-day operations as well as with the intricacies of the nuclear medicine or radiation therapy program. However, there are inherent problems associated with designating a qualified nuclear medicine or radiation therapy technologist as RSO. Because the technologist performs many of the tasks that should be monitored by the RSO, there is a potential for conflict of interest. Also, the technologist–RSO should oversee the radiation safety aspects of the use of radioactive material by the physician user who may be the technologist's supervisor. There is a potential for the physician user/supervisor to intimidate or ignore the technologist–RSO. Therefore, if licensee management decides to select a qualified technologist as RSO, it should provide adequate management support and a clear line of authority to the technologist–RSO for that individual to be effective. Additionally, the technologist should welcome this management challenge and work to build a professional reputation among executive management, the RSC, authorized users, radiation workers, and regulatory agencies.

4.4.4 Nuclear Pharmacist

Nuclear pharmacists are adept at handling large quantities of radioactive material and are familiar with FDA requirements. Such knowledge may be very useful in programs that are involved in nuclear medicine procedures and in research and development. Because the nuclear pharmacist's activities generally involve compounding and dispensing radiopharmaceuticals, not actually administering them, nuclear pharmacists may require experience beyond their scope of use. In addition, the pharmacist may lack sufficient experience with sealed sources used for patient therapy. The licensee should review the nuclear pharmacist's practical experience carefully to verify that it is adequate to meet the facility's needs or should give the potential nuclear pharmacist–RSO an opportunity to gain additional classroom and laboratory experience to become qualified as an RSO.

4.4.5 Consultant

Occasionally, when licensees determine that they do not have personnel who are qualified or willing to assume the role of RSO, they contract for an independent health physics consultant to serve as the authorized RSO. Consultants can amass a wealth of information from experiences gained while consulting in a variety of programs. Many consultants offer such contractual services, as leak testing or instrument calibration, which most licensees need and do not have the facilities or expertise to successfully perform. Executive management should be aware that hiring a consultant may mean engaging a firm of consultants. Some consultants are very busy overseeing several licensed programs simultaneously and may not be able to commit adequate time on site to fulfill their contractual commitments. If licensee management plans to select a consultant to perform the duties of RSO, and not just to augment the RSO, it should ensure that the consultant spends enough time on site to implement the program adequately. If the consultant delegates tasks to other individuals working at the facility or within the consultant's own firm, there should be a clear understanding of each person's responsibility.

4.5 Locating Qualified Candidates

Licensees, particularly those in remote areas, often comment that they have difficulty locating qualified candidates. The method of recruitment will vary with the size and scope of the radiation safety program and the candidate qualifications that are needed. In situations in which the licensee wants an RSO who has special qualifications, the licensee may need to hire a personnel recruiter to organize a national search. Using a personnel recruiter will incur a cost and may not be feasible

for smaller limited specific programs. However, several professional organizations, such as the Health Physics Society, the American Association of Physicists in Medicine, and the Society of Nuclear Medicine advertise job opportunities in their publications. Such advertising may also incur a cost, but these societies often hold local and regional chapter meetings that provide free recruitment opportunities for licensees.

Establishing a network of colleague contacts can provide a source of qualified candidates. Organizations such as the American Hospital Radiology Administrators provide opportunities for midlevel management to make contact with their colleagues nationwide. Colleges and universities that offer relevant educational programs can be a source of technical candidates. Some teaching programs offer the appropriate classroom and laboratory training and the work experience necessary to qualify a candidate for the RSO position. The licensee should ask for information about the content of the particular training program to verify that it satisfies the training and experience criteria for an RSO for the size and scope of the licensed program in question.

4.6 Summary

Careful selection of the RSO is crucial to the effective management and implementation of the radiation safety program. There are many qualities or characteristics that executive management should consider when making this selection. One category of individual as RSO at one institution may not be appropriate at another institution of different size and scope. Each facility should address this issue by considering its unique needs and resources. Executive management should seek a person who is technically qualified, who communicates effectively, and who manages people well. The role of RSO should never be forced onto an individual who does not want the responsibility or is not willing to dedicate enough time to performing the required tasks. Executive management should understand the time commitment and should allocate sufficient time to the RSO to complete the required tasks. None of the people in the RSO categories described in this chapter can be expected to perform adequately as an RSO if they are also expected to perform *full-time* clinical, research, or technical duties. Management should also be certain that the candidate understands the obligations and time commitment before he/she accepts the RSO position.

5 ROLE OF PHYSICIAN AUTHORIZED USERS AND SUPERVISED INDIVIDUALS

5.1 Introduction

In addition to the RSO, other workers assume responsibility for the safe use of licensed material in daily operations by adhering to the policies and procedures established as part of the radiation safety program. Among these individuals are physicians authorized to use licensed material (physician authorized users), physicians (such as residents) working under the supervision of an authorized user, nuclear medicine and radiation oncology technologists, dosimetrists, pharmacists, health and medical physicists, radiation safety technical staff, and nurses and other trained individuals responsible for the care of patients undergoing therapeutic procedures. Also included in the category of supervised individual is anyone who, as part of his/her assigned duties, is responsible for handling licensed radioactive material and patients who have been administered licensed material. Each category of individual will be discussed in terms of the role played in the day-to-day operations of the radiation safety program. This chapter does not address researchers (authorized users who are not physicians) who are employed in most broad scope programs.

5.2 Physician Authorized Users

The discussion herein applies to physicians who are authorized to use licensed materials and any other physicians working under the supervision of a physician authorized user, such as residents, who are responsible for administering licensed material to patients. Licensee management should ensure that authorized users possess the necessary training and experience to handle licensed material safely and to effectively oversee individuals working under their supervision. For example, authorized users will need training with respect to policies and procedures specific to the licensed program, will need to instruct individuals who are responsible for performing certain tasks related to radiation safety under their supervision, and will need to periodically review the supervised individual's work. The goal is to have an adequate system of instruction and supervision in place, including a feedback mechanism, to ensure that the supervised staff knows the proper procedures to follow in the absence of the authorized user, and how and when to contact the authorized user or RSO. Additionally, it is in the best interest of the authorized user to monitor implementation of these procedures. The complexity and formality of this monitoring system differ from facility to facility, depending on a facility's size and the scope of its program, and the responsibility for implementing this system lies with the authorized user. Additionally, although the authorized user may delegate specific tasks associated with the medical use of radioactive material to supervised individuals, the responsibility for its safe use cannot be delegated. Therefore, if a supervised individual, through misunderstanding, negligence, or omission, acts contrary to the requirements of the license or regulations, the licensee remains responsible.

Generally, authorized users have two major areas of responsibility for the safe use of licensed material. First, they are responsible for the safe use of licensed material in humans by prescribing a radiation dose or dosage to be administered to the patient for diagnosis or treatment. More generally, authorized users are responsible for ensuring the safe use of licensed material throughout a department, such as nuclear medicine or radiation therapy, and perhaps throughout a facility, if the physician who is the authorized user is also a member of the RSC or is designated as RSO.

With respect to the safe use of licensed material in medicine, the direct involvement of the authorized user with the procedure may be dependent upon the complexity of, or safety risk associated with, the patient study or medical treatment. For example, when conducting diagnostic procedures, technologists under the supervision of an authorized user typically perform the patient study, with minimal direct involvement by the authorized user. Patient procedures are

successfully performed because the authorized user has established policies and procedures for the safe diagnostic use of the licensed material and has instructed the technologists in these procedures, and because the supervised individuals adhere to the procedures. Typically, the authorized user defines acceptable ranges for patient dosages for specific studies in a diagnostic clinical procedures manual to which technologists refer when conducting diagnostic studies. Technologists need to understand that they should contact the authorized user or RSO if a discrepancy exists between what is indicated through observation or communication with the patient or referring pshysician and what is prescribed or administered. NRC does not typically review the appropriateness of the prescribed radiation dose; rather, NRC relies on the self-policing of physician authorized users to ensure that the prescribed dose is appropriate for a specific patient. It is also important to recognize that when new radiopharmaceuticals or procedures are employed, supervised individuals, including technologists and pharmacists, may need additional training.

The authorized user typically is more closely involved in therapeutic procedures than in diagnostic studies because of the greater risks associated with therapeutic doses of radiation, whether from radiopharmaceuticals or from sealed sources used in brachytherapy or teletherapy. First, the authorized user determines which radiation therapy procedure is appropriate for the patient, and prescribes a dose. For brachytherapy and teletherapy procedures, the dose prescribed initially may not be determined exactly until the treatment planning process is complete and the authorized user, in consultation with the physicist or dosimetrist or both, has determined the optimal treatment plan and total prescribed dose. Once the prescribed dose and treatment regimen (e.g., one 1.5-Gray (Gy) fraction per day for five weeks) are recorded and approved by the authorized user, supervised individuals fulfill their role by ensuring that the prescribed dose is delivered to the correct patient. This process requires that there are policies and procedures in place to ensure that errors do not occur in the delivery of the prescribed dose and that supervised individuals are adequately trained to detect potential problems or errors and to notify the authorized user or RSO when problems or discrepancies arise.

In response to a misadministration, a recordable event, or some other incident, or to identification of a violation, regulatory inspectors will typically determine whether the licensee has procedures for instruction in place, and will verify that the staff not only has been trained in those procedures, but that it also adheres to the procedures. This is particularly true when a misadministration has occurred, since many of such events can be traced to a lack of procedures, inadequate procedures, a failure to implement procedures, or a failure to effectively train supervised individuals.

In addition to being responsible for the safe use of licensed material in patients, many physician authorized users are also directly responsible for how entire departments use licensed material and some are members of the RSC. Physicians who are responsible for the safe use of licensed material in specific departments should also be responsive to the concerns of the RSO regarding regulatory commitments and safe practices, or any other relevant issue. Additionally, the authorized user should assist the RSO in maintaining an up-to-date inventory of licensed material by providing periodic information on material received, taken out of facility inventory, stored, or disposed of. Some authorized users are responsible for the safe use of licensed material *in vitro* in a research laboratory. In cases where the authorized user has no or minimal support staff, the authorized user should be responsible for preparing various types of information to the RSC to gain committee approval to use licensed material. Such information may include, but is not limited to, protocols for the safe use and storage of material, purpose of work, maximum quantity of radioactivity to be on site at any one time, waste disposal procedures, housekeeping responsibilities, contamination controls, ALARA practices, and personnel dosimetry needs.

More generally, physician authorized users who are members of the RSC are responsible for implementing the radiation safety program on a facilitywide basis. This responsibility requires that

the authorized user have a broad knowledge of the medical uses of licensed material, including procedures performed under the direction or supervision of other authorized users. To be effective in this role, the authorized user should gather all pertinent information before making decisions that impact the radiation safety program, in part or in whole. Additionally, the authorized user should strive to ensure that the interests of all medical use areas are adequately represented on the committee and that radiation safety issues are brought to the attention of facility management when indicated. The knowledge, experience, and clout imparted by the authorized user to the committee can have a positive significant impact on the effectiveness of the radiation safety program.

5.3 Supervised Technologists

The importance of providing adequate instruction and supervision to nuclear medicine and radiation oncology technologists delegated to perform specific tasks associated with the administration of radioactive material to patients cannot be overemphasized. In many medical facilities, nuclear medicine and radiation oncology technologists are the day-to-day "hands-on" users of radioactive material. Additionally, these supervised individuals often perform and document the results of many routine tasks for the safe use of licensed material as established in the radiation safety program. For example, in a private physician's office or a small community hospital that provides limited diagnostic services, the nuclear medicine technologist typically prepares and administers the dosage to the patient, performs the study, and conducts required quality control and radiation survey tasks to ensure the safe use of licensed material. These may include, but are not limited to, preparing and maintaining records documenting quality control tests conducted on the imaging equipment and dose calibrator used to measure patient dosages, performing radiation surveys on incoming and outgoing packages, preparing storage and use areas for licensed material, and maintaining storage areas for radioactive waste. In freestanding radiation oncology facilities, the dosimetrist or radiation therapy technologist assists the authorized user and medical physicist in ensuring that the treatment portal or location is accurate and that all instructions and information regarding administration of the prescribed dose are clearly recorded and understood by all responsible parties. Additionally, on a daily basis, the radiation therapy technologist responsible for patient treatment should ensure that, in the absence of the authorized user, the fractionated dose is administered as prescribed each time. In cases such as these, it is imperative that supervised technologists receive comprehensive training on the proper handling and use of licensed material, quality control procedures to ensure that the correct patient receives the prescribed dose, maintaining required records to document safety checks and procedures, and various other aspects of the radiation safety program relative to their area of use.

Part-time cross-trained technologists, technologists who infrequently use radioactive materials, and technologists whose services are used under contract with a temporary employment service should be of particular concern to executive management and the RSO. In some cases, these individuals have not, or have not recently, received site-specific and proper training to ensure that licensed material is handled safely and used in accordance with license commitments. Additionally, if the area of use for which they are responsible has expanded or if new procedures, new radiopharmaceuticals, or new devices are employed, additional training may be needed.

5.4 Health and Medical Physicists

If employed by the licensee, health or medical physicists may be authorized as RSOs, or may have similar support functions where they are responsible for a variety of radiation safety tasks or a portion of the radiation safety program. Through education and experience, both groups of individuals have extensive knowledge of radioactive materials and related health and safety issues, are familiar with regulatory requirements, and, in most cases, have had or presently have hands-on experience with radioactive materials. The physicist's responsibility for the radiation safety program is based on a broad base of knowledge and depends on the physicist's

commitment to find and correct potential health and safety problems. Therefore, health or medical physicists are usually integral players in the radiation safety program and may be assigned responsibility for instructing supervised individuals in areas appropriate for their use. Each category of individual is discussed in more detail below.

5.4.1 Medical Physicists Supported by Dosimetrists

These two groups are discussed together because of their coordinated role in ensuring that the correct patient receives the prescribed radiation therapy dose, and that the radiation safety program is fully implemented and adequate to address all aspects of the therapeutic use of radioactive material. Therapeutic procedures may include the use of cobalt-60 teletherapy units, linear accelerators, brachytherapy procedures including remote afterloading devices, gamma stereotactic radiosurgery, and radiopharmaceutical therapy applications.

A qualified medical physicist is an individual who is certified by one of several professional boards (e.g., American Board of Radiology, American Board of Medical Physics), or who possesses equivalent training and experience, and is competent in many aspects of diagnostic or therapeutic physics. Typically, medical physicists, with assistance from dosimetrists, assist the authorized user in determining the patient treatment plan based on the prescribed radiation dose. A medical physicist may supervise one or more dosimetrists who assist in the treatment planning process. Treatment planning involves complex mathematical computations performed with or without the aid of highly sophisticated computer systems. In a busy department, dosimetrists perform most of these complex tasks, and the physicist independently verifies all work. Particular attention should be paid to the accuracy of dose calculations whether they are done manually or with the aid of computer software programs. Errors in treatment planning dose calculation can potentially result in significant errors in the delivery of the prescribed dose. Additionally, a dosimetrist or a radiation therapy technologist is often responsible for preparing sealed sources or applicators for use in brachytherapy procedures. Such tasks performed by other individuals, particularly those that affect patient safety, should be supervised by the medical physicist.

Medical physicists, because of their expertise and specialized training, are responsible for radiation safety tasks related to the therapeutic use of radioactive material. This may include the conduct of periodic radiation surveys, sealed-source inventory and calibration, instrument or device calibration including calibration of treatment delivery systems, quality control on device control systems and interlocks, and, in some cases, the conduct of training sessions on radiation safety issues for nurses, technologists, or other health care professionals. Additionally, a medical physicist may have responsibilities in such diagnostic areas as nuclear medicine, and in the safe use of radiation-producing equipment found in radiology departments and elsewhere in the facility.

In addition to extensive formal training, medical physicists and dosimetrists should receive detailed training on the licensee's internal procedures and policies developed to ensure that the correct patient receives the prescribed dose since a dose calculation error could seriously overexpose the patient to radiation or could underexpose the patient. For NRC and some Agreement State licensees, this means that these medical personnel should be trained to adhere to the licensee's QM program. Additionally, the importance of not overriding built-in safety features designed to prevent treatment delivery errors should be emphasized to medical physicists, dosimetrists, and radiation therapy technologists in training programs.

5.4.2 Health Physicists

A health physicist is an individual who is certified by one of several professional boards (e.g., American Board of Health Physics) or who possesses training and experience equivalent to certification, and who may be responsible for various aspects of the radiation safety program. Health physicists are typically employed at broad

scope programs as RSOs or they may support a portion of the radiation safety program by performing tasks associated with radioactive waste management and instrument calibration, and by performing radiation shielding calculations for new or remodeled facilities. It should be noted that some health physicists are involved with medical physics support such as that described in the previous section, but this is not usually the case. In programs in which a health physicist is authorized as RSO, there are often radiation support staff members to assist the health physicist. These are individuals who have technical expertise in radioactive materials and are responsible for the conduct of specific tasks or a portion of the licensed radiation safety program. If the licensed program is very small, there may be no radiation safety support staff other than the RSO and, perhaps, a chief of nuclear medicine or a radiation therapy technologist. Regardless of the number of support staff, each staff member should receive training in the radiation safety program and regulatory requirements relative to the particular area of responsibility. Radiation safety support staff are an extension of the RSO and should report to the RSO or to a designated individual who reports to the RSO.

5.5 Nursing Staff

This discussion applies to nursing personnel and other individuals responsible for the care of a patient undergoing a radiation therapy procedure. Therapy procedures include the administration of therapeutic quantities of radiopharmaceuticals or the implementation of brachytherapy sealed sources, including the use of remote afterloading devices. Regulatory agencies require that patients undergoing radiation therapy remain hospitalized until the radiation level emitted from the patient decreases below a specific limit or until the radiation sources have been removed, as is the case for temporary brachytherapy implants.

While patients are hospitalized for the therapeutic procedure, nursing staff should continue to perform routine nursing care. To safely do this, nurses should receive training on radiation safety relative to their involvement with the patient and the therapeutic procedure performed. The goal is to reduce unnecessary radiation exposure to the patient and to the nursing staff, as well as to visitors and other facility personnel who may come in contact with the patient, to minimal levels. The importance of adequate training for nursing care staff cannot be stated too strongly. The NRC has observed several cases of nurses, responsible for care of a therapy patient, being unaware of basic radiation safety guidelines and causing unintentional radiation exposure to the patient, themselves, and, in some cases, to other facility personnel. Regulatory agencies place great emphasis on this area of use because of the potential for harm to individuals. (See NRC Information Notice 93–31, "Training of Nurses Responsible for the Care of Patients With Brachytherapy Implants," issued on April 13, 1993.) Although not technically nurses, other patient care professionals such as physical or respiratory therapists, dieticians, and laboratory personnel should receive similar radiation safety training commensurate with their responsibilities for patient care.

Nurses responsible for radiopharmaceutical therapy patients should receive guidelines from the RSO or radiation safety support staff on such issues as required "posting" of signs for patient rooms; handling radioactively contaminated excreta, bed linens, and other room items; reducing exposure by coordinating the number of times all facility staff enter the patient's room; setting time limits for visitors; using personnel dosimetry devices properly, as needed; addressing an immediate danger or emergency; and following instructions on when and how to alert the RSO or authorized user in the event of an actual or perceived emergency. For nurses responsible for the care of brachytherapy patients, guidelines are needed regarding when and how to contact the authorized user or the RSO or both; how to identify a sealed source, an applicator, or any device containing sealed sources in the event that they become dislodged from the patient; and safe handling of the sealed sources in an emergency to reduce unintended radiation exposure to the patient, nurse, other staff, or visitors. When providing training to nursing staff, the RSO might consider setting up "hands-on" sessions with brachytherapy "dummy" sources for nurses on all

shifts to simulate actual sealed sources, applicators, catheters, and the like, to ensure that nurses are knowledgeable and confident to react responsibly in the event of an incident. There may be other guidelines specific to the facility that will enable the nurse to provide adequate patient care while minimizing the radiation exposure to everyone involved in patient care. It will be necessary to conduct periodic sessions during various nursing shifts to present information and discuss radiation safety issues relative to patient care.

5.6 Ancillary Workers

This category is intended to capture facility personnel who are responsible for transporting patients who have received radioactive material; housekeeping, dietary workers, or security staff who have assigned duties in or around a restricted area; or other such individuals who may need radiation safety training relative to their responsibilities (e.g., animal caretakers, incinerator operators, waste processors). These individuals should receive radiation safety training to reduce their radiation exposure while performing their assigned duties and to assist the worker in identifying potential radiation safety hazards, such as an unintentional spill or a release of radioactive material. Guidelines should include how and when to notify the RSO or radiation support staff and the immediate actions that can be taken to easily mitigate the situation and prevent the spread of contamination or unintentional release or loss of radioactive material. On occasion, licensees will make a licensing commitment to directly supervise ancillary workers who are working in a restricted area. Note that direct supervision of these workers, while in restricted radiation areas, does not obviate the need to train these individuals on the hazards associated with their duties. Problems can occur, in that licensee personnel may not be aware that an ancillary worker has entered a restricted area, personnel may fail to directly supervise the worker when in the restricted area, or personnel may not be familiar with all applicable radiation safety guidelines that the worker should follow. In addition, dietary workers should receive instruction regarding delivering and picking up food trays for patients undergoing radiopharmaceutical therapy. Many facilities do not permit dietary workers to enter the patient's room; however, if they are allowed to enter, dietary workers should receive training relative to their responsibilities. Most importantly, food trays should not be removed and discarded as normal trash until it has been determined that radioactive contamination levels present in the food or on the tray items do not exceed background levels.

5.7 Summary

The effectiveness of the radiation safety program is dependent upon how well supervised individuals know license commitments and the radiation safety program, and their ability to identify deficiencies and potential health and safety problems so that appropriate action is taken by the RSO or other responsible individuals before a minor problem escalates. This feedback system thrives in an environment in which supervised individuals are encouraged by executive management, the RSO, and authorized users to notify the appropriate licensee authority when an apparent radiation safety problem or violation exists or when a potential misadministration has been identified. The goal is to establish an environment that fosters self-identification of minor problems before they become major ones. Additionally, when developing long-term effective corrective actions to address areas of noncompliance and potential safety hazards, executive management, the RSO, and the RSC should solicit the opinion of supervised individuals to identify corrective actions that are effective and practical, and that may prevent similar problems or events from reoccurring. As a final and important point, all allied healthcare workers can play a vital role in addressing a patient's fears and concerns regarding the use of radioactive material and the procedure itself. A few sincere and informative comments can go a long way toward comforting patients and encouraging their cooperation throughout the procedure. Contrarily, a thoughtless remark by nursing care staff can easily lead to a misunderstanding and increase the patient's anxiety.

6 RADIATION SAFETY PROGRAM RESOURCES

6.1 Introduction

Once the members of the management triangle have been identified, their roles have been established, and the tasks to be accomplished have been noted, it is time for the RSO, the executive management representative, and the RSC to identify resources associated with the management of a radiation safety program for medical use. It is important that executive management take an active role in this effort to ensure that adequate resources are allocated to the radiation safety program as defined by the RSO and RSC. Maintaining management's support is particularly important since the radiation safety program typically generates no revenue and may be subject to more severe or frequent budget cuts than other facility departments or areas. Program resources may include, but are not limited to, staff, salaries, time, equipment, and facility space. This chapter discusses each resource category in more detail to provide basic information to assist licensees in determining their resource needs.

6.2 Defining Adequate Resources

Members of the management triangle should commit to the program to maintain exposure to radioactivity as low as reasonably achievable (ALARA) by describing an administrative organization and developing the necessary policies, procedures, and instructions to foster the ALARA program. Obviously, this effort requires some resources, and these may or may not be available. Regulatory agencies recognize that licensees will make modifications to operating procedures, equipment, and facilities in order to reduce radiation exposures, unless they find the cost unjustified. However, regulatory agencies do want to know that management sought or considered improvements and implemented them when reasonable. When improvements are not implemented, the licensee should be prepared to defend its reasons for not implementing the improvements.

Minimum resources for effective radiation safety programs can be categorized as either staffing or as such financial factors as salaries, time, equipment, and space. Each category is discussed individually below.

6.2.1 Staffing Levels

Many factors enter into the evaluation of the number of staff needed to support a radiation safety program. A determination should be made regarding the need for the number of technical, clerical, and consultant or contract staff. In some cases, especially for licensees with small or very limited scope programs, one full-time (or even a part-time) RSO may be able to manage or provide support for the entire program. Larger programs may need a full-time RSO, some radiation safety support staff, some clerical staff, and some contractors to assist with various aspects of the program such as radioactive waste disposal. Keep in mind that many facilities submit excellent procedures and commit to performing several types of tests and surveys during the licensing process, but do not have adequate staffing levels to ensure that the work gets done once the license is issued. This may lead to weak programs and, in some cases, radiation safety problems and violations of regulatory requirements. These can be avoided if resource needs are realistically determined and secured early during the program development phase or when a program is undergoing significant growth.

Technical Personnel

Several types of technical staff at a medical facility might have a role in the radiation safety program. These include the RSO, authorized users, nuclear pharmacists, health and medical physicists, dosimetrists, technologists, nurses, and other radiation safety support personnel. Most regulatory agencies describe training and experience criteria for RSOs and authorized users for each type of use who either directly use or supervise medical use radioactive material. In addition, some regulatory agencies also describe training and experience criteria for health or

medical physicists, and criteria for accrediting technologists. For other categories of staff, regulatory agencies hold licensees responsible for having qualified staff to assist in the administration of radioactive material or radiation and to support the RSO, the authorized user, or the physicist. Training and experience criteria for use of radioactive material for *in vitro* (laboratory) testing or in research are typically not found in the regulations but in regulatory guidance documents, or they may be evaluated on a case-by-case basis.

At minimum, all medical licensees are required to have an RSO. Securing an RSO with training and experience specific to the licensed activities is also a factor to consider when reviewing staff and RSO requirements. Specialized authorizations on a radioactive materials license may necessitate having an RSO with training and experience relative to the licensed activities and can create significant demands on an RSO's time. This is particularly true for large, broad scope licensed programs that provide service in several medical disciplines and conduct research. For example, accelerators require more complex health physics programs for patient therapy procedures, and require additional expertise and training if accelerators are used for research purposes or radiopharmaceutical (radioactive drug) production. Advanced radiation therapy, such as gamma stereotactic surgery, monoclonal antibody therapy, remote afterloader brachytherapy, and other emerging technologies, can make significant demands on available time and expertise of the RSO, the physicist, and the support staff. Advanced diagnostic techniques requiring unique hardware (positron emission tomography scanners), non-standard radiopharmaceutical handling techniques, and production or quality control of radiopharmaceuticals in house, as well as special projects and research projects, will also serve to increase expertise needs and, therefore, basic salary requirements for a particular facility.

The size and scope of the program will dictate the number of additional radiation safety support personnel a facility needs and the training and experience needed by these individuals. For example, technologists who are registered or are eligible for registration with the National Registry of Radiological Protection Technologists (NRRPT) may be good candidates for radiation support staff positions. Large-scale institutional projects, such as radioactive waste incinerators or compactors, accelerator production of radioactive material, and the like, will probably require one or more dedicated technologists with this level of training and experience. Another source of trained personnel may be local institutions or universities involved in similar training programs, such as training programs for health physics technicians.

It is important to emphasize that there are private practices and clinics licensed by regulatory agencies that do not require large staffs. Private practices typically have one individual who is the authorized user, the RSO, and the member of executive management, and who also prepares and maintains all records without clerical assistance. There are also many good radiation safety programs at small hospitals or clinics that have one individual designated as RSO, and in some cases, this individual is also the sole authorized user. The scope of the licensed program is a key factor in determining whether staff, in addition to the RSO, is needed.

Clerical Personnel

Regulatory agencies rely in part on a review of required records to evaluate programs. It is to the licensee's advantage to establish a comprehensive and easily retrievable documentation, recordkeeping, and filing system. Such a system will provide continuity in the program when staff members change, and will allow audits and inspections to proceed more smoothly. Therefore, it may be worth the effort to ensure there is adequate clerical support to manage or support such a system. In addition, part-time clerical support may be needed when notifications, applications, or amendment requests are forwarded to regulatory agencies. For example, the original license application or renewal application will require submittal of policies and procedures that may require some clerical assistance. However, it is also important to note that many small programs do not require clerical or administrative support above that which is routinely available in a physician's office, or in the

radiology, nuclear medicine, or radiation therapy departments of a hospital because the amount of correspondence and paperwork is relatively low.

If management of the radiation safety program requires staff in addition to the RSO, radiation safety or clerical staff familiar with computers could be hired, since software development to manage radiation safety programs is as advanced as in other disciplines. In fact, several software packages are available to assist in such management of program areas as radioactive material inventory, waste disposal, and personnel monitoring. Database specialists may be considered in clerical support job descriptions, and for larger facilities with large inventories of radioactive material or many records, data entry specialists may reduce overall costs by reducing the number of radiation safety professionals required to perform these functions.

Consultants and Service Companies Under Contract

As described in Chapter 7, some functions in a radiation safety program may be performed by a consultant and some services may be performed by a service company. The RSC should identify services to be contracted out and should estimate the associated costs for consideration within the overall operating budget for the radiation safety program. If contractual support is indicated, licensees should establish a contractual arrangement with a consultant, a group of consultants, or with one or more service companies to meet the needs of the program. Many licensees find that contracting certain services with a consultant or service company can be a cost-effective method for augmenting a radiation safety program. For example, most medical facilities contract out personnel dosimetry devices and instrument calibration and leak test services. This conserves facility space, equipment costs, and the technical staff's time.

Some facilities have found ways to reduce expenses for contracted services by evaluating resources available in house. For example, some facilities with complex therapy or pharmaceutical production equipment have realized cost savings on service and repair contracts by training biomedical, physics, or electrical engineering staff in maintenance and repair of these devices. There are usually large up-front costs associated with this approach, and there is no guarantee that the trained individual will remain at the facility beyond some contracted minimum time.

6.2.2 Financial Factors

A discussion of resources would be incomplete without mentioning financial factors, primarily salaries. Many licensees know how to calculate the cost of space at their facility and budget for equipment purchases, yet they are unaware of the resources available for use in establishing competitive salaries for radiation safety personnel to attract qualified candidates. Therefore, the discussion of finances is limited to a description of resources available for developing a salary structure for radiation safety personnel.

When trying to fill positions, licensees can survey their own local salaries by questioning similar facilities about the number and type of credentialed individuals on staff, their position within the radiation safety program, and the salary ranges for those positions.

It may be worth considering filling the RSO position at a salary level equivalent to the management positions of other departments at the facility. This method of estimation is at least partially immune to local and regional variations, but may not factor in participation in unique or specialized projects. Other factors discussed elsewhere in this document may also be considered. When trying to fill positions, it may be cost effective to send individuals already on the staff to specialized training courses to augment their area of expertise in order to assist in other program areas. For example, a physician authorized user may need additional training to qualify as an RSO, or a technologist may require additional training in order to provide support in other program areas.

Generally, salary costs for smaller radiation safety programs may be modest and full-time equivalent staff (FTEs) can be shared with other departments. For large or broad scope programs,

care should be exercised to prevent conflicts of interest when the safety program is substantially supported by users or users' departments. The staff may need to be independently funded to ensure autonomy and the availability of sufficient resources. Also, funding may be needed for a support position to work with other departments, such as partial support of one or two individuals expected to assist separate departments with radiation surveys, accounting and handling of licensed material, or individuals involved with technical or safety support of uses outside the radiation safety department (e.g., cyclotrons or medical physics support).

Many professional organizations survey the salaries of their members. For example, the American Association of Physicists in Medicine (AAPM) publishes an annual "Professional Information Survey Report" analyzing salary information from its members. This information is categorized by types of certifications held, primary discipline, and years of experience, and is adjusted for geographic variables. Such surveys and resulting tables require some study and interpretation to understand how the data were gathered and how the data can be applied to a particular situation. Also to be considered, the fact that the differentiation between rural and urban areas and the scope of the licensed programs are not always identified in the results of these surveys. The extrapolation of salary data to a particular situation should take into account geographical location, size of program, and training and experience required by the regulations. Unique program factors, such as waste handling, support of research operations, or other duties assigned to the particular individual responding to the survey also may not be identified in published salary surveys.

6.2.3 Time

The amount of time it takes to maintain a radiation safety program depends, in large measure, on the size and scope of the program and the manner in which procedures are designed and implemented. Too much time away from management of any program will eventually lead to problems. Specifically, minor radiation safety problems, such as radioactive waste inventory and control, can escalate into major safety or regulatory problems if not well monitored. It is imperative that management support the program by allowing the RSO time to ensure that all duties associated with day-to-day management of the radiation safety program are performed as required by the regulations; allowing the RSO, the radiation safety support staff, and possibly RSC members time to attend professional meetings; and allowing other staff time to perform surveys and attend training sessions as necessary.

Each facility should evaluate the tasks that should be done and should develop the most efficient and most cost-effective methods for ensuring each task is completed. If, for example, the RSO is responsible for performing radiation surveys at the end of each day in all areas in which radioactive material is used, more time is needed than if users at these locations perform these checks and the RSO ensures they are done.

Time for Conducting Training and Program Audits

All individuals should have training before being allowed to use radioactive materials and should have refresher training at intervals not to exceed one year. Additionally, individuals should receive training on new or revised regulations, or when new devices or new models will be used, or when significant changes occur. Particularly important is training for using the devices for patient treatment (e.g., remote afterloading brachytherapy devices, teletherapy, linear accelerators). The RSO or radiation safety staff generally trains users of radioactive material, supervised individuals including nursing staff, and ancillary personnel such as housekeeping and security staff. Training these individuals can practically be a full-time job at a large facility with frequent staff turnover and many authorized areas of use. To help consolidate training sessions, the initial training can be incorporated into new employee orientation and annual training can take place in a classroom situation. It is recognized that the entire department staff will not be able to be trained in a single session. Additional or individual training sessions may be needed to train all individuals

who need training. Sometimes the individuals responsible for doing the training should attend training courses in order to obtain up-to-date information about a subject to ensure they train others properly. Therefore, executive management should be prepared to dedicate resources for attendance at professional society or scientific meetings, as well as for attendance at courses offered by regulatory agencies, teaching facilities, or other facilities providing similar services. Additionally, resources may be needed for preparing training materials, such as brochures, handouts, slides, videos, and other presentation material.

If the RSO has delegated tasks to certain individuals, such as requiring users to perform daily area surveys, task-specific training should be performed to ensure the correct procedures are followed. This training should also include instruction in what to do when a problem arises. Managers should allow employees time to attend this training.

In order to ensure continued safety and regulatory compliance at a facility, each licensee should conduct periodic audits as discussed in Chapter 8. Periodic informal "walk abouts" should not take too much time if a facility is small, but the bigger and more complex the facility, the more time needs to be budgeted for and dedicated to audit functions, both informal and formal.

6.2.4 Equipment

Significant cost can be associated with initiating a licensed broad scope medical use program, from writing procedures to securing and possibly remodeling existing space, securing qualified staff, and equipping facilities. For equipment acquisition, a qualified medical or health physicist should be consulted to ensure that the equipment will meet the needs of the program. This also holds true for the purchase of used equipment. Appendix K contains a sample list of radiation safety equipment used in various departments or laboratories at medical facilities. Some costs can be cut by purchasing used equipment, but all analytical equipment should be calibrated in accordance with regulatory requirements and checked before it can be used.

The regulations are specific on the type and frequency of area surveys to be performed, instruments to be used (i.e., dose calibrators, radiation measuring devices, etc.), and the frequency for evaluating the performance of these instruments. Other specialized equipment may need to be purchased in support of the program, and the cost of purchasing and maintaining this equipment should be factored into cost projections. Additionally, funds may be needed for acquiring, through the institutional library or resource center, books, journals, and other publications deemed necessary by the RSO or RSC.

6.2.5 Facility Space

All programs will need dedicated space for filing and storing records. In addition, radiation safety programs will need adequate space to allow the RSO and any support staff to perform the duties described in other chapters of this report. Some programs may even need to have specialized areas set aside for certain tasks.

For smaller radioactive materials programs, the cost of dedicated space can be shared with other programs. For programs limited to the diagnostic use of radioactive material, for example, radiation protection survey equipment and records documenting surveys can be maintained in the nuclear medicine department or in an area near that department.

For larger programs, the radiation safety program itself will require considerable office and work space. This would include space for reviewing records, storing radiation survey equipment, performing maintenance on technical equipment, and maintaining reference materials and records generated to comply with the regulations; a personal computer could facilitate effective management of data, records, required survey results, and tables. Depending on other centralized services that the radiation safety office is expected to perform, operating space requirements can expand considerably, particularly in the area of radioactive waste

management. See the section that follows entitled, "Radioactive Waste Management."

Centralized service functions can include receiving radioactive material packages and allocating space for their temporary storage (possibly refrigeration or freezer space), performing package surveys, opening packages, inventorying the contents, repackaging for transport to a local institution, entering material into an inventory tracking system, and disposing of surveyed package wastes. These inventory functions may require dedicated work stations. Areas for storing radioactive materials may also require some shielding, such as concrete walls, in order to reduce exposure to workers.

Other centralized service functions requiring operating and storage space often include personnel monitoring services for occupationally exposed individuals, and bioassay services in order to calculate internal committed effective dose equivalents. Tracking personnel monitoring and bioassay results for each individual may require a dedicated work station and large filing capacity, depending on the number of occupationally exposed individuals at the facility and the types of materials they are exposed to.

Additional functions may include specimen collection and sample analysis, radioactive material inventory control, calibration and repair of radiation survey equipment, sealed source leak test services, air- monitoring services, and other safety-related sample- gathering operations. Each has its obvious space demands, but some services have particular needs. For example, if a licensee does not choose to contract with a service company for instrument calibration, a large restricted area will be needed for conducting calibrations. Wipe test sampling and bioassay analysis will require low background or shielded areas. Licensees that have special facilities for handling iodinations will need dedicated air handling and monitoring systems and specialized effluent filtration.

Radioactive Waste Management

Radiation safety personnel are frequently responsible for managing radioactive material waste. This can include waste collection and sorting, decontamination and decommissioning services, and enforcement or impoundment functions. Waste management operations have taken on new importance with regard to demands on space, as efforts to provide national compacts and local radioactive waste disposal sites encounter difficulties. This has driven up the price of shipping radioactive wastes to authorized disposal sites, and has consequently led to more creative waste management plans, some of which may require regulatory review and approval, such as interim storage or storing materials with longer half-lives.

Most programs will usually dedicate some space for sorting and storing certain wastes for decay, verifying the decay of radioactive material after a minimum required length of time by radiation survey, and trans- ferring these wastes to appropriate non-radioactive waste handlers. A short-lived radionuclide (one with less than a 65-day half-life), such as technetium-99m which is routinely used in nuclear medicine depart- ments, requires a minimum of 60 hours for decay before it can be released as non-radioactive trash. For low-volume diagnostic programs, radioactive waste storage needs will not necessarily require significant storage space and may be accommodated within the nuclear medicine laboratory. However, licensees who use large volumes of iodine-131 will need to provide dedicated space for storage of this radioactive waste since iodine-131 is volatile and NRC requires that it be held for decay a minimum of 10 half-lives, or 80 days, before it can be evaluated for disposal as non- radioactive waste.

Longer-lived radioactive material may not qualify for decay-in-storage authorizations, yet will need to be stored in a controlled environment because of changes in the availability of authorized radioactive waste dis- posal facilities. Hence, there may be an advantage to sorting wastes that may immediately qualify for non- radioactive waste streams, but this procedure will need space for additional packaging and batching for disposal to

controlled waste contractors, such as is the case with infectious and other hazardous wastes. Volume reduc- tion operations, such as aggressive sorting, compacting, and incineration, will require dedicated space and additional staffing. If the facility also handles volatile radionuclides, additional monitoring and filtration will be needed when processing these wastes. To minimize the possibility of contamination, waste sorting, storage, and disposal operations are typically isolated from other operations.

However, facilities whose only long-lived radioactive wastes are sealed sources may be able to return them to the manufacturer for disposal, or may be able to store them in shielded containers or in a shielded area in a secured room, depending on the physical size of the source.

For facilities that use long-lived radionuclides or large volumes of radioactive material, perhaps the greatest potential demand on space arises from the need for facilities to plan for extended interim storage of radio- active waste for several years, as a result of limited access to authorized waste disposal facilities. State and Federal regulatory agencies vary on the number of years the medical facility should plan for, but have been recommending that licensees should provide for storage space of accumulated radioactive waste. Depending on the projected volume and the nature of the material to be stored, these storage facilities may need to be dedicated engineered facilities of large size, protected from the weather and from common natural hazards and accidents, with humidity controls and fire protec- tion. Some facilities may also need special refriger- ator or freezer units to hold contaminated animal carcasses or may need segregated areas for radioactive wastes that also contain flammable, corrosive, or oxidizing agents.

Decontamination and Decommissioning

Decontamination and decommissioning are terms generally assigned to the process of cleaning a facility that once contained radioactive material to such a level that there is no longer any radioactive material left to be a risk to anyone entering or using those facilities for any length of time.

However, it may also be necessary to apply these practices when remodeling or relocating a nuclear medicine department or a clinical or research laboratory. When designing a facility, executive management should take this into consideration as it will be cost effective when operations involving licensed material are discontinued and decontamination and decommissioning are performed. Many regulatory agencies have very specific recordkeeping requirements for documenting where radioactive material was used, and the quantity and the chemical and physical form of the material used. This information should be recorded and kept on file until the facility has been cleaned and returned to a condition in which there are no hazards from radioactivity to members of the public. Regulatory agencies typically require the posting of financial assurety, which essentially guarantees the availability of funds when decommissioning is to be performed. It is prudent to become knowledgeable about specific decommissioning and decontamination requirements.

Decontamination and decommissioning projects entail little space costs for technical operations, but can be quite costly in terms of staff time necessary to perform and document the cleanup. This is especially true in situations in which authorized users in a research laboratory fail to notify the RSO in advance that they will no longer be working in the laboratory, and the RSO and staff is expected to decontaminate the area when the exact types and quantities of radioactive material most recently used are not recorded. If in- house staff does not have the experience, the expertise, or the time to decontaminate an area, the facility should budget for these contractual services. Additional expenses in terms of staff time and space allocation should be calculated if the radiation safety program should take possession of waste material from the cleanup and store it for any period of time. In some circumstances, large radiation safety programs have been required to take title to or otherwise support areas or buildings that cannot be released for unrestricted use during or after decontamination. However, costs will be minimal if the facility has been using radionuclides with short half-lives (generally less than 65 days), and if

the radiation safety program has successfully minimized contamination.

6.3 Summary

Very early in the process of establishing a radiation safety program, adequate staff, salary, time, equipment and space needs to fulfill the regulatory obligations should be identified and included in the budget. Generally speaking, if the facility is a clinic or a small hospital authorized for only clinical uses of radioactive material, and if the small facility contracts most personnel monitoring and instrument calibration functions, resource requirements are minimal. Resources for waste disposal and facility cleanup are also minimal because the relatively short half-life of the material allows for disposal after a relatively short storage period. The larger the facility, the more authorized uses on the license, the more types of diagnostic and therapy procedures performed, and the more support services the radiation safety staff provides, the more resources are needed to maintain the program.

7 USE OF CONSULTANTS AND SERVICE COMPANIES

7.1 Introduction

This chapter discusses issues to consider when determining if the services of a consultant or service company are needed, potential problems associated with their use, the various roles of the consultant or service company, and the contractual agreement between the medical facility and the consultant or service company. Available resources and each licensee's individual needs drive the decision to utilize the services of a consultant or a service company and determine the magnitude of their role. Regulatory agencies recognize that consultants and service companies can provide a variety of services and can enhance a radiation safety program when managed properly. Licensees are reminded that executive management is responsible for the licensed program, and that the use of contractual support for the radiation safety program will require RSO and RSC direction and monitoring. For ease of discussion, the terms "consultant" and "service company" are collectively referred to as "contractor" where applicable in this chapter.

7.2 Deciding Whether To Use a Contractor

7.2.1 Defining a Contractor

A contractor could be an individual consultant, a group of consultants, or a service company or organization that can support the program at the licensed facility by performing tasks associated with the radiation safety program. A consultant is typically a trained and experienced health or medical physicist, or an equally qualified individual, who is retained by the facility to provide professional support to the program by augmenting or assuming the role of the RSO, and to assist the licensee in maintaining compliance with applicable NRC or Agreement State regulatory requirements by conducting periodic audits. Typically, the consultant prepares a written report (findings or recommendations) for the licensee.

A service company or organization is typically one or more individuals with similar qualifications that provide limited services to the medical facility, such as supplying and processing radiation personnel monitoring devices, calibrating survey instruments, conducting leak tests on sealed sources, performing quality control tests on equipment, and managing the disposal of radioactive waste.

Most licensees secure contractual support for one or more portions of the radiation safety program because it may not be cost effective to maintain the equipment or expertise in house to perform certain technical tasks.

7.2.2 Defining Responsibility

Since contractors are not employees of the licensee, regulatory agencies consider the contractor and licensee to be independent of one another except for their contractual agreement for the performance of specific radiation safety services. As a result, regardless of the magnitude of the role of the contractor in support of the licensed radiation safety program, the licensee continues to be ultimately responsible for implementation of the radiation safety program and regulatory compliance. Licensees should not assume that by hiring a contractor to perform certain tasks, they have fully satisfied all regulatory requirements or that they have somehow transferred responsibility or liability for their licensed program to a contractor. The licensee, *not the contractor*, will be held responsible for program deficiencies identified during inspections performed by the regulatory agency. Thus, all parties to the contractual arrangement should be aware of the duties and responsibilities of each party (i.e., management, the contractor, the RSO, and the RSC), as well as the reporting and feedback mechanisms implemented to ensure that appropriate actions are taken to address the contractor's findings, particularly, potential regulatory violations.

7.3 Selecting a Contractor

7.3.1 Evaluating a Consultant or Group of Consultants

Each licensee should carefully evaluate the credentials of consultant candidates and determine if the individual, or group of individuals, is qualified to perform the contractual duties and responsibilities. Executive management, the RSO, and RSC members should provide input during the selection process. This is particularly true if the licensee is contracting with a consultant to fill the role of RSO or to augment the RSO who is on the staff at the medical facility. Ideally, the consultant should have experience in performing radiation safety services or the duties of an RSO for a program of similar size and scope. The individual's credentials should be evaluated by contacting the consultant's references to verify the quality of services provided and range of experience. Licensees will often contract with a consulting company that may employ several health or medical physicists, or equally trained individuals, who have various expertise and experience and are qualified to perform radiation safety support functions. Such arrangements can be advantageous since these companies offer the opportunity for several consultants with varied backgrounds to visit a licensee's facilities and detect weaknesses that perhaps a single consultant might overlook. At the same time, it is important to note that a group consultant arrangement can elicit problems in programmatic continuity if different consultants do not ensure coordination of their duties and feedback among themselves.

The NRC normally does not directly regulate a licensee's use of consultants. However, in order for a consultant to be named as RSO on a license, the NRC or the Agreement State should evaluate the training and experience of the individual, as well as other factors which may impact the consultant's ability to perform the duties of RSO (see Section 7.5.1 titled, "Consultant as RSO").

7.3.2 Evaluating a Service Company

Many of the same issues regarding selecting a consultant or group of consultants applies to selecting a service company. Licensees need to ensure that the service company is qualified to perform the requested services and has a clear understanding of the licensee's expectations as outlined in the contractual agreement. Problems can occur when the licensee makes assumptions regarding the magnitude of the role or responsibility of the service company. Many licensees successfully contract with service companies to provide such services as personnel monitoring, instrument calibration, quality control testing on equipment, leak tests, radiation surveys, and radioactive waste management.

In some cases, providers of contractual services may have to be licensed by the NRC or the Agreement State before performing such services. Included in this contractor category are contractors who calibrate and repair survey instruments and teletherapy devices, and who test sealed sources for leakage.

7.4 Contractual Agreements

Formal written contracts between contractors and licensees are good management practice. The use of formal contracts is encouraged and often proves advantageous to the parties involved, since it becomes the framework for a productive working relationship and may help alleviate problems that could arise with the use of contractors. It is important to ensure that the services contracted for are appropriate for the radiation safety program. For example, if a consultant is engaged to perform certain required radiation safety surveys, the licensee should ensure that all elements of the required survey and associated recordkeeping requirements are met. If a service company is used for personnel dosimetry support, the licensee should ensure that the type and number of dosimetry devices, and frequency of radiation exposure reports, are adequate to conform to the monitoring requirements described in the regulations. Additionally, licensees should ensure that radiation detection and measuring equipment is calibrated to the radionuclides used at the facility and in accordance with the regulations. If the facility also uses a cobalt-60 teletherapy machine for patient treatment, there are very specific requirements for calibrating and comparing

teletherapy radiation survey instruments. Other specialized instruments may have other specific calibration requirements, and the licensee should review the regulations and manufacturers' instructions to verify compliance with these requirements.

Licensees are encouraged through the contract to have the contractor prepare periodic (e.g., monthly, quarterly) written reports consistent with the services provided. With the use of a service company, reports could be prepared periodically or only when services are rendered. If a consultant is augmenting the role of the RSO, the licensee should expect a periodic written report of findings and recommendations as described in the contract. This information should be furnished to the RSO, the RSC, and the executive management representative. If management wants the consultant to attend RSC meetings to present findings, this should be arranged and documented during contract negotiations. (Note: If the consultant is named as RSO on the license, the consultant should attend all RSC meetings.) The contract should also address the consultant's authority to access licensee staff for training and the licensee's radiation safety program records. If the licensee chooses to delegate corrective action responsibilities to the consultant, the consultant should have effective enforcement tools available.

Delegation of tasks to the consultant should be reviewed and approved by management and the RSC to prevent any omission. A contractual agreement should be developed to address, at a minimum, the following points:

- the specific services to be provided by the consultant
- the consultant's estimated onsite time commitment (This will usually vary from visit to visit and is difficult to specify with certainty.)
- the communication commitments between the consultant, the RSO, the RSC and management (i.e., written reports, RSC meeting attendance, etc.)
- the licensee resources available to the consultant, such as equipment and technical and clerical staff time
- specification of the individual(s) responsible for ensuring that corrective action is taken when a consultant points out problems in a program
- whether attendance at the RSC meetings is required
- the communication commitments between multiple consultants
- the line of authority between the consultant and the licensee if the consultant is authorized as the RSO

7.5 Roles of the Consultant

The possible roles of consultants for the radiation safety program may be loosely grouped into three categories: consultants who are authorized as RSO on the license, consultants who augment the program by performing many of the RSO tasks, and consultants who provide limited support. Whatever the magnitude of the consultant's role, members of the management triangle should ensure that the consultant is enabled within the program to effectively perform the assigned duties or services.

7.5.1 Consultant as RSO

Licensees should receive regulatory approval before they can assign a consultant to be the RSO. Many Agreement States do not allow consultants to assume the role of RSO at a medical facility. Approval of the consultant–RSO by the regulatory agency is primarily based on a review of the consultant's documented training and experience. Additionally, in some cases, the regulatory agency may require that the consultant commit to being physically present at the facility for a specified minimum amount of time to satisfactorily perform the duties of RSO. The onsite time commitment required of the consultant–RSO should be commensurate with the scope of radioactive materials use at the facility and will differ on a case-by-case basis. In

addition, the time commitment should indicate that the consultant will be on site for some of the dedicated time during normal working hours to provide the opportunity for the consultant, licensee management, and technical staff to work together. It is important for the licensee to establish the consultant's availability to respond to questions, incidents, and emergencies as needed, both by telephone and on site. The consultant–RSO's contractual time commitment may need to be periodically reevaluated as radiation safety programs evolve.

Before approving a consultant as RSO, the NRC will, and an Agreement State may, at a minimum, ask the licensee to address the concerns listed below:

- Describe the control over the radiation safety program that will be delegated so that the consultant–RSO will be able to exercise his/her authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

- Describe the relationship that will exist between the consultant–RSO and the licensee's institutional management regarding expenditure of funds to facilitate the objectives of the licensee's radiation safety program and related regulatory requirements.

- Identify other commitments of the consultant– RSO for other NRC or Agreement State licensed facilities, and describe how the consultant–RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant–RSO's minimum amount of onsite time (hours per week).

- Appoint a licensee representative who will serve as the point of contact during the RSO's absence. It may be prudent to appoint a representative of executive management who speaks with authority when interacting with the regulatory agency, has the authority to act on the consultant's findings, and is allowed to assist the consultant–RSO who has limited authority.

- Describe the overall availability of the consultant–RSO to respond to questions or operational issues that arise during the conduct of the licensee's radiation safety program and related regulatory requirements. What is the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his/her presence?

In recent years, there has been a trend for physicians or groups of physicians to contract with a medical facility or with several medical facilities to provide certain specific professional services. In a sense, the physician is a consultant to the medical facility. Thus, it follows that if one of these physicians is selected to be RSO, the physician–RSO is technically not an employee of the medical facility. Therefore, executive management and the RSC should define the reporting relationship between the physician–RSO and the RSC and executive management, delegate authority to the RSO to adequately fulfill this role, and ensure that the physician– RSO is knowledgeable of the license commitments and regulatory requirements. Qualified licensee personnel may have to train the physician–RSO. Licensees should address the implications of such arrangements and might consider implementing a contractual agreement with a physician–RSO engaged under this arrangement.

Depending on the size and scope of the radiation safety program, the role of the RSO may be filled by a consultant–RSO on a part-time basis. For example, a private medical practice at which a limited number and type of diagnostic nuclear medicine studies are performed may be served well by the use of a part-time consultant–RSO because the onsite time required would be relatively small and the records could be kept by staff technologists and reviewed periodically by the consultant. In contrast, a part-time consultant–RSO may be inadequate for some programs, for example, programs performing

many radiopharmaceutical therapies, remote afterloading brachytherapy, teletherapy, or gamma stereotactic radiosurgery procedures, and for programs performing a high volume of radiopharmaceutical therapy or conventional brachytherapy patient procedures. Additionally, it may be very difficult to adequately supervise highly technical, time-intensive research and development uses of radioactive materials.

7.5.2 Consultant Who Augments the Radiation Safety Program

Most commonly, the consultant performs a significant portion of tasks associated with a radiation safety program. Although many RSO functions may be delegated to a consultant, there are certain regulatory requirements that may only be performed by the individual named on the license as RSO. For example, the signature of the RSO is needed on certain required records to demonstrate review and approval. The RSO may not appoint an alternate (such as the consultant) to attend RSC meetings to represent the RSO. Although licensee management is responsible for the work performed by the consultant, the RSO usually supervises the consultant's performance to ensure that delegated tasks and services are performed as contracted for in the license. The RSC should routinely review the findings of the consultant and ensure that any safety issues and outstanding items are resolved in a timely manner, and that corrective measures or actions are effective in deterring recurrence.

7.5.3 Consultant Who Provides Limited Services

Consultants may be retained by licensees to perform limited tasks, such as annual training or audits of the radiation safety program. For example, in response to an enforcement action and as part of the corrective actions, a licensee may propose to retain the services of a consultant on a "one time only" basis to perform a third-party audit of the program. This arrangement should be treated like any other contractual arrangement, in that, the expectations of both parties should be written down and agreed to by both parties. The RSO should inform the consultant of the expectations of the audit and of any particular areas that should be addressed. However, it is important that the licensee be mindful not to dictate the scope of an audit in so much detail as to color the audit. Additionally, upon its completion, an audit is of value only if it is reviewed and acted upon by the RSO, the RSC, and executive management.

7.6 Use of Multiple Contractors

In some cases, a licensee may find it advantageous to employ more than one contractor to fulfill several program requirements. It is important that the RSO, the RSC, and executive management are aware of the contractual assignments of each contractor, and that the contractors have clear direction from the licensee regarding their specific responsibilities and relationship to one other. Again, the use of a contractual agreement between the respective parties may be helpful. Depending on the services provided, the contractors may need to communicate among themselves to ensure that the findings are followed up and that there are no omissions in the program.

7.7 Potential Problems

Generally, contractors can provide significant support to a radiation safety program, particularly when the licensee lacks sufficient qualified staff in house. However, as with other contractual arrangements, potential problems may be associated with their use. These could include failure of the contractor to complete all required tasks in the specified manner or time frame, or failure to report on all tasks performed. Also, the licensee could assume that all work was completed as specified and fail to review the work of the contractor. Therefore, to reduce the possibility of such problems, licensees need to establish and maintain effective communication mechanisms with the contractor, initiate corrective actions in response to findings and potential items of noncompliance, and periodically verify the quality of work performed.

In addition, regulatory inspectors may review contractor findings as part of a routine inspection. The NRC expects licensees to promptly address a

contractor's findings and has historically held the licensee responsible for findings that go unaddressed. One common problem with programs utilizing consultants is that licensees fail to correct the problems that consultants identify. For example, when a consultant identifies incomplete contamination surveys, the licensee should take timely corrective action to remedy the deficiencies.

There may be many explanations for a lack of licensee action. Sometimes the consultant reports some problems to the individuals responsible for performing the surveys, but the responsible individuals take no corrective action because the consultant has no authority over them. Sometimes the consultant sends audit reports to the RSO for corrective action but the RSO, relying fully upon the consultant and assuming the consultant will provide all corrective action, does not review the reports. Sometimes the RSO reads the audit reports and is aware of the problem but takes no corrective action. The licensee may correct such a situation by officially designating the individual responsible for ensuring corrective action or by requiring that the consultant attend all RSC meetings and report findings directly to the entire committee that includes the RSO and executive management. (Note: If the consultant is named as RSO on the license, the consultant should attend all RSC meetings.)

Another situation that often results in program deficiencies is the use of a contractor who is only on site after normal working hours. After-hours labor may be acceptable and expected for certain contracted services such as instrument repair and calibrations, decommissioning, or decontamination. However, for most other services, use of after-hours consultants will preclude their assessment of routine performance of the radiation safety program by observing and talking with licensee personnel. If such an arrangement is used, it becomes critical for the RSO to spend time observing routine activities during working hours to ensure that the program functions safely and is in compliance. All too often, the RSO, relying heavily on the consultant, does not make such observations, and health and safety problems or items of noncompliance go undetected by both the RSO and the consultant.

Additional common pitfalls include the following: (1) utilizing the services of a contractor who is not qualified or experienced in the area for which services are sought; (2) utilizing the services of an unlicensed or unqualified contractor when the regulatory agency requires that the services be performed by a licensed or qualified contractor (e.g., sealed-source leak testing, survey instrument calibration, teletherapy unit calibration); and (3) a contractor's inability to dedicate the necessary time to fulfill the contractual agreements for the number of facilities serviced.

7.8 Summary

Contractors can enhance management of a licensee's radiation safety program and licensees should utilize the information presented in this chapter to determine if a contractor is needed. The material in this chapter can also help a licensee delineate the appropriate role for a contractor(s) and can guide the licensee toward successful, comprehensive working arrangements between them. Potential problems with the use of contractors should thus be minimized.

8 CONDUCT OF AUDITS

8.1 Introduction

This chapter discusses the purpose and scope of audits and the evaluation of audit findings, and describes types of audits and auditing techniques. Regulatory agencies require that certain elements of the radiation safety program be audited to ensure that regulatory compliance is maintained and public health and safety are adequately protected. For the purpose of this chapter, it is assumed that the RSO primarily performs the audit function, with or without the assistance of other qualified individuals, since it is the RSO who typically is the most knowledgeable and best qualified to perform this task. Each audit required by NRC is discussed below; however, licensees may elect to conduct additional audits to address specific program areas or to comply with license commitments. Licensees in Agreement States should review the appropriate auditing requirements for their particular State.

8.2 Purpose and Scope of an Audit

An audit program provides the RSO, the RSC and executive management with specific information regarding the licensee's overall performance, status of compliance with regulatory requirements, and strengths and weaknesses in the program. Future efforts and resources can be redirected in response to audit findings. The audit process is most effective when audits are performed by individuals who are thoroughly familiar with health and safety standards and regulatory requirements. Additionally, negative findings should be acted upon to ensure that prompt, long-term, and effective corrective action is implemented, and feedback mechanisms should be in place to encourage early identification of potential problems and to ensure that corrective actions are effective. It is in the licensee's best interest to find the problems and potential violations and correct them before they are uncovered by the regulatory agency. This is a particularly important program area for the RSO since it is the RSO who executive management typically holds responsible for the effectiveness of the radiation safety program and for maintaining regulatory compliance.

Objectivity, an important characteristic of a successful audit, can be enhanced when the audit is performed by an individual who is independent of the licensed activities under review. However, it is recognized that in smaller programs the availability of knowledgeable individuals independent of the activities being audited may be limited.

8.3 Initial Audits

When an internal audit system is implemented at a facility for the first time, or perhaps when a new RSO is designated, the audit should focus on overall performance to ensure adequate protection of public health and safety, and to ensure that activities are carried out in accordance with the ALARA principle. First, the auditor should review applicable regulations and related regulatory guidance, the license document and all amendments, and the license application and its attachments to gain full understanding of the scope of the licensed program and its operating limits. Then the auditor will be able to prepare a comprehensive checklist (or some other mechanism) to ensure that all program aspects are reviewed and that the required audits are performed. General program areas for review during an initial audit might include identification of key personnel and their availability; the lines of authority between executive management, the RSC, and the RSO; the roles of the RSO and RSC; whether the number of radiation safety support staff is adequate; the ALARA program; the training program; the RSC meeting minutes; and the scope of radioactive material use. A new RSO auditing an existing program for the first time, should review findings from previous audits to determine if some problem areas were identified in the past, if effective long-term corrective actions have been taken, and whether the scope of the existing audit program is adequate. After completing an initial or "general" audit, the auditor should continue to "fine tune" the audit process to focus more sharply on the

details of each medical use area to ensure compliance with all applicable requirements.

8.4 Required Audits

Most regulatory agencies require that licensees conduct periodic audits of the licensed program to ensure adequate protection of public health and safety and compliance with regulatory requirements. The NRC requires its licensees to conduct (1) an annual audit of the radiation safety program in its entirety; (2) an annual audit of the QMP, if the licensee is required to have a QMP; (3) an annual review of the ALARA program to include quarterly audits of personnel exposure records; and (4) an annual review by executive management of the radiation safety program, including ALARA considerations, if the licensee committed to Regulatory Guide 10.8, Appendix G.

It is common practice and considered acceptable for licensees to consolidate, in whole or in part, the audits listed above. Licensees who combine the required audits into fewer actual audits should ensure that the specific regulatory requirements of each audit are accomplished in a timely manner. Also, licensees should document which regulatory requirements they intend to address in each audit.

Licensees should develop their own auditing checklists by customizing the sample outline in Appendix L, and should audit the radiation safety program at the required frequency. Licensees should consider increasing audit frequencies when experiencing significant changes in operating procedures or equipment, sudden and substantial growth in operations, inadequate staffing, high personnel turnover, previous significant negative audit or inspection results, misadministrations or recordable events, or financial instability.

8.4.1 Annual Radiation Safety Program Audit

NRC regulations require that all medical licensees review, at least annually, the content of the radiation safety program, and implementation of and adherence to ALARA concepts. All licensed program areas and activities should be reviewed to determine whether activities are being conducted safely, in accordance with regulatory requirements, and consistent with the ALARA philosophy, and if existing safety procedures are adequate. Therefore, each licensee should develop an audit program customized to the needs of its own facility. At medical institutions (see Appendix M, "Glossary" for definition), the review should be performed by the RSC with the assistance of the RSO. Therefore, it is usual for the RSO to conduct the audit and prepare a summary report to the RSC. Any changes to the radiation safety program that could enhance its effectiveness should be identified in the report to ensure that appropriate action is taken. For medical facilities that are not required to have an RSC (i.e., some private practices and mobile nuclear medicine), audit findings should be discussed with executive management. In any case, a consensus should be reached regarding corrective actions and associated deadlines.

8.4.2 Quality Management Program Audit

The NRC requires certain categories of medical-use licensees to implement a QMP to ensure that the correct patient receives the correct radiation dose prescribed by the physician authorized user. The licensee should develop policies and procedures to meet the five objectives of the QM rule described in10 CFR 35.32, and should review the QMP at least once every 12 months. This type of audit may require that the auditor solicit the assistance of staff who are responsible for various patient diagnostic and therapeutic procedures to simulate these procedures to determine if they are clear, and if adhered to, would prevent an error in the delivery process. This should include, since the last review, an evaluation of a representative sample of patient administrations, and all recordable events and misadministrations. See Chapter 9 for further discussion on reporting misadministrations. Guidance for developing procedures to meet the required objectives is given in Regulatory Guide 8.33, "Quality Management Program."

8.4.3 ALARA Program Audit

Radiation safety programs should provide for keeping radiation doses to workers and members of the public ALARA. The provisions of a licensee's ALARA program are normally

incorporated into the license application or related correspondence and, thus, are a license commitment. ALARA programs include a management commitment to the program and describe duties and responsibilities within the program for the RSO, the RSC, authorized users, and supervised individuals. The ALARA program should also include radiation exposure levels that will trigger an investigation of the cause and nature of the exposure, and should propose corrective actions. On an annual basis, licensees are required to review the ALARA program. Auditors should focus on activities that have potential for high exposures, such as eluting generators, handling radioactive sealed sources, preparing or administering radiopharmaceuticals or sealed sources for therapy procedures, and decontamination. Auditors should also make any recommendations to the RSC or executive management that have the potential to improve licensed activities from an ALARA perspective.

In addition to the overall annual review of the ALARA program, NRC requires that the RSC review and evaluate, at least quarterly and with the assistance of the RSO, a summary of personnel occupational radiation dose records and incidents involving radioactive materials to ensure that radiation doses to workers and the public are maintained ALARA. In cases in which a licensed facility is not required to have an RSC, the RSO should perform ALARA audits as deemed necessary, based on the nature of the operation and facility-specific problems and conditions, and should discuss those findings with executive management.

8.4.4 Management Audits

NRC licensees are required by 10 CFR 20.1101 and 35.22 to conduct an annual review of the content and implementation of the radiation safety program. Part 35 specifically requires that the RSC, with the assistance of the RSO, review the radiation safety program annually. Additionally, if a licensee has committed to following NRC Regulatory Guide (RG) 10.8, Appendix G, "Model Program for Maintaining Occupational Radiation Exposure at Medical Institutions ALARA," executive management has made specific commitments regarding the licensed program. RG 10.8 states that executive management should perform a formal annual review of the radiation safety program, including ALARA considerations. Management should review operating procedures, patient dose records, inspections, and consultations with the radiation safety staff or contractors.

The management review or audit ensures that the highest ranking licensee official (chief executive officer, president, administrator) has a basic understanding of the scope and implementation of the radiation safety program. In some cases, the highest ranking executive manager represents management on the RSC and, therefore, this regulatory commitment may be satisfied by the manager's active participation on the RSC since the RSC is required to perform an annual review of the program. In other cases, the RSC management representative position is not held by the highest level manager. In that case, the RSC should ensure that at least once a year the highest ranking executive is made aware of the findings of the required annual review.

Executive management could use various methods to become familiar with licensed activities. One method would be to periodically contact the RSO, the RSC chairperson, or possibly principal authorized users to gain first-hand knowledge of the daily activities for which management is accountable. Another way would be to ask the RSO to conduct periodic training for executive management to review licensed activities, and regulatory commitments (including new requirements and audit findings). Additionally, the executive management could review RSC meeting minutes to gain a broad overview of current business (assuming that the RSC minutes are comprehensive). Senior management should be cognizant of these fundamental issues in order to ensure that adequate oversight is directed toward the radiation safety program. Licensees should also be cognizant of changes in executive management personnel and should ensure that as new personnel assume responsibility for the licensed program, they receive basic training in a timely manner.

8.5 Basic Auditing Techniques

There are probably as many different techniques for conducting program audits as there are auditors. However, three basic auditing techniques are discussed below that could be utilized in some fashion by auditors to adequately assess the effectiveness of the radiation safety program.

8.5.1 Performance-Based Approach

A valuable auditing technique is to gather supplemental information about specific uses of authorized users and supervised individuals by observing them perform required tasks or by questioning them about their work. This is especially important for research laboratory operations involving new workers who are not initially familiar with equipment or procedures. Even principal investigators or postdoctoral researchers can experience problems handling radioactive material with unfamiliar equipment or new methods. This technique may also be helpful in determining whether licensee personnel are familiar with certain regulatory requirements and whether they are adequately trained.

It is important that auditors verify that activities are being performed in accordance with the applicable regulatory requirements and as described by the individual performing the task. Instead of asking the individual performing the task a question that can be answered "yes" or "no," the auditor should consider asking open-ended questions that give the individual a chance to explain procedures in detail. This will allow the auditor to determine if the individual fully understands the basis for the tasks performed. After observing the individual, the auditor should consider talking to other people who know about the same activity and comparing the information obtained from more than one person to ensure consistency in the information provided. After obtaining information through this process, the auditor should compare this information with the licensee's approved procedures to determine if changes are needed in the licensed program or in the conduct of the observed individual to ensure compliance.

8.5.2 Periodic Record Review

The auditor should consider interviewing individuals who prepare required records to ensure they understand what they are doing and why they are doing it, and should evaluate the method used to obtain recorded information including safeguards to prevent recording and transcription errors. The auditor should review required records to determine if they are complete, if they appear to be accurate, and if they are signed and initialed by the RSO, when signature is required. The auditor should also observe actual measurements and data record entry periodically. Careful attention should be given to the accuracy of such frequently recorded data as daily measurements and surveys, since such recording tends to become monotonous, leading to errors. If calculations are involved, the auditor might request an explanation or a demonstration of the mathematical method used to ensure the method is technically correct. The auditor might also double check a sample of the calculations to have reasonable assurance that there are no generic errors in the calculations. Some generic errors, such as those made during calibration quality control procedures on dose calibrators, could lead to an error in the delivery of the prescribed diagnostic or therapeutic radiopharmaceutical dosage. Finally, the auditor should determine consistency between the recorded information reviewed and information collected during the observation of work in progress and interviews with personnel before determining whether the recorded activity has been performed in accordance with approved procedures and regulatory requirements.

8.5.3 Informal Audit

Informal audits refer to "walk-throughs" or visits to medical use areas or laboratory areas and consist of casual discussions with individuals handling licensed material and observations of activities in progress. Although informal audits are not required, they are an alternate approach to collecting and confirming, or verifying specific information regarding day-to-day activities in the radiation safety program. They are usually conducted by the RSO or radiation safety support staff or both and are a simple, and effective

technique. At a minimum, the audits involve evaluating how the staff conducts operations, whether existing procedures are adequate or how they can be improved, whether existing facilities are adequate and optimally used, whether existing instrumentation is adequate and functioning properly, and whether there are problems that should be expeditiously brought to executive management's attention. Also, informal audits help keep lines of communication open and are timely indicators of potential problems that may degrade safety.

8.6 Use and Evaluation of Audit Findings

If an audit identifies a situation or activity that appears to pose an immediate threat to public health and safety, the RSO should take prompt action to address the public health and safety concern. This could result in temporarily terminating an "unsafe" activity until an acceptable alternative is found or making modifications to reduce the radiation hazard. When the RSO takes immediate action to remedy a problem or to mitigate the consequences of an event or incident, the RSC should be notified of the RSO's actions at the earliest opportunity.

If an audit identifies violations of regulatory requirements, the licensee should first evaluate the safety significance associated with each individual violation to set priorities and identify resources to address the problem. If there is any doubt regarding reporting requirements, licensees are encouraged to contact their regulatory agency for guidance. Regulatory agencies welcome the opportunity to clarify regulatory requirements or license commitments, particularly since this may lead to improved licensee performance.

For each apparent violation, the licensee should determine why the violation occurred (the root cause) and should promptly implement initial and long-term corrective actions addressing the root cause of the violation in order to prevent its recurrence. It is in the licensee's best interest to document this entire process, from identification of the violation to the corrective actions implemented and the results achieved. The corrective actions should be comprehensive to prevent the same type of violation in similar activities. Violations are likely to recur if there is a failure to identify the actual root cause of the problem, or if the corrective actions implemented are inadequate or too narrowly focused.

The identification of numerous violations, even if only of relatively minor safety significance, may be symptomatic of breakdown in the control of licensed activities. When assessing overall performance, the auditor should consider such factors as the degree of involvement by executive management, the RSC, and the RSO in oversight of the program, staffing, resources, and the licensee's ability to enforce adherence to approved procedures. Indications of overall poor performance should be promptly addressed by management and closely monitored until performance is determined to no longer be a problem.

8.7 Summary

A good internal audit program is the licensee's primary monitor of how well its radiation safety program is being implemented. Licensees are encouraged to assess their own performance by conducting audits such as those discussed in this chapter. Audits should help licensees to promptly identify and address weaknesses to ensure that activities are conducted in a manner that maximizes safety. The auditing process requires followup action on the part of the RSO, the RSC, and executive management to assess the findings and take appropriate action. Once the internal audit system has been fully implemented, the RSO should periodically review the scope of the audit program to determine whether modifications are needed to reflect all uses of licensed

material. In addition, the auditor should not become complacent with the scope of past audits, particularly with those performed by other auditors, for this may lead to inadvertent omissions that should have been addressed.

9 INCIDENT RESPONSE

9.1 Introduction

The potential for serious health and safety implications raised by acute radiological incidents (e.g., spills, loss, or theft) prompted the decision to devote an entire chapter to incident response by discussing typical incidents. NRC notification and reporting requirements have been cited throughout this chapter to aid the reader in promptly identifying necessary actions. In addition, NRC notification and reporting requirements are presented in detail in Appendix F.

9.2 Radiation Safety Officer Response

RSOs should investigate radiological incidents in an expeditious manner to mitigate the consequences of such incidents, determine the root cause and contributing factors, and identify necessary corrective actions. Depending upon the type and magnitude of the event, it may be necessary for the RSO to seek additional technical advice. In the case of accidents or spills, the investigation into the root cause of the incident should be carried out concurrently with giving necessary attention to injured or contaminated victims and performing cleanup activities. If the cause of the accident or spill is not immediately known, it may be necessary to terminate certain activities or to close entire laboratory areas temporarily. If too much emphasis is placed on immediate cleanup of known contaminated areas at the expense of gathering information on the extent and root cause of the contamination, valuable time may be lost in identifying possible offsite contamination which could result in unacceptable risks to public health and safety and adverse publicity.

Generally, the RSO (who is responsible for handling radiological incidents) performs at least the following tasks:

(1) initial response to and initial management of the incident, including:

   (a) immediate assessment of the magnitute of the event based on initial and often limited information

   (b) taking steps to terminate, control, or limit the effects

(2) notification of regulatory agencies as required by regulations

(3) thorough incident investigation to confirm initial information and collect additional information to include, at a minimum:

   (a) interviewing all persons involved in the incident (technologists, physicists, authorized users such as researchers and assistants, ancillary staff, and in some cases members of the public and patients) to determine the sequence of events, amount of radioactive material involved and its associated hazard, and the potential for unintended radiation exposure to occupational workers and members of the public

   (b) in the event of a contamination incident, conducting decontamination activities to control immediate and residual effects of the incident

   (c) performing independent radiation surveys (exposure rate and contamination), bioassay, and dose assessments, if necessary, to determine radiation exposure to potentially affected individuals

   (d) identifying cause(s) of the incident to prevent recurrence

   (e) reviewing any records associated with the incident

(4) identification and implementation of corrective and preventive actions

(5) documentation of the incident

(6) discussing the accident with the RSC, including executive management

Additionally, the RSO should be prepared to meet with the media and provide information through press releases or public announcements in response to certain incidents. Failure of the licensee to provide up-to-date information or comment will whet the appetite of the media and public. If the RSO prefers not to be interviewed by the media, it may necessary for another representative of the facility, such as public affairs or administration personnel, to release information.

9.3 Types of Incidents

Some typical types of incidents that occur at medical facilities are described below. However, the potential for particular incidents at any licensed facility and incident type and magnitude are determined by the nature and extent of a licensee's use of radioactive materials.

9.3.1 External Exposures

Relatively high external exposures may originate from any number of situations involving the use of radioactive materials. Examples include: improper handling of radioactive material (radiopharmaceuticals or sealed sources), loss of shielding of high-activity sealed sources, radiation exposures resulting from exposure to high-activity sealed sources (cobalt-60 teletherapy), and contamination incidents. The RSO should make a prompt estimate of each individual's dose, including that of workers, patients, and members of the public, to determine whether regulatory agencies are required to be notified (10 CFR 20.2202, 10 CFR 20.2203).

9.3.2 Contamination

Spills and contamination incidents at medical institutions are generally classified as either minor or major spills. Minor spills are events involving radioactivity levels in the diagnostic range, and major spills involve higher radioactivity levels in the therapeutic range. Minor spills may be handled by trained individuals with RSO followup, whereas major spills will usually require that the RSO personally manages the cleanup. Appropriate regulatory agency notification may be required (10 CFR 20.2203, 10 CFR 30.50).

The RSO should develop written procedures for steps to be taken by workers immediately following a contamination event. These steps should include, at a minimum, instructions not to leave the immediate area unattended and to call the RSO or appropriate staff for assistance. Procedures developed for this purpose should be given to laboratory workers and posted in a visible area for immediate recognition during an event.

It is possible for an incident involving contamination to result in an external or an internal dose or both to individuals. For example, external contamination may result from skin contact with unsealed or volatile radioactive materials, and an internal dose may result from inhalation or ingestion of unsealed or volatile radioactive materials. In the case of an internal dose, or if one is suspected, the RSO should make a determination of estimated intake; this may require bioassay to determine an individual's uptake of radioactive materials. Refer to 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose"; 10 CFR 20.1203, "Determination of external dose from airborne radioactive material"; and 10 CFR 20.1204, "Determination of internal exposure," for specific requirements.

Regulatory agencies are concerned with contamination incidents at medical facilities, because the general public can be in close proximity to areas in which radioactive materials are used, stored, or administered to patients. Fires, spills, and other accidents involving significant quantities of radiopharmaceuticals or involving sealed sources with significant radiation levels, pose potential health and safety hazards that require prompt notification of the NRC or Agreement State agency (10 CFR 30.50).

In the practice of nuclear medicine, particularly in iodine-131 patient therapy procedures, contamination resulting from patient vomitus or excrement occurs with sufficient frequency that it is considered within the parameters of *normal* operations. However, routine decontamination

procedures which are established in advance of patient treatment should be observed during the course of patient treatment to prevent the spread of contamination. Under these conditions, a report to the regulatory agency of contamination events that fall within predetermined normal operation is not usually required. However, an example, described as normal operation that does require NRC notification (10 CFR 30.50) is an accidental spill of a therapeutic iodine-131 dosage in the preparation area (hot lab) wherein worker access to the area is restricted for more than 24 hours.

Another type of contamination incident that should be reported to the NRC is events in which licensees receive packages containing radioactive materials which, upon receipt, have removable contamination or radiation levels that exceed regulatory limits. Such packages delivered to the licensee require that the licensee notify both the final delivery carrier for appropriate action and the administrator of the appropriate NRC regional office (10 CFR 20.1906(d)). Additionally, to prevent the further spread of contamination and facilitate decontamination, the licensee should secure the contaminated package in a restricted area and consider conducting radiation surveys of potentially contaminated areas and individuals who came in contact with the package.

9.3.3 Loss and Theft

Licensees should secure licensed materials from unauthorized removal or access (10 CFR 20.1801), and licensees should also maintain constant surveillance of licensed material that is not in storage (10 CFR 20.1802). If licensed material is lost, stolen, or unaccounted for, the RSO may be required to make a report to the appropriate regulatory agency (10 CFR 20.2201). The RSO should conduct an immediate and thorough search to locate the material. This search may include contacting personnel in other departments and in other buildings, and contacting service industries that provide support to the facility, such as laundry, radiopharmacy, and facility waste management (including radioactive waste brokers, etc.). On occasion, it may also be necessary to contact local authorities, provide information on the missing material, and request their assistance in disseminating appropriate information to the public. Additionally, the RSO should develop corrective procedures to reduce or eliminate the possibility of a similar event occurring again.

9.3.4 Medical Misadministration

The NRC requires that its licensees report to the agency medical events that meet the definition of misadministration (10 CFR 35.2). Some Agreement States have the same definitions as NRC for misadministrations and related notification, reporting, and recordkeeping requirements; however, this should not be assumed true. NRC's misadministration reporting requirements became effective in 1980, at which time the Commission identified two key purposes for reporting misadministrations to NRC. First, the NRC needed a mechanism to review misadministration cases to identify their causes in order to correct them and prevent their recurrence, and to resolve generic issues possibly affecting other licensees. Secondly, the NRC emphasized the right of patients to know when they had received a misadministration. Therefore, the RSO and appropriate personnel should be knowledgeable of misadministration definitions, and related requirements (10 CFR 35.33). Typically, misadministrations are defined as events in which, for one reason or another, an error occurred and the radiation dose was not delivered as prescribed. As a result, the event should be reported to the NRC because tolerated error (reporting criteria) has been exceeded. In addition, NRC requires that the patient's referring physician and the patient or, in some cases, the patient's responsible relative be notified. If informed verbally, the patient should also receive from the licensee written notification of the misadministration. NRC considers notification of the patient a primary purpose of the identification and reporting of these events and inspects such events thoroughly for compliance with all reporting, notification, and recordkeeping requirements. Details on the reporting requirements regarding misadministrations are discussed in NRC Information Notice 93–36,

"Notifications, Reports and Records of Misadministrations."

Other medical events involving errors in the delivered dose may not exceed the reporting criteria for misadministrations, but may meet the criteria for another category of event referred to as a "recordable event." Although these are not required to be reported to NRC, licensees should maintain a record for review during an NRC inspection.

The NRC requires that the RSO investigate recordable events and misadministrations and implement corrective action, as necessary. The RSO should conduct a thorough investigation following such events to determine the root cause and contributing factors and should implement necessary corrective actions to prevent recurrence. An adequate investigation may include, but is not limited to, (1) talking to all persons involved in the misadministration, including technologists, physicists, nurses, authorized users, and the patient, when indicated, to gather specific details and the sequence of events; (2) reviewing the records associated with the procedure, including the referring physician's request or the written directive or both; (3) performing an independent assessment of the dose delivered to the patient; (4) reviewing any other circumstances or contributing factors associated with the incident; and (5) informing individuals of the medical significance or anticipated consequences of the misadministration. In most cases, it is best if the RSO discusses the event with the patient's referring physician first, before discussing it with the patient, to determine if knowing about such information could be medically harmful to the patient. If there appear to be any discrepancies in the information gathered from all interviewed individuals, the RSO should reexamine all available information to resolve these discrepancies and should make the best determination of the root cause of the event. All of this information would be used to identify the best course of corrective action. Licensees should also review the policies and procedures described in the quality management plan to determine whether modifications are needed to ensure adequate corrective action to prevent recurrence. Problems sometimes occur when, although comprehensive corrective actions were developed, corrections were not implemented universally or to the same degree in all medical use areas of the program, or when training on the new procedures was not provided to all individuals responsible for the safe use of licensed material or involved with the patient procedure. Details on NRC expectations for RSOs investigating and reporting misadministrations are discussed in NRC Information Notice 93–04: "Investigation and Reporting of Misadministrations by the Radiation Safety Officer."

9.3.5 Equipment and Device Failure

An ambient radiation dose survey should be performed on equipment or devices that contain or control the use of radioactive materials if they fail or are suspected of being faulty. Additionally, it may be necessary to take the equipment or device out of service immediately if a radiation hazard or a potential for hazard exists. The item should be clearly labeled as "out of service" and, if possible, should be physically disabled to prevent further use or tampering. (Note: To determine if a device should be dismantled, repaired, or serviced by the manufacturer or other authorized provider, the license should be consulted.) If the failure or suspected failure involves or results in increased radiation levels, any entry to the area should be restricted and posted with appropriate warning signs to prevent unauthorized or inadvertent entry. Additionally, it may be necessary to lock or otherwise physically secure the area to prevent unintended entry.

Failure of new or aging devices that contain radioactive materials is of particular concern to regulatory agencies, including the Food and Drug Administration (FDA). Such devices include high-dose-rate remote afterloaders, teletherapy and gamma stereotactic radiosurgery devices, brachytherapy sources and applicators, and bone mineral analyzers used for diagnosis. In addition to the NRC notification and reporting requirements (10 CFR 21.21 and 10 CFR 30.50) discussed later in this chapter, the Center for Devices and Radiological Health of the FDA has mandatory reporting requirements applicable to "device user facilities" (21 CFR 803—"Medical

Devices Reporting"). FDA also maintains a voluntary program for reporting problems with products called "Medwatch" to solicit information on such devices. Forms and instructions can be obtained by writing to MEDWATCH, 5600 Fishers Lane, Rockville, MD 29857–9787 or by phoning 1–800–FDA–1088.

9.4 Management of Victims of Radiation Accidents

The discussion that follows is primarily intended to address licensees' management of victims of radiation accidents that occur on roads and highways, and at nuclear power plants, fuel cycle facilities, processing or manufacturing plants, or at any location other than the licensed medical facility. It is prudent for any medical facility providing emergency services or housing a trauma center to be prepared to handle patients who have been involved in radiation accidents. It is important to note that each nuclear power plant has prearranged agreements with nearby medical facilities to care for personnel or members of the public who have been injured or contaminated or both. However, in the unlikely event that a radiation accident does occur at the licensed facility, the principles discussed below could be applied.

Although the NRC and Agreement States have no specific requirements regarding treatment of victims of radiation accidents at medical facilities, the NRC does require that licensees report any event in which unplanned medical treatment at a medical facility is provided to an individual with radioactive contamination on his/her clothing or body or both (10 CFR 30.50(b)(3)). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that accredited medical facilities have procedures in place for treating radiation accident victims at the facility. The National Council on Radiation Protection and Measurements (NCRP) addressed this important subject in NCRP Report No. 65, *Management of Persons Accidentally Contaminated with Radionuclides* (1980).

Incidents at nuclear power plants, at research laboratories using radioactive material, or during transportation of radioactive material can potentially result in contamination of, or radiation exposure to, victims who may require medical attention because of suspected radiation exposure or injury. When an accident occurs, the local public safety agency (fire department or law enforcement) will probably be the first to respond. Victims will usually be transported to an emergency medical facility for treatment of their injuries and for decontamination. Medical facility plans and procedures for handling victims of radiation accidents should include facility preparation for the receipt of contaminated patients, effective patient treatment, management of contaminated waste, recordkeeping to document decontamination activities, and training of designated facility personnel to organize, respond to, and treat patients. Medical facilities that utilize radioactive materials have professional and technical personnel on staff (radiologists, radiation oncologists, nuclear medicine physicians and technologists, medical and health physicists, radiation therapy technologists, and specially trained nurses) who possess the needed skills to assist in managing the radiological aspects of patient care. Ambulance service personnel should receive proper training in handling and transporting victims of radiation accidents to reduce the spread of contamination. Additionally, the licensee should ensure that the ambulance, its equipment, and all emergency personnel are surveyed for contamination and decontaminated before releasing the ambulance from the licensed facility. Safely accommodating and managing victims of radiation accidents requires some specialized radiation safety equipment which is not typically kept in the emergency department but is readily available from the radiation safety office. However, patient receiving and treatment areas as well as radioactive material storage and supply areas should be previously identified, and responsible individuals should know where these areas can be accessed. The designated space should not require that contaminated victims or contaminated equipment pass through busy main corridors of the medical facility. If possible, the designated space should be remotely located and should have a separate entrance/exit. Survey meters and dosimetry are available in nuclear medicine and radiation oncology departments.

Protective clothing, such as lab coats and surgical scrub clothing and shoe covers, and decontamination materials, such as sponges, brushes, and various cleansers, are readily available at all medical facilities. Historically, victims are rare and very few radiation victims have been contaminated to a level at which they posed a significant risk to their rescuers or to individuals delivering medical care.

An excellent resource for any licensee needing technical assistance on the management of radiation accident patients is the Radiation Emergency Assistance Center/Training Site (REAC/TS) in Oak Ridge, Tennessee. REAC/TS also maintains a 24-hour emergency telephone number, (615) 481–1000. It may be useful for licensees to put this number on their facility's emergency contact list.

9.5 Allegations

All allegations of unsafe practices or potential violations concerning (1) management of a licensed program, (2) a licensee's use of radioactive materials, or (3) incident response should be investigated by the RSO. Additionally, the RSO should discuss such issues with the RSC chairperson or with the full committee. Often the individual who makes the allegation will inform regulatory agencies and the media of their concerns. Regulatory agencies typically react aggressively to allegations of wrongdoing. Thus, it is in the licensee's best interest for the RSO to pursue each allegation to determine its validity and take appropriate corrective action when necessary before regulatory personnel become involved. The RSO should document the investigation and report results to the RSC. If the allegation involves the RSO, then the RSC, executive management, or possibly, an independent third party should conduct the investigation.

9.6 Summary

The potentially serious health and safety issues surrounding radiological incident response bear strong consideration and response by licensees. This chapter provides a basis for licensees to develop and prepare incident response programs and required reports for any incidents that may occur at, or be received and handled by, their facilities.

10 INTERACTIONS WITH THE NRC

10.1 Introduction

This chapter describes the working relationship between NRC representatives, such as inspectors and license reviewers, and the medical licensee or license applicant. The purpose of this chapter is to familiarize licensee executive management, individuals responsible for the radiation safety program, and other interested persons with the NRC's methodology to promote open and effective regulatory interactions during license reviews, inspections, and enforcement conferences, and through correspondence. Although most of the discussion focuses on the NRC, the practices discussed here are generally applicable to most Agreement States.

10.2 The Licensing Process

Upon request, NRC staff will forward an application package to the prospective applicant containing standardized forms and guidance documents to assist the applicant in the preparation of required information. When followed, this guidance can expedite the licensing review process. The RSO usually prepares the license application with input from the RSC, authorized users or prospective users, and consultants when needed. The license application should comprehensively describe the radiation safety program and will require attachments to transmit the required information. The license document forms the legal basis for the possession and use of radioactive material. The commitments made in the license application and described in conditions listed on the license are legally binding. Most regulatory agencies require that executive management sign the license application; therefore, before signing the license application, executive management should review its contents to gain a general understanding of the scope of the program and the commitments made. The RSO should be involved whenever questions arise concerning the application or any communication to the regulatory agency.

In addition to the original license application or renewal request, regulatory agencies require that licensees submit "amendment" requests to the agency for prior approval of certain changes to the licensed program. Changes to the licensed program that require an amendment are described in 10 CFR 35.13 and include such items as changes in authorized users, locations of use, and types and quantities of licensed materials. However, NRC allows its licensees to make certain "ministerial" or administrative changes to the licensed program without submitting an amendment request. Examples are given in 10 CFR 35.31. All license application, renewal, and amendment requests should be accompanied by the appropriate fee as determined by the regulatory agency.

10.2.1 Role of the License Reviewer

The regulatory agency's license reviewers are radiation safety professionals who have successfully completed the training required by the agency and who continue to be educated in relevant subject areas. The license reviewer performs the technical evaluation of the license application to ensure that if the license is issued, the licensed activities, when performed as described in writing, will comply with all applicable regulations. Regulatory agencies place great emphasis on the quality of the technical review of the license application or amendment performed by their personnel.

Often the license reviewer will request additional information or clarification concerning the licensing action. If the needed information is fairly straightforward and minimal, the reviewer may discuss the matter by telephone with the RSO. In most cases, the RSO will be asked to submit a written response to confirm these discussions. Often, licensing questions are described in a letter sent from the regulatory agency to the licensee or applicant. This letter is commonly referred to as a "deficiency" letter. These questions should be answered as clearly as possible and replies normally should be sent within 30 days of the date of the reviewer's letter. Licensees are encouraged to contact the agency when questions arise concerning the requested information or when

guidance is needed. Time extensions for the required reply are granted, when necessary; however, licensees are encouraged to notify the regulatory agency at the earliest opportunity of any delay in responding to the information request or to any other deadline. Additionally, it is prudent for licensees to contact the regulatory agency via telephone or facsimile to confirm receipt of forwarded correspondence and to inform the regulatory agency of time constraints associated with the licensing request.

10.2.2 Prelicensing Visits and Meetings

In some cases, regulatory staff will need to visit the facility before the licensing action is completed. For more complex licensed operations, it is often advantageous for the reviewer to view work areas and equipment, and meet and talk with licensee personnel. These visits are not normally considered inspections and are usually announced. In some instances, license reviewers will personally deliver the license document when visiting the facility. In other cases, it may be desirable for the licensee or applicant to attend a prelicensing meeting held at the regulatory agency's office.

10.2.3 License Conditions and Referenced Licensee Documents

Appendix N contains a sample limited specific medical license and Appendix O contains a sample broad scope medical license. It is important to note that most information contained in written correspondence from the licensee in, or related to, the application will be referenced by date in the last license condition. Regulatory agencies often refer to the last license condition as the "tie-down" condition, and the commitments described in the referenced communications are enforced during an inspection.

Once the license application is approved, the license reviewer will issue the signed license document reflecting the licensee's program as requested. To make it available to the staff at the medical facility, the licensee should either post a copy of the current license or should post a notice referencing where at the licensed facility a copy is located for review.

10.3 The Inspection Process

Regulatory agencies conduct inspections of the licensed program to observe day-to-day operations and ensure an adequate level of public health and safety and regulatory compliance. NRC and most State agencies have standard inspection procedures or field notes that each inspector uses as a guide to conduct a routine or reactive inspection. Sections 10.3.1 through 10.3.6 describe the typical inspection methodology to help familiarize licensee personnel with a process that, although not the regulators' intent, can be somewhat intimidating, especially when experienced for the first time.

10.3.1 Role of the Inspector

The regulatory agency's inspectors are radiation safety professionals who have successfully completed agency- required training and receive continuing education in appropriate subjects. Because of time constraints, it is generally not possible for inspectors to review every aspect of the licensed program in the same detail. Therefore, the inspector selects certain program areas to review more closely than others. As a result, the inspection emphasis on the licensed program will vary from one visit to another. In addition, previous inspection findings may determine which program areas are reviewed in more detail. Therefore, to prepare for the inspection, the inspector reviews license information on file, such as the license application, amendments, reported incidents and misadministrations, and corrective actions implemented by the licensee.

10.3.2 Scheduling the Inspection

The regulatory agency expects the licensee's radiation safety program to be fully and correctly implemented at all times. Therefore, most routine inspections are not announced to the licensee. Admittedly, an unannounced arrival often creates inconvenience and raises stress levels; however, regulatory agencies consider it important to view the licensed program to observe the daily routine. The inspector should be sensitive to the

inconvenience that a regulatory inspection can create and should be as flexible as possible in accommodating to the licensee's schedule. The inspection agendum, persons interviewed, and facilities visited can be altered, if necessary, to conform to the licensee's schedule. This is often necessary during medical inspections and under no circumstances should the inspection process interfere with patient care. At the same time, the licensee is expected to make reasonable accommodations to the inspection process.

Medical inspections are routinely scheduled every 1 to 5 years, depending on the size of the facility and types of licensed activities. Inspection frequencies can be increased or decreased depending on the inspection history and such other factors as the occurrence of an incident, major changes in the radiation safety program or key personnel, or new ownership. Inspections typically last from a few hours to several days, depending on the size and scope of the licensee's program and the extent and severity of past violations and any related problems. Also, the inspection may involve only one inspector or at a broad scope medical facility, a team of inspectors may be sent.

10.3.3 Entrance Briefing

Upon arriving at the facility, the inspector(s) will usually contact executive management to announce the inspection and conduct an entrance briefing. The entrance briefing, although usually of short duration, is important in setting the tone of the inspection. The inspector will generally explain the inspection process, describe a tentative schedule for completion, and set a tentative exit briefing date and time which are compatible with management's schedule. The licensee may be asked to provide a reasonably private area which allows for conferences, interviews, and use of a telephone. By meeting with management, the inspector conveys from the start the importance of licensee management in the inspection process. In the event that the top executive management official is unavailable, another high-level management official should attend this normally brief meeting. If it is not possible to hold an entrance briefing, the inspector will usually proceed with the inspection and request that facility management be notified as soon as possible. A management briefing can be held later, if desired.

10.3.4 Conduct of Inspection

After completing the entrance briefing, the inspector will complete components of the inspection that may include observing licensed activities, discussing various aspects of the licensed program with responsible licensee personnel, reviewing required records, and conducting independent radiation measurements. Each area is discussed in more detail below.

The inspector will usually directly observe how licensee personnel use radioactive material and will focus on program areas with significant safety potential, while striving not to interfere with or distract the worker. It is often helpful to the inspector to ask questions of the authorized users or supervised individuals about the work being done and the individual's knowledge and understanding of related radiation safety procedures. When using this inspection technique, it is important to observe a variety of individuals performing the same tasks to gain a general impression. Employees of the licensed facility have the right to speak privately with NRC inspectors to discuss program operations or practices. However, if the inspector's visit or inspection technique is creating an undue burden on the user, then the RSO or some other licensee representative should tactfully discuss the matter with the inspector.

Since onsite inspection time is limited and allows only a brief look at licensed activities occurring between inspections, the inspector often relies on the review of required records to document compliance with radiation safety requirements. Records should be organized, complete, accurate, and readily available for an unannounced inspection. Few problems cause more aggravation to the inspector or apprehension to the licensee than a disorganized and poorly maintained record system. Considerable time is wasted by both the inspector and licensee when lengthy record searches have to be conducted. The inspector may request copies of certain records and will often

review minutes of the RSC meetings in detail because these offer a quick and comprehensive snapshot of the effectiveness of radiation safety program over an extended period of time. In addition, the inspector may choose to review other records, such as those maintained for personnel monitoring, radiation surveys, instrument calibration, or waste disposal.

The inspector will usually perform one or more types of independent measurements of ambient radiation and radioactive contamination levels in various radioactive material storage and use areas. Among the areas typically surveyed are countertops, floors, shelves, clothing, hands, equipment, storage containers, and possibly adjacent unrestricted areas. The inspector usually carries one or more calibrated radiation survey instruments to perform such measurements. In addition, contamination wipes may be taken in laboratory and clinical areas if the potential for surface contamination exists. Usually, the licensee is required to conduct these surveys and take wipes on daily, weekly, and monthly bases, and the inspector attempts to confirm the measurements that have been recorded by the licensee. The inspector may also ask the RSO or other person who conducts surveys to make simultaneous measurements for direct comparison.

Inspections may be performed in response to a particular event; these are typically referred to as "reactive" inspections. Obviously, such inspections are not scheduled; however, in most cases, they are announced to the licensee, particularly when more than one inspector will be present. During a reactive inspection, the inspector or team of inspectors will primarily focus on identifying the circumstances surrounding the event; determining the root cause, contributing factors, and potential regulatory violations; and assessing the effectiveness of licensee-proposed or implemented corrective actions to prevent recurrence. In some cases, depending upon the type of incident, its magnitude, or root cause, or if the agency has concerns regarding management oversight of the licensed program, the inspection effort may be expanded to other areas of the radiation safety program.

Inspections may also be performed in response to an allegation made regarding the operations of the licensed facility, submitted in writing to the NRC and signed by the alleger. In this case, the inspection is performed as soon as practical to determine if there is sufficient evidence to support the allegation or if violations have occurred. Inspections pursuant to an allegation are not necessarily limited to matters related to the allegation. During the inspection, it may be necessary for the inspector to consult privately with the alleger concerning radiation safety issues or regulatory compliance. It should be noted that, upon the request of the alleger, his/her name shall not appear in any record or in any copy of a record, published or released, in relation to the allegation, except where good cause is shown.

10.3.5 Inspection Summary and Exit Briefing

The inspector will normally keep the RSO apprised of the inspection findings at various times during the inspection process. By the end of the inspection but before the management exit briefing, the inspector will normally discuss all significant findings with the RSO so that the information discussed at the exit meeting is not new to the RSO. The RSO will be encouraged to resolve discrepancies at this time, if not earlier, by providing additional written or verbal information concerning potential violations.

The exit briefing should be attended by executive management and such key radiation safety personnel as the RSO and RSC chairperson. The licensee may elect to have additional licensee personnel attend. The exit briefing provides an opportunity for the inspector to summarize the inspection findings, describe any apparent violations, and answer the licensee's questions. It also gives the licensee an opportunity to further discuss the potential violations and effectiveness of proposed or implemented corrective actions. If questions, disagreements on findings, or other issues exist, this is the best opportunity to address them. The licensee should not be hesitant to ask questions or challenge the inspector's findings. It is much easier to discuss and resolve differences at the exit briefing than by telephone or mail at a later date. Occasionally, one or more inspection findings may require further study not possible

during the initial inspection period. In these cases, the inspector may officially list the finding(s) as "unresolved item(s)". These items will be further evaluated and described in the inspection report.

10.3.6 Inspection Report

The inspection report is the official agency record of the inspection and may be documented using different formats depending on the inspection findings and the regulatory agency's procedures. Regardless of the format, the inspection report should not contain new information on violations or areas of concern, since inspection findings are discussed at the exit briefing or in subsequent discussions between the regulatory agency and the licensee. Generally, if the inspection reveals no violations or only a few minor violations with no minimal health and safety significance, the inspector may document the results in informal field notes and issue NRC Form 591, "Safety Inspection," to the licensee while on site. If violations exist, the licensee manager or director may be requested to sign the Form 591 indicating that the minor violations will be corrected within 30 days from the closing date of the inspection. Typically, these findings are followed up in subsequent inspections.

10.4 Enforcement

Significant inspection findings are summarized in a Notice of Violation (NOV) or in an analogous written report forwarded to the licensee from the regulatory agency at a later date. Upon receipt of an NOV or an inspection report, most regulatory agencies require the licensee to address each violation in writing. The reply should admit or deny each violation, explain the causes of the violation, and describe corrective actions taken or planned to prevent recurrence of the violation. If the violations pose an immediate threat to health and safety, if the licensee has a history of repeated violations, or if there appears to be a degradation of the radiation safety program, the regulatory agency may implement escalated enforcement actions. Escalated actions may include civil penalties or license revocation. The NRC enforcement process is discussed in more detail in Appendix P. An Agreement State licensee should contact the appropriate Agreement State office for information about the State's enforcement process.

10.5 Summary

Licensees have contact with regulatory agencies for many purposes, beginning with the initial request for information regarding the submittal of a license application. Regulatory agencies assist their licensees by providing current and accurate information regarding requirements, and the licensing, inspection, and enforcement processes. Therefore, licensees should not hesitate to contact the appropriate regulatory agency if questions arise regarding the license, inspection and enforcement process, inspection findings, regulatory requirements, associated fees, proposed rules, or any other issue that may affect the licensed program. Both the regulatory agencies and their licensees benefit from open lines of communication.

Additional information is offered in Appendices Q, R, and S, which detail printed material on radioactive material safety programs.