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Radiation Safety Officer Qualifications for Medical Facilities

Report of AAPM Task Group 160

November 2010

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1 INTRODUCTION

1.1 Purpose

The purpose of the Task Group is to develop a document that addresses the role of a Radiation Safety Officer (RSO) in the Radiation Protection Program (RPP) of a medical facility. The document includes a discussion of the authority, responsibility, and duties of the RSO and the radiation safety responsibilities of other members of the facility's "radiation safety team" from facility management to the supervised individuals who work directly with the ionizing radiations.

The regulatory training and experience requirements for an individual to function as the RSO are summarized and guidance is provided to assist facilities management when adding an individual as an RSO on a license. The document discusses RSO qualifications based on facility size and the scope and complexity of ionizing radiation use and the role of medical physicists and other medical professionals as an RSO.

1.2 Scope

This document addresses the position of Radiation Safety Officer (RSO) at a medical facility using ionizing radiations, including byproduct material (sealed and unsealed), diagnostic x-ray equipment, and radiation therapy equipment.

A medical facility's RPP may also address the safety of non-ionizing radiations (e.g., MRI magnet, laser, etc.). In this case, individuals with expertise in these areas should be available to advise management and to serve as members of the facility's Radiation Safety Committee (RSC).

2 RADIATION PROTECTION AT A MEDICAL FACILITY

2.1 Authorization To Use Ionizing Radiation

In order to use ionizing radiation in the practice of medicine, a medical facility must obtain a license or a permit from and/or register with a regulatory authority. Regulatory authorities include the Nuclear Regulatory Commission (NRC) and the radiation control agencies of the various Agreement and Non-Agreement States. Some federal agencies (e.g., Veterans Health Administration [VHA]) use radioactive materials under an NRC Master Materials License and issue Medical Permits to their facilities. These agencies also regulate the use of radiation-producing machines at their facilities.

For NRC and Agreement States there are two types of licenses issued for the medical use of byproduct material[1]: specific licenses of Limited Scope and specific licenses of Broad Scope. Specific licenses of Limited Scope are typically issued to private or group medical practices; specific licenses of Limited Scope or specific licenses of Broad Scope are issued to medical institutions. A medical

institution is defined as "an organization in which more than one medical discipline is practiced."

2.2 The Radiation Protection Program (RPP)

A licensee that uses ionizing radiations for medical use may be required to have a Radiation Protection Program (RPP). The program must be commensurate with the scope and extent of the license activities and the hazards associated with the use of ionizing radiations, and must adequately protect patients, workers, and members of the public. The program must also be sufficient to ensure compliance with the applicable regulations. The RSO implements and directly oversees the RPP. The RSO and other individuals at the facility perform specific duties to meet the requirements of the RPP. A Radiation Safety Committee (RSC), having specific requirements and responsibilities, is required for most NRC and Agreement State licenses.

2.3 Licensee/Executive Management Responsibilities

2.3.1 Licensee

(For simplicity, for most of the document, the term "licensee" will be used to indicate a license/permit holder or a registrant.)

The licensee is ultimately responsible for radiation safety and for the conduct of all licensed activities at the facility. A review of current regulations applicable to medical licenses[2-4] clearly identifies the licensee as being responsible for license activities. Each article of the regulations typically includes the wording "a licensee shall" followed by the regulation. Licensee's management needs to be fully aware of the extent of the licensee's responsibilities. In addition, the licensee is also responsible for the "acts and omissions of individuals using license material"[4] and for the completeness and accuracy of all information provided to and all records required by the regulatory agency. Typical responsibilities of a licensee that relate to the RPP, the management, and the RSO include the following.

The licensee is responsible to:

- Apply for a license/permit/registration, amendment, or renewal
- Identify an individual from management to manage, direct, and administer the licensee activities required by regulation and/or license conditions
- Establish a Radiation Safety Committee (RSC) (if applicable) that includes the RSO to oversee all uses of ionizing radiation
- Identify the RSO on the license and/or registration
- Establish, in writing, the authority, responsibilities, and duties of the RSO
- Provide an individual(s) with sufficient authority, organizational freedom, time, resources, and management prerogative to function as RSO

- Ensure (through the RSO) that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements
- Develop, document, and implement (through the RSO) a Radiation Protection Program (RPP) commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with applicable regulations
- Revise the RPP as required and in accordance with ionizing radiation use, applicable regulations, and license conditions
- Assure that affected individuals are instructed on the revised program before the changes are implemented
- Periodically (at least annually) review the RPP content and implementation.

2.3.2 Executive Management

Strong management participation is essential to ensure that approved activities are properly conducted. Management is defined as "the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates".[4] Although all personnel who use ionizing radiation in the practice of medicine have radiation safety responsibilities and the licensee has the ultimate responsibility for the RPP, management has been given the authority to "manage, direct, or administer the licensee's activities."[4] Management can delegate duties, but not its responsibilities, to a management delegate. Management is required to sign the application for a license, a license amendment, or a license renewal; thus acknowledging its commitments and responsibilities.

The licensee's management is required to appoint an RSO, who must agree in writing to be responsible for implementing the RPP. In addition, management must provide the RSO "sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding NRC regulations and license provisions."[4]

Executive management is responsible to:

- Appoint an RSO who agrees, in writing, to be responsible for implementing the RPP
- Ensure that the RSO has the education, training, and experience required by regulation and by the specific requirements of the facility's RPP
- Review and approve (with the RSO) revisions of the RPP
- Approve, in writing, RPP changes that do not require a license amendment and are permitted by regulations
- Allocate the resources necessary to meet the needs of the RPP
- Serve as a member of the RSC (if applicable) and attend the meetings
- Approve, in writing, requests for a license/registration application, renewal, or amendment before submission to the regulatory authority
- Sign the application for a license, amendment, or renewal

- Approve, in writing, any individual before allowing that individual to work as an Authorized User (AU), Authorized Nuclear Pharmacist (ANP), or Authorized Medical Physicist (AMP).

2.4 The Radiation Safety Officer's Role in the RPP

The RSO is responsible for the implementation, coordination, and day-to-day oversight of the RPP. In addition, the RSO has the authority to enforce radiation policies and procedures regarding radiation safety and regulatory compliance of the use of ionizing radiations. The RSO is normally not responsible for the direct supervision of individuals using ionizing radiation in their daily routines. These individuals are supervised (under RSO oversight) by other members of the "radiation safety team" as required by regulation and/or by the RPP.

2.5 Other Members of the Radiation Safety Team and Their Roles in the RPP

Although the licensee is ultimately responsible for radiation safety at the facility and must identify an individual from management and an RSO (both who have assigned radiation safety responsibilities), other individuals at the facility also have radiation safety responsibilities. Together, they form the facility's "radiation safety team." It is essential that the radiation safety responsibilities of each member of the radiation safety team are clearly and formally stated and understood. Other members of the team include the members of the RSC (if applicable), authorized users, individuals supervised by authorized users, and qualified experts (both internal and external).

2.5.1 Members of the Radiation Safety Committee

In the past, regulations often required "institutional" licensees to have an RSC. Private or group medical practices were not required to have an RSC. At present, the regulatory agencies require an RSC for "Broad Scope" medical licenses and for "Limited Scope" medical licenses, depending upon the scope and complexity of use.

Specifically, an RSC is required when a licensee is authorized "for two or more different types of use"[4] that require a written directive for unsealed byproduct material. By definition, a written directive is required for patient administrations involving greater than 30 microcuries of I-131 NaI (whether for diagnosis or for therapy) and for any other radiopharmaceutical therapy. In addition, licensees approved for manual brachytherapy, afterloader units, teletherapy (sealed source) units, or gamma stereotactic radiosurgery units for "two or more types of units" are also required to have an RSC.

If an RSC is required by regulation, it is responsible for the oversight of all uses of ionizing radiation permitted by the license. Members of the committee

must include an authorized individual for each type of use, the RSO, a representative of the nursing service, and a representative of management. The management representative cannot be either an authorized user or the RSO. The Committee may include other members that the licensee considers appropriate. The Committee must meet at least semiannually; quarterly meetings are recommended. Additional meetings may be convened as necessary. Written minutes of all meetings must be maintained.

An RSC is not required (by regulation) for a licensee only using byproduct material for diagnostic purposes. However, for a facility that routinely performs some therapies (but less than the "two or more different types"), and whose imaging services include both routine and more complex studies (e.g., F-18 FDG PET [positron emission tomography] and interventional radiology) management should consider the advantages of having an RSC to help oversee the RPP. A diagnostic facility with complex studies and where more than one department within the facility uses ionizing radiation may also benefit from the oversight of an RSC.

The RSC may also deal with non-ionizing radiation safety and with other hazardous materials associated with the use of sources of ionizing radiation (e.g., hazardous waste). The RSC serves as an advisory group to senior management and if properly constituted can be of great service to the facility.

2.5.2 Authorized Individuals (Byproduct Material)

"Medical use" is defined as "the intentional internal or external administration of byproduct material, or radiation from byproduct material, to patients or human research subjects under the supervision of an Authorized User."[4] An Authorized User (AU) is by definition a physician, dentist, or podiatrist who meets specific regulatory requirements. Typically, on most medical use licenses the AUs are nuclear medicine physicians, radiologists, cardiologists, and radiation oncologists. Regulations also define an Authorized Medical Physicist (AMP) and an Authorized Nuclear Pharmacist (ANP). These authorized individuals (along with the RSO) are listed on the byproduct material license. Other individuals may be approved on the license as authorized individuals for non-medical use (e.g., research scientists, PET chemists).

For medical use, the licensee permits "the receipt, possession, use, or transfer of byproduct material" under the supervision of an AU who is approved on the license for the specific use. Thus, AU physicians supervise technologists, therapists, or other personnel (not listed on the license) when they work with radioactive material. The licensee also "permits" an AU physician (or an ANP) to supervise individuals in the preparation of byproduct material for medical use. In effect, these authorized individuals function as radiation protection supervisors and are permitted by the licensee to either directly or indirectly supervise the day-to-day use of byproduct material.

Authorized individuals are responsible to:

- Help ensure (in cooperation with the RSO) that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements
- Supervise (directly or indirectly) individuals who work with radioactive materials in the receipt, possession, use, or transfer of byproduct material
- Supervise (directly or indirectly) individuals in the preparation of byproduct material for medical use (AU and ANP) and in the medical use of the byproduct material (AU). The use must be in compliance with applicable U.S. Food and Drug Administration (FDA), and other Federal, and State requirements
- Direct the documentation of prescribed dosages and prescribed doses in accordance with regulatory requirements
- Date and sign written directives (AU) in accordance with regulatory requirements
- Serve as a member of the RSC (if applicable) and attend the meetings.

2.5.3 Supervised Individuals

Typically, it is the supervised individuals who are directly working with and applying the ionizing radiation to the patient. It is their skill and care that helps optimize patient dose. They are the members of the radiation safety team who perform the day-to-day radiation safety activities in accordance with the license conditions and are key to a successful RPP. Some radiation safety duties may be delegated to these supervised individuals. These duties need to be clearly defined, preferably in writing. The authorized individuals may directly or indirectly (e.g., through a senior or chief technologist) supervise these individuals.

It is the responsibility of licensee/management to assure that supervised individuals are competent, properly instructed, and trained in radiation safety (including the RPP, applicable regulations, and license conditions), and follow the instructions of the authorized individuals.

Supervised individuals are responsible to:

- Work safety with the sources of ionizing radiations to ensure that occupational doses and doses to the members of the public are below regulatory limits and as low as reasonably achievable (ALARA)
- Help ensure that patient exposure is optimized
- Remain knowledgeable of the applicable licensee-approved procedures and regulatory requirements
- Help ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements
- Wear and return the assigned personal monitoring devices as required
- Help maintain complete and accurate records in accordance with regulatory requirements

- Report violations of regulatory requirements to the supervising authorized user and/or the RSO as appropriate.

2.5.4 Qualified Experts

An RPP can benefit greatly from the support of individuals (in addition to the RSO and authorized users) who have special radiation safety expertise in the types of use approved on the license. These individuals may be regulatory experts and/or radiation safety experts in nuclear medical physics, diagnostic x-ray physics, or radiation oncology physics and radiation protection.

These qualified experts may be employed by the facility or may be outside experts. They may also contribute as members of an RSC.

For a licensee with a part-time RSO whose main expertise and responsibilities are not radiation safety and regulatory compliance, the advice of a radiation safety expert with an intimate knowledge of the current regulations and regulatory issues can be a valuable asset. A full-time RSO can also benefit from the input and support of a qualified expert for complex problems.

The input of medical physicists who specialize in the imaging and/or therapy modalities approved on the license can also be invaluable for facility design and shielding; instrument calibration, acceptance testing, and quality control; and optimization of patient dose. It is these individuals who are typically responsible for instructing student technologists, residents, and faculty/staff in the radiation safety aspects of their imaging/therapy modalities.

3 AUTHORITY, RESPONSIBILITIES, AND DUTIES OF AN RSO

The RSO is responsible for the implementation, oversight, and management of the RPP. The authority, responsibilities, and duties of the RSO may be codified in applicable State or Federal regulations.

3.1 RSO Authority

The RSO must have sufficient authority to:

- Implement the written RPP
- Identify radiation safety problems
- Initiate, recommend, or provide corrective actions
- Terminate unsafe operations
- Verify implementation of corrective actions.

3.2 RSO Responsibilities

The RSO is responsible to:

- Implement and oversee the operational aspects of the RPP
- Ensure (for the licensee) that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements
- Review and approve (with licensee management) RPP changes before implementation
- Help identify and investigate radiation safety problems
- Initiate, recommend, or provide corrective actions for identified safety problems
- Verify implementation of corrective actions
- Stop operations identified as unsafe
- Notify management of radiation safety problems, unsafe operations, and corrective actions
- Serve as a member of the RSC (if applicable) and attend the meetings
- Provide a link between the RSC and the users of ionizing radiation
- Provide the contact between the licensee and the regulatory agencies
- Be available for contact by facility staff per regulations and license conditions
- Sign semiannual sealed-source leak tests and inventories of sealed sources per regulation.

3.3 RSO Duties

The specific duties of an RSO at a medical facility are at the discretion of the licensee. There are duties or tasks that must be performed in order for the facility to comply with regulations and license conditions (typically incorporated into the written RPP). The licensee must delegate these duties or tasks to specific individual(s) who are competent and properly trained. Some duties or tasks are best performed by the RSO, while others may be delegated to other individuals by management (through the RSO).

However, when such delegations are made, the RSO helps ensure that the duties are properly performed. Licensee management must clearly identify what duties are to be performed by the RSO and what duties are to be performed by another individual or job function. The duties to be performed by the RSO depend upon the scope and complexity of the RPP, the training and experience of the RSO, and the time allocated by management to the RSO position.

Appendix I contains a list of typical “RSO duties” that may be performed by the RSO or other members of the radiation safety team. The list is obtained from the published literature, including NRC regulations and guidance.

4 THE RSO "LETTER OF UNDERSTANDING"

The RSO must agree, in writing, to be responsible for implementing the Radiation Protection Program. The same document can be used to meet the additional requirement to "establish the authority, duties, and responsibilities of the RSO, in writing." Since the "duties" of the RSO will vary with the scope and complexity of the program and some duties can be delegated, RSO duties are best documented as an attachment to the "letter of understanding." RSO authority and responsibilities can be in the body of the letter. Appendix II is a suggested "letter of understanding" that can be printed on the medical facility's letterhead. Appendix I (RSO duties) can be used to develop the attachment to the agreement.

5 SELECTING AN RSO

5.1 Education, Training, and Experience of the RSO: NRC Regulations

In order for an individual to be approved as RSO, he or she must meet the education, training, and experience requirements of the licensing regulatory agency. The following is an analysis of the current NRC RSO regulatory requirements. Agreement State requirements and guidance will reflect those of the NRC.

5.1.1 NRC Regulations

The NRC includes in the definition of RSO an individual who meets the training and experience requirements in Title 10, Chapter 1, *Code of Federal Regulations* Part 35 – Medical Use of Byproduct Material,[4] §35.50 and §35.59. An individual meeting these requirements can potentially be approved as RSO. Section 35.59 addresses "recentness of training"; specifically, the RSO training and experience must have been obtained within 7 years preceding the date of application. If not, the individual can still be considered for RSO if the licensee can document related continuing education and experience since the required training and experience was completed.

The requirement to appoint an RSO is found under 10 CFR §35.24; the requirements for education, training, and experience are found under 10 CFR §35.50 and §35.57 (§35.57 addresses individuals already listed as an RSO); the requirements for amending a license to change radiation safety officers are under 10 CFR §35.13; and, the requirements for notifying the NRC when an individual functions as a temporary RSO are found under 10 CFR §35.14.

Also included in the definition of RSO is an individual already identified as an RSO on a specific medical use license issued by the NRC or on an Agreement State, or on a medical use permit issued by a master material license (e.g., the VHA master material license). Amending a license or permit to add an RSO who

is currently identified as RSO on a license or permit may only require a copy of the license or permit.

For a new RSO, there are three types of training and experience typically recognized by regulatory bodies:

a. Certification by a specialty board recognized by the NRC or an Agreement State;
b. Identification as an authorized user, authorized medical physicist, or authorized nuclear pharmacist on the license;
c. Completion of a structured educational program that has the required 200 hours of classroom and laboratory training plus one year of full-time radiation safety experience under the supervision an approved RSO.

In addition, the new RSO must:

- Have experience in radiation safety for "similar types of uses for which the licensee is seeking the approval of the individual as Radiation Safety Officer" and
- Must obtain a written attestation signed by a preceptor Radiation Safety Officer.

The preceptor RSO must attest that the individual:

- Has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use license; and
- Has training in radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval.

5.1.2 Board Certification

The NRC posts the specialty boards that they recognize on their web site (http://www.nrc.gov/materials/miau/med-use-toolkit.html). Currently (November 2010), three specialty boards are recognized under "Training for Radiation Safety Officer"; in addition, a medical physicist who is certified by a specialty board recognized by the NRC or an Agreement State under "Training for Authorized Medical Physicist" and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval, also meets the RSO training and experience requirements.

Board recognition only applies to individuals who were certified after the date for which the NRC recognized the specialty board. This, in effect, disallows this pathway to experienced individuals who (in the past) did not need to function as RSO but who may be required to do so in the future. In addition, presence on the list of approved specialty boards may imply (to licensee/management) that the certifications are equal. However, the various certifications are different and the qualifications indicated by one board certification may be more applicable to a specific medical facility's need.

5.1.3 Authorized Individuals

An AU, AMP, or ANP may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of byproduct material use for which he or she has RSO responsibilities[4], and, as required, has sufficient time, authority, organizational freedom, resource, and management prerogative to perform the duties.

5.1.4 Structured Educational Program

This is an alternate pathway for individuals who do not meet the requirements of the board certification path or are not listed on the license as authorized individuals.

The educational program includes two categories of training: classroom and laboratory. The trainee must also gain radiation safety experience under the supervision of an individual identified as the RSO on an NRC or Agreement State license that authorizes similar types of byproduct material use. The 200 hours of classroom and laboratory training must include the following:

a. Radiation physics and instrumentation,
b. Radiation protection,
c. Mathematics pertaining to the use and measurement of radioactivity,
d. Radiation biology,
e. Radiation dosimetry.

The hours required per topic are not stipulated in the regulations and may be obtained at a single facility or at multiple training facilities. However, in the application, the applicant must document the number of clock hours for each topic; if considered insufficient, the licensing agency may require additional hours for specific topics. “Classroom and laboratory training” is often broadly defined and may include various types of instruction, including on-line training if the subject matter is related to radiation safety and the safe handling of byproduct material. The licensing regulatory agency does not (typically) evaluate the quality of the training received. It is the preceptor RSO who must attest in writing to the sufficiency of the training and the licensee who is responsible for the accuracy of the information submitted to the regulatory agency.

The radiation safety experience must be full-time for one year and must include the following:

a. Shipping, receiving, and performing related radiation surveys;
b. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
c. Securing and controlling byproduct material;
d. Using administrative controls to avoid mistakes in the administration of byproduct material;

e. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
f. Using emergency procedures to control byproduct material;
g. Disposing of byproduct material.

5.1.5 License: Size, Scope, and Complexity of Ionizing Radiation Use

If an individual meets the regulatory requirements to be an RSO, he/she can be added to a license/permit; however the qualifications required for an individual to be effective as RSO at a specific medical facility are dictated not only by statutory considerations but also by other key factors, including:

- The size of the medical facility
- The scope and complexity of ionizing radiation use
- The time allocated to the RSO function, including:
- The time spent by the RSO
- The time delegated to other members of the radiation safety team in support of the RSO function
- Other resources allocated to the RSO function.

Size, Scope, and Complexity

For convenience (in this document), medical facilities are classified by size, with increasing size implying increasing scope and complexity of ionizing radiation use. The classifications are large healthcare organizations, intermediate healthcare organizations, and small healthcare organizations.[5] The dividing line between a large healthcare organization and an intermediate healthcare organization as far as scope and complexity of use may be blurred, with an intermediate healthcare organization potentially more complicated than a large healthcare organization. A small healthcare organization can be a small- to medium-size hospital or an office/clinic. For byproduct material use, the license/permit type may also be a good indicator of the scope and complexity of use, i.e., a license of Broad Scope (complex) versus a license of Limited Scope (less complex). As noted earlier, it is assumed that radiation-producing machines will be tested, calibrated, and quality controlled by a medical physicist. These functions are not considered RSO functions. Thus, RSO qualifications are dictated more by byproduct material use than by diagnostic x-ray or therapeutic machine use.

5.2 Medical Professionals as RSO

As noted above, an individual can be approved as an RSO if he or she successfully completes all of the training and experience requirements published in the current applicable regulations, and agrees, in writing, to be responsible for implementing the RPP. The medical professionals most likely to be qualified to

serve as RSO are medical physicists and medical health physicists, nuclear pharmacists, nuclear medicine technologists, and physicians.

A large healthcare organization typically has a wide range of ionizing radiation use, including complex applications of both sealed and unsealed radioactive materials and radiation-generating machines. Such an organization with a specific license of Broad Scope may require a full-time RSO with extensive medical radiation safety experience and board certification, e.g., Medical or Health Physicists certified by the American Board of Radiology (ABR) in Medical Nuclear Physics or by the American Board of Health Physics (ABHP).

For a specific license of Broad Scope with limited research activities and less complexity, a full-time RSO may not be necessary and a qualified radiation safety expert with other facility responsibilities may suffice. For example (in addition to the two previous board certifications), a physicist with certification by the ABR in Diagnostic Radiologic Physics or Therapeutic Radiologic Physics with extensive radiation safety experience could serve as RSO. License type alone does not always define the need for a full-time RSO and a large or intermediate healthcare organization with a specific license of Limited Scope (versus Broad Scope) may also require a full-time, board-certified physicist.

Strong support for the RSO function is essential at both large and intermediate healthcare organizations; this includes management support, the availability of a viable, well-appointed RSC, authorized users who understand and accept their supervisory responsibilities, and technologists who understand and accept their roles in the RPP (see section 7, RSO Support).

In an intermediate or small healthcare organization, an Authorized User (AU), or an Authorized Medical Physicist (AMP), or an Authorized Nuclear Pharmacist (ANP) may be an appropriate choice for RSO, if the individual has the training and experience and time to address the needs of the program adequately.

For a small healthcare organization with limited scope and complexity (e.g., a private medical or group practice clinic/office limited to routine diagnostic use of ionizing radiations) it may be acceptable for an authorized user, a qualified Nuclear Medicine Technologist, or an outside qualified expert to be appointed as the RSO. At this level of use, the need for an "officer" to implement and oversee the RPP seems somewhat excessive, given the limited use, the limited number of individuals to be supervised, and the limited risk. Authorized users are already responsible for supervising the few individuals who are working with the ionizing radiations, and management is still ultimately responsible for implementing and overseeing the RPP. Therefore, for this type of license and scope and complexity of use, an individual who is qualified to be an AU should (in the opinion of this Task Group) be qualified to be RSO without the current requirement for an attestation by an approved RSO.

The key issue is that individuals working with ionizing radiation at a medical facility are supervised by an individual qualified to be a radiation protection supervisor and that the facility have the support of a radiation safety/regulatory expert to help assure regulatory compliance and a safe working environment.

5.3 Other Considerations

An individual can be added to a license as RSO if he or she successfully completes all of the education, training, and experience requirements in the current regulations and agrees, in writing, to be responsible for implementing the radiation safety program. However, in selecting the RSO, management should consider other qualifications beyond those required by regulation.

5.3.1 RSO Commitment

A qualified individual employed full-time as the RSO will most likely have the time and motivation to fulfill the required functions. An individual who functions as the RSO part-time and has other professional responsibilities (e.g., nuclear medicine physician, nuclear cardiologist, nuclear medical physicist, radiation oncology physicist, nuclear pharmacist, nuclear medicine technologist) can also function well as RSO given an appropriate balance of allotted time and institutional support.

5.3.2 Management Skills

The level of management skills required to function as an RSO depends upon the size and complexity of the program. However, since the RSO helps oversee the RPP, good organizational, communication, and interpersonal skills are important, including the ability to:

- Coordinate the radiation safety activities of the members of the radiation safety team
- Interact effectively with medical facility staff
- Present radiation safety information in a clear manner
- Organize and maintain a record keeping system (refer to appendix III)
- Interact with regulatory agencies.

6 ADDING/REMOVING AN RSO FROM A LICENSE/PERMIT

6.1 NRC/Agreement State Approval of an RSO

6.1.1 Permanent RSO

The regulations require either a license amendment or a notification whenever an RSO is added to or removed from a license. If the individual is to become the permanent RSO, a license amendment must be "applied for and received" before he or she can begin work as the RSO on the license.

6.1.2 Temporary RSO

For up to 60 days each year, a licensee may permit an authorized user (AU, AMP, or ANP) or an individual that is qualified (per regulation) to be an RSO to function as a temporary RSO. Prior approval is not required before an individual can begin duties as a temporary RSO; however, the licensee must assure the following:

a. The individual must have radiation safety experience with similar types and uses of byproduct material for which he or she will have RSO responsibilities and duties.
b. The temporary RSO must agree, in writing, to be responsible for implementing the RPP.
c. The authority, duties, and responsibilities of the temporary RSO are established in writing.
d. The Radiation Safety Officer has sufficient authority, organizational freedom, time, resources, and management prerogative to
   (1) Identify radiation safety problems
   (2) Initiate, recommend, or provide corrective actions
   (3) Stop unsafe operations
   (4) Verify implementation of corrective actions.
e. Retain a record of these actions per regulation.

Although prior approval is not required, the licensee must notify the regulatory authority no later than 30 days after permitting the individual to perform the functions of the RSO.

A licensee may simultaneously appoint more than one temporary RSO in accordance with the regulations, if needed to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different types of uses of byproduct material permitted by the license.

6.2 Other Notifications

If the RSO named on the license has permanently discontinued performance of duties under the license or has a name change, the licensee must notify the regulatory authority in writing within 30 days.

See appendix IV for a listing of events requiring RSO notification.

7 RSO SUPPORT

The qualifications required for an RSO at a medical facility also depend upon the time allocated to the individual to function as the RSO and the resources available in support of the RSO position.

7.1 Time

An individual employed as a full-time RSO is expected to be a regulatory compliance and radiation safety expert for the types of ionizing radiation uses at the medical facility. A part-time RSO should also be a regulatory compliance and radiation safety expert and have appropriate expertise in both areas.

The appropriate amount of time that a part-time RSO should devote to the position is difficult to specify. The applicable regulations do not codify a required time commitment, and the main regulatory guidance document [Consolidated Guidance About Materials Licenses, NUREG 1556 Vol. 9, Rev. 2 (2008)][1] notes only "in order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff." A physician who is part of a teleradiology service may have difficulty fulfilling the supervisory duties of an AU or fulfilling the duties and responsibilities of an RSO.

However, management is responsible to assure that the RSO function is properly supported so as to optimize the use of ionizing radiation at the medical facility. This is accomplished by the correct balance of contributions from all members of the radiation safety team given their respective responsibilities and duties.

7.2 Resources

7.2.1 Technical/Professional Support

A full-time RSO can benefit from the input of other radiation safety experts for new uses for which the RSO has no personal experience. The licensee is responsible to either have the RSO obtain the experience and/or to provide the necessary expert support. The RSO should also have access to qualified experts for additional input on the radiation safety aspects in their areas of expertise. The RSO should be proactive in requesting this support as needed from management.

A part-time RSO may need the support of a regulatory compliance and radiation safety expert. How much support depends upon the time allocated to the RSO position and the individual's training, experience, and other professional responsibilities.

7.2.2 Management Support

The RSO ultimately derives his or her authority from licensee management. Without strong management support, the RSO cannot function as necessary. Although the responsibilities of the RSO are captured as a license condition and are, therefore, enforceable by regulatory authorities, for the day-to-day success of the RSO position, visible management support is essential. For large and intermediate size healthcare organizations with many administrative layers, the RSO should report immediately to a high level of executive management, e.g., at the

Department Director level or (for uses that cross departmental lines), the vice presidential level.

7.2.3 Secretarial/Clerical Support

For all medical facilities, some professional secretarial/clerical support for the RSO function is important. For large and intermediate healthcare organizations, secretary/clerical support is essential. For example, this may include assistance with the personnel monitoring program, RPP document maintenance, RPP record keeping, and RSC meeting support (agenda preparation, meeting minutes), and scheduling assistance.

7.2.4 Additional/Other RSOs

If a healthcare organization has more than one licensee, the licensing authorities typically allow a different permanent RSO for each license. However, some licensing authorities may not allow multiple permanent RSOs on a single license. For example, the NRC notes that "10 CFR 35.24(b) allows only one RSO to be designated by the licensee at any given time. That individual must be identified on the license. The single RSO identified on the license retains overall responsibility for implementing the total radiation protection program."[6]

This Task Group feels that a single RSO may not be the best approach for every medical facility license. The RSO function and implementation of the RPP for some licensees may be best served by multiple RSOs. For example, in a large or intermediate healthcare organization with a part-time RSO there may be several individuals on-staff with extensive radiation safety experience in different licensed activities (e.g., Nuclear Medicine/Diagnostic Radiology vs. Radiation Oncology) that interact frequently with the supervised staff regarding use-specific radiation safety issues. In this case, one RSO to implement and oversee the Nuclear Medicine/Diagnostic X-ray RPP and another RSO to implement and oversee the Radiation Oncology RPP would best utilize the facility's radiation safety expertise and serve its needs. Management is ultimately responsible for assuring that the RPP is implemented. Two individuals (for this example) with extensive radiation safety experience to implement and manage the RPP for their area of expertise directly could be the best choice for an effective program. As another example, a facility may have distinct clinical and research applications of radioactive materials. In such a case, an individual may be well qualified to be RSO of the clinical activities, but may not have the expertise required to successfully oversee the research activities, and vice versa.

In the temporary absence of the RSO, management (through the RSO) should identify a qualified individual to perform the RSO duties. For an extended absence, a licensee may permit an authorized user (AU, ANP, AMP) or an individual qualified to be RSO (per regulation) to function as a temporary Radiation Safety Officer up to 60 days per year. In this case, a licensee may appoint more than one temporary Radiation Safety Officer.

8 SUMMARY

Medical facilities that use ionizing radiation for the diagnosis and treatment of disease or for research are responsible for the radiation safety of patients/research subjects, radiation workers, and members of the public. A medical facility must be authorized by a regulatory authority to use the ionizing radiation at a specific address(es) of use. The authorization may be a license, a permit, or a radiation machine registration. The facility must comply with the applicable regulations and approval conditions. For some programs a written Radiation Protection Program (RPP) is required and the facility is responsible for the implementation, management, maintenance, and enforcement the Program. This takes a team of competent, properly trained individuals. Members of the team include facility management, members of the Radiation Safety Committee (RSC) (if applicable), authorized users, individuals supervised by the authorized users, and a Radiation Safety Officer (RSO). The RSO is the team member with the authority and responsibility to implement the RPP. The regulatory authority does not always require an RSC; however, an RSO is required. The various regulatory authorities have established education and training requirements for an individual to be listed as an RSO at a medical facility. These training requirements are meant to ensure that the RSO has a basic understanding of the radiation safety issues associated with the approved uses.

The licensee is ultimately responsible for compliance with the regulations and other license conditions. Members of the radiation safety team are assigned duties to help maintain compliance. Some of the duties may best be assigned to the RSO other duties may be delegated. Appendix I contains a list of typical duties that may be performed by the RSO or other members of the radiation safety team.

To expect an individual RSO to be a radiation safety and a regulatory expert for all the potential uses at a medical facility may be unrealistic. For medical facilities with ionizing radiation uses of limited scope and complexity, the RSO function is often a part-time responsibility, with the individual having other primary functions and required expertise. For large medical facilities, the RSO may be a radiation safety and regulatory expert. The RSO function may best be accomplished by a single RSO with the support of radiation safety experts in those areas in which the RSO has limited (or no) experience. For some medical facilities, multiple RSOs may be the best approach to assure regulatory compliance and radiation safety. It is management who is ultimately responsible to assure that the proper levels of radiation safety and regulatory expertise are available and that radiation workers are properly trained and supervised.

APPENDIX I

RSO Duties

The licensee/registrant is ultimately responsible for radiation safety and for the conduct of all licensed activities at the facility. A review of NRC regulations applicable to medical licenses clearly identifies the licensee as being responsible for most license activities. However, the licensee must identify specific individuals or specific "job functions" to perform allocated tasks or duties to maintain regulatory compliance. These duties are often referred to as "RSO duties" and, in fact, some duties are best performed by the RSO; however, other members of the radiation safety team may perform other duties.

The duties assigned to the RSO are at the discretion of licensee/management and must be established in writing (per regulation). They will vary with the training and experience of the RSO, the complexity of the RPP, the time allocated to the RSO function, and the training and experience of the other members of the team. RSO duties may be delegated to other members of the radiation safety team by licensee/management through the RSO. These duties should be documented and clearly understood by the individual and the individual's immediate supervisor.

The following table contains a list of those duties typically associated with a medical facility RPP. An **X** in column 3 (**RSO**) indicates those duties that are best assigned to the RSO. However, for some duties, another member of the radiation safety team (with specific radiation safety expertise) can advise or assist (**A**) the RSO or the duties can be totally delegated (**D**) to another individual. Four classifications of individuals are used in the table, medical or medical health physicist (**1**), authorized individual (on license) (**2**), nuclear medicine technologist (**3**), and nuclear pharmacist or nuclear pharmacy technician (**4**). This is a suggested approach and the degree of assumption and/or delegation of duties and the team member(s) involved will vary with the medical facility and license conditions.

RSO Duties

Duties	Description	RSO	A	D
Action or Trigger Levels	Establish investigation levels for: • Personnel exposures • Area surveys: dose rate and contamination • Bioassays • Xe-133 trap exhaust	 X X X X	 1 1 1 1	
ALARA	• Enforce the ALARA regulatory/license requirements • Inform/instruct workers of licensee/management commitment to ALARA license requirements • Investigate deviations from ALARA practices for cause, and implement changes	X X X	1,2 1,2 1,2	
Audits/ Reports/ Reviews	• Review (at least annually) the RPP content and implementation with management • Audit (at least semiannually) the RPP and the ALARA program; document and report results to management • Review (quarterly) occupational doses and prepare a summary report including individuals exceeding trigger levels and regulatory limits • Review doses to members of the public and prepare a summary report • Review (quarterly) dose rate and contamination survey results and prepare a summary report • Audit (at least annually) the adequacy of procedures for preventing medical events; including, written directive compliance and patient identification • Review incidents involving ionizing radiation with respect to cause and subsequent actions taken • Report incidents as required by regulation, including: –Doses, radiation levels, or concentrations of radioactive materials exceeding a constraint or limit	X X X X X X X X X	1 1 1 1 1 1 1 1 1	

RSO Duties *(continued)*

Duties	Description	RSO	A	D
Audits/ Reports/ Reviews *(continued)*	–Individuals of exceeding the regulatory dose limits	X	1	
	–Leaking source	X	1	
	–Report and notification of a medical event per regulation	X	1	
	–Report and notification of an unintended dose to an embryo/fetus or a nursing child that exceeds the regulatory limits	X	1	
	–Theft or loss of licensed materials	X	1	
Contamination/Spill Response	• Establish a procedure for spill response in the RPP, including:	X	1	
	–Liquid spills	X	1	
	–Gas and aerosol releases	X	1	
	• Establish a procedure for skin and other surface decontamination	X	1	
	• Train workers in spill response and decontamination techniques			1,2,4
	• Estimate skin/organ dose	X	1	
Facility Designation, Design, and Shielding	• Identify addresses and areas of use	X	1	
	• Identify restricted, unrestricted, and controlled areas	X	1	
	• Consult on facility design and shielding	X	1	
Instruction of Workers	• Instruct workers likely to receive >100 mRem/year	X	1,2	
	• Provide radiation safety instruction to personnel caring for radiopharmaceutical patients per regulation	X	1,2	
	• Instruct supervised staff in RPP and RPP revisions before implementation, including:	X	1,2	
	–Operating procedures	X	1,2	
	–Department of Transportation (DOT) training	X	1,2	
	–Declared Pregnant Woman (DPW) regulations	X	1,2	
	–Notification of RSO	X	1,2	
	–Regulations and license conditions	X	1,2	
	–Written directive procedures	X	1,2	

RSO Duties *(continued)*

Duties	Description	RSO	A	D
License	• Maintain a current license, submit amendment, and renewal requests in a timely manner	X	1	
	• Develop, distribute, and implement up-to-date RPP procedures	X	1	
	• Assure that the possession, use, and storage of byproduct material is consistent with the regulations, the license conditions, the Sealed Source and Device Registry (SSDR) certificate(s), and any manufacturer's recommendations and instructions	X	1	
Machine Registration/ Calibration	• Maintain current machine registrations	X	1	
	• Assure that calibration and testing are performed per regulations and/or license conditions and according to professional standards of good practice	X	1	
Medical Events	• Develop, implement, and maintain written procedures to prevent medical and other addressable events	X	1,2	
	• Investigate medical events as to cause(s); identify and take timely, appropriate corrective action(s)	X	1,2	
	• Report medical events to management and to regulatory authorities per regulations	X		
Ordering/ Receiving/ Transporting Packages Containing Radioactive Material	• All orders authorized by the RSO, RSO designee, or authorized user	X	1,2	
	• Receipt address and area of use approved by the RSO	X		
	• Packages properly secured when not attended		3,4	
	• Packages received, surveyed, swiped, and processed per regulations and license conditions		3,4	
	• Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements		1,3,4	

RSO Duties *(continued)*

Duties	Description	RSO	A	D
Patient Protection				
Dosage Assay	• Establish dose calibrator calibration and quality control procedures per regulations	X	1	
	• Perform dose calibrator calibration and quality control procedures			1,3,4
	• Establish prescribed dosage list (AU approved)			2
	• Assay and record patient dosages			3,4
	• Measure, calculate, and record Mo-99, Sr-82, Sr-85 eluate concentrations			3,4
Pregnant Patient	• Enforce policy for identifying pregnant patients	X		
	• Perform fetal dose measurements/ estimations			1
Breast-Feeding Patient	• Release per approved criteria/ regulations			2,3
	• Radiation safety instructions provided			2,3
Patient Release from Regulatory Control (Outpatient)	• Develop release protocol in RPP	X		1,2
	• Release per approved protocol/regulations			1,2,3
	• Radiation safety instructions provided			1,2,3
	• Perform patient-specific calculations			1,2,3
	• Perform retained activity measurement/calculations			1,2,3
Personnel Monitoring	• Establish a system to ensure that monitors are worn and returned in a timely manner, including:	X	1	
	–Advise on who and when individuals should be monitored	X	1	
	–Advise on where and how personnel monitoring devices shall be worn	X	1	
	• Enforce the use of personnel monitoring devices	X	1,2,3,4	

RSO Duties *(continued)*

Duties	Description	RSO	A	D
Personnel Monitoring *(continued)*	• Establish a bioassay program consistent with regulatory requirements and use	X	1	
	• Perform and record bioassay measurements			1,3
	• Interpret the results of personnel monitoring and bioassay measurements	X	1	
	• Advise the staff of their personnel monitoring and bioassay results	X	1	
	• Investigate doses exceeding trigger levels as to cause	X	1	
	• Provide annual written reports to supervised staff	X		
Post/ Reference Documents and Notices	Post or reference:			
	• Applicable rules or regulations			1,4
	• License, license conditions, documents incorporated into the license by reference, and amendments			1,4
	• Operating procedures applicable to license activities			1,4
	• Post Notices			1,4
	–Notice to Employees			1,4
	–Any notice of violation, proposed imposition of civil penalty or order, and any licensee response			1,4
Posting and Labeling	Post or label:			
	• Doors and/or rooms and areas			1,3,4
	• Containers, syringes, or syringe shields			1,3,4
	• Emergency liquid spill procedures			1,3,4
	• Emergency Xe-133 spill procedures			1,3,4
	• Emergency Tc-99m aerosol spill procedures			1,3,4
Pregnant Workers	• Review previous occupational doses	X	1	
	• Advise worker on dose reduction	X	1	
	• Discuss Declared Pregnant Woman (DPW) status	X	1	
	• Monitor monthly doses	X	1	
	• Modify DPW job functions as necessary to keep conceptus dose below regulatory limit	X	1	

RSO Duties *(continued)*

Duties	Description	RSO	A	D
Radiation Accidents	• Serve on the institution's radiation accident committee	X		
	• Advise on the design of the radiation accident response plan	X	1,2,3,4	
	• Assist in the response to radiological accidents or emergencies	X	1,2,3,4	
Radiation Safety Committee	• Attend meetings	X		
	• Advise on changes to the RPP	X		
	• Assist the RSC in the performance of its duties	X		
	• Serve as a technical consultant to RSC	X		
	• Provide a link between the RSC and the users of ionizing radiation	X		
Radiopharmaceutical Therapies (Inpatient)	• Provide radiation safety instruction to personnel caring for radiopharmaceutical patients per regulation			1,2,3
	• Instruct patient in radiation safety precautions			1,2,3
	• Provide/prepare patient room per regulation			1,2,3
	• Administer patient dosage			2,3
	• Measure/calculate/record dose rates per regulation			1,2,3
	• Measure/calculate/record retained activity			1,2,3
	• Provide patient radiation safety release instructions per regulation			1,2,3
	• Release patient per approved criteria/regulations			1,2,3
	• Release patient room per RPP protocol			1,2,3
	• Record/maintain required records			1,2,3
Records	• Oversee a record system to help assure that the appropriate records are maintained in accordance with applicable regulations (See appendix III)	X		
Sealed-Source Leak Test and Inventory	• Perform semiannual sealed-source leak tests			1
	• Perform semiannual sealed-source inventories			1,3

RSO Duties *(continued)*

Duties	Description	RSO	A	D
Security	• Assure that rooms/areas containing stored radioactive material actively secured	X	1,2,3,4	
	• Assure that radioactive material not in storage under control and constant surveillance	X	1,2,3,4	
Surveys and Survey Instruments	• Measure ambient exposure rates			1,3,4
	• Measure surface contamination			1,3,4
	• Measure/calculate airborne concentrations	X	1	
	• Advise on survey meter selection, use, calibration, and repair	X	1	
	• Advise on area and effluent monitor selection, use, calibration, and repair	X	1	
Waste Disposal	• Return radioactive waste to supplier, authorized recipient, including:			1,3,4
	–Package the waste			1,3,4
	–Survey and swipe waste			1,3,4
	–Offer the waste for transport			1,3,4
	–Maintain transfer papers			1,3,4
	• Disposal-by-decay			1,3,4
	–Secure in storage			1,3,4
	–Segregate by half-life			1,3,4
	–Survey/deface labels at final disposal			1,3,4
	–Maintain records			1,3,4
	• Release into effluents			
	–Calculate derived air concentrations (DACs)	X	1	
	–Release radioactive waste into sanitary sewerage			1,3,4
	–Calculate activity concentration/ total activity released	X	1	

APPENDIX II

Sample RSO/Executive Management Letter of Understanding

Date

Radiation Safety Officer
Facility Address

Re: Radiation Safety Officer/Executive Management Letter of Understanding

Dear _____:

You have been appointed Radiation Safety Officer (RSO) by facility management and are/will be identified as RSO on the following byproduct material license:

Licensee _____ License # _____

As RSO you are required by regulation to agree, in writing, to be responsible for implementing the Radiation Protection Program. In addition, the above licensee is responsible to ensure, through you (as RSO), that radiation safety activities are being performed in accordance with licensee-approved procedures and all regulatory requirements.

The licensee agrees to provide you (as RSO) sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and,
4. Verify implementation of corrective actions.

Furthermore, the licensee has established the authority, responsibilities and duties of the RSO in writing (see the attached documents). By signing below, you are agreeing to be responsible for implementing the Radiation Protection Program and are attesting that you have read and understand the information in this document and the attachments. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

(Signature)	(Signature)
_____	_____
Name (Type)	Name (Type)
Executive Management	Radiation Safety Officer

APPENDIX III

Record Keeping

The following list of records is not necessarily comprehensive; consult specific applicable regulations and license conditions.

License/License Conditions

- A current copy of license/permit/registration, license application, amendments, and documents incorporated into the license by reference
- Management's approval of requests for license applications, renewals, or amendments
- Management's approval of individual to work as authorized user, authorized nuclear pharmacist, or an authorized medical physicist
- Records, reports, written policies, and procedures required by regulatory agencies

Patient Dosage

- Dosages of unsealed byproduct material for medical use
- Calibrations of instruments used to measure activity of sealed and unsealed byproduct material
- Mo-99, Sr-82, and Sr-85 concentrations

Patient Release from Regulatory Control

- Release of individuals containing unsealed byproduct material or implants containing byproduct material
- Breast-feeding radiation safety instructions

RSO

- A copy of the authority, duties, and responsibilities of the RSO
- Signed copy of Management/RSO Agreement

RPP

- A signed copy of each RSO agreement to implement the RPP
- A current management/RSO-approved version of the RPP
- Audits and other reviews of the RPP content and implementation

Sealed-Source Leak Tests and Inventory

- Leak tests and inventory of sealed sources and brachytherapy sources

Surveys and Survey Instruments

- Surveys for ambient radiation exposure rate
- Surveys for fixed and removable contamination
- Surveys after source implant and removal
- Surveys of therapeutic treatment units
- Radiation survey instrument calibrations

Waste Disposal

- Return to supplier
- Transfer to authorized recipient
- Disposal-by-decay
- Release in effluents
- DAC calculations
- Release into sanitary sewerage
- Concentration / total released calculations

Written Directives

- Written directives and procedures for administrations of written directives

Brachytherapy

- Brachytherapy source accountability
- Calibration measurements of brachytherapy sources
- Decay of Sr-90 sources for ophthalmic treatments
- Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
- Records of safety procedures
- Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units
- Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations
- Records of periodic spot-checks for teletherapy units
- Records of periodic spot-checks for remote afterloader units
- Records of periodic spot-checks for gamma stereotactic radiosurgery units
- Records of additional technical requirements for mobile remote afterloader units
- Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units

APPENDIX IV

Notification of the RSO

There are regulatory requirements for the notification of the RSO (or, in some cases, a designee) for certain events. The requirements may be codified in the regulations and/or captured as a license condition in the RPP. In addition to being available for questions or concerns regarding regulatory compliance and radiation safety, the following is a list of events requiring RSO notification.

Per Regulation

- Personnel caring for patients who cannot be released from regulatory control are instructed to **notify the Radiation Safety Officer**, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies
- A licensee shall **notify the Radiation Safety Officer**, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies
- Under safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units, written procedures are required that include the names and telephone numbers of the authorized users, the authorized medical physicist, and the **Radiation Safety Officer to be contacted** if the unit or console operates abnormally

Per License Conditions (Typical)

- Instruction of each individual's obligation to **report unsafe conditions to the Radiation Safety Officer**
- Spill procedures
  –Minor spills
  –Report the incident to the **RSO**
  –Major spills
  –Notify the **RSO** immediately
- For safely opening packages containing radioactive material:
  –Visually inspect the package for any sign of damage (e.g., wet or crushed). If damages noted, stop the procedure and immediately notify the **RSO** (**or the designee of the RSO if the RSO is not present**).
  –Check the integrity of the final source container. Notify the **RSO (or the RSO's designee)** of any broken seals or vials, loss of liquid, condensation, or discoloration of the packaging material.
- Instruction in procedures for **notification of the Radiation Safety Officer** and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner.

- For the emergency surgery of patients who have received therapeutic amounts of radionuclides, if an injury occurs during surgery that results in a cut or care in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The **Radiation Safety Officer will be informed** of any possible radiation hazard.
- For the autopsy of patients who have received therapeutic amounts of radionuclides, immediately **notify the AU in charge of the patient and the RSO** upon death of a therapy patient.
- For a patient who still potentially contains therapeutic quantities of radioactive material and presents at Emergency Room or is readmitted to the medical facility, immediately **notify the RSO**.

REFERENCES

1. U.S. Nuclear Regulatory Commission. Consolidated Guidance About Materials Licenses. NUREG 1556 Vol. 9, Rev. 2. Office of Federal and State Materials and Environmental Management Programs. Washington, DC, 2008. http://nrc-stp.ornl.gov/narmtoolbox/nureg1556vol9_rev2_012408.pdf. (Accessed October 15, 2010).
2. Title 10, Chapter 1, *Code of Federal Regulations* Part 19 – Notices, Instructions, and Reports to Workers: Inspection and Investigations. U.S. Nuclear Regulatory Commission, Washington, DC. http://www.nrc.gov/reading-rm/doc-collections/cfr/part019. (Accessed October 15, 2010).
3. Title 10, Chapter 1, *Code of Federal Regulations* Part 20 – Standards for Protection Against Radiation. U.S. Nuclear Regulatory Commission, Washington, DC. http://www.nrc.gov/reading-rm/doc-collections/cfr/part020. (Accessed October 15, 2010).
4. Title 10, Chapter 1, *Code of Federal Regulations* Part 35 – Medical Use of Byproduct Material. U.S. Nuclear Regulatory Commission, Washington, DC. http://www.nrc.gov/reading-rm/doc-collections/cfr/part035. (Accessed October 15, 2010).
5. Standards of Qualifications and Practice (SQ/P). Qualifications for Healthcare Facility Radiation Safety Officer. SQ/P-002 (January 2003). American Academy of Health Physics and Medical Health Section of the Health Physics Society. http://hps1.org/aahp/public/quals/SQP-002.pdf. (Accessed October 15, 2010).
6. Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35. U.S. NRC Web Site: http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html. (Accessed October 15, 2010).

General References

International Atomic Energy Agency (IAEA). Safety Standard Series No. RS-G-1.5: Radiological Protection for Medical Exposures to Ionizing Radiation: Safety Guide. IAEA, Vienna, 2002. http://www-pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf. (Accessed October 15, 2010).

National Council on Radiation Protection and Management (NCRP). Report No. 155, Management of Radionuclide Therapy Patients. NCRP: Bethesda, Maryland, 2006. http://www.ncrponline.org/Publications/155press.html. (Accessed October 15, 2010).

The Health and Safety Executive (HSE) (Merseyside, UK) Web Site (www.hse.gov.uk/) has useful guidance on radiation protection experts, advisors, and officers.