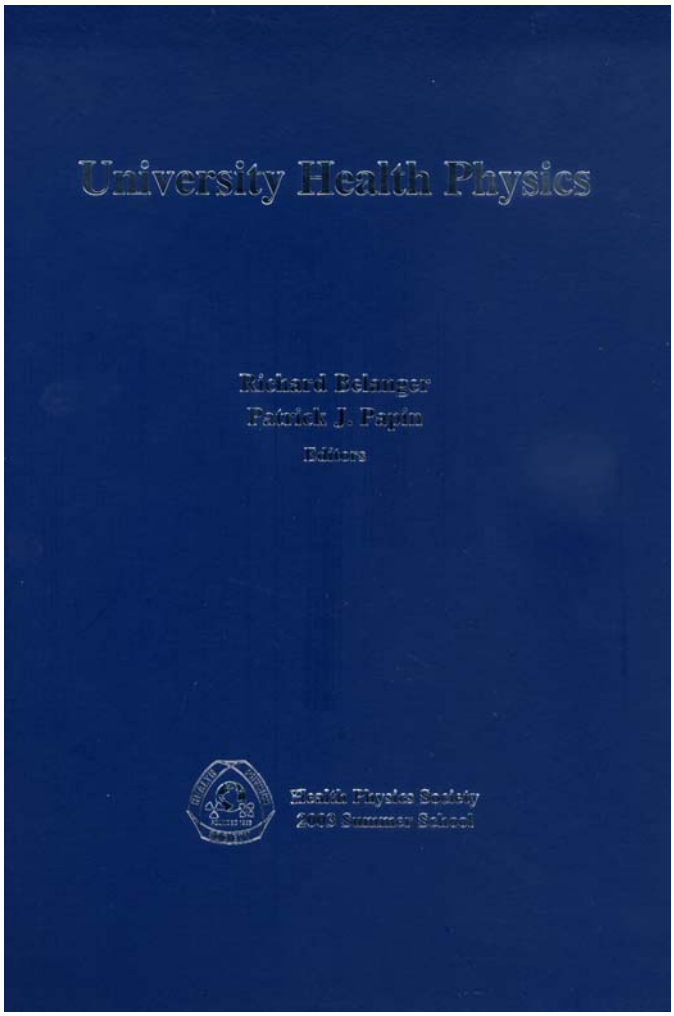

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Chapter 9

Operational Issues Associated with the Medical Use of Radiopharmaceuticals and Brachytherapy

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9.1 INTRODUCTION

This chapter first provides a brief background on the medical use of radiopharmaceuticals and brachytherapy, along with key safety and regulatory challenges associated with these medical uses of radioactive material. It is not an all-encompassing report on the subject of the use of radioactive material in medicine but rather attempts to cover the major radiation safety issues pertaining to the use of radiopharmaceuticals and brachytherapy and provides recommendations to the radiation safety officer for enhancing radiation safety and regulatory compliance.

9.2 BACKGROUND

Radiopharmaceuticals are radiolabeled compounds. Physicians use radiopharmaceuticals to obtain information about a physiological condition or to treat a disease. In brachytherapy, the physician uses sealed sources to deliver a radiation dose for the treatment of a disease.

The first reported use of a radiopharmaceutical in medicine was at the University of California at Berkeley in 1937 when a patient was treated for leukemia. However the beginning of "nuclear medicine" is generally considered to have occurred in 1946 when a patient was treated with radioiodine and the patient's cancer completely disappeared. The value of radiopharmaceuticals such as radioiodine quickly became apparent. Radiopharmaceuticals not only could be used to treat diseases, they also allowed for a "picture" to be taken of the progress of the disease. In the 1960s there was significant growth in nuclear medicine as a medical specialty, and that growth continues today. Currently, there are nearly 100 different procedures involving the use of radiopharmaceuticals and an estimated 10 to 12 million procedures are performed each year in the United States. Diagnostic nuclear medicine procedures provide significant medical information with minimal risk to the patient. The procedures are noninvasive and the effective dose equivalent to a patient undergoing a diagnostic nuclear medicine procedure is generally less than 500 mrem.

The most common radiopharmaceutical is Tc-99m MDP (methylene diphosphonate), which is used for bone scans. Bone scans can diagnosis bone trauma, arthritic changes, and bone infarctions from sickle cell disease. Tl-201 as thallium chloride, Tc-99m tetrophosmin, and Tc-99m sestamibi are used to diagnose cardiac problems such as heart disease, effectiveness of bypass surgery, and acute heart attacks. Xe-133 and Tc-99m MAA (macroaggregated

albumin) are used for the diagnosis of lung problems, and Tc-99m MAG3 (mercaptoacetyltriglycine) is used to detect renal problems. Positron-emitting radionuclides used in PET (positron emission tomography) imaging have become increasingly popular. F-18 FDG (fluorodeoxyglucose) is the primary PET radiopharmaceutical and is used in the evaluation of the metabolic condition of tumors, the heart, and the brain. In addition to diagnostic procedures, radiopharmecuticals are also used for therapy. The oldest and most common therapeutic radiopharmaceutical is I-131 sodium iodide, which is used in the treatment of hypothyroidism and thyroid cancer. Sm-153 lexidronam and Sr-89 strontium chloride are radiopharmaceuticals used in the palliative treatment of bone pain in patients whose cancer has spread to the bone. More recently, monoclonal antibodies labeled with Y-90, I-131, or other radionuclides are being used to treat non-Hodgkin's lymphoma and other malignant diseases.

Brachytherapy is a word derived from the Greek word *bracios*, meaning "short." For a brachytherapy procedure sealed radiation sources are placed within or close to a tumor (i.e., a short distance from the cancer). Brachytherapy is believed to have begun in 1901 when Pierre Curie suggested a small radium tube be inserted into a tumor and the results revealed the radiation caused the cancerous tumor to shrink. The "after-loading" technique is believed to have started in 1905 when Dr. Robert Abee, the chief surgeon at St. Luke's Hospital in New York, placed tubes into a tumor and later inserted radium sources. Brachytherapy was replaced in large part by teletherapy in the mid-1900s. In the late 1900s the interest in brachytherapy was revitalized as safety increased with remote after-loading devices and lower-energy, man-made sources were established as useful brachytherapy radionuclides. The increased interest is also the result of better imaging devices and the use of brachytherapy for nonmalignant treatments, such as restenosis after cardiac catheterizations (see Chapter 10). Brachytherapy is routinely used to treat cancers of the breast, cervix, uterus, esophagus, head and neck, lung, prostate, and soft tissues.

9.3 REGULATORY CHALLENGES

The use of radioactive material in medicine can present a variety of regulatory challenges for the radiation safety officer. The Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT), and the Nuclear Regulatory Commission (NRC) all have regulations that apply to licensees who use radioactive material in medicine.

FDA regulations for radiopharmaceuticals, in general, are very similar to those for other pharmaceuticals (i.e., drugs). FDA regulations for brachytherapy sources are similar to those for other devices. If research involves radiation being administered to a human research subject, an institutional review board (IRB) must approve the protocol. If the research does not involve a standard clinical application approved by the FDA, or is not performed under an FDA-approved investigational new drug (IND) application, then the use must also be approved under a Radioactive Drug Research Committee (RDRC).

Regulations applicable to a RDRC are found in 21 CFR 361.1. Health physics aspects of applications involving human research subjects are addressed in Chapter 11.

OSHA regulations affecting the use of radioactive material in medicine are relatively basic. The OSHA regulations are no different because of the medical environment; however, there are differences between OSHA regulations and the corresponding NRC regulations that the radiation safety officer needs to be aware of; the OSHA regulation may be more restrictive in some cases. Some OSHA regulations defer to NRC or agreement state regulations. Regulations that do not defer include signage and labeling requirements, dose limits and monitoring requirements, and personnel instruction and notification requirements. The signage and labeling regulations are essentially a reiteration of NRC regulations. The OSHA-specified dose limits are equivalent to the old limits the NRC used prior to the 1994 revision and can be more restrictive than the NRC limits. OSHA also requires training of anyone who may frequent a radiation area (defined by OSHA as an area with a dose rate greater than 5 mrem per hour or 100 mrem per week). Depending on the amount of time an individual spends in a radiation area, this requirement may be more restrictive than the NRC regulation, which requires training only if an individual may receive a dose greater than 100 mrem per year.

The DOT requirements come into play when radioactive material is either received or shipped. DOT regulations apply to transportation in commerce; however, the NRC and agreement states have made DOT regulations applicable to all licensees by including within their individual regulations a requirement that licensees follow DOT regulations regardless of the commercial status of the shipment. The result is that all licensees must follow DOT regulations when shipping or receiving radiopharmaceuticals or other radiation sources.

The primary regulators for radioactive material in medicine are the NRC and state radioactive material regulatory agencies. Some commonly used radiopharmaceuticals are labeled with accelerator-produced materials, such as Tl-201, In-111, and F-18, which are only regulated by the states (by federal statute states are responsible for the regulation of naturally occurring and accelerator-produced radioactive material, referred to as NARM). Other radiolabels, such as Tc-99m, I-131, Xe-131, Sm-153, Sr-89, Y-90, and P-32 are considered by-product material (i.e., reactor-produced) and are regulated by either the NRC or an agreement state. Brachytherapy may also involve the use of radionuclides produced either by an accelerator or a reactor. Pd-103 and I-125 brachytherapy sources, depending on the source, may be either accelerator- or reactor-produced. In agreement states, one set of regulations covers both NARM and by-product material. In an NRC-licensing state, different regulations may apply to different radionuclides, depending on the source of the radionuclide. For example, oversight of NARM in NRC-licensing states may require licensing or may only require registration. In states that register NARM, there may be few or no regulations that specifically apply to the medical use of NARM. Having different regulations because of a difference in the source of the radionuclide can be a regulatory challenge. This has been recognized by the NRC (as well as other organizations), which has proposed to assume regulation of all radioactive material used in medicine, regardless of its means of production.

The regulatory challenges for the radiation safety officer were further complicated when the NRC issued a major revision to 10 CFR 35, the NRC regulations that apply to the use of radiopharmaceuticals (see Chapter 8 for a discussion of these changes and their implications). On 24 October 2002, the revised 10 CFR 35 became effective in NRC states. Agreement states have 3 yr to establish "compatible" rules. Because the NRC revision includes the deletion of some prescriptive regulations applicable to radioactive material in medicine, particularly with radiopharmaceutical usage, there will initially be significant differences in regulatory requirements between NRC-regulated states and agreement states. In many instances this means that the regulations will be stricter in agreement states. It should be noted that some of the differences might not change within 3 yr, because many agreement-state regulators have expressed concern over the deletion of some regulatory requirements in the NRC revision.

9.4 INTRODUCTION TO OPERATIONAL ISSUES

One of the major differences between the in vitro use of radioactive material and the use of radioactive materials in medicine (human-use) is the need to weigh potential radiation dose to workers and members of the public against the benefits to a patient. The difference is highlighted even in regulations. Licensees must limit the dose to members of the public from licensed activities to 100 mrem per year; however, the dose from a patient that has been administered a radiopharmaceutical or a permanently implanted brachytherapy source is not included in the 100-mrem limit. The dose to members of the public from individuals administered a radiopharmaceutical or who have a permanently implanted brachytherapy source can be as high as 500 mrem per patient per procedure after the patient is released from regulatory control. Effective with the 24 October 2002 revision of NRC regulations, visitors of radiation therapy patients not released from regulatory control can receive an additional 500 mrem. (Note: licensees in agreement states may be restricted to visitors of patients under regulatory control receiving 100 mrem without obtaining a license amendment. License amendments requesting higher dose limits for visitors of radiation therapy patients under regulatory control may be submitted in accordance with 10 CFR 20.1301(c) or compatible agreement-state regulations.)

Basic good health physics practices for radiopharmaceuticals are similar to those for most other uses of unsealed radioactive material. Basic good health physics practices for brachytherapy are similar to those for other types of sealed sources:

1. All personnel who handle radiation sources should be appropriately trained in the risks associated with using radiation and applicable good health physics techniques to keep doses ALARA.
2. Individuals who routinely work with radiopharmaceuticals and brachytherapy sources have the potential to receive a dose in excess of 10% of the regulatory limits; therefore, whole-body and ring dosimeters should be issued. Individuals who are issued

dosimeters must be instructed how to properly wear and care for the dosimeters. The individuals must be held responsible for ensuring they wear and care for the dosimeters appropriately and must submit dosimeters for analysis within a reasonable time after the end of a monitoring period.

3. Eating, drinking, and smoking by workers and visitors must be prohibited wherever unsealed radioactive material is present. No food or drink, other than that applicable to radiopharmaceutical patient procedures, should be stored in areas where radioactive material is present. (Food or drink that is necessary for patient procedures should be clearly labeled.)
4. Laboratory coats, gloves, and other protective clothing should be worn when handling unsealed radioactive material.
5. Pipetting by mouth is prohibited in areas where unsealed radioactive material may be present.
6. All containers of radioactive material must be clearly labeled with a "caution radioactive material" sign and appropriate identifying information.
7. Radioactive waste must be disposed of in receptacles separate from standard waste and these containers must be appropriately labeled.
8. Survey meters must be readily available when handling radioactive materials. Meters should be used to routinely monitor hands and clothing during and after working with unsealed radioactive materials.
9. Volatile radioactive material must be stored in a hood with face velocity between 75 and 125 linear feet per minute (lfm).
10. Blood-borne pathogen precautions need to be followed. Direct recapping of needles, including those used in conjunction with the preparation and/or administration of radiopharmaceuticals, is prohibited.
11. Hands should be washed and surveyed before leaving the work area.
12. Remote handling equipment should be used whenever possible.

Preparing written policies and/or procedures is also good practice, and for some aspects of a medical radiation safety program this may be required by license condition or regulation. These may include policies and/or procedures for ordering radioactive material, receiving and opening packages containing radioactive material, storing radioactive material, controlling and recording inventory, using radioactive material safety, and ensuring the correct dose or dosage is administered only to the correct location of the correct patient.

9.5 RESPONSIBILITIES

By regulation, the preparation of radiopharmaceuticals must be performed by or under the supervision of an authorized nuclear pharmacist or an authorized user. (Note: *authorized nuclear pharmacist* is a new designation started by the NRC with the 24 October 2002

revision of 10 CFR 35.) By regulation, administration of radiopharmaceuticals or radiation from a radiation source (i.e., brachytherapy or radiation therapy procedure) to humans must be performed under the supervision of an authorized user. For broad-scope licensees, the authorized nuclear pharmacist or authorized user must be an individual approved by the radiation safety committee. For other licensees, the authorized nuclear pharmacist or authorized user must be approved by the regulatory authority (e.g., by the NRC or an agreement state). NRC and agreement state regulations include minimum training and experience requirements or professional credentials that must be obtained by individuals prior to their being named authorized nuclear pharmacists or authorized users.

Regulations also establish minimum qualifications for, and the duties of, the radiation safety officer. The 24 October 2002 revision of the NRC regulations do not specify the duties of the radiation safety officer in as much detail as the previous version. However, both sets of NRC regulations (new and old 10 CFR 35) establish the radiation safety officer as the individual responsible for implementing the radiation safety program and ensuring that activities performed under the license are in accordance with license and regulatory requirements.

Regulations require that the administration of a radiopharmaceutical or a brachytherapy procedure be in accordance with the requirements of an authorized user. If the activity is sufficient, the requirements must be in the form of a "written directive." Unless specified by license condition and/or state specific regulations, an authorized user does not have to be present during the administration of a radiopharmaceutical. For standard brachytherapy an authorized user does not have to be present during the implant or removal of the radiation source(s). For medium- and high-dose rate after-loading brachytherapy procedures an authorized user or authorized medical physicist must be present during at least part of the procedure. (Note: *authorized medical physicist* is a new designation started with the 24 October 2002 revision of 10 CFR 35. It is an expansion of and replaces the term *teletherapy physicist* in the old 10 CFR 35.) These are important items to note because the licensee, not the authorized user, authorized nuclear pharmacist, or authorized medical physicist, is ultimately responsible for errors and omissions made by supervised individuals. Regulations require that the licensee ensure that supervised individuals are adequately trained on the licensed activities they will be performing. Authorized medical physicists, authorized nuclear pharmacists, authorized users, radiation safety officers, and licensee management need to reinforce their commitment to minimizing errors by encouraging supervised individuals to ask questions and obtain all needed information *prior to* administration of a radiopharmaceutical to a patient or initiation of a brachytherapy procedure and by supporting supervised individuals who do ask questions.

9.6 THE USE OF RADIOPHARMACEUTICALS FROM CRADLE TO GRAVE

As with other forms of radioactive material, the use of radiopharmaceuticals is regulated from cradle (receipt) to grave (disposal). This section of the chapter traces the major

radiation safety issues from cradle to grave, including guidance on identifying potential problems. To simplify explanations, the "users" of the radiopharmecuticals will be called the "nuclear medicine department." anyone responsible for overseeing the radiation safety program will be called the "radiation safety officer," and any regulatory references will list the NRC regulation. The nuclear medicine department may not be the sole user of the radiopharmaceuticals; other departments may also use radiopharmaceuticals, either in conjunction with and/or separate from a nuclear medicine department. These departments include, but are not limited to, departments with practices in radiation oncology, endocrinology, cardiology, or general radiology. It should also be noted that the radiation safety officer is not the only individual responsible for oversight of the program; rather, authorized nuclear pharmacists, authorized users, the radiation safety committee, and licensee management also have program oversight responsibilities.

9.6.1 The Radiopharmaceutical Cradle

Unless the quantities of specific radiopharmaceuticals allowed by the license are "as needed," mechanisms need to be in place to ensure the specified possession limits are not exceeded. This may not be as easy as expected because most of the activity is removed from the license inventory when a patient is released from licensee control (e.g., released from the nuclear medicine department). A good way to ensure license limits are not exceeded is to set limits for radionuclides used for diagnostic purposes at two to three times the total activity that may be received in a week. For radionuclides used in therapy, a general rule might be to set the license limits at five times the highest dose probable to be administered to a therapy patient.

All individuals involved in the receipt process must be trained compensatory to their involvement with the process. These individuals can include dockworkers, who may accept the shipment prior to transport to the nuclear medicine department, and/or security personnel, who may accept shipments after normal work hours for the nuclear medicine department. The type of training for a dockworker or security personnel does not necessarily have to include all the items listed in 10 CFR 19.12 because it is unlikely they would receive doses greater than 100 mrem per year. The training does need to include procedures for quickly transferring the package to the nuclear medicine department and/or a designated secured storage location, and what to do if the package is damaged.

Per regulations (10 CFR 20.1906) all labeled packages (i.e., those bearing a DOT diamond radioactive material label) must be surveyed within 3 hr of receipt or, if received after normal working hours, within 3 hr of the start of the next business day. The survey must include a wipe test of the outside of the shipping container and a dose rate measurement at contact and 1 m from the shipping container. An important point for the radiation safety officer to stress during training on package receipt is that if surveys indicate a higher radiation dose rate than that recorded for the preshipment or higher than that for the shipment classification, or if contamination is detected on the outside of the package, investigations

should be performed prior to opening the package. Higher dose rates can be an indication of movement of shielding. Contamination on the outside of a package indicates leaking radioactive material and/or poor contamination control practices at the point of packaging or package receipt, or contact with a contaminated package on route.

When overseeing the receipt part of the program, the radiation safety officer needs to pay close attention to those areas that more frequently result in notices of violations. Items that have led to notices of violation include the following:

1. The individual performing the survey must be trained in accordance with DOT regulations for a HAZMAT employee. This includes retraining every 3 yr.
2. A wipe test is not completed until the swipe is counted.
3. The survey area is the entire outer surface of the shipping container. The wipe test area must cover at least 300 cm^2 *and* involve all sides of the shipping container.
4. The surface meter survey needs to focus on locating the areas of highest dose rate. The survey at 1 m should be taken 1 m from the location of highest surface dose rate.
5. External monitoring must be performed within 3 h of package receipt. For normal work-hour deliveries, the 3-h clock starts at the time receipt is accepted by the licensee, which may or may not be the time of receipt at the nuclear medicine department.

9.6.2 The Use of Radiopharmaceuticals

Radiopharmaceuticals may be received as unit dosages (i.e., dosages prepared and measured by a nuclear pharmacy for an individual patient), as bulk doses, or as stock radioactive material that must be synthesized into a radiopharmaceutical. Under the old NRC regulations (10 CFR 35.53), the activity of unit dosages had to be remeasured in a dose calibrator, unless the radionuclide is an alpha or beta emitter. Under new NRC regulations (10 CFR 35.63) a remeasurement is not required for any unit dosage. However, remeasuring the activity of any dosage just prior to administration to a patient is recommended and may be required by state regulations, institutional requirements, or license conditions. There have been several incidents in which the activity shipped by a nuclear pharmacy or other supplier was different from the activity listed on the label. A recheck can also help uncover errors that may not be readily noticed in the small print of a label, such as power of 10 differences in activity. Measurement of beta-emitters can be tricky, but a remeasurement for "ball-park" assessment of dosage does at least provide a good check for significant errors. The radiation safety officer and authorized users should stress to nuclear medicine personnel that if a recheck of a dosage indicates a problem it is important to investigate prior to administration of the dosage.

Dose calibrators are generally required, unless a licensee is performing only procedures using only unit dosages under the new NRC regulations. Dose calibrators must be checked frequently to ensure proper operation. Routine tests include constancy, accuracy, linearity and geometry. A constancy test is generally performed daily. A dedicated standard is

measured in the instrument and a constant reading, after accounting for decay, is expected. For the accuracy test a radiation source is read several times to see whether the readings remain the same. Linearity tests are performed to ensure the reading is linear throughout the activity range of the dosages measured. The geometry test looks at the effect on different volumes and different source holders (e.g., 10-mm syringe versus 20-mm syringe versus a vial). Dose calibrator-related items that should be assessed by the radiation safety officer include the following:

1. Are the readings for the daily constancy check within ± 10%? Do the readings seem reasonable when decay is considered? Regulators have caught nuclear medicine technologists not checking to ensure the data are within specified limits, and even faking the data.
2. Do the linearity and geometry tests cover all types of procedures that may be performed? A common violation is that linearity tests do not cover the top and/or bottom of a range for an infrequently performed study, and geometry tests do not cover all the different sizes and types of containers used.

During preparation and administration of the radiopharmaceutical dosage it is critical that the individual preparing or administering the dosage follow the principles of good radiation safety techniques:

Time – As with all radioactive material the time spent handling or near the radiation source should be minimized. Dry runs and a clear understanding of the procedure are critical for ensuring exposure time is minimized. The use of indwelling ("butterfly") lines versus direct stick can reduce injection time.

Distance – Individuals need to maximize their distance from a radiation source. Use remote handling tools whenever possible.

Shielding – When practical, shielding should be used. Vial shields and/or syringe shields may be required by regulations (i.e., old 10 CFR 35.60 and 35.61). Syringe shields can significantly decrease the dose rate; however, syringe shields are bulky and cumbersome. If syringe shields are not required by regulations, the decrease in dose rate must be weighed against the increase in handling time. Also, when deciding on appropriate shielding, the emission from the radiopharmaceutical must be considered, especially with the increased use of beta-only-emitting radiopharmaceuticals. In most cases in which the radiopharmaceutical involves the administration of positron-emitting and/or gamma-emitting radionuclides, lead or tungsten syringe shields decrease overall dose to the worker. Syringe shields with plastic or other material of low atomic number need to be considered for therapeutic dosages of beta-emitting radionuclides. Finally, most syringe shields do not provide much shielding at the top, so doses to the portion of the hand that manipulates the plunger are generally the highest. For accurate hand-dose assessment, it is important to evaluate the area of highest dose rate and ensure the hand dosimeter is being worn in an appropriate location.

The NRC has cited nuclear pharmacies for under-reporting hand doses after determining the dosimeter was being worn in an inappropriate location for measurement of the maximum extremity dose and the maximum doses were not being assessed.

Survey – Performing routine surveys of potentially contaminated areas is important. The frequency of documented surveys may be regulated (old and new 10 CFR 35.70). Regulations may also require that surveys of contiguous areas be performed to ensure dose rates in the contiguous areas are within regulatory standards. Contiguous area surveys are generally only required for therapy procedures. The new NRC regulations allow calculations to be performed in lieu of contiguous area surveys. Regulators have also allowed variances from performing contiguous area surveys once data have been collected. When performing contiguous area surveys or evaluations, remember that there are at least four sides, an above, and a below to every room. Contiguous area survey or evaluation requirements apply to those areas that can be occupied.

Contamination control – Minimizing contamination is critical. There are a large number of individuals, including patients, who come and go within the nuclear medicine department and contamination can be spread widely very quickly. One of the most common sources of contamination from radiopharmaceutical usage is from the manipulation of the syringe and needle. Releasing air bubbles needs to be done only with great care. Quick release of an air bubble can result in a small volume of the radiopharmaceutical being aerosolized. Air bubbles should be released with the needle inside the vial or by lightly tapping the syringe with the needle covered. Transport of a radiopharmaceutical across floors should be done on a tray, to eliminate the possibility of a droplet falling onto the floor from the end of a syringe. Injections should be performed over a tray or piece of absorbent paper to catch any drops that may be released during the injection process. The use of indwelling ("butterfly") lines also helps with contamination control, because they minimize leakage during an injection. However, it is important when using indwelling lines that checks are performed prior to injection to ensure all connections are tight.

Correct patient – One radiation safety item unique to medical use of radioactive material, including radiopharmaceutical usage, is ensuring the correct dosage is administered to the correct patient. Prior to administration of a radiopharmaceutical dosage, a patient's identification should be checked using at least two different methods. These methods can include, but are not limited to, asking the patient and/or a companion their name, checking the patient's hospital wristband, checking a photo ID, or using an employee's knowledge to identify the patient. Prior to administration of a radiopharmaceutical the dosages need to be checked. If the individual performing the administration is not the individual who prepared the dosage, a double-check of the dosage by the individual performing the administration is recommended.

For individuals who monitor or provide care to a patient, it is critical that they follow good radiation safety principles. At this point in time the primary radiation source is the patient:

Time – Unnecessary social contact with patients after administration of a radiopharmaceutical should be minimized.

Distance – When imaging a patient and/or providing care, it is important to be aware of the most probable accumulation location(s) of the radiopharmaceutical within the patient. Duties should be performed to maximize the distance between the worker and the location(s). For example, if a patient has a heart stress test, the radiopharmaceutical will accumulate in the heart and the bladder. If the patient is lying down during the imaging, and the worker must be within physical contact of the patient, it is best not be at the patient's side, but rather to be above the patient's head or below the patient's feet. For a bone scan, the radiopharmaceutical accumulates not only in the bones, but also in the bladder. Thus, for a bone scan patient maximizing distance from the bladder is best.

Shielding – The use of shielding must be weighed against the increase in time due to use of the shielding and patient care needs. It is a common misconception that wearing a lead apron 0.5 mm thick will significantly reduce an individual's whole-body dose when administering care to a patient that has been administered a radiopharmaceutical. If the radiopharmaceutical is a beta-emitter, the patient's body will have already maximized the use of shielding. If the radiopharmaceutical is a gamma-emitter, the energy of the gamma and the shielding benefit of the 0.5 mm of lead needs to be analyzed. The majority of diagnostic radiopharmaceuticals emit a gamma with an energy of about 100 keV; therefore, the 0.5 mm of lead attenuates about 30% of the radiation. Wearing a lead apron has a significant effect on mobility. If wearing the lead apron increases task time, then the lead apron may not be beneficial because the small shielding benefit is overridden by the increase in time to perform a task. If practical, area shielding, with or without viewing windows, can be placed between the worker and the patient.

9.6.3 The Use of Sealed Sources Associated with the Use of Radiopharmaceuticals

Associated with the use of radiopharmaceuticals are sealed sources. The sealed sources are used to perform quality assurance tests on dose calibrators, survey instruments, and gamma cameras. The sealed sources may be authorized by regulation (old 10 CFR 35.57 and new 10 CFR 35.65). In non-agreement states, the radiation safety officer needs to be careful. A common sealed source associated with radiopharmaceuticals is Co-57, which is accelerator-produced and thus state licensing or registration rules apply.

Unlike nonmedical uses, leak test requirements are regularly not a license condition, but rather are required by regulation. NRC and corresponding agreement state regulations require leak tests every 6 mo if the activity is greater than 100 mCi and the half-life of the radionuclide is greater than 30 d.

Additional regulations apply to the medical licensee that possesses sealed sources. Regulations generally require that sealed sources be inventoried regularly (quarterly under old 10 CFR 35.59(g) and semi-annually under new 10 CFR 35.67(g)). Regulations also may

require that areas where sealed sources are stored be surveyed for ambient dose rates quarterly (old 10 CFR 35.59(h)). These regulations are essentially no different from requirements that regulators routinely add to nonmedical licensees as a license condition.

9.6.4 The Radiopharmaceutical Grave

Much of the radiopharmaceutical activity leaves the licensee's "possession" as the patient either excretes it into the sanitary sewer and/or walks away with it still in his or her body upon discharge. These deletions from the licensee's inventory do not have to be specifically recorded as a disposal. However, other parts of the disposal cycle do have to be documented.

First there is the contact waste. This waste includes syringe, needles, contaminated gloves, and other items from the use cycle. When the radiopharmaceutical use includes a housed therapy patient, waste items may include paper and plastic wrap used to cover surfaces in a patient's room, objects contaminated during a patient's stay (e.g., telephone or nurse call button), and decontamination materials. Because of the short half-life, most of this waste can be held for decay-in-storage, which is subject to regulatory requirements. At a minimum, the regulations require performing surveys after holding for decay to ensure the decayed waste cannot be distinguished from background and obliterating labels indicating the radioactive content. Items of concern with decay-in-storage of radiopharmaceutical waste include ensuring that:

1. Any interposing shielding is removed prior to performing the survey. Shielding is more likely with radiopharmaceutical waste, including the waste container itself.
2. The individual performing the survey uses an appropriate survey instrument. An ion chamber is not a sensitive enough piece of equipment to perform the surveys.
3. Signage or labeling is obliterated as required. It may be beneficial to develop and implement procedures in which signage is removed or obliterated prior to being placed into the radioactive waste disposal container.

Sealed sources decayed beyond usage have become waste that must be disposed of. Because of the half-life of the radionuclides in most sealed sources, decay-in-storage is not an option. The unusable sealed sources can be disposed of through a licensed waste facility. However, it is a common, and an often cost-effective practice, for sealed sources to be "replaced," with contracts for purchase of a new sealed source including provisions for the return of an old sealed source.

The human use of radiopharmaceuticals also brings about an unexpected waste stream. This waste stream is one often called "hot waste." Regulations allow for disposal of patient excreta (e.g., urine and blood) into the sanitary sewer, without regard to its radioactivity. However, waste contaminated with patient excreta is not always disposed into a sanitary sewer. This waste includes diapers, syringes from blood drawing, and/or gauze from surgery. Though "hot waste" is not part of the licensed radioactive materials, many states

expect licensees to ensure that such waste does not enter the biological, infectious, or normal trash waste streams. Because the patients that may generate "hot waste" may have been released from regulatory control and/or may not even have been administered radiopharmaceuticals under a hospital's license, controlling this waste is very difficult. Many licensees have installed trash monitors to check all waste that leaves the facility. If "hot waste" is detected, placing the waste to the side and holding it for 3 d generally results in the radioactivity decaying to background levels. However, when waste is contaminated with radionuclides other than Tc-99m (e.g., Tl-201) the decay period could be longer.

9.7 BRACHYTHERAPY

Radioactive sources used for brachytherapy sources are small, sealed sources that may be in the form of "needles," "tubes," or "seeds." "Needles" and "tubes" are generally 2.54 to 3.81 cm (1 to 1.5 inches) in length and 0.16 cm (1/16 inch) in diameter. "Needles" have the appearance of a large sewing needle with one pointed end. "Tubes" have both ends flat or slightly rounded. "Seeds" are very small and have the appearance of a tomato or small apple seed. The sealed sources may be individual or may be strung together in a "ribbon." In a "ribbon" the sealed sources are spaced through a length of generally thin nylon tubing.

Brachytherapy sources may be Cs-137 "tubes" or "needles" that are keep on hand for very long periods of time and used for multiple patients. Brachytherapy sources may be ribbons of Ir-192, P-32, or Sr/Y-90 sources that are used for a short period of time (e.g., a month to a year) and used for single or multiple patients. Ir-192 sources may be contained in low dose rate, medium dose rate, or high dose rate remote after-loaders (an after-loader is a device that allows the brachytherapy source to be implanted remotely). Brachytherapy sources may be I-125 or Pd-103 seeds that are received on a patient-by-patient basis. Brachytherapy sources may be implanted temporarily or permanently. The sources may be implanted interstitially, intracavitarily, topically, or intravascularly. (Intravascular brachytherapy is discussed separately in Chapter 10.) Each of these differences affects the radiation safety program.

Many of the regulations that cover brachytherapy sources are the same or similar to those that cover radiopharmaceuticals. As with radiopharmaceuticals the sealed sources used for brachytherapy are regulated from cradle to grave.

9.7.1 The Brachytherapy Cradle

Unlike radiopharmaceuticals, it is uncommon for brachytherapy source possession limits to be listed on a license "as needed." For larger activity sources (e.g., those 100 mCi or more per source), it is not unusual for the license to list the sources individually by make and model. As with radiopharmaceuticals, ensuring that license limits are not exceeded may not be easy. Brachytherapy procedures may involve permanently implanting the sources into a

patient. In these cases, as with radiopharmaceuticals, the activity is removed from the license inventory when the patient is released from regulatory control.

The receipt process for brachytherapy sources is similar to that for radiopharmaceuticals. The major difference is that the licensee needs to ensure a leak test certificate was provided that demonstrates that an acceptable leak test was performed within the last 6 mo or the source must be leak-tested by the licensee prior to use.

9.7.2 The Use of Brachytherapy and Teletherapy Sources

Inventory control of brachytherapy sources is a critical part of the radiation safety program. Brachytherapy sources may be on-hand or received for a specific patient or procedure. Regulations require that the licensee account for all sources at all times (new 10 CFR 35.406). Documented quarterly (old 10 CFR 35.60(g)) or semi-annual inventories (new 10 CFR 35.67(g)) may also be required. Removal from and return of sources to a storage location must be documented in accordance with regulatory requirements (old 10 CFR 35.406 or new 10 CFR 35.2406).

All medical uses of brachytherapy sources require a written directive (old 10 CFR 35.32; new 10 CFR 35.40). In the written directive the authorized user must provide sufficient information to ensure the chosen radionuclide and source strength is implanted in the correct location and the desired dose results from the implant.

Measurement in a dose calibrator is not normally required for brachytherapy sources. Because of the small size and high specific activity of brachytherapy sources geometry problems are more prevalent. However, a dose calibrator can readily determine significant source strength errors. Communication problems and lack of attention to detail have resulted in sources being implanted into a patient with the activity off by a power of 10 or more. A double-check with a dose calibrator is good at detecting major errors.

While preparing brachytherapy sources for implant, during source implant, and during removal of the sources it is critical that individuals follow the principles of good radiation safety techniques:

Time – As with all radioactive material the time spent handling or near the radiation source should be minimized. Experience obtained from dry runs with dummy sources and a review before implant of the implant procedure are critical for ensuring exposure time is minimized.

Distance – Individuals need to maximize distance from the brachytherapy source. The use of remote handling tools is strongly recommended. Following manufacturer's handling procedures, which often include the use of remote handling tools, is required by regulations (old 10 CFR 35.59(a) and new 10 CFR 35.67).

Shielding – Shielding should be used whenever practical. Brachytherapy sources should be stored in shielded storage areas and/or containers. Area shielding should be used when loading or unloading sources from source holders or implant devices. Brachytherapy sources

should be transported from the storage area to the implant area in an appropriate shielded container.

Surveys – Routine surveys to ensure sources are not misplaced are required by regulation. Surveys must be performed at the time of implant (old 10 CFR 35.406(c) and new 10 CFR 35.404) and at the time of source removal (old and new 10 CFR 35.404). In addition, surveys must be performed of contiguous areas immediately following temporary implants. With brachytherapy sources it is important to have the correct instrument. An ion chamber is appropriate for performing the contiguous area surveys. A sodium iodide probe survey meter is more appropriate for ensuring that misplaced sources, especially Pd-103 or I-125 seeds, are found.

Contamination Control – Because brachytherapy sources are sealed sources there is not a significant concern about contamination; however, there is always the possibility of a source leaking. Brachytherapy sources must be leak-tested routinely, generally every 6 mo (old 10 CFR 35.59; new 10 CFR 35.67). In addition, sources, especially "seeds," are fragile. Rough handling or forceful loading of a source into a source holder may result in damage of the outer casing and a leaking source. Anytime procedures call for rough or forceful handling of brachytherapy sources a quick survey for leakage should be performed. The quick check can be as simple as wiping a cotton swab over the source(s) or source holder(s) and checking the cotton swab for contamination with a survey meter.

Individuals who provide care to patients with a temporary brachytherapy implant must be instructed in radiation safety principles (new and old 10 CFR 35.410). The instruction must include the size and appearance of the brachytherapy sources and visitor control. The application of radiation safety principles by caregivers and visitors include:

Time – Minimizing the time in the patient's room. Caregivers should not spend unnecessary time in a patient's room. Visitation time should be limited to ensure that visitors will not receive greater than 100 mrem, unless the authorized user has determined before the visit that a higher dose is appropriate (10 CFR 20.1301 as revised with new 10 CFR 35).

Distance – Distance from the implant site should be maximized. Caregivers need to be aware of the implant site. Chairs for visitors should be placed to maximize distance.

Shielding – Area shielding is commonly used and is placed so the shielding is between the implant site and the location in which caregivers will most often stand while providing care. Area shielding should also be placed between the implant site and visitor chairs.

9.7.3 The Brachytherapy Grave

As with radiopharmaceuticals, "disposal" of brachytherapy sources may be in a patient who is released from regulatory control. For some radionuclides, such as I-125 and Pd-103, the licensee has the option of disposing of the sources by decay-in-storage; however, the

radiation safety officer needs to be aware that holding the sources for the standard 10 half-lives typically does not result in the sources decaying to background. It is more common for shorter half-life brachytherapy sources to be returned to the vendor. Finally, the longer half-life brachytherapy sources, primarily Cs-137, may continue to be used for many years before ultimate disposal may be required. If disposal of the longer half-life brachytherapy sources becomes necessary, the only viable option may be shipment to a burial site as a Type C waste.

9.8 ENHANCING RADIATION SAFETY OFFICER OVERSIGHT

The radiation safety officer needs to know and keep current on all the applicable regulations, along with the basics of the procedures being performed and how good health physics practices can be applied. Routine auditing of the nuclear medicine department is important. Audits should look at the control of the radioactive material, regulatory compliance by the users, users' knowledge and use of good health physics practices, and the application of regulations to the specific uses. Good questions to ask during audits the nuclear medicine department are the following:

1. In what situations would you need to contact the radiation safety officer?
2. How soon after receipt does a survey have to be performed on an incoming package?
3. How frequently do you perform surveys? How frequently are the surveys documented?
4. What would you do if a reading of a dosage is different than expected?
5. How do you ensure that you are a performing the correct procedure on the correct patient?
6. What steps do you take to ensure a diagnostic dosage is administered according to departmental policies?
7. What dosages require a written directive? What steps do you take to ensure the dosage is administered according to the written directive?

Other recommended radiation safety officer checks of nuclear medicine department operations include these:

1. Ask for a demonstration of a package receipt survey.
2. Ask for a demonstration of survey meter use during a routine injection and a documented survey.
3. Observe a technologist prepare and administer a radiopharmaceutical.
4. Perform meter and wipe surveys of radiopharmaceutical preparation, administration, and patient care areas. If surveys performed by the radiation safety officer routinely indicate contamination:

   a. Review the results of documented surveys performed by nuclear medicine staff. If contamination is not routinely indicated as being detected perform a detailed review of survey practices and survey documentation.
   b. Investigate procedures to determine possible sources of the contamination.
5. Examine written directives and dose books or equivalent records to ensure all regulatory required records are being maintained and that the administrations are being performed in accordance with regulations and departmental policy.
6. Assess security practices. Focus on storage areas for stock material, radiopharmaceuticals prior to administration, and sealed sources. Can you enter a storage area without anyone acknowledging or questioning your presence?
7. Audit other records generated and/or maintained by the nuclear medicine department to ensure regulatory requirements are being met. These records may include, but may not be limited to, incoming package surveys and waste records.

Equivalent questions and checks should be included in audits of brachytherapy. Additional issued to be considered are for brachytherapy area audits are the following:

1. Inventory control. Can personnel readily locate sources?
2. Source storage dose rates. Single brachytherapy sources may have lower dose rates and/or shielding can be relatively effective at reducing dose rates to at or near background. However, a significant change in activity of a source or multiple sources stored together can result in a significant change to previously measured dose rates.

9.9 CONCLUSION

For programs that use radiopharmaceuticals and sealed sources in a medical setting it is important that the radiation safety officer have knowledge about the specific uses of these materials and the associated operations. It is also important that the users of radiopharmaceuticals and sealed sources have knowledge of good health physics practices and how regulations apply to their use of radioactive material. When the use of radiopharmaceuticals and sealed sources involves patients, this knowledge and application of the knowledge ensures good radiation safety along with enhancing patient care.

9.10 REFERENCES

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