Radiation Safety Annual Refresher Training for the Authorized User

The intent of this tutorial is to satisfy training requirements for the authorized user in radiation safety issues and procedures as they pertain to ICANL accredited Nuclear Laboratories. The regulations that are relevant to your radioactive materials license and to you, the Authorized User, are spelled out in the Commonwealth of Massachusetts, Department of Public Health regulations for Ionization Radiation - 105 CMR 120.000. A full copy of these regulations must be on site at your facility. The Nuclear Medicine technologist can assist in locating your copy of these regulations. In addition, if you have general questions about the regulations as they pertain to your facility's license, please do not hesitate to contact F.X. Masse Associates at 978-283-4888.

ICANL accreditation requires that you have at least one hour of radiation safety training annually. A testing requirement accompanies this tutorial. Please take time to read this document and fill out the training documentation form, certifying that you have done so. Maintain the training documentation in your facility's records. The ICANL may ask for proof of this training when it comes time for your facility to apply for accreditation renewal.

The Authorized User - Definitions and Responsibilities

The State regulations specific to the Authorized User (AU) can be found under the main header: 105 CMR 120.500 - "Use of Radionuclides in the Healing Arts". This part of the regulations also contains a comprehensive list of definitions and terms pertinent to the medical use of radionuclides. There are two definitions that you should know well - the definition of an Authorized User and the definition of a Radiation Safety Officer. The main points of these two particular definitions are given below.

Authorized User (AU) - means a physician, dentist or podiatrist who:

- meets the requirements as outlined by the regulations
- is identified as an AU on a Commonwealth of Massachusetts issued license to permit the medical use of radioactive material.

Radiation Safety Officer (RSO)- assumes the role of overseeing and implementing a radiation control program at a licensed medical or research facility, and is so identified on the license.

Usually for smaller facilities such as a cardiology office or outpatient nuclear laboratory, a physician serves as both an Authorized User and the RSO. Larger facilities such as hospitals

often have an independently named individual charged with the duties of the RSO. An RSO need not always be a physician, but the RSO must meet certain training and experience requirements to fulfill the RSO responsibility.

The role of the RSO is to be taken seriously. In order to maintain a radioactive materials license, an RSO must be appointed by the facility, approved by the licensing agency, and agree in writing to become responsible for implementing and overseeing the "radiation safety program". The specific duties are outlined in the state regulations. In general, the RSO is charged with the following duties:

- Identifying radiation safety problems.
- Initiating, recommending and overseeing corrective action.
- Stopping unsafe operations.
- Verifying the implementation of license conditions and regulations.

There is a provision in the regulations for appointing a qualified temporary replacement of the RSO, should the RSO be unavailable for an extended period of time.

The Radiation Protection Program & the Nuclear Cardiology Laboratory

This tutorial is intended as a training reference for nuclear cardiology laboratories. These facilities will have a smaller set of elements that must be considered in their radiation safety program than a hospital based, all encompassing Nuclear Medicine department. However the following requirements are discussed because they are universal for all licensed facilities. This list should not be regarded as a complete set of elements that must be overseen by the RSO, rather they should be considered the most important aspects of your radiation control program that you should become familiar with:

- Types of radioactive materials commonly found in Nuclear Cardiology laboratories
- Posting, labeling and access control of radioactive materials
- Ordering, receipt, shipment and delivery of radioactive materials
- Surveys and assessments of occupational radiation exposure
- Training and education of radiation and non-radiation workers
- Dosimetry training and record keeping for radiation workers

Types of Radioactive Materials Commonly found in Nuclear Cardiology Laboratories

Long-lived sealed sources must be purchased and held on site in a secure area where access is restricted to trained and authorized personnel. The nuclear medicine technologist may be granted this access because they are licensed and trained to handle and use these materials

properly. A nuclear cardiology laboratory will have a small number of these sealed sources. The most frequently used sealed sources and their functions are listed below:

- 57Co - in a sealed vial, usually 5 mCi or less activity. This source is used for the daily check of the dose calibrator* in the hot lab.
- 57Co flood - in a large round or rectangular thin source, usually 15 mCi or less activity. This source is used for the daily calibration of the gamma camera. This isotope is very close to the same energy level as 99mTc. It is required and helps to ensure the proper field uniformity of the gamma camera each day prior to patient use, as necessary QC procedure.
- 137Cs - in a sealed vial, usually less than 300 uCi (0.3 mCi) of activity. This source is used in conjunction with the 57Co sealed vial source for the daily check of the dose calibrator* in the hot lab.
- smaller "button" point sources, usually 57Co or 137Cs with a less than 10 uCi range of activities. They are used for patient land marking such as at the xyphoid process or the sternal notch. These sources are more commonly used for general nuclear medicine exams but may be used with cardiac nuclear exams.

Below are some images of some typical sealed radioactive sources as described above:

courtesy of: Eckert and Ziegler Isotope Products

Some of the regulatory requirements regarding these sources are briefly listed below:

- the sealed source may only be purchased and received from companies authorized to manufacture and distribute sealed radioactive sources to authorize recipients.
- the sealed sources must be surveyed and inventoried quarterly (four times per year).
- if it has a half-life of > 30 days and contains >100 uCi of activity, the sealed source must undergo a special "leak test" at receipt, bi-annually, during suspicion of damage, and prior to shipment in order to check for leaking radioactive material from the sealed container.
- your facility must hold a manufacturers calibration certificate for each sealed source on site.

- your facility must keep records of the incoming and shipment of all sources on site.
- your facility area where the sealed sources are stored must be kept secured at all times.

Short-lived unsealed radiopharmaceuticals are used for patient doses. In the cardiology nuclear laboratory, these isotopes are most often 99mTc and 201Tl. (PET scanning, is not discussed here). Some of the regulatory requirements regarding the use of these materials is listed below:

- patient dosages prescribed by the Authorized User must be verified and recorded prior to medical use. For unit doses, it is permissible to rely on the identification and quantity presented by the radiopharmacy and the unit dosage can be recorded from the unit label of the calibration dose and time. Decay correction should be done prior to the recording of a patient dose, if applicable.
- dosages must be prescribed by the Authorized User for each medical indication and diagnostic nuclear exam. These prescribed dosages may be authorized in a standing order with a list of procedures which must be reviewed and updated on an annual basis.
- Administered patient dosage must not differ from the prescribed dosage by > 20% without AU authorization.
- patient dose records must be kept on file for three years.
- Although it is possible to rely on the suppliers dose assay, it's always advisable to check the dose in a dose calibrator before administration. If the dose is fractionated or re-compounded it must be measured in a properly maintained dose calibrator before administering to a patient.

Posting, Labeling and Access Control of Radioactive Materials

Since the numerous poisoning events and thefts that have occurred since the 1990's, most states have adopted very strict standards regarding the control of access to radioactive materials. The terrorist events that occurred on 9/11/01 have caused a reemphasis on the overall security of radioactive materials. Maintaining an accurate inventory of radioactive materials in order to guard against theft or loss is imperative. Even minor amounts of radioactivity can cause wide-spread contamination. Below are some examples of common posting and labeling of radioactive materials in the Nuclear Laboratory where radioactive materials are secured.

This is posted in area that could result in an individual receiving a dose equivalent of greater than 5 mrem per hour. This is usually not applicable in a nuclear cardiology lab where all sources are individually shielded.

This is posted in an area (such as a hot lab) where radioactive materials are used or stored.

Ordering, Receipt, Shipment and Delivery of Radioactive Packages

The AU is ultimately responsible for all use of licensed material in this program. It is the licensed nuclear medicine technologist who is usually assigned to carry out day-to-day activities. In addition to the above, it is required that the appropriate monitoring and record keeping be performed as it relates to each activity. There are also time requirements for these records to be maintained at your facility. Most radioactive ordering, receiving and shipping records and their related surveys must be kept for three years. Decay of used radioactive materials or waste can be done on site in a secured and shielded area such as the hot lab. The most common unsealed source used in the nuclear cardiology laboratory is 99mTc. It has a half life of six hours. A good rule of thumb to remember is that most of radioactivity will be "gone" (decayed down to background levels) after about 10 half-lives. For 99mTc, this is 60 hours or a little less than three days. Once at background levels, these materials can be disposed of as if they were regular waste or regulated biohazard waste. Good record keeping must be maintained with decay-in-storage radioactive waste.

These records are often kept via a computerized program in the hot lab where the radioactive sources are stored. It is acceptable to keep hard copy records in three ring binders. Records involving these activities must be dated and initialed by the individual performing the activity and must be kept in an organized way for complete inspection by the licensing agency in their unannounced inspection program.

Surveys and Assessments of Occupational Radiation Exposure

Below is a picture of a G-M (Geiger-Muller) survey meter.

This instrument is used in the nuclear laboratory to detect radiation. . There are usually at least two of these instruments at each site; an extra one is always available in case the other is found to be inoperable or needs to go out for repair or recalibration. There are regulatory requirements that must be followed concerning the use of these survey instruments:

- An operating survey meter must be available when radioactive material is in use.
- These instruments must be calibrated at least annually.
- Battery and instrument checks must be performed, but not recorded, prior to each use.

These instruments are used by the nuclear medicine technologist to perform routine surveys of the nuclear laboratory, to survey all incoming and outgoing radioactive packages, and to look for radioactive contamination whenever suspected, such as when a small spill or droplet of body fluid contamination occurs in the laboratory. In this way, the contamination can be located, contained and then cleaned up so that no other individuals or areas are further contaminated unnecessarily. Below is a list of some common regulatory requirements regarding the surveys and assessments of occupational exposure.

- perform surveys at the end of each work day on all areas of the nuclear laboratory where contamination might have occurred.
- perform surveys of incoming packages to assess for any external contamination or possible leakage.
- perform surveys of radioactive waste materials prior to storage and then prior to normal waste disposal following decay in order to ensure that the radioactivity is at the level of background when released.
- perform surveys whenever radioactive contamination is suspected. If found, the results of the survey are to be recorded. Steps taken to remove the contamination are also recorded, with follow-up surveys performed.

- perform wipe surveys weekly or whenever contamination is suspected in order to assess areas of removable radioactive contamination.

Training and Education of Radiation and Non-Radiation Workers

There are many radiation safety training activities that must be performed annually. These activities are designed to ensure that the personnel involved with the handling of radioactive materials or who could be exposed to radioactive sources possess the knowledge and ability to keep their exposures ALARA (as low as reasonably achievable). Below is a list of activities that are performed at your facility each year:

- annual radiation safety training for the Authorized User.
- annual radiation safety training for radiation workers (nuclear medicine technologists).
- every three years - DOT (Dept. of Transportation) training for the nuclear medicine technologists to ensure the knowledge of transportation regulation for the receipt and shipment of radioactive packages.
- annual nuclear medicine technologist evaluation of RAM handling techniques by the Authorized User to ensure the proper performance of their entrusted duties.
- annual radiation safety training for non-radiation workers (EKG techs and stress nurses) that may be briefly exposed to radioactive sources or patients.
- annual training of outside personnel (fire department, maintenance and housekeeping, dose vendors, etc.) to ensure familiarity with your facility and specifically to learn how and where your radioactive materials are stored in case of off-hours emergencies.

It is important that all AU's are aware that these activities, how often they must be performed and that the documentation and training for these activities must be updated regularly.

Dosimetry Training and Record Keeping for Radiation Workers

Dose limits to radiation workers are found in the regulations, 105 CMR 120.200, "Standards for Protection Against Radiation". These MA state regulations follow the dose limits set forth by the federal NRC regulations for radiation workers. A radiation worker is allowed a maximum effective dose limit of 5 rem (5000 mrem) each calendar year.

Radiation workers whose assignments involve the possibility of exceeding 10% of the annual limit (500 mrem) from radioactive sources must be monitored with approved radiation dosimetry devices. Rarely and only in very busy cardiology facilities will any radiation worker reach the 10% levels of exposure. However, license conditions require us to badge the personnel directly involved in the handling of radioactive sources and radioactive patients on a regular basis. This

group will include nuclear medicine technologists, and may also include the physicians performing radioactive stress tests and any full time EKG techs or nurses that are routinely involved in nuclear stress testing. An additional requirement is that dosimetry equipment is properly worn and returned in a timely manner so that the readings can be available to your facility as soon as practical after each wear period.

There are additional regulations for the monitoring of radioactive exposure to pregnant workers. This regulation more specifically pertains to the exposure of the unborn fetus. Pregnant radiation workers have a choice of "declaring" their pregnancy status to their employer. Once declaration occurs, the pregnant worker is entitled to receive additional education and is also issued a fetal badge during the rest of her pregnancy. More information on the pregnant radiation worker and the declaration of a pregnancy can be found in the regulations under 105 CMR 120.226 (A)(3).

Conclusion

Managing a medical radiation safety program can be a simple task or it can be complex. The role of the Authorized User is often perceived as a minor task compared to the many other daily activities that must be performed in your role as a physician, but the importance of the crucial role of the AU and the RSO will be greatly emphasized if something goes astray.

A well-maintained, comprehensive radiation safety program should minimize unfortunate events from occurring at your facility. If your employees are trained in the aspects of ALARA and radiation safety, and good record keeping is enforced and maintained on a regular basis, continuing compliance with regulations will become routine..

This brief document serves as a quick refresher to help remind you of some of the radiation safety activities that occur regularly within your facility. Please complete the accompanying quiz and fax the results to our main office at 978-281-6702. You should maintain your training records along with the other ICANL training documentation at your facility.