

X-ray

Newsletter

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Division of Environmental Health ~ Radiation Protection Section

Inside This Issue

- HIPAA and Radiology 2
- Being a Radiation Safety Officer ... 3
- Shielding by Design 3
- Frequently Asked Questions 4

Check out our Web site!

www.ncradiation.net

You can now download and print the following from our new Web site:

- ☛ Written Radiation Safety Program Guide (replaces old versions of model guide)
- ☛ Inspection Checklist
- ☛ Reference Guides

What's New?

The Notice to Employees has been updated.

Copies can be downloaded from the X-ray Web site, or you can call (919) 571-4141 to obtain a printed copy.

Newsletter/notification listserves have been created!

To subscribe, go to:

<http://lists.ncmail.net/mailman/listinfo/xraynews>

or

<http://lists.ncmail.net/mailman/listinfo/mammographynews>.

New Name, Same Purpose

The Mammography and X-Ray Inspection Branch recently changed its name to the Radiology Compliance Branch. This change came about because the two programs have merged under one branch. To better serve our customers, many of the inspectors have been cross-trained to work in both programs. The staff voted to rename the branch to reflect both mammography and X-ray as one unified program.

The key to radiation safety: a written radiation safety program

A radiation protection program is intended to ensure that all activities and operations involving the use of X-rays are performed in such a way as to protect users, staff, patients and the public from exposure to unnecessary levels of radiation in practices that use X-ray equipment.

The basis of this plan is to maintain all radiation exposures as low as reasonably achievable, which is abbreviated and known as ALARA. This philosophy – ALARA – is defined as making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, remaining consistent with the purpose for which the licensed or registered activity is undertaken.

The written radiation protection program is a unique document for each facility, based upon the scope of activities provided by each practice, and is required by the *North Carolina Regulations for Protection Against Radiation*. Rule .1603, titled "Radiation Protection Programs," states that each licensee or registrant shall develop, document and implement a radiation protection program. Since each facility is unique, each written radiation protection program should be customized to its facility's specific activities. Certain records and documents as listed in the regulations may be consistent for all regulated facilities; however, the day-to-day activities performed within a facility will differ and should be documented to provide radiation protection safety for staff and the public.

Developing a customized radiation safety program can be challenging, so the following information is being provided to assist you when developing or updating your facility's written safety program.

In the past, a model guide for the Preparation of Operation and Safety Procedures has been used but is no longer available from the Radiation Protection Section. This guide has been replaced with a written safety program outline. If a facility has an outdated model guide and would like to continue with that format, a few items must be updated to ensure it is specific to the facility. To update your safety program, follow the steps below.

Radiation Safety Program *(continued from p. 1)*

- Compare the model guide to the safety program outline. Be sure to add activities that staff are performing that were not addressed in the model guide.
- Change the model guide heading to the facility's name.
- Remove sections that do not apply to the facility.
- Remove the following words in the document: model procedures and sample set of procedures.

Written safety program(s) must be reviewed annually. Documentation of annual updates must be kept on-site for inspection purposes.

how in order to list the item(s) on the outline and include the appropriate safety measures. It is important to remember to detail exactly how a facility performs an activity on your written radiation safety program.

- Available online are reference guides and links that may be helpful when developing a written safety program. A few of the guides and links are ALARA, Pregnancy-Employee/Patient, and Signs and Posting.

An outline of a written safety program is available on the Radiation Protection Web site at www.ncradation.net, or it can be obtained by calling (919) 571-4141. Carefully, review each item listed in the outline to see if it applies to an activity that must be performed or is being performed at the facility. To determine if an item is required or is already being done at the facility and should be included on the written radiation safety program, ask the questions *who, what, when, where, why or*

Once a written safety programs is developed, it must be effectively implemented. Every individual working in or near sources of radiation should be trained on the program's scope, content and requirements. The regulations require an annual review of the safety program, which provides a perfect opportunity for the facility to evaluate the written program against actual practice – either updating the program or retraining staff about the proper procedures. Documentation must be available for review during inspections.

HIPAA and the Radiology Compliance Branch

Health care staff has often struggled with compliance with the Health Insurance Portability and Accountability Act. As the HIPAA rule was implemented and phased in, questions frequently arose as new privacy scenarios emerged. Some questions we have been asked are “Can an X-ray inspector who is present in patient areas compromise patient confidentiality?” and “Is our facility in violation of the HIPAA rule if an inspector views sensitive patient information?” As a health care provider, you must balance between protecting your patient's privacy and adhering to your agreement for state-mandated inspections (15A NCAC11.1005).

The following guidance may help clarify questions you may have regarding HIPAA and inspections performed by the Radiology Compliance Branch.

HIPAA was enacted by Congress on Aug. 21, 1996, and can be found in the Code of Federal Regulations under title 45, sections 160, 162 and 164. It was originated to:

- o Protect individuals who are transitioning between insurance companies.
- o Reduce costs and increase efficiency among health insurance and health care providers by encouraging the use of and standardizing the transfer of electronic patient data.
- o Protect the privacy and security of patient health information.

Radiation Protection Section and HIPAA

In 2001, the N.C. General Assembly directed the formation of a statewide HIPAA Assessment Team to determine the role of state government agencies in HIPAA compliance during interaction with regulated facilities. The team concluded that state government agencies, like RPS, were exempt due to the lack of a business-associated agreement (exchange of goods or services) with covered entities. Therefore, a facility is not in violation of the HIPAA rule during inspection.

State Inspectors and Patient Confidentiality

Inspectors in a diagnostic radiology department or dental facility have no reason to access or remove sensitive patient information from the facility. The inspector is focused solely on your equipment and operating procedures. However, Mammography Quality Standards Act inspectors in a mammography department will, on occasion, remove patient mammography reports from a facility to support violations. If an inspector removes a report, it is placed in the facility's file in the branch's central office. Since most state records are subject to the N.C. Public Records Law, sensitive patient data is carefully removed from patient reports before placement in the files. An MQSA inspector is performing “health oversight activities” as stated in the Code of Federal Regulations, and therefore, will not compromise facilities' compliance with HIPAA.

Being a radiation safety officer: What does it take?

By definition in 15A NCAC 11 .0104 (95), a radiation safety officer is one who has the knowledge and responsibility to apply appropriate radiation protection rules. Rule .1603 (c) requires the licensee or registrant to annually review the radiation safety program content and implementation. However, the definition does not provide any further detailed requirements other than the knowledge and authority for radiation protection.

Ideally, the RSO should be instructed in the fundamentals of radiation safety, characteristics of gamma radiation, units of radiation dose (mrem, sievert) and quantity of radioactivity (curie, Becquerel). This person should also have had instruction in the hazards of exposure of radiation, levels of radiation from sources of radiation, methods of controlling radiation dose and use of personnel monitoring equipment.

It is preferred the RSO be a licensed practitioner*, but some duties may be delegated to other persons with appropriate training. In those situations the delegated responsibilities and persons should be identified. In large institutions, the medical physicist is often delegated as the RSO. Whoever is delegated as RSO should be someone that is present in the facility to oversee the daily activities of radiation safety.

The RSO should also be familiar with the applicable rules in Section .0100, General Provisions; .0200, Registration of Radiation Machine and Services; .0600, X-Rays in the Healing Arts; .1100, Fees and .1600, Standards for the Protection against Radiation – all of which can be found in the *North Carolina Regulations for Protection Against Radiation*.

The specific duties and authorities of the radiation safety officer shall include but are not limited to:

- Establishing and overseeing emergency operations and ALARA procedures, reviewing them regularly to ensure that the procedures are current and conform with these rules and license condition;
- Overseeing and approving all phases of radiological safety training, including radiographic personnel, so that appropriate and effective radiation protection practices are taught;
- Ensuring required surveys and leak tests are performed and documented in accordance with the *Regulations*, including corrective measures when levels for radiation exceed established limits;
- Assuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, records are kept of the monitoring of results and timely notifications are made as required by Rule.1646; and
- Assuring that operations are conducted safely, assuming control and having the authority to institute corrective actions, including stopping of operations, when necessary in emergency situation or unsafe conditions.

In summary, the person identified as the RSO must be named by the licensee or registrant and must have the knowledge and responsibility to apply appropriate radiation protection rules.

*Licensed Practitioner (M.D., D.D.S., D.O., D.P.M., D.C. and D.V.M)

Shielding by Design

Shielding is the use of lead-lined equipment, personnel protective devices and planned designs in order to decrease the harmful effects of exposure to ionizing radiation. Any piece of equipment that uses ionizing radiation to produce a diagnostic image must adhere to shielding specifications as mandated by the Radiology Compliance Branch.

There are many federal and state regulations that help protect the patient, public and employee from unnecessary radiation exposure. Shielding designs, plan reviews and surveys of imaging spaces are regulated to ensure safety. In addition to the regulations, imaging professionals are governed by basic ALARA principles that adhere to safe radiation protection policies designed to maximize

image quality while maintaining a dose as low as reasonably achievable. Failure to use shielding materials like lead aprons, thyroid shields and mobile barriers, which all have been designed and regulated to decrease the harmful effects of ionizing radiation, can permit unnecessary radiation exposure to the patient, employees and public.

We all have been touched by the miracles of modern medicine and technology. As professionals, we are proud and amazed at the advances in each of our fields. However, data exists that demonstrates radiation-induced diseases can occur at levels of 50mSv. For example, CT-scans have revolutionized the way medicine is performed, enabling people to live healthier, longer lives. One CT-scan exam can

Shielding by Design *(continued from p. 3)*

expose up to **10-15mSv**. The College of Radiology 2007 white paper journal on radiation safety demonstrates a significant increase of usage rates in imaging studies. In 1980, approximately 3 million CT-scans were performed in the United States; that number rose to 60 million in 2005.

Radiation-induced diseases can be minimized with good radiation protection practices. The three fundamental rules of radiation protection are time, distance and shielding. The exposure time should be minimized to the level that still achieves good quality images. Increased distance between the source of radiation and exposed persons reduces personnel

exposure. Shielding inserted between the source and exposed person reduces exposure.

Clearly the number of imaging studies performed in the United States is increasing. Each exposure, no matter how small, contributes to the cumulative lifetime exposure of patient, personnel and the public. It is the responsibility of every diagnostic imaging professional to use proper shielding techniques and adhere daily to their radiation safety procedures. As medical professionals, you contribute to someone's lifetime dose with every exposure or scan. Each time you shield the patient and apply the appropriate techniques, you are helping to reduce the cumulative lifetime exposure to the public.

Frequently Asked Questions

Q: Do we have to contact RPS for our inspections?

A: No. Facilities are on a scheduled frequency set up by RCB. Inspections range from a frequency of two to four years depending on the type of facility. If your facility is past due, we are aware of it and your facility is on our list of facilities to visit.

- *Every two years* - hospitals, health departments, industrial radiography facilities
- *Every three years* - dental, chiropractic, podiatry, medical clinics, radiology offices, mobile units
- *Every four years* - government, education, veterinary

Q: Do I need another plan review when an X-ray room goes digital?

A: Yes. The workload and output has the potential to increase with digital technology. Visit the RCB Web site for a reference guide on this topic.

Q: I forget to do my annual review of the radiation safety program!

A: Nevertheless, it is required. We have learned from facilities that they often have a day set apart for review of their OSHA program. We suggest that the radiation safety program be added to the agenda for that day. Another idea is to have a client named X-Ray Safety Program in your database. You can automatically mail yourself a reminder once a year on a day or your choice.

Q: How often do I have to update my registration?

A: Notification to the registrations coordinator of the Radiation Protection Section must occur anytime there is a change to any information on the registration, including equipment and contact information, phone number and mailing address, or the name of the facility. The corrected registration must be submitted as soon as the change is made.

Q: Is it acceptable to state that we will stop the person from doing X-rays if they are pregnant?

A: No, the worker must be declared pregnant in writing. Pregnancy is not a preclusion to radiation work. It is the responsibility of the radiology employee to inform the supervisor that they may be pregnant, this declaration should be in writing, with estimated due date. Until there is a declaration of pregnancy, the occupational dose limits shall remain those guidelines set for adult employees. The Declared Pregnancy Policy must be included in your Radiation Safety Program. See our Web site, <http://www.ncradiation.net>, for a reference guide on this topic.

For your information!

The RCB is responsible for the protection of the health and safety of the public, patient and personnel when radiation is used. The branch staff often receives calls regarding radiation safety or ethical concerns, which results in an investigation.

Most complaints concern failure to shield or protect an adult patient or child, repeat exams leading to unnecessary exposures, excessive occupational exposures, untrained staff taking exposures and staff/public concerned about exposure while in an adjacent area to an X-ray room.

Information requests from inside the agency are most often generated over failure to register the facility, failure to update the registration or failure to obtain a plan review that has been acknowledged prior to equipment installation.

Standard follow-up procedures for complaints or concerns are to perform an investigation based on each call. If the inspection is due at that time, it is generally performed simultaneously. The next steps are to review the written radiation safety program and to interview appropriate personnel and observe the facility radiation safety practices. Ensuring proper radiation safety practices are developed, documented and implemented in the facility is key to reducing the potential for complaints resulting in investigations.