

# X-ray

# Newsletter

February 2006

Division of Environmental Health ~ Radiation Protection Section

## Inside This Issue

- Installing Equipment ..... 2
- Inspections Help ..... 2
- X-ray Retention Guidelines ..... 3
- Types of Records Reviewed ..... 3
- Inactive X-ray Equipment ..... 3
- For Your Information ..... 4

## Check out our Web site!

[www.ncradiation.net](http://www.ncradiation.net)

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

- ☛ Registration applications for Healing and Non-Healing Arts
- ☛ Model Guides for Written Safety Program

**Effective July 1, 2006:  
Stored X-ray facilities with X-ray equipment will be subject to annual fees.**

## Employee News

Happy days have arrived for William Johnson and Larry Jackson. William Johnson retired from his position as the X-ray and Tanning Branch manager after 32 years of service. Larry Jackson, after 42 years of service to the X-ray program, has also retired. Gov. Mike Easley present both with the Order of the Longleaf Pine award for their service and dedication to the state of North Carolina.

***Thank you, William and Larry, for your years of service!***

## Top Six Violations

Inspection results based on fiscal year 2004-2005:

1. An area radiation survey was not performed within 30 days following initial operation of equipment;
2. X-ray control device(s) not permanently mounted in a protected area;
3. Plan review was not submitted for review and acknowledgment prior to installation;
4. Registrant failed to have a current copy of the "North Carolina Regulations for Protection Against Radiation" at the facility;
5. Registrant failed to provide a working technique chart for each diagnostic X-ray system; and
6. Failure to register the facility or update registration in a timely manner.

## Proper Storage and Disposal of X-ray Equipment

X-ray-producing equipment is used in many applications like health care, industry and law enforcement. In North Carolina, users of such equipment are required to register the equipment with the section, except for federal and Native American operations. Contact the branch manager or X-ray registration coordinator using the following information.

**Address:** Radiation Protection Section

1645 Mail Service Center | Raleigh, NC 27699-1645

**Phone number:** (919) 571-4141 | **Web site:** <http://www.ncradiation.net>

For a variety of reasons, it may be necessary to take X-ray equipment out of service temporarily or permanently. According to state regulation .0209, when the equipment is sold, donated, stored or disposed, RPS must be notified in writing of the inactive equipment. The options include:

- Place the X-ray equipment in storage on site.
- Transfer or sell the X-ray equipment to a colleague or affiliate.
- Transfer or sell the X-ray equipment to a service company.
- Donate the X-ray equipment to a charitable organization.
- Dispose of the X-ray equipment.

## Radiation Protection Inspections Help Lower Radiation Doses to Patients

Digital radiography is an emerging modality many practices are beginning to use as they replace conventional film-screen systems. With digital systems, images can be taken, immediately examined, deleted, corrected and sent to a network of computers. In medical radiography, digital radiography can lower the X-ray dose to the patient while achieving high quality pictures. While digital radiography is beneficial in most offices, it does have some drawbacks.

A recent inspection was performed at a dental office, which was a modern facility using digital radiography. One of the benefits of the proper use of digital radiography is lowering the dose to the patient. During this particular inspection, the inspector found the radiation dose to the patient to be 322 mR per exposure. This is a dose expected from the use of D-speed film; however, the facility was using digital equipment, so the inspector knew that the dose could be much lower. With the use of a phantom, the inspector took two films. The first was taken using the same time setting the facility used, and the second was taken with a 2/3 drop in the time setting. The dentist reviewed the results for comparison and could not see a difference between the two films. This actually lowered the radiation dose to the patient from 322 mR per exposure to 64 mR per exposure.

Digital radiography and computed radiography are unlike conventional film-screen systems because proper exposure levels to patients can no longer be monitored easily by the appearance of the images. Digital has a greater dynamic range that enables images to be taken over a wide range of exposure levels. With digital systems, two images that are acquired at very different radiation exposure levels may appear the same. If an image was acquired with too much exposure, the new systems will compensate for the overexposure. Because of the simple physics of higher exposure resulting in less noisy images with conventional film-screen imaging, there is a tendency by operators of digital equipment to overexpose the patient in order to get better images. With digital systems, dose should be decreasing rather than increasing. Dose creep has become a national trend as more facilities are converting to digital radiography and computed radiography to replace conventional film-screen radiographic systems.

Although the dose magnitude in general radiography is low compared to computed tomography and fluoroscopy, the dose to the patient is more critical in pediatric exams than in adults, due to the greater radio-sensitivity of children. It is important facilities implement quality control and feedback avenues to verify that the goals of image quality, dose and ALARA are achieved as well as to ensure staff is trained in appropriate techniques.

## What You Should Know Before Installing X-ray Equipment

### Before you install

Rule .0603 of the regulations requires a shielding design/plan review shall be:

- ❖ Performed by a qualified expert registered to perform the service in North Carolina (.0205);
- ❖ Submitted to the Radiation Protection Section (.0204); and
- ❖ Acknowledged by RPS **prior** to installation. Upon receipt of the shielding design/plan review, an acknowledgment letter and application for registration will be mailed to the facility contact person listed on the plan review (.0210).

### After you install

Rule .0603 requires a post-installation radiation survey shall be:

- ❖ Performed by a qualified expert registered to perform the service in North Carolina (Rule .0205), except intraoral and panorex units;
- ❖ Performed **within 30 days of initial operation** of the X-ray unit (.0603); and
- ❖ Submitted with application containing any updated or new information regarding the

installation within 30 days of initial operation (.0203 and .0209).

### Service providers must be registered (Rule .0205)

- ❖ Health physicists and registered service providers who perform shielding designs/ plan reviews and post installation surveys must be registered with RPS to perform those services (Classes III, IV, V).
- ❖ All service companies installing, selling or servicing X-ray equipment must be registered with the RPS prior to performing services (Classes I-II).

Registered service providers can provide you a current copy of their registration. A list of registered companies and qualified experts can be found online at <http://www.ncradiation.net>.

Federal Rule 21CFR Part 1020 and North Carolina Rule .0206 require that the registered installer provide the facility with an U.S. Food and Drug Administration Report of Assembly Form 2579. The installer must submit within 15 days of the installation a copy of Form 2579 to the facility, FDA and RPS.

## X-ray Film Retention Guidelines

The Division of Environmental Health's Radiation Protection Section does not regulate film retention; however, the following information was compiled in an effort to assist you in developing a film retention policy.

- According to the North Carolina Attorney General, there is no state law opinion, but consider keeping adult X-ray film three to four years and pediatric film three to four years past age 18.
- The Joint Commission of Accreditation of Healthcare Organizations recommends a facility follow state law on this issue.

- The American College of Radiology recommends retaining film archives for five years.
- Through a recent survey of area hospitals, most hospitals retain X-ray archives for five years. Some hospitals discard X-ray archives upon the death of the patient unless litigation is involved.
- The FDA requires that mammography films be retained for five years. If there has only been one mammogram, then it must be retained for a minimum of 10 years.

## Types of Records Reviewed During Inspections

The facility shall maintain the following documentation, which will be reviewed for compliance with the regulations at the time of inspection(s). North Carolina rule references follow each item.

### For all X-ray Units

- Copy of the plan review (.0603)
- Copy of the letter of acknowledgment (.0210)
- Copy of the safety survey (.0603)
- Copy of the Form 2579, FDA Report of Assembly Form (.0206)

### General Documents

- Current copy of the Notice of Registration from RPS (.0203 and .0209)

- Previous inspections reports and correspondence regarding inspections with RPS (.1002)
- Current copy of the current state regulations (.1002)
- Dosimetry records for personnel (.1638, .1640 and .1644)

### Radiation Safety Program

- Current copy of the radiation safety program (.1603 and .1636)
- Documentation of annual review (.1603)

### Posting of Signs

- Notice to employees (.1002)
- Radiation Caution signs (.1623 and .1624)

## Inactive X-ray Equipment

If registrants decide to store the equipment, it may be stored on site in an inactive status. However, storing equipment that is no longer used is not desirable unless it is to be returned to service after a brief period of time. Storing equipment that is neither operable or repairable is not desirable because the long-term accountability of those units has proven to be poor. In addition, some units may contain hazardous materials. Written documentation must be submitted stating that equipment is stored. When the equipment is to be used again, RPS must be contacted in writing within 30 days of operation.

Equipment or its components that is either operational or repairable may have some future value and may be transferred or sold to a colleague or a service company. A list of service companies that repairs or refurbishes X-ray equipment can be found at <http://www.ncradiation.net>. To sell or transfer equipment to a colleague or service company, consult with your service company, place

ads in professional publications or conduct an online search.

Operational or repairable equipment also can be donated to a charitable organization. Charities that accept such donations can be located through professional societies, community groups, religious organizations or conducting an online search.

Regardless of to whom the equipment is transferred or sold, the Radiation Protection Section must be contacted in writing when it is sold or transferred. Be sure to include the name and address to whom it is sold/transferred.

If the equipment or its components possess no future value, disposal is the best option. Disposal of the tube and transformer must be handled by companies equipped to handle such materials.

For more information, contact RPS at (919) 571-4141.

## For Your Information

### **Any Change To Your Registration Must Be Reported Immediately:**

Rule .0209 states that any registrant shall notify the agency in writing when any change will render the information contained in the application for registration or notice of registration no longer accurate.

### **Only Registered Persons Can Sell, Service, Transfer, Design Plan Reviews, Perform Room Surveys Or Provide Personnel Dosimetry Services:**

Rule .0204(a) and (b) state the following (a) Except as provided in Paragraph (b) of this Rule or otherwise authorized in writing by the agency each person registered pursuant to Rule .0203 of this Section shall prohibit any person from furnishing equipment services described in Rule .0205(d) of this Section to his facility until such person provides evidence that he is currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section. (b) No person registered pursuant to the provisions of Rule .0203 of this Section shall perform any services listed in Rule .0205(d) of this Section in his facility unless such person satisfies the applicable requirements in Rules .0205, .0213, and .0214 of this Section and has received written authorization from the agency to perform such services.

### **Every Facility Must Have A Written Safety Procedure Program That Is Reviewed Yearly:**

Rule .1603 states that each licensee or registrant shall develop, document and implement a radiation protection program commensurate with the scope and extent of licensed or registered activities and sufficient to ensure compliance with the provisions of this Section. Record-keeping requirements relating to these programs are provided in Rule .1636 of this Section.

### **State Guidelines for Testing Lead Protection Garments:**

The section does not have regulations for the care, testing or retention period for lead garments. However, it does recommend facilities periodically check all protective equipment for cracks, tears or holes.

The following links may be useful:

- American College of Radiology: <http://www.acr.org>
- Health Physics Society: <http://www.hps.org>
- Implementation of an X-ray radiation protective equipment inspection program:  
[http://www.dicer.org/jsp/journal/show\\_article.jsp?jid=JA-132-82-2-S51](http://www.dicer.org/jsp/journal/show_article.jsp?jid=JA-132-82-2-S51)

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N.C. Department of Environment and Natural Resources  
Division of Environmental Health

#### **Radiation Protection Section**

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Raleigh, NC 27699-1645