In the Pink

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Division of Environmental Health ~ Radiation Protection Section

Inside This Issue

- Key to Radiation Safety 2
- Frequently Asked Questions 3
- Calibration for Sensitometers 3
- CMS Reimbursements Issues 4
- On That Note (Briefs) 4

Check out our Web site!

www.ncradiation.net

- U.S. Food and Drug Administration -- **www.fda.gov/cdrh/mammography**
- American College of Radiology -- **www.acr.org**

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.*

North Carolina Mammography Program Staff

- Jenny Rollins ---------- Manager
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When a Facility Closes...

In the event that your facility closes, following the steps below will both ensure compliance with state and federal requirements as well as provide patient instruction regarding retention and retrieval of prior mammograms.

A. Contact the American College of Radiology to submit a withdrawal letter. The phone number for the ACR is (800) 227-6440.

B. Send notice to the Radiation Protection Section regarding the status of the equipment (ie. stored, sold or salvaged) and where the patient films will be stored so that information can be placed on the RPS Web site. The address for the RPS is as follows: 1645 Mail Service Center; Raleigh, NC 27699-1645.

C. Send notice to U.S. Food and Drug Association as to where the films will be stored. Mail this information to:
FDA/CDRH/OHIP/DMQRP
Attn: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

What's New for Digital Facilities

If you've wondered how useful the current inspection checklist is for digital facilities . . . so have we. Therefore, a digital inspection checklist for inspection confirmation has been developed for 2008. Checklist questions were designed to help facilities recognize potential areas of deficiency and reinforce notification of the RPS regarding digital facility practice trends.

Digital and Computed Radiography Mammography Inspections

The following are items inspectors will be looking for during an inspection:

- Current quality control manuals for all components (unit, printer, review workstation) are in place;
- All quality control tests have been performed;
- Mammography equipment evaluations and quality control for off-site printers and quality control for any off-site review workstations have been provided; and
- Documentation of initial eight-hours of new, modality training for technicians, physicians and physicists has been provided.

Tips:

- Do not overlook new, initial modality training.
- If interpreting physicians' eight hours of new modality training are not Category 1 credits, it cannot be counted toward the required 15 continuing medical education credits.
- Computed radiology: The QC manual states that compression testing is performed initially, then every six months. Even though the unit has not been replaced, compression testing is required before patient use after conversion.
- Ensure that <u>all</u> quality control required by the manufacturer is accurately performed and documented.

The Key to Radiation Safety – A Written Radiation Protection 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 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 the staff and 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 old 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 written safety program:

- Compare the model guide to the safety program outline. Be sure to add activities staff members 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.'

An outline of a written safety program is available online at the RPS Web site: **http://www.ncradation.net**. It also 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 already being done at the facility and should be included in the written radiation safety program, ask the questions *who, what, when, where, why or 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 its written radiation safety program.

Available on the section's Web site 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, Signs and Postings, and links to the Conference of Radiation Control Program Directors and American Registry of Radiologic Technologists.

Once a written safety program 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 program, which provides a perfect opportunity for the facility's staff to evaluate the written program against actual practice — either updating the program or retraining the staff in the proper procedures.

Calibration for Sensitometers

It has come to the branch's attention that X-Rite will soon cease calibration services for the model 334 sensitometers. As of this newsletter print date, the following companies continue to offer calibration services for this model.

Fluke Biomedical
1-800-850-4606

NDS Products (radiation detection instruments)
1-800-413-4750

Please be advised that the state does not endorse any particular vendor. If you know of any other laboratories that offer calibration services for this model, please contact the Radiology Compliance Branch, so that staff may notify registrants.

Frequently Asked Questions

Is my facility's unit installed according to the plan review?

Mammography units must be installed as directed in the acknowledged shielding plan review. To ensure compliance, you or your physicist should look at the acknowledged plan review to confirm the unit was installed in the same orientation as the plan review indicates. If the installation does not match the plan review, you must submit an amended plan to the RPS for acknowledgment.

Do I have to have another plan review when an X-ray or mammography room goes digital?

Yes. The work load and output has the potential to increase with digital technology. However, a conversion to CR, since the unit itself is not replaced, does not require repeating the plan or survey unless patient volume and technical factors are significantly increased. Visit the branch's Web site for more information.

When do I need to get a new radiation survey?

A new radiation survey is needed when a facility gets new equipment or when a major component, such as a generator, is changed. Visit the branch's Web site at **http://www.ncradiation.net/mammo/index.htm** for a reference guide on this topic.

I have a new technologist I would like to train for mammography. Where can I find an initial training program to meet the 40 hours required by Mammography Quality Standards Act?

Visit the branch's Web site at **http://www.ncradiation.net/mammo/index.htm** to find information on a new program being provided at Wake Technical Community College along with other out-of-state providers. Be advised that some programs do not provide the full 40 hours, but a person can meet the remainder of the requirement with up to 12.5 well-documented hours performing the required 25 supervised exams. Documentation must be available for review during inspections.

Helpful Information via the Branch Web Site

You can now download and print the following from the updated mammography Web site at **http://www.ncradiation.net**. *Make sure you are in the Mammography Program's portion of the Web site.*

- Written Radiation Safety Program Guide *(replaces the out-of-date versions of the model guide)*
- Reference Guides
- Equipment
- ALARA
- Pregnancy Policies
- New Installations
- Disposal
- Plan Reviews
- Signs and Posting
- Adding/Changing Units
- Donation
- Inspection Record Review
- Upcoming Presentations

CRCPD is Coming to Greensboro!

The N.C. Radiation Protection Section is proud to host the annual Conference of Radiation Control Program Directors, May 19 –22.

The annual conference will be held in Greensboro at the Greensboro Marriott.

The CRCPD anticipates offering mammography continuing education credits in conjunction with this meeting. For more information go to **http://www.crcpd.org**.

Sign Up for Online Newsletters and Notices

The Radiology Compliance Branch is trying to develop new ways to inform registrants of updates and notices. The branch's staff will use electronic means to achieve this goal in a more quick and efficient manner. Anyone can subscribe to branch newsletters, updates and notices. Simply go to the links below to sign up.

- **http://lists.ncmail.net/mailman/listinfo/xraynews**
- **http://lists.ncmail.net/mailman/listinfo/mammographynews**

One link is specifically for X-ray facilities, although mammography facilities could benefit from this resource. The other one is specifically for mammography facilities. You may manually enter these addresses into your Web browsers or find a link on either the X-ray or mammography Web sites. There will be directions informing you on how to register for this service.

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 customers, mammography inspectors have been cross-trained to work in both programs. The staff voted on the new name to better represent both the mammography and X-Ray branches as a unified program.

Problems with CMS Reimbursement for Mammography

The FDA sends the Centers for Medicare and Medicaid Services an electronic file every Tuesday night, which contains the most recent information on facilities approved by FDA to provide mammography services, including digital mammography. Mammography facilities must be certified by FDA in order to be eligible for reimbursement under Medicare. As a first step you might want to ensure that your carrier or fiscal intermediary is looking at the most recent FDA mammography file. If the carrier or intermediary has the most recent file and there is still a reimbursement issue, please contact CMS as follows.

For Medicare carrier issues, contact Eric Coulson either by phone at (410) 786-7169 or e-mail at eric.coulson@cms.hhs.gov.

For Medicare fiscal intermediary issues, contact Bill Ruiz either by phone at (410) 786-9283 or by e-mail at william.ruiz@cms.hhs.gov.

On That Note

The FDA has issued a public health notification to avoid hazards with using cleaners and disinfectants on electronic medical equipment. The notification describes the hazards of using excess cleaning and disinfecting liquids on certain electronic medical equipment and recommends ways to avoid these hazards. The article, in its entirety, can be found at **http://www.fda.gov/cdrh/safety/103107-cleaners.html**.

Updated Version of Notice to Employees

There has been an update to the 'Notice to Employees' sign. It is now also available in Spanish. Copies can be downloaded form the branch's Web site, **http://www.ncradiation.net**, or you can call (919) 571-4141 to have a copy sent directly to your facility.

Radiation Warning Signs

Posting of the Radiation Warning Sign is required by the *North Carolina Regulations For Protection Against Radiation*, Rule .1623(a)(1)(2). Unless otherwise authorized by the agency, the symbol prescribed by the rules of this Chapter shall use the colors magenta, or purple, or black on yellow background. The radiation symbol prescribed by the rules of this Chapter is the standard three-bladed design. The blades and interior circle shall be magenta, purple or black; and the background shall be yellow. Rule .1624(a) states that the licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words: CAUTION RADIATION AREA. The use of radiation warning signs can only be used as indicated. If you choose to print your own caution signs, be sure to print the signs as directed. Not printing the signs with the correct color of paper or ink may result in the facility not meeting the intent of the regulations.

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