In the Pink

November 2006

Division of Environmental Health ~ Radiation Protection Section

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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
- Regina Stowe --- Review Specialist
- Wendy Moore -- Review Specialist
- Lane Green ------ Review Specialist
- Jon Granger ----- Review Specialist

Continuing Education News

The Food and Drug Administration has indefinitely delayed the enforcement of the requirement for six continuing education credits in each mammographic modality used.

The general requirement of obtaining 15 hours of continuing education in mammography or related topics is not under reconsideration and will not change. There is no change in the requirement for eight hours of initial training in each new mammographic modality prior to independent use. The initial training requirement is still being enforced. There has not been a change in the enforcement of the 15 hours of continuing education every 36 months.

Find more topics of interest on the program's Web site – **http://www.drp.enr.state.nc.us/Mammo/mammohome.htm** – under "Hot Topics in the World of MQSA."

Hot Topics

Using the Plus-Minus Density Settings on the Phantom
The plus-minus density control settings on the mammography equipment should not be used to keep the phantom chart in limits. When a change in film optical density is confirmed due to a change in the film emulsion batch, then an adjustment of the density control setting to bring the phantom background optical density back into control is an appropriate action. If for any other reason your phantom falls out of limits, then the service provider must be called to correct the problem.

Continuing Experience Documentation for Interpreting Physicians Who Read at Multiple Sites
Physicians' continuing experience documentation may include a letter, table or printout from each facility that is signed by the official responsible person stating that he has interpreted a given number of mammograms in a given time period.

Inspectors will no longer accept printouts from the interpreting physician's office for all locations where interpretations are made. The facility that is certified is responsible for providing and maintaining supporting documentation verifying the number of interpretations per interpreting physician. The only exception would be if the owner of the facility and the interpreting physician(s) are the same person. For example: a radiologist's office owns five different sites where they read, and one coordinator maintains their continuing experience for each of these sites. That coordinator can provide a list documenting the continuing experience for each site and sign as the responsible facility official.

Your Questions...The Answers

What should a facility do if there is more than one processor?

The annual survey or equipment evaluation must include all processors used clinically, even those at remote sites or back-up processors. It is the responsibility of the facility to inform the medical physicist prior to introducing a different processor into mammography. This information should also be provided on the annual survey.

What is considered adequate weekly phantom quality control (QC) monitoring for a facility that has multiple processors and multiple units?

It depends on whether the units and processors are used interchangeably, whether the processors are matched (established operating levels for mid-density and density difference for all processors are within 0.05 optical density), and whether each processor is operating within its own pre-established action limits.

If the processors are not matched and the facility is processing clinical films from its multiple units interchangeably through its processors, the facility must conduct the weekly phantom image test for each unit-processor combination.

If the processors are matched and the facility is processing clinical films from its multiple units interchangeably through its processors, it is acceptable to produce a weekly phantom image from all units and process them through any processor as long as each processor is tested with a phantom image at least once a week, reducing the number of phantom images performed. (Note: In this scenario each processor must be operating within its own pre-established action limits.)

What quality assurance (QA) records and written standard operating procedures for QC testing will be reviewed during the inspection?

The QA records that must be maintained are as follows:

- Personnel responsibilities – qualified mammography personnel assigned appropriate QA tasks;
- Technique charts/tables – the mammography techniques and procedure used in conducting mammograms; and
- Quality Control test records – this includes QC test procedures, test performance and monitoring, data analysis and timely corrective actions for each.

The inspector will look for the written standard operating procedures for the QC tests. If the facility's staff has not written its standard operating procedures, then the staff must document what it uses. If a facility has adopted the American College of Radiology manual for their QC test procedures, they must adhere to it.

When can processing aims be changed?

The ACR manual has listed a number of circumstances – shown below – under which it may be appropriate to re-establish the processor QC operating levels.

- When a film manufacturer makes a change to a film currently in use and recommends that the processor QC program be re-established;
- A change in film volume, brand or types of chemicals used, film brand or type, replenishment rates, development time or settings on a specific gravity automixer;
- Different processor;
- Using a different sensitometer or densitometer; or
- Running out of film thus preventing a crossover from being done correctly.

Remember that changing the chemistry as part of routine preventive maintenance is not justification for changing the QC operating levels. The reason for re-establishing the operating levels must be noted in the remarks section of the QC chart.

How are additional films taken after a procedure and charged as a mammogram viewed during an inspection?

In general, inspectors review for appropriate assessment categories, that letters are transmitted within specified time frames, and that a report is sent to the referring physician and a

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What You Need to Know for Your Next Inspection

When does a Mammography Equipment Evaluations (MEE) need to be conducted?

When a mammography facility installs new radiographic equipment (X-ray units or processors), the new equipment must be evaluated by a qualified medical physicist. The accreditation requirements of the facility's accreditation body must also be met before the unit is placed into service (21 CFR 900.12(e)(10)). In this context, "new" means "new to the facility," and therefore, includes used equipment. Mammography equipment evaluations must also be performed whenever equipment is disassembled and then reassembled at the same or a new location, or whenever a major component is changed or repaired. The MEE is required even if a full survey has recently been completed to verify that all functions, which may have been affected by the change or repair, have been successfully restored.

What test must the physicist perform during an MEE of a newly-installed or reassembled processor?

For a newly installed or reassembled processor, the medical physicist must perform the following tests and tasks:

1. Sensitometric strip as described in 21 CFR 900.12(e)(1);
2. Phantom image quality as described in 21 CFR 900.12(e)(2);
3. System artifact evaluation as described in 21 CFR 900.12(e)(5)(ix);
4. Dose determination as described in 21 CFR 900.12(e)(5)(vi) – if clinical techniques increase significantly; and
5. Verification of the appropriate processing solutions as described in 21 CFR 900.12(b)(13).

It is also recommended that the medical physicist conduct the Darkroom Fog test if the integrity of the darkroom is compromised and conduct the fixer retention analysis test, if deemed necessary. Each processor used clinically must have an MEE, even those at remote locations.

What are examples of major repairs that might require a physicist to come to a facility to perform an MEE?

For a newly installed or reassembled laser printer, the medical physicist needs to follow the applicable full field digital mammography QC manual.

Examples of major changes or repairs that would call for an MEE include but are not limited to:

- Replacement of an X-ray tube, collimator, filter, automatic exposure control (AEC) or AEC sensor, or
- A total overhaul of the processor.

Routine processor preventive maintenance, pump replacement, replacement of the developer or fixer racks, and replacement of the control board or changes in chemistry brand are not considered to be major changes or repairs. Consequently, these examples would not require evaluation by a medical physicist.

Your Questions...The Answers (continued)

letter is sent to the patient. Failure to do so for <u>any</u> subject mammogram will result in a violation. It is required under the Mammography Quality Standards Acts regulations that a letter to the patient and a report to the referring physician should be sent following images taken after a stereotactic procedure or after localization and clip placement when these procedures are charged with a mammogram code as a screening or diagnostic exam.

Please check our Web site frequently for changes. (www.ncradiation.net/Xray/reference.htm)
New information includes:

- Quick reference guides for facilities,
- Radiation protection programs,
- Disposal of X-ray equipment,
- Information for installing equipment,
- Registration information and
- Much, much more!

Types of Records Reviewed at State Inspection

It is often confusing about which items fall under MQSA regulations and which fall under state regulations. Below is a list of the state records an inspector will be looking for during the inspection for each X-ray unit.

- Plan review (.0603)
- Letter of acknowledgment (.0210)
- Safety survey (.0603)
- Form 2579, FDA Report of Assembly Form (.0206)
- Current Notice of Registration from RPS (.0203 and .0209)
- Previous inspections reports and correspondence regarding inspections with RPS (.1002)
- Current North Carolina regulations (.1002)
- Dosimetry records (.1638, .1640 and .1644)
- Radiation safety program (.1603 and .1636)
- Documentation of annual review (.1603)
- Notice to employees (.1002)
- Radiation Caution signs (.1623 and .1624)
- Dissolution Policy

Items to consider for the Radiation Protection Program

- Name of Radiation Safety Officer

- Location of the following items:

  - Regulation book,
  - Notice to Employees,
  - Plan review and survey,
  - Safety survey and
  - Notice of Registration.

- Anything that is being done for the safety of personnel and patients:

  - Personnel training policy,
  - Safety for personnel,
  - Safety for patients and
  - QC and QA records.

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N.C. Department of Environment and Natural Resources
Division of Environmental Health
Radiation Protection Section
1645 Mail Service Center
Raleigh, NC 27699-1645