Bureau of Radiological Health
Mammography Program

INFORMATION NOTICE 2013-01
6/17/2013

The following information is intended to inform facilities and staff of important changes and reminders regarding mammography regulations. Please review these items within your facility to ensure continued compliance with both State of Iowa and Mammography Quality Standards Act (MQSA) regulations.

- The State of Iowa has been approved by the FDA to Serve FDA as Accreditation Body for the 2013-2020. http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm

- **Soft-Copy Clinical and Phantom Image Review:**
  One of the requirements of IDPH's renewal as a Food and Drug Administration (FDA) approved accreditation body is the development of processes to facilitate the review of clinical and phantom images submitted by facilities in a soft copy format. The IDPH accrediting body plans to begin accepting clinical and phantom images in DICOM format by August 2013. During this transition time, it is possible that IDPH may request images in various formats; hard copy printed format, CD or other electronic DICOM format, or both. Follow the instructions on the documentation sent by IDPH at the time of your reaccreditation or new unit application. IDPH staff will contact your facility directly if images need to be submitted in a manner that differs from the instructions. Please contact the IDPH mammography program staff if you have questions throughout this transition.

- **Mammography Units, RWS, and Printers:**
  Facilities accredited, certified and authorized to provide mammography services are responsible for all components within the mammography system used to acquire, process, interpret or print images. This typically applies to the mammography unit, radiologist review workstation (RWS), and printer. Your facility's responsibility for these components remains the same regardless of whether the equipment is located onsite or offsite at another facility. IDPH relates each component to your facility through your reporting on the accreditation application. If it is possible that a mammogram performed on your mammography unit will be interpreted on an RWS or printed on a printer, even if not routinely, it must be reported on the accreditation forms. Please monitor offsite equipment repairs and replacement, and maintain records as if they were located onsite at your facility. While the QC and actual maintenance of the offsite equipment may be performed by the offsite personnel, it is your facility's responsibility to be aware of all issues and changes related to these components.

- **Inspection Update Form:**
  When your facility inspection is scheduled, the IDPH mammography inspector will send an inspection update form with the confirmation of inspection. This document will need to be completed prior to the inspector's arrival onsite for inspection. This document is being drafted and you will be notified when it is ready for implementation.

- **Initial 40 Hour and New Modality 8 Hour Mammography Training Programs:**

  Revisions to Iowa Administrative Code 641 Chapter 42 rules that govern permit to practice holders and continuing education became effective on 3/13/2013. You may review these rules: https://www.legis.iowa.gov/DOCS/ACO/IAC/LINC/Chapter.641.42.pdf

  As a part of this revision, IDPH will no longer review and approve continuing education courses. Providers of continuing education courses must obtain approval from an American Registry of Radiologic Technologists Recognized Continuing Education Evaluation Mechanism (RCEEM). You can find a list of RCEEM's at: https://www.arrt.org/Registration/RCEEMs

  This impacts mammography training program providers because IDPH will no longer be able to issue a CEU number for facility in-house mammography training programs. All currently approved training programs will remain approved until 12/31/2013 and continuing education credit for the trainee will be issued as indicated by the program approval. New requests for trainer credit will no longer be accepted as of 3/13/2013.

  The Mammography Quality Standards Act (MQSA) and IDPH rules require that radiologic technologists complete the appropriate number of contact hours as a part of initial or new modality mammography training. This means that it is possible for your facility to continue to maintain an initial 40 hour or new modality 8 hour training program. However, no CEU credit will be available for completion of these courses unless your facility also applies to a RCEEM for approval. If your facility would like to maintain an in-house mammography training program beyond 12/31/2013 or would like to apply with a new training program, please contact the IDPH mammography program staff.

- **Synthesized 2D images for 2D Full Field Digital Mammography (FFDM) accreditation:**

The FDA recently approved the use of tomosynthesis projection images to create a synthesized 2D image. This approval means that each screening examination may consist of:

- a 2D FFDM image set, or
- a 2D and 3D image set, where the 2D can be either a FFDM or a 2D image generated from the 3D image set (i.e., synthesized 2D image)

Facilities choosing to implement this new protocol may use these 2D synthesized images for the clinical image accreditation requirement. If you have questions or are planning to implement this protocol, please contact IDPH mammography program staff.

Mammography Modality Breakdown in Iowa as of 6/17/2013

Units – 180

FFDM – 166

Film Screen – 3

Tomosynthesis – 11

Facilities – 141

FFDM – 138

Film Screen – 3

Tomosynthesis – 9

Tomosynthesis units are currently approved directly through the Food and Drug Administration's certificate extension program.

- **Mammography Website:**

  Remember to visit IDPH Mammography website to stay up to date and to find answers to questions regarding mammography.

http://www.idph.state.ia.us/eh/mammography.asp

Questions:

Kellee Kemp (641) 227-2585

Angie Leek (515) 285-3246

Janet Kent (515) 281-0405