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 2013-2020. http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114147.htm

- **IDPH Staff Updates:**
  In 2014, the IDPH Bureau of Radiological Health added Gina Fuller as an inspector and Angela Leek was appointed Bureau Chief of Radiological Health.

- **Mammography Units and RWS:**
  Your facility's responsibility for all components remains the same regardless of whether the equipment is located onsite or offsite at another 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 have the records available for inspection.

- **C-View images:**
  C-View images are created from tomosynthesis projections rather than conventional 2D imaging. Facilities choosing to implement C-View imaging are able to use C-View images for clinical image review accreditation and reaccreditation.

- **Breast Density reporting- is it required in Iowa yet?**
  As of the date of this information notice, there is no Iowa requirement that Iowa facilities need to include breast density information in the mammography report and patient lay letter. We will notify you if this changes.

- **40 hour mammography training programs:**
  The State of Iowa no longer issues continuing education. The requirements for the 40 hour training program have not changed as it only needs to be "contact hours". You still must complete a 40 hour training program prior to performing mammography. Previously IDPH approved mammography training programs have been accepted as IDPH approved "contact hour" training programs and IDPH will provide documentation the next time your facility uses it. You can submit your program to ASRT or another Recognized CE Evaluation Mechanism (RCEEM) for CEU approval if you would like to earn CUEs for the training program.

- **Initial training for tomosynthesis systems:**
  In March 2015 the Food and Drug Administration (FDA) sent out a notification that **each** tomosynthesis manufacturer system is considered to be a new modality. Radiologists, technologists, and medical physicists will need 8 hours of initial tomosynthesis training that include the unique features of the manufacturer's system they will be using. If using 2 systems such as Hologic and GE, 8 initial hours is needed for the first tomosynthesis system used and only hours including the unique features for the second system is needed as long as the unique feature hours plus the generic tomosynthesis hours from the first system total at least 8 hours.

- **Mammography printers:**
  FDA recently came out with printer guidance (see second page). They are now leaving it up to each facility to decide if they need to keep a printer or not. IDPH will not ask for printer QC, service reports, or medical physicist surveys any longer on inspection. For facility sites with a Selenia unit and there is no radiologist reading workstation (RWS) or printer on site, IDPH will allow the QC technologist to score the phantom image on the AWS as long as the facility has a written procedure to address if the score fails on the AWS, it will be scored on the RWS and outline how that will take place. For facility sites with a Selenia unit and RWS onsite, we want you to still score the phantom on the RWS.

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http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityScorecard/ucm473469.htm

Printers and the Evolution of Mammography

Over the past 20 years, there has been significant evolution in mammography, with the shift from screen-film to digital imaging being the most prominent change. As the technology has evolved, so has the role various peripheral devices played. The utilization of film printers by facilities was prevalent, especially when digital mammography first entered the market. Some of the needs the printers served at that time were the provision of hard copy comparison images from digital facilities to requesting facilities that were not capable of viewing digital images, the submission of images for accreditation, and providing copies of mammograms to be viewed in the operating room.

Digital mammography was introduced into clinical use fifteen years ago, and today fewer than 350 screen-film units remain in use in the U.S. The nearly universal availability of computers for viewing of digital images diminishes the need for a facility to maintain a printer. Another change in current practice was the introduction of digital breast tomosynthesis (DBT) in 2011 and its rapid clinical adoption. DBT images are intended solely for soft-copy interpretation.

Today, with many mammograms shared on computer media such as compact discs or via online access, the provision of printed hard copies is becoming obsolete. Many medical facilities have the ability to review images on monitors throughout their facilities. Please note that any exchange of images between requesting and image-providing facilities is to be accomplished in a mutually agreed-upon format since there is no regulation dictating format. Additionally, all FDA-approved accreditation bodies can accept images electronically needed for accreditation, additional mammography reviews, etc.

Therefore, in today's world, the option to maintain a printer and/or the ability to print hard-copy images is a decision left to each individual facility.

If a facility chooses to maintain a printer, it must follow all the quality control requirements that are prescribed by the manufacturer of the printer and mammographic unit. The manufacturer's quality control program benefits the facility that wants to provide the best possible quality in any hard copy mammography images it prints. Although the FDA's MQSA inspection program has removed printer QC questions from its inspection procedures, if a facility decides to maintain a printer, medical physicists must continue to include that printer QC in the Mammography Equipment Evaluation upon installation, after a major repair, and annually, if required by the printer's or image receptor's manufacture quality control program.