ARC 1401C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby amends Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials," Iowa Administrative Code.

These amendments expand soft copy review workstations requirements to allow for the use of workstations that meet an additional criterion option of being cleared by the United States Food and Drug Administration 510K process with an intended use for digital mammography; expand the initial new modality training requirements for physicians to allow the use of training provided by a vendor manufacturing new modality equipment; adjust wording from "full field digital mammography" to "new mammographic modality" to be consistent with the multiple modalities for which physicians may need to obtain training; remove the reference to outdated film screen technology; and add a reference to require adherence to quality control procedures outlined by new stereotactic breast biopsy equipment manufacturers. The amendments will better match industry practices for training, equipment requirements and quality control tests. These changes will maintain the protection of public health while reducing the burden on the regulated community.

Notice of Intended Action was published in the February 5, 2014, Iowa Administrative Bulletin as **ARC 1317C**. No comments were received. These amendments are identical to those published under Notice.

The State Board of Health adopted these amendments on March 12, 2014.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 136C.15.

These amendments will become effective on May 7, 2014.

The following amendments are adopted.

ITEM 1. Rescind the definition of "Soft copy review workstation" in subrule **41.6(1)**.

ITEM 2. Amend paragraph **41.6(2)"i"** as follows:

i. Soft copy review workstation requirements.

(1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two ~~5 megapixel~~ monitors~~.~~ that meet one of the following criteria:

1. Have 5 megapixel resolution; or

2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer's quality control manual or that outlined by the image receptor manufacturer's designated soft copy review workstation quality control manual.

ITEM 3. Amend subparagraph **41.6(3)"a"(1)**, numbered paragraph **"5,"** as follows:

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret ~~full field digital mammography~~ a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa ~~full field digital mammography~~ new mammographic modality interpretation.

ITEM 4. Rescind subparagraph **41.7(7)"e"(3)** and adopt the following **new** subparagraph in lieu thereof:

(3) Phantom image (weekly). Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures must be corrected before further procedures are performed.

ITEM 5. Rescind subparagraph **41.7(7)"e"(5)** and adopt the following **new** subparagraph in lieu thereof:

(5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/2/14.