



GE Medical Systems

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: Docket No. 99D-4910

We wish to submit comments on material presented in *Compliance Guidance: The Mammography Quality Standards Act Final Regulations, Document #3*.

Regarding 21 CFR 900.12(b)(9), Technique factor selection and display

This rule deals with the display of technique factors set prior to exposure during AEC. In the draft guidance, the FDA expressed the view, "With units where the kVp is the only factor under direct control of the operator, the corresponding preset mA or mAs may be set automatically by the unit and may not be normally visible on the control panel. However, these corresponding values should be available from the manufacturer, if standard for the model, or from the installer, if they can be set to meet the needs of the facility."

While recently introduced systems use closed-loop control of mA and have a nominal mA for each kVp, earlier systems controlled tube current indirectly, for example, through control of the x-ray tube filament current. The systems are mAs-controlled. The actual mA achieved for a particular filament current will depend on the emission characteristic of the tube, the heat state of the tube, the age of the tube, and the kVp accuracy. Hence, the mA that will be used for any given exposure is not well-defined for these systems. Additionally, since it is the main purpose of the AEC to determine the mAs needed for the exposure, there is no automatically selected mAs (except the backup mAs) for any AEC exposure. FDA's assumption that "corresponding values [mA or mAs] should be available from the manufacturer" is not entirely valid. This is not the way these systems were designed to operate.

In addition to the practical matter of system design, there are other issues to consider.

1) To whom does MQSA apply?

MQSA is a regulation that applies to the facilities, not the manufacturers. When the rule states, "... technique factors that are set prior to the exposure shall be indicated," who is doing the setting?

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Since MQSA applies to the facilities, this should be interpreted as setting of the parameters by the facility. The draft guidance seems to re-interpret the intent of the rule such that settings made by the manufacturer, that are in no way accessible by the facility, become subject to this regulation. If there is no setting that the facility can make, then there should be no need for indication prior to the exposure.

2) What is the value to the user?

For mAs-controlled systems, tube current is commonly not a user-accessible parameter. A table or other display of mA vs. kVp provides no information that can be used by the facility to modify the operation of the system.

3) What is the value to the quality of mammography?

Does a table of mA vs. kVp provide any improvement in the “quality of mammography”? Is the only value of a display of mA vs. kVp the simplification of equipment testing? If the person acquiring the mammograms has no control of this parameter, can knowledge of the parameter contribute in any real way to the production or interpretation of the mammogram?

It is apparent that the MQSA rule follows 21 CFR 1020.31(a)(1) in stating that, when AEC is used, “the technique factors which are set prior to the exposure shall be indicated.” Sec. 1020.30(b) defines “technique factors” for this type of system as “peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.” Considering these technique factors,

- *peak tube potential in kV*: This technique factor is selectable by the operator and the pre-selected value is displayed.
- *tube current in mA AND exposure time in seconds*: The rule appears to combine the tube current and exposure time as a second technique factor. For many mAs-controlled systems, neither of these two elements can be set by the operator prior to the exposure. Exposure time is not known until the completion of the exposure, so there is no pre-exposure value to display. On older systems the tube current may not be directly controlled (as discussed previously), so tube current itself is not set prior to exposure on these systems. Viewed either as a combined technique factor or singly, neither the combination of tube current AND exposure time nor either parameter individually is set prior to the exposure.
- *the product of tube current and exposure time in mAs*: In all mAs-controlled systems, this is the parameter controlled by AEC. Hence, it is not known until the completion of the exposure, at which time it is displayed.

For those systems in which there is an algorithm linking kVp and tube current and for which there is feedback circuitry to ensure the linkage, kVp - mA tables could be made available to the facilities. For those systems without such a direct linkage, such tables would not provide reliable information and will not provide an improvement in the quality of mammography.



We request that FDA revise this proposed guidance to relate to display of parameters for which the facility has control. Parameters that are established by the manufacturer or installer and are not accessible to the facility should not be regulated by MQSA.

Regarding 21 CFR 900.12(e)(2), Weekly quality control tests

In this section FDA's guidance is that the "Full Auto" mode of image acquisition must be used for phantom imaging if that mode is most commonly used for imaging the standard breast. In fact, given the nature of the commonly used accreditation phantom, it is not unreasonable to expect that the imaging parameters chosen by the "Full Auto" mode may not represent those used for the "standard breast."

The "standard" breast is defined as having a compressed thickness of 4.2 cm. The thickness of the phantom is 4.4 to 4.5 cm. However, on some phantoms, thumbscrews are used to hold the cover on the phantom, and these extend the thickness to 4.9 to 5.0 cm. Many automatic parameter selection algorithms depend on the measurement of compressed breast thickness to set the parameters. When the system senses a thickness of 5 cm, it will likely not set the parameters appropriate for a thickness of 4.2 cm, i.e., the "standard" breast.

In addition to a question of accuracy, there is also the question of precision. From the elaboration in the guidance it is apparent that FDA is aware that "Full Auto" systems may not identically reproduce the same parameter selection every time a fixed phantom is imaged. There are numerous reasons why this might be the case.

Sources of Uncertainty Contributed by the User

User practices that might lead to variations in automatic parameter selection include

- (a) inconsistent phantom positioning
- (b) inconsistent AEC detector cell positioning
- (c) inconsistent selection of the cassette used for phantom imaging
- (d) inconsistent selection of the compression paddle. Not all compression paddles have the same x-ray attenuation or the same degree of deflection under compression.
- (e) inconsistent application of compression force. Some automatic parameter selection algorithms depend on the physical breast thickness as sensed by the compression paddle height above the breast support surface. The height that is sensed can be altered by the amount of compression force applied to the paddle and the resulting deflection of the compression paddle and breast support surface.
- (f) differences in the x-ray attenuation among phantoms at a facility where more than one phantom is available.

Most of these can be addressed through the protocols established in the QA program. However, a reminder to check for consistency of setup may be an appropriate addition to the guidance.

***Sources of Uncertainty Contributed by the System***

Some aspects of parameter selection might be random and beyond the user's control. Automatic parameter selection algorithms that depend on a measurement of the x-ray attenuation of the phantom could be affected by

- (a) kVp fluctuation
- (b) mA fluctuation
- (c) timer error
- (d) AEC detector sensitivity fluctuation

These various sources of uncertainty in setup and system operation can lead to small variations in the estimations of physical phantom thickness or attenuation. In many cases there will be no effect. However, these parameter selection algorithms are often based on "lookup tables," and the uncertainty of the estimations can be enough to move the selection back and forth across a lookup table boundary. As pointed out in the draft guidance, this can result in a change of kVp and a consequent change in mAs.

However, the level of parameter variation is not considered to be a clinically relevant problem. Usually the only parameter that varies is the kVp, and that variation is no more than 1 kVp, not plus-or-minus 1, but 1. Additionally, the film density is usually consistent despite the kVp change. The situation is only a problem when imaging the phantom.

Recommendations for System Operation during Phantom Imaging

We are in general agreement with the FDA that if a "Full Auto" mode is most frequently used for clinical imaging, then it should also be used for phantom imaging. While this may not lead to a selection of parameters appropriate for the "standard" breast, it does provide QC of the entire clinical imaging system. However, the facilities, medical physicists, and inspectors must be made aware that these automatic parameter selection systems were designed to provide ease of use and consistency of image quality for clinical imaging, but may not be absolutely precise when imaging an immutable phantom.

The guidance is helpful in that regard, but it is limiting in terms of offering procedures to follow when the automatic selection algorithm provides an unexpected parameter choice. It is likely that many technologists, medical physicists, and inspectors will interpret the recommendation in the guidance as the only "FDA-approved" process by which to re-establish the most frequently observed parameters. Furthermore, given the uniformity of the phantom, it is unlikely that the process of moving the phantom laterally will have any fundamental effect on the operation of the algorithm. More likely in the process of re-positioning, re-compressing, and re-imaging the phantom, possibly with a different cassette, one or more of the factors listed above might change enough to cause a change in the parameter selection.

What Can Be Done

- 1) Before taking the image, check for consistency of all the setup variables mentioned above.



2) Use AEC mode.

We agree with the FDA in suggesting this as an alternative means of acquiring the phantom image if the only difficulty encountered with the "Full Auto" mode is a 1 kV shift in tube potential or other trivial change of parameter selection. In fact, if the film density and image quality were both acceptable on the original image, there probably is little value in repeating the exposure. If the facility follows recommended practices and uses only a single cassette and allows 15 minutes for the escape of air each time the cassette is loaded, acquiring multiple images to try to obtain one with the commonly selected, "Full Auto" techniques is probably not an effective use of the QC technologist's time.

3) Keep two sets of QC logs.

Some physicists have suggested that the technologist keep one set of QC logs for parameter selection "A" and a second set for selection "B." Perhaps a simpler alternative would be to include kVp as one of the parameters tracked as part of the QC program. Then the correlation of an alternative mAs with an alternative kVp simultaneous with acceptable film optical density could be viewed as a system operating "within control limits" given the nature of the automatic selection algorithm.

4) Re-set the phantom.

If a system is operating near a look-up table boundary, random changes may be enough to change the parameter selections, with or without lateral re-positioning.

5) Contact the manufacturer of the mammography unit.

As there is considerable variation among parameter selection algorithms, one solution will not likely work for all systems. The manufacturer may have a recommendation that works specifically with its systems.

We recommend that FDA make clear in the guidance that there is more than one way to deal with this situation.

Thank you for your consideration of these comments.

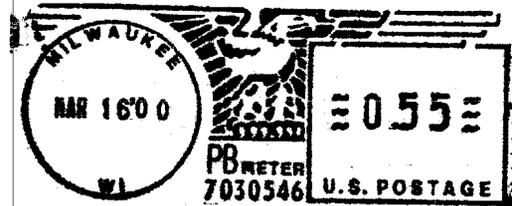
Sincerely,

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