

Gundersen LutheranSM

November 20, 2000

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Docket No. 00D-1497
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

To Whom It May Concern:

I am writing to comment on the draft guidance *The Mammography Quality Standards Act Final Regulations Document #4*. We have several concerns with the provisions of this guidance that require the medical physicists to personally inspect a system after a "major" repair.

1. The guidelines are unfair and unrealistic to the rural facilities that are located hours away from their physicist. While it is simple to test a system that is in-house or across town, it is another matter to check a system that is far away. We provide physics support for facilities with 34 mammography units, of which 13 are located at least 3 hours away. In the winter, it can take even longer to get to these locations. Our schedules do not always have the flexibility to respond immediately so, between the weather and our workload, it can sometimes take days for us to get to a remote facility. If they have to wait for us to inspect their system following a "major", but routine, repair, it will take the only mammography service in a community out of operation.
2. Many of the required physicist tests, following "major" repairs, can be performed by department personnel at the direction of the physicist and the results or films can be given to the physicist for approval. MQSA requires that, as physicists, we must have advanced degrees, board certification, experience with mammography inspections, and continuing education. We know what the technologists at each facility are capable of testing and what is beyond their capabilities. Give us some room to use our judgment on these matters. The results will be scrutinized by MQSA inspectors as closely as if we had personally performed the test so the correct testing will be verified. Without this option, facilities may be tempted to not notify the physicist and avoid the delay and high cost for an extra inspection.

One of our remote facilities replaced their film processor a few months ago. They checked their sensitometry results and there was no change. They took multiple phantom images and there were no artifacts or change in technique. They faxed me the QC results and mailed the films to me to inspect and approve. I feel this was adequate and had no reservations in telling them that the processor was ready for use. But this was not acceptable to the MQSA inspector who made an inspection shortly after the equipment change, so I made a trip to the facility and repeated the tests. The results of the tests were exactly the same but other facilities had to reschedule my inspections and this facility had to absorb the cost of my visit.

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Another one of our more distant facilities had their collimator blades replaced by their service engineer. I directed them over the telephone in the method of testing the alignment and they sent me the films by courier for my inspection and approval. Once again, I felt that adequate precautions had been taken to ensure the proper operation of the equipment but this was not acceptable to the MQSA inspector.

3. For most of the required physicist inspections, if a problem is found during the annual inspection, the facility has 30 days to correct it. Following a major repair, however, the facility must have the physicist personally inspect it and have any problem corrected before the system can be put back into clinical use. Why is a 30 day period acceptable in one situation and not in the other?
4. Some of the individual repairs listed as "major" in the guidance are not consistent with others that are not included as "major". For example, both **KVp internal adjustment** and **High voltage generator adjustment** are on the list. The first is not a major repair but the second is. The distinction between the two is not clear and they appear to be the same thing to me.

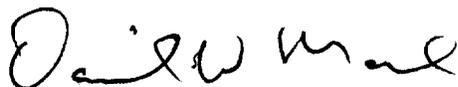
Another concern of ours is that all adjustment or replacement of parts related to the AEC (except **Density control – internal adjustment**) is listed as a "major" repair that requires our personal inspection. We recently had an intermittent problem with an in-house system where the unit would occasionally halt the exposure with an AEC error message. The problem continued for a number of weeks and the dealer's service engineer showed up with no advance notice several times to change a circuit board to see if that corrected the problem. It was not a problem to check the AEC each time since we were in the facility, but it would have been prohibitively costly in both time and cost had this been one of our more remote facilities.

5. Repairs that are necessitated by an identified problem are included in the list that requires a physicist follow up inspection but routine (preventive maintenance) inspections that can make the same adjustments are not addressed. If a service engineer makes a service call to correct a problem, it is almost certain that he will correct it. It is probably more likely that an item will be out of tolerance after a PM inspection than after a repair.

The radiation calibration and AEC tracking are routinely adjusted at these times and are probably more likely to need testing after these service calls than after a repair that the service engineer came out to specifically address. The facility usually does not have the ability to test the radiation calibration but, with a set of 2 cm acrylic blocks on hand, they can verify the proper operation of the AEC.

I hope that you will reconsider the provisions in the guidance and allow us to have alternatives to personal inspections, at least for more remote facilities.

Sincerely,



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