

Boulder Community Hospital



September 27, 2000

9 8 2 2 '00 OCT 26 P 2 :00

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

Dear Sir or Madam:

This letter details specific and general comments regarding The Mammography Quality Standards Act Final Regulations Document #4, Draft Guidance.

On page 11, in the table at the top of the page, the statement is made, "The decision as to what constitutes applicable tests and equipment requirements for the repaired component should be made by the medical physicist." I laud this statement, as it places the issue under the professional judgment of the medical physicist. I wish that this philosophy had carried through other aspects of this document, as the trend has to become increasingly prescriptive in the regulations and guidance.

Guidance documents such as this can take on regulatory weight, and could easily be used by inspectors to issue a citation if the guidance document is not followed. Therefore, the degree of prescription within the document should be carefully controlled.

On page 19, the answer to the question asked on page 18 includes a comment that images may be sent to the medical physicist for evaluation and approval. It is then stated, "If approved by the medical physicist, the facility may begin using the equipment." Even if an overnight delivery service is used, it could be two days between the installation of the new bucky and approval by the physicist. It is not reasonable to potentially close a facility because they have acquired a new bucky. Facilities should be allowed to begin imaging patients pending acceptance by the medical physicist. Even when I have failed a grid or breast support surface due to artifacts, I have never felt that patients should be recalled because of it.

The table beginning on Page 20 entitled, "Medical Physicist Involvement in Equipment Repairs," contains, in my opinion, a number of questionable points. These will be enumerated below. Several general comments precede the specific comments.

00D-1497

C5

P.O. Box 9019 North Broadway & Balsam Boulder, Colorado 80301-9019 303-440-2273

It seems to me that it would be appropriate to give the justification or standards used for determining whether a given repair is major or not. As it is, the decisions seem arbitrary.

Additionally, some discretion should be left to the Medical Physicist as to when it is necessary for certain non-major repairs to be re-checked. If the physicist and facility have a good rapport with the service engineer, and the physicist is confident that the engineer will perform the repair acceptably, the physicist should be allowed the option of checking the item at a later date. A clear distinction should be drawn between an ideal situation and a practically reasonable compromise that still ensures that no woman receives a mammogram of sub-standard image quality.

Finally, for non-major repairs, such as repair of auto-decompression or collimation, the service report should serve as acceptable documentation of completion of and verification of the repair.

Under Automatic Exposure Control, Thickness compensation adjustment is listed as a major repair, requiring verification by a Medical Physicist prior to patient use. I believe that this is unreasonable, since a failure of the AEC during an annual survey requires the facility to take corrective actions within 30 days. Such a requirement could pose a major burden to rural facilities that may incur a significant travel charge. I believe that this is a case in which the decision should be left up to the considered discretion of the Medical Physicist and facility.

I believe that a Film Type Change should be considered a major repair, requiring the involvement of a Medical Physicist. Not only could the response of the Automatic Exposure Control system be affected, but the average glandular dose and phantom image quality might well also be affected. The potential for extensive impact presented by a Film Type Change should put it into the category of a major repair.

It is not clear what a "KVp internal adjustment" is, particularly given that a "High voltage generator adjustment" follows later in the table.

The table states that an adjustment to the film processor replenishment must be verified before further use of the unit. This is unreasonable, as such adjustments are often undertaken to reverse a trend in the QC data and prevent the film processor from going out of control. Such adjustments are often an iterative process, and it might well be days before it is clear that the adjustment has had the desired effect. It has already been stated explicitly that a film processor that is out of control must be brought back into control before patient films are processed, and therefore further mention within a guidance document is unnecessary.

Radiation Output internal adjustment is listed as a major repair, requiring verification by the Medical Physicist before further use of the unit. I believe that this is unreasonable. The only impact that such an adjustment will have is on the time of the exposures under the AEC system. While I certainly agree with the intent of the regulation governing radiation output, it should be sufficient for the service engineer to sign off that the

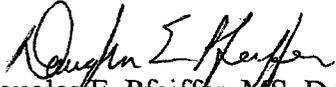
necessary adjustment has been made following a failure by the Medical Physicist. This is particularly true for rural facilities where an additional visit by the Medical Physicist can be prohibitively expensive. It would be ideal for a Medical Physicist to recheck the unit, but it should not be necessary. This should not be a major repair.

A similar comment applies to the High voltage generator adjustment. Once again, the regulations allow 30 days for repairs to be made following a kVp failure by the Medical Physicist. It is not reasonable to require this repair to be verified by the Medical Physicist prior to patient use. The service engineer can easily make a simple adjustment to the high voltage generator, and documentation from the service engineer should suffice as verification. It would be ideal for a Medical Physicist to recheck the unit, but it should not be necessary. This should not be a major repair.

The asterisk at the bottom of this table states that verification must be made within 30 days of the repair or within 30 days of the test necessitating the repair, whichever is less. This effectively eliminates the 30 period for getting repairs completed. Facilities would be essentially required to ensure that the repairs are completed within a few days to ensure that a final verification can be made by a third party within the 30 day period allowed. Unless service engineer documentation is acceptable, this should be changed to within 30 days of the repair, period, for non-major repairs.

Thank you for your consideration of these comments.

Sincerely,

  
Douglas E. Pfeiffer, MS, DABR



Boulder Community Hospital

P.O. Box 9019 North Broadway & Balsam Boulder, Colorado 80301-9019



U.S. POSTAGE  
\$00.33

BOULDER, CO

||OCT 23 2000 00330 034768||  
||FP0593188 JMB01 0391E756||

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

20857+0001

