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Docket # OOD-1497
Dockets Management Branch
Div. of Management Systems & Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fisher's Lane, Rm 1061 (HFA-305)
Rockville, MD 20852

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Dear Sir or Madam:

I am very concerned about some of what is considered a "major repair" in the draft of mammography guidance document #4. I believe this needs to be considered very carefully before the items in the "Medical Physicist Involvement in Equipment Repairs" table becomes part of any guidance document.

In my opinion, the physicist needs to do testing before patients are imaged for some of the repairs mentioned. Tube or generator replacements are good examples of when this should be done. However, I don't believe that level of urgency exists for some of the other items mentioned. AEC "thickness compensation adjustment" and "high voltage generator adjustment" are two good examples of very common, routine adjustments that are included in the document as major repairs. The service person is allowed 30 days to make these adjustments if I find it necessary during my annual physics inspection. However, I have to be there immediately after service does their tweaking or they can't image patients! It doesn't make sense that the urgency to retest these relatively straightforward adjustments should be greater than the urgency to make them in the first place.

Retesting within 30 days of the repair would be sufficient for these two examples, in my opinion. Additionally, the other items listed that must be tested "within 30 days" should be within 30 days of when the repair was made not 30 days from when service was called. Since service has 30 days to make those adjustments in the first place, the physicist may be left with very little time to make arrangements. Please do not make emergencies where there isn't one.

The items I've commented on here are not intended to be complete. I've addressed just a couple of items that stood out. The definition of what is considered a major repair needs to be very carefully considered since it is both important and likely to cause a lot of hardship for the facilities and physicists trying to maintain compliance. I would recommend further consideration on this topic with heavy input from the physics community.

Sincerely,

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