

Comments on:

Compliance Guidance:
The Mammography Quality Standards Act '00 DEC 18 P2 03
Final Regulations Document #4
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This is a very helpful publication and clarified a number of items for me. However, I offer the following suggestions.

Question on Certification, Page 3: The answer is very clearly written. However what are the ramifications of two or more interacting groups (who may also interact with other parties) having MQSA certificates? I presume that the answer is that each MQSA certificate holder must be sure that all of its partners satisfy all the requirements regardless of whether or not one of them also holds a certificate. Perhaps a brief comment describing multiple interacting MQSA certificate holders would be helpful.

Documentation for Physics Courses, Page 5: The answer is clear and correct and I had read the requirements. Nonetheless, I was surprised when I had to contact my university for a transcript. I suspect that for many (if not most) Ph.D., Master of Arts or Master of Science degree certificates the word "Physics" is not mentioned. Perhaps your comments could be reworded to warn the physicist to check his or her diploma. In my case, getting a transcript was not very difficult but in some cases it may prove to be a major inconvenience. (Your wording suggested to me that I should probably *expect* my diploma to say "Physics.")

AEC, Pages 7 and 8: I appreciate your comments on magnification. One also has to be very careful in *defining* optical density equivalent between magnification and non-magnification configurations because of the much larger heel effect with the small focal spot. For this configuration, I measure close to the chest wall edge of the film since this is near the central ray. I compare this to the chest edge of the film taken using the small Bucky, large focal spot and contact configuration at the same kV.

Page 7, second line: The word "the" should be inserted before "FDA."

21 CFR 900.12(c)(4), Page 10: In some "film transfer" cases, the recipient of the image (e.g., physician) may have the capability of using a digital copy. This should be an option.

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21 CFR 900.12(e)(4), Page 14: Unfortunately, this section of the law was not very well thought out. In so far as the strain on the machine is concerned, force may be relevant, but for the patient, pressure is the important parameter and technologists have complained to me that for some large breasted women, 45 pounds is inadequate. (For a small-breasted woman, that same force would likely be greatly excessive.) The only sensible way that I've seen for determining the proper force to use for a specific patient is the scheme that Siemens uses which is to monitor the change in compression with a change in force. (We do not have a Siemens machine and I've only seen it at shows.) The law as it presently stands is flawed and probably results in an inferior image for some large-breasted women who would suffer no more pain from a larger force than a smaller-breasted woman would from less force. Since larger breasts would be thicker in the first place, this law might very well have unnecessarily resulted in missed diagnoses of cancer. It needs to be fixed.

Page 18: I believe that "Bucky" is supposed to be capitalized since it is a proper name. Most textbooks follow this convention. (You *do* capitalize it on the first line but not the third line of the following page.)

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