

2005D-0195 Guidance for Industry and FDA Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System
FDA Comment Number : EC3

Submitter : Ms. Terry Kidd

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Organization : Aurora Health Care

Category : Health Care Association

Issue Areas/Comments

GENERAL

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I would like to comment on F. Personnel/Question 6. Consider discarding the date of 01/01/01 when referring to the(M) certification for technologists. Why are you just now coming out with a date that is not relevant, has no regulatory merit and 4 years old? As a former inspector the final regulation date of 4/1999 is more relevant, regulatory and less confusing than the added date 01/01/01 from the ARRT, a non-regulatory faction.

I would like to comment on G. AQ/Equipment/Question 2. Consider including language allowing sites to re-establish phantom aim points due to the increase in density.