

DEPARTMENT OF NUCLEAR SAFETY

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George H. Ryan
Governor

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Director



July 3, 2000

Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

REF: Federal Register Vol. 65, No. 62, March 30, 2000
pp 16847-16859: 21 CFR Part 900
[Docket No. 99N-4578]

Amended at Federal Register Vol. 65, No. 88, May 5, 2000

Dear Sir:

The Illinois Department of Nuclear Safety (IDNS) hereby submits its comments on the above identified proposed rule, implementing section (q) of the Mammography Quality Standards Act of 1992 (MQSA). This rule will, in part, establish requirements for the Food and Drug Administration (FDA) to approve states as certification bodies for mammography facilities.

Cost Analysis

In its cost analysis, FDA thoroughly reviewed the current and potential costs of MQSA and SAC programs, but neglected to examine the possibility of reducing costs. From our perspective, there exist many opportunities for reducing costs, and in keeping with the Regulatory Flexibility Act, we believe FDA should reexamine options to minimize significant impacts on small businesses.

The potential cost savings available in the SAC program are limited by FDA's imposition of an annual inspection fee of \$509. The 440 mammography facilities in Illinois are collectively paying \$223,960 annually to FDA for inspection related services. In our view, that figure is excessive. IDNS believes that FDA should consider further whether the FDA annual inspection fee of \$509 per Illinois facility could be eliminated. FDA's inspection related responsibilities supported by the \$509 fee are described as

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inspector training, equipment calibration, and inspection computer and data transfer systems. IDNS believes that inspector training should be the responsibility of the state agency. We also believe FDA should objectively review its nationwide database and software systems to determine whether such elaborate and costly systems are really necessary. Finally, FDA should reduce the cost, scope and time of the inspection, recognizing the role of the accreditation bodies and medical physicists, and the numbers and types of inspection deficiencies currently being cited. Reduction of costs in these areas will benefit mammography facilities and the patients they serve, regardless of their location in SAC or non-SAC states.

General Comments

FDA notes that women in certifying states can be assured of high quality mammography. It is also important to note that certification programs can be managed efficiently and effectively at the state level.

It would be helpful for FDA to note that state agencies can attest that they have adequate staffing, finances and other resources to implement and maintain a mammography certification program, and that detailed information is not required.

FDA's discussion regarding the need to transmit large amounts of data could be misleading. FDA's suggestion that delay in the rapid transfer of data to FDA from certifying entities could put the public at risk is questionable. Timely identification and correction of inspection deficiencies is the responsibility of the certifying state and is not dependent upon the speed of data transfer to FDA. In our experience, keeping FDA timely informed of new certifications and renewals has been neither complex nor cumbersome.

Specific Comments

FDA could clarify proposed Section 900.21(a), which states that to be eligible to become a certification agency, a state agency must be authorized by state law to enter into an agreement with FDA to certify mammography facilities.

FDA specifically invited comments on the nature and extent of the information collection burden that is included in Section 900.21. We believe the requirements in Section 900.21 could be shortened. From our perspective, the level of detail that FDA is seeking seems unnecessary. Section 263b(q)(2) of the MQSA requires that a state implementing a State Program under MQSA must implement the standards established

by the Secretary. That is, applicant agencies must implement essentially the requirements of Subpart B of Part 900. Consequently, much of the information required by subsections 900.21(b)(iii)(A) – (O) will be sufficiently covered in the applicant's draft or proposed rules which FDA will likely review as part of the application. If the applicant's draft rules do not sufficiently allay FDA concerns, FDA can ask for more information under the catch-all, proposed (O).

More specifically, we believe that 900.21(b)(iii)(A), (B), (C), (D), (E), (H), (K), and (L) are likely to be covered in the applicant agency's draft rules. (M) and (N) allude to serious cases where health and safety may have been compromised and may consequently constitute emergencies. The certifying agency should maintain flexibility to tailor emergency responses as the circumstances of the particular situation may dictate. For example, if an uncertified facility performs mammography, additional mammography review is irrelevant and patient notification is paramount. On the other hand, additional clinical image review by the accreditation body may be justified in some cases depending on the circumstances. In our view, requesting additional mammography review from the accreditation body and patient notification are obvious options available to certification agencies in appropriate circumstances. These available options should not require detailed written policies and procedures. Consequently, we suggest shortening the 900.21(b)(iii) application requirements to:

- (A) The rules and regulations to be implemented that are the equivalent of subpart B of FDA's part 900;
- (B) Education, experience, and training requirements of the applicant's professional and supervisory staff;
- (C) Statement of policies to avoid conflict of interest;
- (D) Description of the applicant's mechanism for handling facility inquiries and complaints;
- (E) Any other information that FDA identifies as necessary to make a determination on the approval of a State as a certification agency.

Subsection 900.22(c) should be deleted. The subsection implicitly seeks to make the certification agency a guarantor of facility compliance with MQSA standards. Mammography facilities are required by law to meet applicable standards. FDA and certification agency inspection and enforcement efforts should increase awareness of those standards and compliance with them, but such efforts do not guarantee facility compliance. Given that Section 900.23 will ensure that a certifying state meets its responsibilities, subsection (c) is unnecessary.

The Department agrees with Section 900.22(g), in that the certification agency should be prepared to notify patients should the agency have reason to believe that mammography quality has been compromised. In a related vein, subsection 21 CFR 900.12(j) has no proposed changes but we suggest revision as noted below.

As written, 900.12(j) requires additional clinical image review prior to patient notification. IDNS believes that in cases where facilities have performed mammography without certification to do so, affected patients should be notified without delay. Subsection 900.12(j) should be amended accordingly.

The purpose of the certificate requirement is to ensure that standards are met. IDNS believes that where a facility has performed mammography without certification, additional image review is irrelevant. The underlying assumption should be that if a facility has not complied with the fundamental legal requirement of obtaining a certificate prior to performing mammography, there is no assurance that the facility has met any of the applicable standards for certification. If standards were not met in obtaining images, additional image review is not going to rectify the problem. Delaying notification of affected patients until additional clinical image review is conducted unnecessarily puts those patients at risk.

Consequently, in cases where mammography has been performed by uncertified facilities, the facilities should always be required, by administrative order if necessary, to inform affected patients accordingly. In Illinois, for example, IDNS has statutory authority and rules in place to issue Emergency Orders when necessary to enforce the provisions of the Radiation Protection Act of 1990. Certification agencies should also be prepared to inform affected patients in the event an uncertified facility fails to do so.

State agencies such as IDNS receive their authority from state statutes. It would certainly be prudent for a certification agency to discuss contemplated changes in state standards with FDA before such changes are proposed through the rulemaking process. Coordination with FDA should assure that the standard is consistent with MQSA. If a standard is inconsistent with MQSA in FDA's view, FDA can make that issue known. If the certification agency refuses or is unable to cooperate, FDA can take appropriate action. In our view, however, it is inappropriate and unacceptable for FDA, as described in Section 900.22(i), to require a formal FDA "authorization" for any changes a state agency may propose to make in its standards.

Interim Notices

An issue not addressed in the proposed regulation is the practice of the certification agency issuing interim notices to facilities. An interim notice is issued when there is a delay in certification due to a delay in accreditation at no fault of the facility. Interim notices are also issued as temporary certificates for the interim period while actual certificates may be "in the mail". Although not called certificates, interim notices serve as temporary certificates until the accreditation and certification processes are completed. The need for interim notice letters commonly results from a time-crunch caused by the failure of accreditation bodies to complete the accreditation process in a timely manner. A common delay seems to be that accreditation bodies often must wait for the completion of clinical image reviews by their contract physicians. If the expiration of a facility's certificate is imminent, the certification agency may have to choose between issuing a temporary certificate, such as an interim notice, or shutting down a mammography facility until accreditation and certification are completed.

To deal with this problem, on May 4, 1999, FDA issued a guidance document entitled, "Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities under the Mammography Quality Standards Act, 42 U.S.C. 263(b)." However, FDA's rule does not provide for the issuance of interim notice letters, nor does it define the interim notice as a temporary certificate. Given that there is an apparent need for an interim notice process, IDNS believes that most state administrative procedure statutes will require that certification agencies put such a process into their administrative rules. Consequently, IDNS believes it would be helpful for the interim notice process to be included in FDA's rule to serve as a model for state rules. In the interim, IDNS is planning to promulgate regulations to include criteria and processes for issuing interim notices.

Closing Remarks

IDNS and radiation control agencies in other states have requested implementation of MQSA subsection (q) almost since the implementation of MQSA in 1994. IDNS has participated in the States as Certifiers (SAC) Demonstration Project since its inception in August 1998, and we are particularly interested in this proposed rule. We feel it is important to note the fact that the proposed regulations are neither complex nor sufficiently voluminous to require more than five years to achieve publication in the Federal Register. However, the cost analysis and various scenarios considered by FDA to determine the impact of the proposed regulations were extensive. Unfortunately, the analyses omitted important alternatives for cost reduction that we believe should be reconsidered.

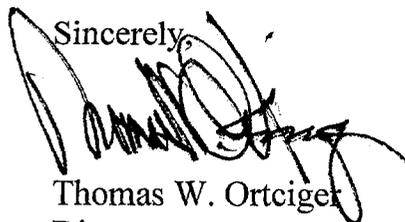
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We appreciate the opportunity to comment on this proposed rule and hope these comments are received in the constructive spirit in which they are offered. We look forward to continued cooperation with FDA in implementation of the SAC program. If you have any questions or need clarification of any of the issues raised in this correspondence, please contact Paul H. Brown at 217-785-9974.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas W. Ortciger', written over the word 'Sincerely,'.

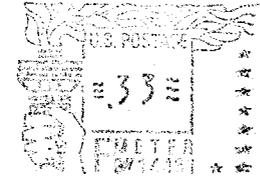
Thomas W. Ortciger
Director

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