interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* Any approval of an alternative standard, amendment, or extension may be implemented only by the entity to which it was granted and under the terms under which it was granted, except that when an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(g) *Withdrawal of approval of alternative requirements.* The Director shall amend or withdraw approval of an alternative standard whenever the Director determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when the Director determines that such action is necessary to prevent an imminent health hazard.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7830 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0192]

RIN 0910–AA24

Proposed Requirements for Accreditation Bodies of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its interim regulations for application procedures for FDA approval as an accreditation body under the Mammography Quality Standards Act of 1992 (the MQSA). FDA is proposing these amendments based on experience gained in administering the interim regulations, advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC), and public comments received in response to the interim regulations. This proposal would also establish new requirements and responsibilities for accreditation bodies. This proposal is the second of five proposed rules published in this issue of the Federal Register regarding MQSA requirements applicable to mammography facilities. These proposed rules are being issued to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis.

DATES: Written comments on this proposed rule by July 2, 1996. Written comments on the information collection requirements should be submitted by May 3, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the second of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565) implementing the MQSA (Pub. L. 102–539). The first proposed rule, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of the proposed rules, a description of the information collection requirements, proposed revisions to §§ 900.1 *Scope* (21 CFR 900.1) and 900.2 *Definitions* (21 CFR 900.2), and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

This proposed rule covers procedures for application to FDA for approval as an accreditation body and the requirements and responsibilities of such bodies. As with the interim regulations, FDA was guided in the development of this proposed rule by the intent of the legislation to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1). FDA also relied upon three major sources of information, in addition to the expertise and research of FDA personnel.

First, the agency considered public comments received on the interim regulations. The agency received 103 comments from individuals and organizations, including professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists. The proposed regulations were also discussed in a series of quarterly meetings with the NMQAAC. Members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the NMQAAC and guests invited to attend the committee meetings in recognition of their expertise in mammography also participated in these discussions of the proposed regulations. Finally, the agency's experience over the last year with the four accreditation bodies approved under the interim regulations also influenced the development of the proposed regulations. A discussion of the proposed amendments and a summary and analysis of both NMQAAC input and public comments regarding the regulations are provided below.

B. Application for Approval as an Accreditation Body

In § 900.3 (21 CFR 900.3) of the interim regulations, FDA established standards for approving the applications of prospective accreditation bodies. These standards are expanded in proposed § 900.3 to provide FDA with more thorough criteria for assessing a

prospective body's capabilities. FDA is also proposing regulations to establish renewable terms of authority and the scope of authority of accreditation bodies.

1. Accreditation Body Assessment Criteria

To identify more comprehensive criteria for evaluating prospective accreditation bodies, FDA researched Federal oversight of other accreditation organizations in the health care field. This included review of HCFA regulations and of an assessment of those regulations by GAO.

In the Federal Register of December 14, 1990 (55 FR 51434), HCFA published a proposed regulation entitled ''Medicare Program: Granting and Withdrawal of Deeming Authority to National Accreditation Organizations.'' GAO reviewed that proposed regulation and stated in a 1991 report that, with only one exception, the proposed regulation met all of the criteria that GAO considers important in the evaluation of an accreditation organization (Ref. 2). This regulation was finalized in the Federal Register of November 23, 1993 (58 FR 61816).

Based on GAO's review of the proposed HCFA regulation, and FDA's experience with accreditation bodies under the interim regulations, FDA considers it essential to require a complete description of a prospective accreditation body's review and decisionmaking processes, including policies and procedures used to notify facilities of deficiencies and to monitor the correction of deficiencies. In addition, FDA considers the following criteria to be important in evaluating a prospective accreditation body's application: (1) Qualifications of the body's professional staff; (2) adequacy of the body's staffing level, finances, and other resources; (3) the body's ability to provide data and reports in an electronic format compatible with FDA data systems; and (4) adequacy of the body's consumer complaint mechanism. These additional criteria, together with the interim criteria, are reflected in proposed § 900.3(b)(3).

Several comments on the interim regulations as well as members of the NMQAAC noted the importance of timely processing of accreditation applications. These comments requested that accreditation body applications include satisfactory assurances that the applicant will be able to complete the accreditation process for a given facility within 6 months if the facility submits the required information in a timely manner.

FDA agrees that timely processing of accreditation materials is necessary in order to: (1) Meet statutory requirements, that, in most cases, allow new facilities to be provisionally certified for only 6 months, and (2) ensure that reaccreditation applications will be processed before expiration of a facility's accreditation. Therefore, FDA is proposing to add a requirement in § 900.3(b)(3)(iii)(J) for prospective accreditation bodies to submit such assurances with their application for approval, along with a description of their policies and procedures for ensuring timely processing of accreditation materials.

To gain further insight regarding appropriate criteria for evaluating prospective accreditation bodies, FDA reviewed a regulation entitled ''Secretary's Procedures and Criteria for Recognition of Accrediting Agencies,'' which was finalized by the U.S. Department of Education in the Federal Register of April 29, 1994 (59 FR 22250). Based on FDA's review of that regulation, along with the agency's experience under the interim regulations and comments by NMQAAC members, FDA is proposing to add new § 900.3 (b)(3)(iii)(K), (b)(3)(viii), and (b)(3)(ix). These sections would require each prospective accreditation body to submit with its accreditation application: (1) A description of the body's appeals process for facilities contesting accreditation decisions; (2) a description of the body's mechanism for ensuring against conflicts of interest; and (3) information disclosing any commercial products used in mammography that the body develops, sells, or distributes.

2. Term Limits and Scope of Authority

In § 900.3(g), FDA is proposing to establish renewable 5-year terms of approval for accreditation bodies. The agency believes that a body should not be approved for an indefinite amount of time without undergoing periodic comprehensive reviews. Although the interim regulations addressed the possibility of withdrawing the approval of an accreditation body for unsatisfactory performance, the interim regulations did not establish a regular term limit for accreditation body approval.

FDA is proposing in § 900.3(c) a schedule and requirements for application for renewal of an accreditation body's approval. These schedule and renewal requirements would also apply to accreditation bodies approved under the interim regulations that seek to continue serving as accreditation bodies under the final regulations. FDA's intention in establishing such a schedule is to ensure sufficient time for the review and processing of applications in order to avoid interruption in the availability of the services of the accreditation body. The agency solicits comments on whether the 90-day timeframe for application is appropriate.

Proposed § 900.3(d) describes the process the agency would use for reviewing accreditation body applications and renewals. The proposed process includes a provision for extending an accreditation body's previous approval if FDA has not reached a final decision on renewal before the previous approval expires.

FDA is proposing new provisions in § 900.3 (e) and (f) requiring the accreditation body to notify facilities and FDA, and to transfer records in instances where the body: (1) Voluntarily ceases its accreditation functions before expiration of its 5-year term, (2) decides not to reapply for an additional term of approval, or (3) fails to become reapproved by FDA.

In addition to limiting the term of approval of accreditation bodies, FDA believes that the agency should be permitted to limit the scope of authority of an accreditation body (for example, geographically, for State agencies). This is proposed in § 900.3(g).

FDA plans to issue application guidance to prospective accreditation bodies to assist them in preparing materials and supporting documentation required by the revised accreditation regulations, when finalized. It is expected that for accreditation bodies applying for renewal, the supporting documentation will consist primarily of updates of information previously provided to FDA.

C. Standards for Accreditation Bodies

In § 900.4 (21 CFR 900.4), FDA is proposing expanded requirements and responsibilities for accreditation bodies. These standards are intended to ensure that accreditation bodies work together with FDA and mammography facilities to achieve and maintain high quality mammography at all facilities.

Proposed § 900.4(a) establishes a code of conduct and general responsibilities for accreditation bodies to assure the integrity and impartiality of accreditation body actions and appropriate oversight of the quality of mammography at all accredited facilities. Other proposed paragraphs in § 900.4 and the accreditation body requirements they address include: § 900.4(b)—standards that the accreditation body must apply to

accredit facilities; § 900.4 (c) and (d)—accreditation body review of facility clinical and phantom images; paragraph (e)—accreditation body review of reports of mammography equipment evaluation, physics surveys, quality control records, and personnel updates at facilities; § 900.4(f)—accreditation body onsite visits to facilities and performance of random clinical image reviews; § 900.4(g)—consumer complaint mechanisms; § 900.4(h)—other reporting and recordkeeping requirements; and § 900.4(i)—fees that accreditation bodies may charge facilities for accreditation. While most of these requirements were addressed by the interim regulations, FDA is proposing additions and modifications that are described in this preamble.

1. Code of Conduct and General Responsibilities

In § 900.4(a)(1), FDA is proposing to require an accreditation body to take certain actions if the agency believes that the clinical image quality or other aspects of a facility's practice are seriously compromised and would pose an unreasonable risk of substantial harm to the public. The agency's intention is that this authority would only be used in those situations, hopefully rare, where the mammography-specific health hazard is serious enough to warrant actions beyond the scope of those normally used to meet the facility quality standards. It is not intended to replace the normal interaction between accreditation bodies and facilities as they seek to meet the quality standards.

This section was added in response to discussions with the NMQAAC and public comments requesting additional measures to ensure timely compliance with regulatory requirements by facilities. For example, one comment questioned whether the loss of a facility's certification would assure termination of a facility's ability to provide mammography services. Another comment stated that accreditation bodies should have the authority to take action against miscreant facilities.

FDA advises that there are a number of mechanisms in place to ensure that decertified facilities no longer provide mammography services. When facilities lose their certification, they can no longer provide mammography services lawfully and are required to return their certificate to the agency. Consumers have been advised through various publicity campaigns to check for the presence of an FDA certificate when they go for a mammogram, so many consumers will be aware that they should not have a mammogram performed at a facility that does not display an FDA certificate. In addition, the statute provides for civil money penalty and injunctive sanctions against facilities that practice mammography without a certificate. Nonetheless, for circumstances where FDA believes there is a risk of substantial harm to the public, proposed § 900.4(a)(1) would provide an additional means of monitoring facility compliance with MQSA requirements and would allow FDA to require accreditation bodies to assist the agency in taking actions or requiring facilities to take actions that the agency deems necessary to prevent harm to consumers. FDA solicits comments on the nature and appropriateness of this proposed additional monitoring.

Similarly, § 900.4(a)(2) and (a)(3) propose additional steps to be taken by accreditation bodies in circumstances where a facility's operations may compromise the quality of mammography or otherwise pose a health or safety hazard that is within the scope of the MQSA but not as severe as situations addressed by § 900.4(a)(1). In accordance with these proposed paragraphs, accreditation bodies would be required to notify FDA any time the accreditation body becomes aware that there has been actual loss of life or serious injury or illness associated with facility noncompliance with MQSA requirements. Such notification would have to be provided to FDA within 5 business days of the accreditation body's learning of the event. The 5-business day interval was chosen as a compromise between the agency's need to be informed as soon as possible of serious mammography-specific health hazards and the need for the accreditation body to have sufficient time to identify and report the event. Comments are specifically invited upon the appropriateness of the allowed length of time. Accreditation bodies would also be required to obtain, review, and monitor plans of correction from facilities not in compliance with the facility standards. These provisions should further address the concerns of the comments mentioned above.

One comment requested that all time period designations related to requirements for action by accreditation bodies be specified in ''business'' days rather than ''calendar'' days.

FDA agrees that some time period designations should be specified as business days and has proposed changes to the interim regulations accordingly. Where proposed time periods are not explicitly specified as business days, they should be interpreted as calendar days. In addition, in order to afford accreditation bodies and facilities increased flexibility, FDA is proposing to eliminate some of the mandatory schedules specified under the interim regulations. For example, FDA is eliminating the interim requirement that accreditation bodies with minor deficiencies submit a plan of corrective action within 90 days. Thus, under the proposed regulations, certain schedule requirements would be left to the discretion of the accreditation body or FDA or would be subject to FDA approval during the accreditation body application process.

In § 900.4(a)(4), FDA is proposing that accreditation bodies be required to establish a quality assurance (QA) program that includes clinical and phantom image review. This QA program would establish policies and procedures to ensure consistent and accurate evaluation of facility images with respect to both methods of review. The QA program would also address training and evaluation of staff performing the reviews.

In proposed § 900.4(a)(5), FDA calls for new measures to reduce the possibility of conflict of interest or bias on the part of an accreditation body or anyone acting on an accreditation body's behalf with regard to specific facilities. NMQAAC members and consultants expressed concern about conflicts of interest or bias with regard to clinical image reviewers evaluating images from their own States or from geographically limited areas where the reviewers may know the facilities and their interpreting physicians. Also, various comments expressed concern that: (1) ''Innumerable 'non-profit' health care corporations'' could be approved as accreditation bodies and accredit their own facilities as long as clinical image reviewers had no financial interest in the facilities; (2) a professional organization serving as an accreditation body has members with ''vested interests in the outcome of the body's decisions;'' (3) individuals employed by a professional organization that is an accreditation body have a conflict of interest with regard to the establishment of standards by which their facilities would be evaluated under the MQSA; and (4) members of a professional organization that was an approved accreditation body would be prevented from conducting clinical image reviews.

The proposed code of conduct in § 900.4(a) is intended to address the various concerns raised regarding conflict of interest considerations for accreditation bodies. In addition, FDA notes that all standards used by accreditation bodies to accredit facilities

are subject to review and approval by the agency. However, neither the interim requirements nor the proposed code of conduct would preclude members of a professional organization that is designated as an accreditation body from conducting clinical image reviews for that organization solely on the basis of membership in that organization. In addition, the proposed standards include conflict of interest provisions that would preclude other situations suggested by the comments.

Several comments and presentations at the NMQAAC meetings, on behalf of a trade association of software vendors, expressed concern that a currently approved accreditation body that markets mammography reporting software might have a sales advantage because of its MQSA accreditation functions and a perceived ''imprimatur of government approval'' for its products. In particular, this trade association proposed that the following language be incorporated into FDA's standards for approval of an accreditation body:

> Satisfactory assurances that the body does not have any interest in the development, sale, promotion, or distribution of any product (including computer software) under circumstances where the product will be the subject of inspection or review by the accreditation body in facility quality assurance or quality control or other aspects of the accreditation process. This restriction does not apply to educational programs or educational material typically prepared or disseminated by an accreditation body.

Although FDA has not proposed the standard suggested by this comment, the agency specifically solicits public comment on this alternative. This issue has been raised repeatedly during the open public sessions of the NMQAAC meetings, and FDA wants to be certain that there is full opportunity for the public to comment on the underlying question: Is there an inherent conflict in an accreditation body also being a product vendor for a mammography-related product? As currently proposed, the requirements in § 900.4(a)(6) minimize the possibility of accreditation body conflict of interest with regard to the marketing of commercial products by prohibiting an accreditation body from representing in any way that the purchase of a particular product is a condition of accreditation. However, proposed § 900.4(a)(6) would not require accreditation bodies to divest all interests in commercial products. Moreover, the proposed regulation would permit an accreditation body to require the use of a product by facilities it accredits, even when there is the possibility of a conflict of interest, if FDA determines that such use is in the best interest of public health. As noted previously, FDA encourages further public comment on the conflict of interest issue, including comment on whether the outcome of any conflict of interest issue would be affected by: (1) The cost of the product sold by an accreditation body, i.e., by the magnitude of the financial interest; or (2) the number of accreditation bodies available to choose from.

Proposed § 900.4(a)(6) would require an accreditation body to state the bases for denying accreditation in a written notification to the affected facility. In accordance with proposed § 900.3(b)(3)(iii)(K), each accreditation body will establish procedures for appeal of adverse accreditation decisions to the accreditation body. The accreditation body's notification of denial of accreditation also would be required to describe the appeals process available from the body if the facility wishes to contest the adverse decision.

Proposed § 900.4(a)(8) would explicitly prohibit any State that has been approved as an accreditation body from precluding any other FDA-approved accreditation bodies from operating in that State. This amendment is intended to codify what has been FDA policy and practice under the interim regulations.

Several comments stated that FDA should allow only one accreditation body to operate in a given State or should allow only States to serve as accreditation bodies.

FDA disagrees with these comments. The statute itself does not provide for such exclusivity. The MQSA allows FDA to approve either State agencies or private nonprofit organizations to serve as accreditation bodies, as long as they meet the standards established by FDA. The agency believes that facilities, consumers, and the professional community can benefit from the existence of more than one accreditation body.

Consistent with the interim regulations, the proposed regulations would require that accreditation bodies obtain FDA authorization before changing accreditation body standards previously approved by FDA (§ 900.4(a)(9)). Several comments expressed concern that this requirement would preempt section 354(m) of the PHS Act, which permits States to enact and enforce laws that are more stringent than those mandated by the MQSA. There was also discussion during the January 1995 NMQAAC meeting as to whether accreditation bodies could have more stringent requirements than those mandated under MQSA.

FDA requires State agencies and private nonprofit organizations approved as accreditation bodies by FDA to establish and implement facility standards that have been approved by FDA. FDA will approve such standards only if FDA determines that they are substantially the same as the standards required under MQSA. In addition, all accreditation bodies, whether State agencies or private nonprofit organizations, must determine the MQSA accreditation status of a facility using only FDA-approved standards. However, accreditation bodies may use more stringent standards under other (non-MQSA) authorities for purposes other than that of determining the MQSA accreditation status of facilities. For example, a State public health agency approved as an MQSA accreditation body by FDA may require facilities in the State to meet additional standards (beyond those required by MQSA) under the body's authority as a State accreditation agency. However, the body may not require facilities to meet these additional standards in order to obtain MQSA accreditation. Similarly, a private nonprofit organization approved as an accreditation body may recommend compliance with more stringent standards than those mandated under MQSA, but may not use such standards in determining the MQSA accreditation status of a facility.

Proposed § 900.4(a)(10) states the accreditation body's obligation to protect the confidentiality of nonpublic information acquired in connection with carrying out accreditation body responsibilities. The accreditation body may not use or disclose information it receives from facilities, other than to FDA or its designated representatives, without the consent of the facility. The accreditation body must also protect the confidentiality of nonpublic information it receives from FDA or its duly designated representatives.

2. Facility Standards

In proposed § 900.4(b), FDA outlines the quality standards for mammography that accreditation bodies would have to apply to facilities they accredit (facility standards). The details of the facility standards required under the MQSA are being proposed elsewhere in this issue of the Federal Register. FDA is also proposing in § 900.4(b) actions to be required by the accreditation body with respect to facilities not in compliance with the quality standards, such as reviewing and monitoring the implementation of facility plans of correction and revoking a facility's accreditation.

One comment recommended that a single quality standard be implemented nationwide by all accreditation bodies.

FDA intends to ensure that each accreditation body's standards are substantially the same as those promulgated by the agency, in accordance with the requirements of section 354(e)(1) of the PHS Act (42 U.S.C. 263b(e)). However, FDA notes that mammography standards are unlikely to be identical across the country because the MQSA allows for both private nonprofit organizations and State agencies to serve as accreditation bodies, and also permits States to establish more stringent mammography standards under their own authority. In addition, FDA believes it is necessary to allow some flexibility in accreditation body operations in order to provide for efficient accreditation services for the more than 10,000 mammography facilities nationwide. Nonetheless, the statute and proposed regulations are intended to establish minimum nationwide facility standards, and proposed § 900.4(b) would require all accreditation bodies to adopt and apply these standards.

3. Clinical Image Review

FDA believes that effective clinical image review is essential to ensure high quality mammograms. A primary purpose of the MQSA is to ensure that all mammography facilities have the benefit of such review and that accreditation bodies be qualified to perform that function. Accordingly, FDA is proposing to establish more specific requirements with respect to clinical image review than were established under the interim regulations. The requirements proposed are based on advice from the NMQAAC and public comments.

The areas covered by the proposed standards in § 900.4 for clinical image review are as follows: § 900.4(c)(1)—requirements for the minimum frequency of review; § 900.4(c)(2)—clinical image attributes to be evaluated (with a provision for FDA approval of alternatives, including ones that may be appropriate for new technology); § 900.4(c)(3)—scoring of clinical images; § 900.4(c)(4)—selection of clinical images for review; § 900.4(c)(5)—qualifications and procedures for clinical image reviewers; § 900.4(c)(6)—management of clinical images to ensure their timely return to facilities and the reporting of unsuspected abnormalities; and § 900.4(c)(7)—corrective measures for unsatisfactory image quality. With respect to this last paragraph, it is FDA's intent that the accreditation process be a constructive one that helps facilities improve mammography quality. Therefore, FDA is proposing that clinical image reviewers be required to provide information to facilities that can help them correct deficiencies identified from their clinical images.

Several comments as well as NMQAAC discussions concerned the interim requirements for clinical image review. Some NMQAAC members and consultants expressed uncertainty about whether States would have the expertise to perform clinical image reviews, because States had no prior experience with such reviews. Some comments called for increased standardization and the establishment of minimum requirements for clinical image review. One comment believed that all clinical images should be selected randomly in order to prevent facilities from merely selecting their best images for accreditation body review. Two comments questioned the need for clinical image review requirements at all. These two comments believed that other requirements in the interim regulations adequately addressed image quality. Another comment believed that clinical images should be independently reviewed by more than one radiologist.

In response to these comments, FDA notes first that the MQSA mandates clinical image reviews and FDA fully supports the need for such reviews. FDA does not intend to approve any entity as an accreditation body, including a State agency, without first determining that the prospective body will be capable of performing or providing satisfactory clinical image reviews. The proposed regulations concerning clinical image review add specific details and requirements that are in addition to those set forth in the interim regulations. FDA believes that these additions in the proposed regulations, as well as anticipated agency guidance, will ensure that prospective accreditation bodies understand what FDA expects of them regarding such reviews and will be prepared to establish their ability to perform or provide these reviews as part of their application to become accreditation bodies. In addition, FDA will monitor accreditation bodies' compliance with the agency's standards and expectations, including their clinical image review functions. This will be done through annual performance evaluations and other oversight mechanisms.

FDA agrees with the comment that clinical images should be independently reviewed by more than one radiologist. Although such a requirement was not explicitly established in the interim regulations, it has been the practice established by FDA and the accreditation bodies under those regulations. FDA is proposing to codify this policy in § 900.4(c)(3)(ii).

FDA disagrees with the comment that all clinical images submitted by facilities should be selected completely at random. For example, it is important in assessing the quality of a facility's mammography that accreditation bodies evaluate, for each mammography unit in a facility, mammograms for women with different types of breast composition (e.g., with predominantly glandular versus adipose tissue). FDA believes that systems for clinical image review under the MQSA can be implemented using random or nonrandom methods of image selection. FDA also notes that nonrandom methods for clinical image review were used by the ACR as part of its voluntary accreditation program before the passage of the MQSA.

4. Phantom Image Review

FDA is proposing a new requirement in § 900.4(d) for review of phantom images by the accreditation body. This is being done on the recommendation of the NMQAAC. To the extent that issues in the review of phantom images parallel issues in the review of clinical images, the requirements of this paragraph parallel those of § 900.4(c). However, a unique issue with respect to phantom images is determining what constitutes acceptable phantom characteristics for radiographically modeling aspects of breast disease and cancer.

FDA recognizes that a variety of phantoms may be useful for this purpose, and that the desirable phantom characteristics may change over time, particularly with the introduction of new technology. Consequently, FDA is not proposing that any specific attributes, such as specks, fibers, or masses, or their dimensions, be required by regulation. However, to assure the adequacy of phantoms used, FDA is proposing to require that accreditation bodies obtain FDA approval for the phantoms and methods of use that the bodies specify for facilities they accredit. This approach will provide needed flexibility for accreditation bodies and facilities and will enable FDA to respond in a timely manner to technological advances in this area.

5. Reports of Mammography Equipment Evaluation, Surveys, and Quality Control

Consistent with the interim regulations and statutory requirements, FDA is proposing to require in § 900.4(e) that accreditation bodies mandate submission of a survey by facilities in

order to obtain accreditation. ''Survey'' is defined in § 900.2 (published elsewhere in this issue of the Federal Register) as an onsite physics consultation and evaluation of a facility performed by a medical physicist. This survey would have to demonstrate the facility's compliance with the MQSA standards adopted by the accreditation body.

The statute does not require new facilities to submit a survey in order to qualify for provisional certification from FDA. Therefore, new facilities may perform mammography for up to 6 months without undergoing a survey. Both the agency and the NMQAAC believe that postponement of the survey required for full accreditation under MQSA should not be interpreted as permitting the clinical use of equipment that has not been evaluated for safety. Accordingly, FDA is proposing that all facilities, whether seeking full or provisional certification, be required to submit with their initial accreditation application a mammography equipment evaluation demonstrating that the facility's equipment is in compliance with the requirements in § 900.12(e) (21 CFR 900.12)(e)) for equipment quality assurance (published elsewhere in this issue of the Federal Register). This requirement would ensure that provisionally certified facilities verify the proper functioning of their mammography equipment prior to clinical use.

FDA will be developing a guidance document outlining the criteria for an adequate equipment evaluation. The agency invites comments on possible criteria for inclusion within this guidance document. A complete survey, which includes reviews and information in addition to equipment QA, would still have to be submitted in order for a provisionally certified facility to obtain accreditation and full certification.

There was some discussion with the NMQAAC regarding who should perform the mammography equipment evaluation that is part of the initial application for accreditation. In deference to comments from rural health care providers, FDA has decided against requiring that this evaluation be performed by a medical physicist. Rural health care providers have indicated that, because of the limited availability of medical physicists in rural areas, it might be difficult for a physicist to visit a rural facility twice over a short time period in order to perform the mammography equipment evaluation and, later, the survey required for accreditation and full certification. In addition, the agency's experience under the Radiation Control for Health and Safety Act (Pub. L. 90–602) shows that the types of measurements being requested for the mammography equipment evaluation can be performed effectively by nonphysicists. Therefore, FDA believes it would not be cost-effective or practical to require performance of the mammography equipment evaluation by a medical physicist.

FDA is proposing specific time periods for facility submission and accreditation body review of mammography equipment evaluations and surveys. These requirements are being recommended as a result of FDA's experience with MQSA over the last year and advice from the NMQAAC. In particular, both the agency and the NMQAAC believe it is important that facilities be required to submit survey and evaluation data that reflects current practice in the facility at the time of application for accreditation.

FDA is proposing to require in § 900.4(e) that accreditation bodies mandate annual submission of certain materials by the facility to the accreditation body for review. These materials would include the annual survey and quality control records, personnel updates, and other information that the body may require. This requirement is intended to assure continued compliance with the facility standards and to provide continued accreditation body oversight of facilities' quality control programs as they relate to such standards.

Several comments addressed issues related to accreditation and certification of facilities with more than one mammography unit (consisting of the x-ray generator and associated image receptor and auxiliary equipment). In particular, clarification was requested regarding the status of multiple-unit facilities that had not undergone all tests to assure compliance with standards or that had failed to meet all requirements. Some comments favored requiring the complete evaluation of all units in a facility, with measures to ensure that only equipment meeting the necessary requirements is used to perform mammography.

FDA agrees that only equipment meeting necessary requirements should be used to perform mammography. Under both the interim and proposed regulations, all units that are used for mammography in a facility must be reported to the accreditation body and meet applicable standards. As discussed previously, FDA is proposing to require that facilities submit the results of mammography equipment evaluations with their initial application for accreditation. Those evaluations will establish compliance with equipment QA standards under § 900.12(e) for every unit in the facility. In addition, surveys (§ 900.4(e)), as well as clinical (§ 900.4(c)(4)(i)) and phantom images (§ 900.4(d)(4)), would have to be submitted for each mammography unit at a facility during specified time periods. FDA is also proposing in § 900.4(c)(2)(viii)(G) that facilities with multiple units have a mechanism for identifying the unit used to produce each mammography image. This would enable inspectors and accreditation body visitors to check facility images against the compliance status of facility equipment and would facilitate problem identification and corrective measures, if necessary.

It is FDA's policy that similar requirements apply to new and repaired equipment, i.e., such equipment may be used clinically after the mammography equipment evaluation has demonstrated compliance of the equipment with the requirements in § 900.12(e). A survey and clinical and phantom image reviews may be required after the initiation of clinical use. Such image reviews and a survey are now, and would continue to be, necessary for new equipment; however, the accreditation body will specify, with FDA's approval, the circumstances under which repaired equipment will require a survey or image reviews by the accreditation body. Any facility that performs mammography with equipment the facility has reason to believe does not meet MQSA standards will be subject to sanctions under section 354(h)(2) of the PHS Act, including civil money penalties.

One comment questioned the value of requiring annual submission of all facility quality control records to both the accreditation body and FDA. The comment also suggested that quality control records may be useful for internal evaluations, but that documents that are to be submitted to the accreditation body may be screened or amended by the facility in order to avoid negative publicity or regulatory action.

FDA advises that no routine requirement exists to submit all quality control records to FDA. In addition, the use of the phrase ''quality control records'' in § 900.4(e)(2)(iii) of the interim regulations is not intended to mandate submission of all quality control records to the accreditation body every year. The records to be submitted will depend on the specific requirements established by the accreditation body, subject to FDA approval. FDA agrees that quality control records can serve as an

important internal source of information for helping facilities identify problems and appropriate solutions. However, FDA would regard any purposeful alterations of records to be acts of fraud.

6. Accreditation Body Onsite Visits and Random Clinical Image Reviews

The MQSA requires that accreditation bodies make a ''sufficient number'' of onsite visits to facilities they accredit ''to allow a reasonable estimate of the performance'' of the body (42 U.S.C. 263b(e)(4)). The MQSA also requires the accreditation body to conduct random reviews of clinical images from the facilities it accredits, in addition to the clinical image reviews required for accreditation (42 U.S.C. 263b(e)(1)(B)). These requirements are listed in § 900.4(f) of the proposed regulations (corresponding to § 900.4(e) in the interim regulations). In the proposed regulations, the word ''visits'' is substituted for the previously used word ''inspections'' in order to reduce any confusion between onsite visits by accreditation bodies and annual inspections by State or FDA inspectors.

One comment disputed the need for onsite visits by accreditation bodies and another comment questioned the need for the interim requirement that the accreditation body submit a copy of the visit report to FDA.

FDA disagrees with both of these comments. The need for onsite visits is established by the statute. The purpose of the visits is to provide a mechanism by which an accreditation body can both ensure facility compliance with quality standards and monitor its own performance of accreditation functions. The accreditation body would be able to compare the results from visits for consistency with information obtained through other accreditation body functions. Also, because FDA is required to evaluate annually the performance of each accreditation body, the reports of onsite visits would provide valuable information on which to base such evaluations. Therefore, although the agency is proposing to delete the requirement that a full copy of each onsite visit report be provided to FDA at the conclusion of the accreditation body's onsite visit, FDA would continue to require that a summary of findings obtained as a result of accreditation body visits to facilities be included in the accreditation body's annual report to FDA. As discussed previously, notification about situations involving health hazards and death or serious injury or illness cannot wait for annual reports.

Several comments addressed the selection process, number, and need for advance notification of facilities for accreditation body onsite visits. Some comments stated that the percentage of visits performed by accreditation bodies should be established by FDA (at perhaps 5 or 10 percent of accredited facilities). One comment suggested that a means be established to ensure proportionate distribution of visits to facilities with regard to facility size and geographic distribution. Several comments believed that accreditation bodies should be required to give facilities advance notice of a visit, although one comment believed that FDA should specify certain circumstances for which unannounced visits might be appropriate.

In response to these comments, FDA is proposing in § 900.4(f)(1) that accreditation bodies select some facilities for onsite visits on a random basis and select other facilities based on specific reasons for concern with those facilities, such as previous history of noncompliance with quality standards. In general, each accreditation body would have to visit annually at least 5 percent of facilities it accredits, up to a maximum of 50 facilities, but no less than 5. The number could exceed 50 if many facilities need to be visited because of previously identified concerns.

Regarding advance notification of facilities by accreditation bodies, FDA believes that accreditation bodies will need flexibility in scheduling onsite visits. In some cases, particularly if an accreditation body has serious concerns about a facility's ability to meet quality standards, significant advance notice would not be appropriate. In general, however, for facilities selected randomly for onsite visits, FDA will encourage accreditation bodies to work with facilities to schedule visits so as to minimize examinee inconvenience and disruption to facility operations.

For random clinical image reviews, FDA is proposing that, on an annual basis, 3 percent of facilities (but no less than five facilities) accredited by an accreditation body would have to be chosen randomly to submit clinical images for review. These clinical images would be in addition to those submitted every 3 years as part of the accreditation process. As the requirements have been proposed, the accreditation body would be able to count toward this 3 percent requirement all facilities that have undergone an additional clinical image review because of random selection for the onsite visits in § 900.4(f)(1)(i)(A).

The requirement for selecting a 3 percent random sample of facilities is changed from that in the interim regulations, which required random clinical image review for each facility accredited by a body. The change in the sampling requirement is based on FDA experience with implementing the interim regulations. The agency believes that annual random clinical image review for every facility in addition to the clinical image reviews required for initial accreditation and renewal is not an effective use of accreditation body resources. In addition, accreditation bodies should not schedule random clinical image reviews at facilities that have received their notification of their need to begin the accreditation renewal process or at facilities that have completed the accreditation renewal process within the previous 6 months.

7. Consumer Complaint Mechanism

The interim regulations required accreditation bodies to establish processes for receipt, investigation, and records maintenance of consumer complaints about facilities they accredit. In accordance with 42 U.S.C. 263(n)(3)(E), FDA has worked with the NMQAAC to develop mechanisms to investigate consumer complaints. The committee and FDA agree that the investigation of ''serious complaints'' and the correction of underlying problems that may have precipitated them can help improve the practice of mammography. The proposed role of accreditation bodies in this process is specified in § 900.4(g).

A ''serious'' complaint is defined in proposed § 900.2 (published elsewhere in this issue of the Federal Register) as a report by a consumer of: (1) A ''serious adverse event'' that significantly compromises, or has the potential to significantly compromise, clinical outcomes, or (2) an ''adverse event'' for which the facility fails to take appropriate corrective action. ''Consumer'' is defined in proposed § 900.2 as an individual who chooses to comment or complain in reference to a mammography exam. Consumers, therefore, may include the examinee or representatives of the examinee (e.g., family members or referring physicians).

In the proposed regulations, the consumer complaint mechanism focuses on serious complaints related to incidents over which FDA has regulatory authority under MQSA. FDA acknowledges that there may be additional kinds of serious complaints that are legitimate and worthy of investigation, but that do not fall under the agency's regulatory authority under MQSA (e.g., sexual harassment or discrimination). FDA encourages the channeling and resolution of such complaints through appropriate existing mechanisms, such as State oversight

organizations and professional licensing boards.

The proposed consumer complaint mechanism would set minimum requirements for facilities and accreditation bodies. FDA has worked extensively with NMQAAC in developing this mechanism and believes that the proposed requirements meet the important needs of the consumer without imposing undue burden on mammography facilities. The proposed regulations would allow facilities flexibility in instituting their own complaint resolution procedures. FDA encourages facilities to design their complaint mechanisms to be responsive to language, ethnic, and literacy differences among consumers served by the facility.

FDA believes that all comments and complaints should be directed first to the facility, where there is the greatest opportunity for resolution. FDA is proposing that facilities be required to establish and administer a documented consumer complaint mechanism that complies with standards in proposed § 900.12(h), published elsewhere in this issue of the Federal Register. However, FDA also recognizes that, under certain circumstances, consumers may want to report serious complaints that they have been unable to resolve with the facility to a more impartial organization. FDA believes that a facility's accreditation body should receive these complaints because the accreditation body has the responsibility for assuring that facilities meet quality standards. To fulfill this responsibility, accreditation bodies need data on serious complaints related to mammography quality. Therefore, FDA is proposing that the accreditation body be the second level in the complaint process to receive, investigate, and resolve serious consumer complaints.

The third level of the complaint process, should the complaint go unresolved at the accreditation body level, would be FDA. The accreditation body could recommend that FDA take regulatory action, including inspections, sanctions, or revocation of the facility's certificate. Some consumers might want to address complaints about facilities directly to FDA, and this option is also open to them.

FDA is proposing to require accreditation bodies to review and evaluate each facility's plan for handling consumer complaints. The agency is also proposing that the accreditation body be required to maintain a record of each serious complaint it receives regarding facilities it accredits, whether or not the accreditation body is able to resolve the complaint. All records of serious complaints would have to be retained for at least 3 years after the date of receipt of the complaint by the accreditation body. Accreditation bodies would also be required to submit to FDA an annual report summarizing serious complaints.

One comment on the interim regulations requested that complaint information be shared with States and the public.

The MQSA does not include a provision requiring public disclosure of individual consumer complaints or release of such information by individual facilities to State authorities. However, the MQSA does require in 42 U.S.C. 263b(l)(1) that information FDA determines to be useful in evaluating the performance of mammography facilities be made available to the general public no later than October 1, 1996, and annually thereafter. This information must include a list of facilities that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks, have been subject to sanctions, have had certificates revoked or suspended, or have had accreditation revoked.

One comment on the interim regulations noted that the mechanism for handling complaint information contains no provision for protecting confidentiality and that unsubstantiated allegations should not be made publicly available.

As discussed above, FDA does not believe the MQSA is intended to authorize public disclosure of details concerning specific complaints or allegations. FDA encourages all individuals involved in resolution of complaints to protect the confidentiality of consumers and health professionals to the full extent required by State law and professional ethics. However, knowledge of the identity of individuals involved in the complaint process may be necessary in order for the accreditation body or FDA to investigate the complaint. The agency's own regulations prohibit disclosure of information that would be an unwarranted invasion of personal privacy and FDA will not release names or personal identifiers without consent of the individuals involved (21 CFR 20.63 and 20.111).

8. Reporting and Recordkeeping

In § 900.4(h), FDA is proposing to require that accreditation body reports to FDA be submitted in the format and medium prescribed by the agency. This requirement would facilitate the use of uniform methods for efficient data management and analysis, including the use of computer-based systems by FDA.

One comment stated that the timeframes specified in the interim regulations (§ 900.4(g)) for accreditation body reporting were unreasonable.

FDA agrees that changes in this area are needed and the proposed regulations have been designed to allow greater flexibility in specifying timeframes for reports to FDA, based on FDA and accreditation body needs.

One comment expressed concern that the wording of the interim requirement in § 900.4(g)(6) might result in a request for proprietary information not specifically required by or relevant to the MQSA. Another comment indicated concern that the interim requirement in § 900.4(d)(1) for a facility to provide its accreditation body with, ''any other information the body may require, as a part of the annual report about the facility'', was excessively broad.

FDA believes that the MQSA provides the agency with the authority to determine the information that is necessary to meet the agency's statutory responsibilities under MQSA (e.g., 42 U.S.C. 263b(d)(1)(B)(iii) and (e)(1)(C)(vi)). In addition, FDA has considerable experience with receiving and protecting proprietary information. However, in response to the comments, FDA has modified the regulatory language to specify that any information collected by an accreditation body from a facility should be relevant to the MQSA. In addition, as part of FDA's approval and oversight responsibilities, the agency will review the information required by accreditation bodies with regard to its relevance to such bodies' responsibilities under MQSA.

As discussed earlier, FDA has also addressed the issue of confidentiality in the accreditation body code of conduct and general responsibilities. Proposed § 900.4(a)(9) states the obligation of the accreditation body to keep confidential all nonpublic information it acquires in connection with carrying out its accreditation body responsibilities.

9. Fees

In proposed § 900.4(i), FDA is continuing to require that accreditation body fees charged to facilities be reasonable, as in § 900.4(c) of the interim regulations.

Several comments regarding accreditation fees mentioned the relatively small amounts of various third party reimbursements for screening mammography and hoped that FDA would consider this information when establishing requirements for fees. Two comments disagreed with the interim requirements for limiting fee increases to adjustments in the consumer price index (CPI). A

few other comments raised additional issues related to determining the reasonableness of fees, including expansion costs and accreditation body activities specifically attributable to MQSA responsibilities. The latter issue was raised with respect to State agencies with multiple responsibilities in addition to those associated with MQSA.

FDA is proposing certain changes in the fee provisions in response to comments. The proposed regulations would permit variation in accreditation body fees, and adjustments would no longer be limited to changes in the CPI. However, FDA is proposing that accreditation bodies only be allowed to recover costs that are a result of MQSA-attributable functions. Consequently, fee changes might be appropriate for changes in accreditation body activities that have been approved by FDA. However, accreditation body activities that are not FDA-approved activities could not be considered in determining fees charged for MQSA accreditation functions. Consequently, the relationship of fees to costs incurred because of accreditation body responsibilities under these regulations would be an important factor in determining the reasonableness of fees.

One comment questioned whether providers would have an opportunity to question the reasonableness of fees before they are approved by FDA.

Although there is no official provision for public comment on accreditation fees, anyone who feels that fee increases are excessive may raise these concerns with FDA at any time.

D. Evaluation of Accreditation Bodies

In proposed § 900.5, FDA states that the agency will evaluate all accreditation bodies at least annually and at other times if specific circumstances warrant.

Two comments suggested the following additions to the factors specified in the interim regulations for evaluating accreditation bodies: (1) Responsiveness of the body to FDA and to complaints from other sources, and (2) compliance of the body with requirements for approval as an accreditation body. One of these comments also suggested that more detail be added related to the sample size of facilities and clinical images to be assessed by FDA as part of FDA's evaluation of accreditation bodies.

In response to these comments, FDA advises that the proposed regulations contain more extensive requirements (in § 900.3) for approval as an accreditation body than did the interim regulations. As part of its annual evaluation of accreditation bodies, FDA will consider compliance with these requirements, including the responsiveness and timeliness with which accreditation bodies meet their various responsibilities. In order to perform these evaluations, FDA will have access to the results of annual inspections of facilities by FDA or State inspectors, information from annual and other reports from accreditation bodies, and visits to facilities or accreditation bodies to evaluate their compliance with the standards specified under subparts A and B of part 900 (21 CFR part 900). FDA also will be able to request more data, such as additional clinical images, at any time the agency determines that it needs further information to complete its evaluation.

E. Withdrawal of Approval

In § 900.6, FDA has proposed certain changes to the interim criteria for withdrawal of approval of an accreditation body and the addition of certain other actions the agency may take against accreditation bodies, when warranted.

Under the interim regulations, FDA was precluded from reinstating approval of an accreditation body if withdrawal of approval was based on fraud or material false statements. FDA has reconsidered these criteria in drafting these proposed rules and in light of the agency's experience implementing the interim regulations.

FDA continues to believe that certain actions are so egregious that they should automatically preclude an accreditation body from continuing or ever resuming service as an accreditation body. The agency believes that, in addition to the commission of fraud, willful disregard of the public health constitutes an action by an accreditation body that should permanently disqualify that body from future approval. Accordingly, FDA has added willful disregard of the public health as a bar to reinstatement as an accreditation body.

However, FDA is proposing to review on a case-by-case basis applications from former accreditation bodies whose approval was withdrawn due to the submission of material false statements. The agency is persuaded that there may be instances where the submission of material false statements was unintentional or had limited consequences. FDA has drafted the proposed regulations to retain discretion to reinstate accreditation bodies if the agency determines there is evidence to demonstrate that such conduct will not recur.

The proposed regulations also clarify that FDA reserves the right to withdraw approval or place an accreditation body on probationary status, depending on the specific deficiencies involved. Unlike the interim regulations, the proposal gives FDA discretion about how to proceed, even with respect to accreditation bodies that have demonstrated major deficiencies. FDA would make these determinations on a case-by-case basis. In addition, FDA would have discretion to specify particular corrective actions that the accreditation body must take or to offer the accreditation body an opportunity to submit its own plan of corrective action (including timetables) for FDA approval.

Two comments stated that the specification in the interim regulations of a 90-day time period for submitting a corrective action plan to FDA for minor deficiencies should be shortened from 30 to 60 days, and that FDA should respond to the proposed plan within the same timeframe.

FDA has concluded that establishing fixed time periods for submission or implementation of corrective action plans does not allow the agency or accreditation bodies sufficient flexibility. Timeframes for correction of minor deficiencies should be based on the specific deficiencies that must be addressed. Therefore, the agency has not set forth specific timeframes in proposed § 900.6(b)(2). Instead, FDA will determine the necessary implementation schedules on a case-by-case basis.

F. Hearings

Under proposed § 900.7 on hearings, a facility that has been denied accreditation would be entitled to an appeals process from the accreditation body (§ 900.7(b)). The facility could then appeal the results of this process to FDA and the Department of Health and Human Services in accordance with proposed § 900.15, published elsewhere in this issue of the Federal Register.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on general facility requirements, personnel requirements, and quality standards for mammography equipment and quality assurance, published elsewhere in this issue of the

Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches,'' published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection are contained in the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches,'' published elsewhere in this issue of the Federal Register, with an estimate of the annual reporting and recordkeeping burden.

The agency has submitted a copy of this proposed rule to OMB for its review and approval of these information collection requirements. Other organizations and individuals desiring to submit comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, rm. 10235, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA. Written comments on the information collection requirements should be submitted by May 3, 1996.

VI. Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written commentsregarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Report on the Mammography Quality Standards Act of 1992,'' U.S. Senate, Report 102–448, October 1, 1992.

2. ''Health Care: Hospitals with Quality-of-Care Problems Need Closer Monitoring,'' U.S. GAO, GAO/HRD–91–40, May 1991.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Sections § 900.3 through 900.7 are revised to read as follows:

§ 900.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart may apply for approval as accreditation bodies.

(b) *Application for initial approval.* (1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality and Radiation Programs, Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch, of its requested scope of authority.

(2) Following receipt of the request, FDA will send application guidance to the applicant.

(3) In accordance with the guidance provided, the applicant shall furnish to FDA at the address in paragraph (b)(1) of this section three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State agency;

(ii) Detailed description of the accreditation standards the applicant will require facilities to meet and a discussion substantiating their equivalence to FDA standards required under 42 U.S.C. 263b(e)(3);

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing clinical image review;

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for performing onsite visits to facilities;

(E) Procedures for assessing facility personnel qualifications;

(F) Copies of the accreditation application forms, guidelines, instructions, and other materials the applicant will send to facilities during the accreditation process;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for revoking a facility's accreditation;

(J) Policies and procedures that will assure processing of accreditation applications and renewals within a timeframe approved by FDA and assurances that the body will adhere to such policies and procedures; and

(K) A description of the applicant's appeals process for facilities contesting adverse accreditation status decisions.

(iv) Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;

(v) Description of the applicant's electronic data management and analysis system with respect to accreditation review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;

(vii) Fee schedules with supporting cost data;

(viii) Statement of policies and procedures established to avoid conflicts of interest or the appearance of conflicts of interest by the applicant's board members, commissioners, professional personnel (including reviewers of clinical and phantom images), consultants, administrative personnel, and other representatives of the applicant;

(ix) Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells, or distributes;

(x) Description of the body's documented consumer complaint mechanism;

(xi) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xii) Any other information as may be required by FDA.

(c) *Application for renewal of approval.* An approved accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of a body's approval, an applicant for renewal shall inform FDA at the address given in paragraph (b)(1) of this section.

(2) FDA will notify the applicant of the applicable information, materials, and supporting documentation from paragraph (b)(3) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 6 months before the date of expiration of a body's approval, the applicant shall furnish to FDA at the address in paragraph (b)(1) of this section three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with paragraph (c)(2) of this section.

(4) No later than July 2, 1996, any accreditation body approved under the interim regulations published in the Federal Register of December 21, 1993 (58 FR 67558) that intends to continue to serve as an accreditation body under the final regulations shall apply for renewal of approval in accordance with the procedures set forth in paragraphs (c)(1) through (c)(3) of this section.

(5) Any accreditation body that does not plan to renew its approval shall so notify FDA at the address given in paragraph (b)(1) of this section at least 90 days before the expiration of the body's term of approval.

(d) *Rulings on applications for initial and renewed approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the accreditation standards the applicant will require facilities to meet are substantially the same as the quality standards published under subpart B of this part.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be rectified within a specified time period. If the deficiencies are not rectified to FDA's satisfaction within the specified time period, the application for approval as an accreditation body will be rejected.

(3) The applicant will receive a formal notice from FDA stating whether the application has been approved or denied and a statement of the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the accreditation body of the circumstances under which a denied application may be resubmitted.

(6) If FDA does not reach a final decision on a renewal application in accordance with this paragraph before the expiration of an accreditation body's approval, the approval will be deemed extended until the agency reaches a final decision on the application, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of authority.* An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA at the address in paragraph (b)(1) of this section at least 90 days before relinquishing such authority.

(f) *Transfer of records.* An accreditation body that does not apply for renewal of accreditation body approval, is denied such approval by FDA, or relinquishes its accreditation authority and duties before expiration of its term of approval, shall:

(1) Transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

(2) Notify, in a manner and time period approved by FDA in accordance with §§ 900.3(d) or 900.4(a)(9), all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* The accreditation body's term of approval is for a period of 5 years. FDA may limit the scope of accreditation authority.

§ 900.4 Standards for accreditation bodies.

(a) *Code of conduct and general responsibilities.* The accreditation body shall accept the following responsibilities in order to ensure safe and accurate mammography at the facilities it accredits and shall perform these responsibilities in a manner that ensures the integrity and impartiality of accreditation body actions.

(1) Upon request by FDA, the accreditation body shall review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether or not the facility's practice poses an unreasonable risk of substantial harm to the public. Such reviews would be in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities. If FDA determines that a facility's practice poses an unreasonable risk of substantial harm to the public:

(i) The accreditation body shall require the facility to take appropriate corrective actions as determined by the accreditation body or FDA, including, but not limited to, notifying examinees or referring physicians; and

(ii) The accreditation body shall monitor the facility's implementation of corrective actions in accordance with a schedule specified by FDA.

(2) The accreditation body shall provide guidance to facilities regarding reporting requirements for conditions within the scope of 42 U.S.C. 263b that arise at the facility and that pose a health hazard to examinees, personnel, or others in the facility.

(i) The accreditation body shall require that such information and a plan of correction addressing the conditions be submitted by the facility in a manner and time period specified by the accreditation body.

(ii) The accreditation body shall require the facility to cease use of any equipment or to eliminate any practices that may contribute to such potentially harmful conditions as soon as possible. In those circumstances where the accreditation body has reason to believe a hazard exists, the accreditation body shall notify the facility that use of the equipment or continuation of the practice shall stop immediately.

(iii) The accreditation body shall monitor the facility's compliance with the plan of correction and progress

toward meeting applicable standards and minimizing health hazards.

(3) The accreditation body shall inform FDA within 5 business days of becoming aware of equipment or practices that pose an unreasonable risk of substantial harm to the public.

(4) The accreditation body shall establish and administer a quality assurance (QA) program that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section. Such quality assurance program shall:

(i) Include requirements for clinical image review and phantom image review;

(ii) Ensure that clinical and phantom images are evaluated consistently and accurately; and

(iii) Specify the methods and frequency of training, evaluation, and performance improvement for clinical and phantom image reviewers, and the bases and procedures for removal of such reviewers.

(5) The accreditation body shall establish measures that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the body's behalf. Such individuals who review clinical or phantom images under the provisions of paragraphs (c) and (d) of this section or who visit facilities under the provisions of paragraph (f) of this section shall not review clinical or phantom images from or visit a facility with which such individuals maintain a financial relationship, or when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.

(6) The accreditation body may require specific equipment performance or design characteristics that FDA has approved. However, no accreditation body shall require, either explicitly or implicitly, the use of any specific brand of imaging system or component, measuring device, software package, or other commercial product as a condition for accreditation by the body, unless FDA determines that it is in the best interest of public health to do so.

(i) Any representation, actual or implied, either orally, in sales literature, or in any other form of representation, that the purchase or use of a particular product brand is required in order for any facility to be accredited or certified under 42 U.S.C. 263b, is prohibited, unless FDA approves such representation.

(ii) Unless FDA has approved the exclusive use and promotion of a particular commercial product in accordance with this section, all products produced, distributed, or sold by an accreditation body or an organization that has a financial or other relationship with the accreditation body that may be a conflict of interest or have the appearance of a conflict of interest with the body's accreditation functions, shall bear a disclaimer stating that the purchase or use of such products is not required for accreditation or certification of any facility under 42 U.S.C. 263b. Any representations about such products shall include a similar disclaimer.

(7) When an accreditation body denies accreditation to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body for the facility to contest the decision.

(8) No State agency that is approved as an accreditation body may require facilities in the State to be accredited under 42 U.S.C. 263b only by the State agency and not by other FDA- approved accreditation bodies.

(9) The accreditation body shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted under § 900.3(d).

(10) An accreditation body shall protect confidential information it collects or receives in its role as an accreditation body.

(i) Nonpublic information collected from facilities for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to FDA or its duly designated representatives, without the consent of the facility;

(ii) Nonpublic information that FDA or its duly designated representatives share with the accreditation body concerning a facility that is accredited or undergoing accreditation by that body shall not be further disclosed except with the written permission of FDA.

(b) *Facility standards.* (1) The accreditation body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those in this subpart and in subpart B of this part.

(2) The accreditation body shall notify a facility regarding equipment, personnel, and other aspects of the facility's practice that do not meet such standards and take reasonable steps to ensure that such equipment, personnel, or other aspects of the practice are not used by the facility for activities covered by 42 U.S.C. 263b.

(3) The accreditation body shall specify the actions that facilities must take to correct deficiencies in equipment, personnel, and other aspects of the practice to ensure facility compliance with applicable standards.

(4) If deficiencies cannot be corrected to ensure compliance with standards or if a facility is unwilling to take corrective actions, the accreditation body shall revoke the facility's accreditation in accordance with the policies and procedures in § 900.3((b)(3)(iii)(I).

(c) *Clinical image review.* (1) Frequency of review. The accreditation body shall review clinical images from each facility accredited by the body at least once every 3 years.

(2) Requirements for clinical image attributes. The accreditation body shall use the following attributes for all clinical image reviews, unless FDA has approved other attributes.

(i) Positioning. Sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning.

(ii) Compression. Compression shall be applied in a manner that minimizes the potential obscuring effect of overlying breast tissue and motion artifact.

(iii) Tissue exposure. Tissue exposure shall be adequate to visualize breast structures. Images shall be neither underexposed nor overexposed.

(iv) Contrast. Image contrast shall permit differentiation of subtle tissue density differences.

(v) Sharpness. Margins of normal breast structures shall be distinct and not blurred.

(vi) Noise. Noise in the image shall not significantly obscure breast structures or suggest the appearance of structures not actually present.

(vii) Artifacts. Artifacts due to lint, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present.

(viii) Examination identification. Each image shall have the following information indicated on it in a permanent and unambiguous manner and placed so as not to obscure anatomic structures:

(A) Examinee identification.

(B) Date of examination.

(C) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(d) or

paragraph (a)(9) of this section shall be used to identify view and laterality.

(D) Facility name and location. At a minimum, the location shall include the city, state, and zip code number of the facility.

(E) Technologist identification.

(F) Cassette/screen identification.

(G) Mammography unit identification, if there is more than one unit in the facility.

(3) Scoring of clinical images. Accreditation bodies shall establish and administer a system for scoring clinical images using all attributes specified in paragraphs(c)(2)(i) through (c)(2)(viii) of this section or an alternative system that FDA has approved in accordance with § 900.3(d) or paragraph (a)(9) of this section. The scoring system shall include an individual scoring scale for each attribute. Each scoring scale shall cover the range from unacceptable deficiencies that markedly reduce the clinical value of an image to no significant deficiencies. Each clinical image submitted shall be scored for each attribute.

(i) The accreditation body shall establish and employ criteria for a pass-fail system for clinical image review that has been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(ii) All clinical images submitted by a facility to the accreditation body shall be reviewed independently by two or more clinical image reviewers.

(4) Selection of clinical images for review. Unless otherwise specified by FDA, the accreditation body shall require that for each mammography unit in the facility:

(i) The facility shall submit craniocaudal (CC) and mediolateral oblique (MLO) views from two mammographic examinations that the facility produced during a time period specified by the accreditation body;

(ii) Clinical images submitted from one such mammographic examination for each unit shall be of dense breasts (predominance of glandular tissue) and the other shall be of fat-replaced breasts (predominance of adipose tissue);

(iii) All clinical images submitted shall be images that the facility's interpreting physician(s) interpreted as normal.

(iv) If the facility has no clinical images meeting the requirements in paragraphs (c)(4)(i) through (c)(4)(iii) of this section, it shall so notify the accreditation body, which shall specify alternative clinical image selection methods that do not compromise care of the examinee.

(5) Clinical image reviewers. Accreditation bodies shall ensure that all of their clinical image reviewers:

(i) Meet the interpreting physician requirements specified in § 900.12(a)(1);

(ii) Are trained and evaluated in the clinical image review process, for the types of clinical images to be evaluated by a clinical image reviewer, by the accreditation body before designation as clinical image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to assure the security and return to the facility of all clinical images received and to assure completion of all clinical image reviews by the body in a timely manner. The accreditation body shall return all clinical images to the facility within 60 days of their receipt by the body, with the following exceptions:

(i) If the clinical images are needed earlier by the facility for clinical purposes, the accreditation body shall work with the facility to accommodate such needs.

(ii) If a clinical image reviewer identifies an abnormality on a clinical image that the facility interpreted as normal, and this finding is not clearly specified on mammography reports submitted with the clinical images, the accreditation body shall ensure that this information is provided and the clinical images returned to the facility no later than 10 business days after identification of the suspected abnormality.

(7) Corrective measures for unsatisfactory image quality. If the accreditation body determines that the clinical images from a facility it accredits are of insufficient quality, the body shall notify the facility of the nature of the problem and its possible causes. The accreditation body shall monitor facility progress in correcting the problem and take appropriate action if the necessary corrective measures are not implemented in a manner and time period satisfactory to the body.

(d) *Phantom image review.* (1) Frequency of review. The accreditation body shall review phantom images from each facility accredited by the body at least once every 3 years.

(2) Requirements for the phantom used. The accreditation body shall require that each facility submit for review phantom images that the facility produced using a phantom and methods of use specified by the body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section.

(3) Scoring phantom images. The accreditation body shall use a system for scoring phantom images that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section.

(4) *Phantom images selected for review.* For each mammography unit in the facility, the accreditation body shall require the facility to submit phantom images that the facility produced during a time period specified by the body.

(5) *Phantom image reviewers.* Accreditation bodies shall ensure that all of their phantom image reviewers:

(i) Meet the requirements specified in § 900.12(a)(3) or alternative requirements established by the accreditation body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section;

(ii) Are trained and evaluated in the phantom image review process, for the types of phantom images to be evaluated by a phantom image reviewer, by the accreditation body before designation as phantom image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any phantom image and provide information to the facility for use in improving its phantom image quality with regard to the significant deficiencies identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to assure the security and return to the facility of all phantom images received and to ensure completion of all phantom image reviews by the body in a timely manner.

(7) Corrective measures for unsatisfactory image quality. If the accreditation body determines that any phantom images are of insufficient quality, the body shall notify the facility of the nature of the problem and its possible causes. The accreditation body shall monitor facility progress in correcting the problem and take appropriate action if the necessary corrective measures are not implemented in a manner and time period satisfactory to the body.

(e) *Reports of mammography equipment evaluation, surveys, and quality control.* The following requirements apply to all facility equipment covered by the provisions of subparts A and B:

(1) The accreditation body shall require every facility applying for accreditation to submit:

(i) With its initial accreditation application, a mammography equipment evaluation performed no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in § 900.12(e).

(ii) A survey which was performed no earlier than 6 months before the date of application for accreditation by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.

(2) The accreditation body shall require that all facilities undergo an annual survey to assure continued compliance with the standards referenced in paragraph (b) of this section and to provide continued oversight of facilities' quality control programs as they relate to such standards. The accreditation body shall require for all facilities that:

(i) Such annual surveys be conducted no later than 14 months after the most recent prior survey;

(ii) Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and

(iii) Facilities submit the results of such surveys, together with quality control records, personnel updates, and other information that the body may require, to the body at least annually.

(3) The accreditation body shall review and analyze the information required in this section and use it to determine the accreditation status of a facility and to identify necessary corrective measures for facilities.

(f) *Onsite visits to facilities and random clinical image reviews.* The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with the facility standards imposed under § 900.3. The accreditation body shall submit annually to FDA, at the address given in § 900.3(b)(1), 3 copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

(1) Onsite visits. (i) Sample size. Annually, each accreditation body shall visit at least 5 percent of the facilities it accredits. However, a minimum of 5 facilities shall be visited, and visits to no more than 50 facilities are required, unless problems identified in paragraph (f)(1)(i)(B) of this section indicate a need to visit more than 50 facilities.

(A) At least 50 percent of the facilities visited shall be selected randomly.

(B) Other facilities visited shall be selected based on problems identified through State or FDA inspections, complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or FDA.

(C) Before, during, or after any facility visit, the accreditation body may require that the facility submit to the body for review clinical images, phantom images, or any other information relevant to applicable standards in this subpart and in subpart B of this part.

(ii) Visit plan. The accreditation body shall conduct visits according to a visit plan that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section. At a minimum, such plan shall address review of the following elements during visits to facilities selected randomly and facilities selected because of previously identified concerns:

(A) Assessment of overall clinical image QA activities of the facility;

(B) Review of facility documentation to determine if appropriate mammography reports are sent to examinees and physicians as required;

(C) Selection of a sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner that does not compromise care of the examinee as a result of the absence of the selected images from the facility;

(D) Review of the facility's medical audit system and assessment of correlation between film and pathology reports for positive cases;

(E) Verification that personnel specified by the facility are the ones actually performing designated personnel functions;

(F) Verification that equipment specified by the facility is the equipment that is actually being used to perform designated equipment functions;

(G) Verification of facility compliance with its consumer complaint mechanism; and

(H) Review of all factors related to previously identified concerns or concerns identified during that visit.

(2) Clinical image review for random sample of facilities. (i) Sample size. In addition to conducting clinical image reviews for initial and renewed accreditation for all facilities, the accreditation body shall conduct clinical image reviews annually for a randomly selected sample of 3 percent of the facilities the body accredits. However, a minimum of five facilities shall be selected for such random clinical image review. Accreditation bodies may count toward this 3 percent requirement all facilities selected randomly for the onsite visits described in paragraph (f)(1)(i)(A) of this section. Accreditation bodies shall not count toward the 3 percent random sample requirement any facilities selected for a visit because of previously identified concerns described in paragraph (f)(1)(i)(B) of this section.

(ii) Clinical image review. In performing clinical image reviews of the 3 percent random sample of facilities, accreditation bodies shall apply the same standards as those in paragraph (c) of this section for review of clinical images for initial and renewed accreditation.

(iii) Accreditation bodies should not schedule random clinical image reviews at facilities that have received notification of need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous 6 months.

(g) *Consumer complaint mechanism.* The accreditation body shall develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility. Such system shall have been approved by FDA in accordance with § 900.3(d) or paragraph (a)(9) of this section. Accordingly, all accreditation bodies shall:

(1) Provide a mechanism for filing a serious complaint with the accreditation body if the complaint has not been resolved at the facility;

(2) Maintain a record of every serious complaint received by the body on all facilities it accredits for a period of at least 3 years from the date of receipt of each such complaint;

(3) Submit to FDA, at the address in paragraph (b)(1) of this section, in a manner and time period specified by FDA, an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them.

(h) *Reporting and recordkeeping.* All reports to FDA specified in paragraphs (h)(1) through (h)(4) of this section shall be prepared and submitted in a format and medium prescribed by FDA and shall be submitted to a location and according to a schedule specified by FDA. The accreditation body shall:

(1) Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated, in a manner and at a time specified by FDA.

(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.12(b)(2) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies or revokes accreditation, or for which the accreditation body denies submission to FDA of information required from facilities for provisional certification or for extension of provisional certification, as described in paragraph (h)(3) of this section, and the reason(s) for such action;

(4) Provide to FDA other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

(i) *Fees.* Fees charged to facilities for accreditation shall be reasonable. Costs of accreditation body activities that are not related to accreditation functions under 42 U.S.C. 263b are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different facilities.

(2) At FDA's request, accreditation bodies shall provide financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees. Such material shall be provided to FDA in a manner and time period specified by the agency.

§ 900.5 Evaluation.

FDA will evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5, or through other means, that an accreditation body is not in substantial compliance with this subpart, FDA shall initiate enforcement actions as follows:

(a) *Major deficiencies.* If FDA determines that an accreditation body has failed to perform a major accreditation function satisfactorily, has demonstrated willful disregard for public health, has violated the code of conduct, has committed fraud, or has submitted material false statements to the agency, FDA may withdraw its approval of that accreditation body.

(1) FDA will notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify facilities accredited or seeking accreditation by it that its approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that an accreditation body has demonstrated deficiencies in performing accreditation functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, FDA shall notify the body that it has a specified period of time to take particular corrective measures directed by FDA or to submit to FDA for approval the body's own plan of corrective action addressing the minor deficiencies. FDA may place the body on probationary status for a period of time determined by FDA, or may withdraw approval of the body as an accreditation body if corrective action is not taken.

(1) If FDA places an accreditation body on probationary status, the body shall notify all facilities accredited or seeking accreditation by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems.

(3) If FDA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the accreditation body. The accreditation body shall notify all facilities accredited or seeking accreditation by it of its loss of approval authority, within a time period and in a manner approved by FDA.

(c) *Reapplication by accreditation bodies that have had their approval withdrawn.* (1) A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If FDA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, FDA may reinstate approval of the accreditation body.

(3) FDA may request additional information or establish additional conditions that must be met by a former accreditation body before FDA approves the reapplication.

(4) FDA will not accept an application from a former accreditation body whose approval was withdrawn because of fraud or willful disregard of public health.

§ 900.7 Hearings.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval or reapproval of accreditation bodies, withdrawal of approval of accreditation bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body. The appeals process shall be specified in writing by the accreditation body and shall have been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(c) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeals process may appeal to FDA for reconsideration in accordance with § 900.15.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 900

[Docket No. 95N–0215]

RIN 0910–AA24

Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.