



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. FDA-2013-N-0134]

RIN 0910-AH04

Mammography Quality Standards Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). We are proposing updates to modernize the regulations by incorporating current science and mammography best practices. These updates would improve the delivery of mammography services by strengthening the communication of healthcare information; allowing for more informed decision making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

*REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2013-N-0134 for “Mammography Quality Standards Act; Amendments to Part 900 Regulations.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or email to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title, Mammography Quality Standards Act; Amendments to Part 900 Regulations.

FOR FURTHER INFORMATION CONTACT: Preetham Sudhaker, Division of Mammography Quality Standards (DMQS), Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301-796-5911.

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I. Executive Summary

A. *Purpose of the Proposed Rule*

Mammography is an x-ray imaging examination used to identify signs of breast cancer. For women to receive the full benefit of mammography, the service must be of high quality, including performance of the examination by qualified technologists; using equipment that is tested and properly functioning; interpretation by qualified physicians; and clear and prompt communication of results to patients and their referring healthcare providers. The MQSA establishes uniform baseline Federal standards designed to ensure that all women nationwide have access to quality mammography services, and its implementing regulations address standards for accreditation bodies and certifying agencies, qualifications of personnel at mammography facilities, standards for mammography equipment, quality assurance testing, recordkeeping, and communication of results. Based on technology changes in mammography and our experience with the administration of the MQSA program, FDA is proposing to modernize and improve the regulations as well as improve the information, including breast

density information, provided by mammography facilities to patients and their healthcare providers. The proposed changes would require that the lay summary provided to patients identify whether the patient has low or high density breasts and include a prescribed paragraph on the significance of breast density. They would also establish four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider.

### *B. Legal Authority*

The MQSA (Pub. L. 102-539) was enacted on October 27, 1992, and is codified under the Public Health Service (PHS) Act (42 U.S.C. 263b; section 354 of the PHS Act). Under the MQSA, all mammography facilities, except facilities of the Department of Veteran Affairs (VA), must be accredited by an approved accreditation body and certified by FDA (or an approved State certification agency) to provide mammography services (42 U.S.C. 263b(b)(1), (d)(1)(iv)). FDA is proposing these amendments to the mammography regulations (set forth in part 900 (21 CFR part 900)) under section 354 of the PHS Act (42 U.S.C. 263b), and sections of the FD&C Act (sections 519, 537, and 704(e); 21 U.S.C. 360i, 360nn, and 374(e)).

### *C. Summary of the Major Provisions of the Proposed Rule*

FDA is proposing three categories of improvements to our mammography regulations: improvements that address changes in mammography technology; improvements that enhance enforcement of quality standards; and improvements in the way mammography results are categorized, reported, retained, and transferred to patients and healthcare providers.

- New and amended proposed provisions related to technology would, among other things, update several equipment and quality control provisions in the regulations to address current technology, including digital mammography.

- Improvements that enhance enforcement would, among other things:
  - Require that mammograms submitted for interpretation be presented in the mammographic modality in which they were originally produced, and not be copied or digitized, which could adversely affect the accuracy of interpretation;
  - Prohibit accreditation bodies from accepting an application for accreditation from a facility that has failed to become accredited after three consecutive attempts until 1 year after the most recent accreditation failure;
  - Expressly state that a facility's certificate may be suspended or revoked due to a failure to comply with reasonable requests by FDA, the State certification agency, or the accreditation body for records, including clinical images for an additional mammography review (AMR), or with reasonable requests by current or former facility personnel for records documenting their qualifications;
  - Add the State certification agency as an entity that may initiate an AMR, which can help detect quality issues, and also to state expressly that FDA and the State certification agency can notify patients and their providers individually or through the mass media when a facility is unable or unwilling to perform a required patient and referring physician notification (PPN), which would help to ensure that patients and providers are informed of serious risks to human health resulting from mammography that fails to meet quality standards;
  - Require that, before a facility closes or no longer provides mammography services, it must make arrangements for access by patients and healthcare providers to mammography images and reports; and

- Require facilities to provide personnel with copies of their MQSA qualification records, which are often needed to work at additional or new facilities.
- Improvements in the way mammography results are categorized, reported, retained, and transferred to patients and healthcare providers would, among other things:
  - Require that the mammographic examination report include the facility name and location (at a minimum, the city, State, and ZIP code of the facility), in order to help to ensure that healthcare providers can obtain the necessary information to enable them to assist women in making informed healthcare decisions;
  - Change the explanatory language in one final assessment category (“benign”) to promote greater consistency and accuracy in the use of the category, and add three new categories of mammographic assessment to the existing categories in the regulations, which would allow mammography facilities to more precisely classify and communicate findings;
  - Add a specific, required timeframe for facilities to deliver medical reports to healthcare providers and the summary written in lay language to patients whose mammograms have either “Suspicious” or “Highly suggestive of malignancy” final assessment categories, which could lead to earlier definitive tissue diagnosis of malignancy and earlier start of treatment, and avoid, for the patient, the anxiety of a protracted waiting period;
  - Require reporting to patients and healthcare providers to include an assessment of breast density, in order to provide them with additional information about their mammography and the potential limitations of their mammogram results so they and their healthcare providers can make informed healthcare decisions;

- Require each mammography facility to implement policies and procedures to minimize the loss of mammography images and reports because the loss of these records can have a significant, negative impact on clinical care, and also specify the timeframe within which facilities must transfer original mammograms and copies of reports to patients, healthcare providers, and others because delays in the transfer of these records can lead to delays in diagnosis or treatment; and
- Clarify the minimum information that facilities must collect during the mammography medical outcomes audit because calculating and tracking these values is important to the evaluation of accuracy in detecting breast cancer, allowing facilities and interpreting physicians to review their performance and enact quality improvement measures.

#### *D. Costs and Benefits of the Proposed Rule*

The primary public health benefits of the proposed rule come from the potential for earlier breast cancer detection, improved morbidity and mortality, resulting in reductions in cancer treatment costs.

The quantified benefits are derived from reduced mortality and breast cancer treatment costs resulting from the breast density reporting requirements. The estimate of annualized benefits over 10 years ranges from \$16.27 million to \$466.75 million at a 7 percent discount rate and \$16.27 million to \$534.03 million at a 3 percent discount rate. The costs of the proposed rule include costs to mammography facilities to comply with the proposed requirements and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years ranges from \$34.96 million to \$60.50 million at a 7 percent discount rate with a primary value of \$47.03 million. Using a 3

percent discount rate, the annualized costs range from \$33.86 million to \$59.40 million with a primary value of \$45.92 million. The primary estimate of the present value of costs over 10 years is \$330.29 million at a 7 percent discount rate and \$391.74 million at a 3 percent discount rate.

## II. Table of Abbreviations and Acronyms Commonly Used in This Document

American College of Radiology	ACR
Centers for Disease Control and Prevention	CDC
Conference of Radiation Control Program Directors, Inc.	CRCPD
Division of Mammography Quality Standards	DMQS
Food and Drug Administration	FDA or we
Federal Food, Drug, and Cosmetic Act	FD&C Act
Institute of Medicine	IOM
Mammography Quality Standards Act of 1992	MQSA
Mammography Quality Standards Reauthorization Acts of 1998 and 2004	MQSRA
National Mammography Quality Assurance Advisory Committee	NMQAAC
Public Health Service Act	PHS Act

## III. Background

According to the Centers for Disease Control and Prevention (CDC), in 2014, the most recent year for which numbers are available, over 235,000 women were diagnosed with breast cancer, and more than 41,000 women died of the disease (Ref. 1). According to the National Cancer Institute of the National Institutes of Health, in 2017, over 250,000 women were projected to be diagnosed with breast cancer, and over 40,000 women were projected to die of the disease (Ref. 2). Among women, breast cancer is now the most common non-skin cancer and the second leading cause of cancer deaths after lung cancer (Ref. 3). Early detection of breast cancer, typically involving breast physical examination and mammography, is the best means of preventing deaths that can result if the diagnosis is delayed until the onset of more

advanced symptoms (Ref. 4). Mammography is a type of medical imaging that uses x-rays to create images (mammograms) of the internal structures of the breasts. There are three types of mammography referred to in this document: screen-film mammography, full field digital mammography, and digital breast tomosynthesis. In screen-film mammography, x-rays are transmitted through the breast and expose a sheet of x-ray film enclosed in a cassette. In full field digital mammography, the x-rays go through to an image receptor that is a radiation-sensitive electronic device or plate. Images are displayed on a computer work station, and can, for example, be digitally magnified. Digital breast tomosynthesis also uses an electronic image receptor and a computer work station, and obtains multiple images at different angles around the breast, then uses a computer to reconstruct a series of parallel images that resemble slices through the breast.

Mammography can help detect breast cancer in its earliest, most treatable stages, when it is too small to be felt or detected by any other method (Ref. 5).

However, as noted by the Government Accountability Office (GAO), a mammogram is among the most difficult radiographic images to interpret (Ref. 6). The mammogram must be of high quality for accurate image interpretation. If the image quality is poor, the interpreter may miss a cancerous lesion. Such a false negative diagnosis could delay treatment and result in an avoidable death or increased morbidity. It is equally true that poor quality images or inaccurate interpretations can lead to a false positive diagnosis when normal tissue is misinterpreted as abnormal. This could lead to needless anxiety for the patient, costly additional testing, and unnecessary biopsies.

#### *A. FDA's Current Regulatory Framework for Mammography*

The MQSA was enacted on October 27, 1992. The passage of the MQSA came after the Senate Committee on Labor and Human Resources held hearings on breast cancer and found a wide range of problems with mammography practice in the United States, including poor quality equipment, a lack of quality assurance (QA) procedures, poorly trained radiologic technologists and interpreting physicians, and a lack of facility inspections and consistent governmental oversight (Refs. 7 and 8). Under the MQSA, a comprehensive statutory scheme for the certification and inspection of mammography facilities was established to ensure that only those facilities that comply with Federal standards of safety and quality could continue to operate after October 1, 1994. Operation after that date is contingent on receipt of an FDA certificate attesting that the facility meets the mammography quality standards. All mammography facilities are subject to the MQSA, except for those under the jurisdiction of the VA. All covered facilities have to meet baseline standards in the areas of radiation dose, equipment, and personnel, and other general practices, such as quality control and quality assurance, are required to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) (42 U.S.C. 263b(b)(1) and (d)(1)(A)(iv)). Facilities must also undergo annual inspections to ensure compliance with the MQSA requirements (42 U.S.C. 263b(g)(1)). The MQSA also provides for oversight and enforcement to help to ensure that mammography services meet these Federal quality standards (42 U.S.C. 263b(h), (i), and (j)).

The Mammography Quality Standards Reauthorization Acts of 1998 and 2004 (MQSRA) (Pub. L. 105-248 and 108-365) amended the MQSA by, among other things, enhancing patient notification concerning health risks and clarifying the types of certificates that could be issued under the MQSA.

Specifically, the MQSA requires the following:

1. Accreditation of mammography facilities by private, nonprofit organizations or State agencies that have been approved by FDA as meeting the standards established by FDA for accreditation bodies and that continue to pass annual FDA reviews of their activities (see 42 U.S.C. 263b(e)(1) and (3)). The MQSA also requires that, as part of the overall accreditation process, actual clinical mammograms from each facility be evaluated for quality by the accreditation body (see 42 U.S.C. 263b(e)(1)(B)(i)).

2. An annual mammography facility physics survey, consultation, and evaluation performed by a qualified medical physicist (see 42 U.S.C. 263b(e)(1)(B)(iv)).

3. Annual inspection of mammography facilities, to be performed by FDA-certified Federal or State inspectors (see 42 U.S.C. 263b(g)(1)(E)). If State inspectors are used, the MQSA requires a Federal audit of the State inspection program by direct Federal inspections of a sample of State-inspected facilities (see 42 U.S.C. 263b(g)(3)).

4. Establishment of initial and continuing qualification standards for interpreting physicians, radiologic technologists, medical physicists, and mammography facility inspectors (see 42 U.S.C. 263b(f)(1)(C)-(E) and (g)(1)(D)).

5. Specification of boards or organizations eligible to certify the adequacy of training and experience of mammography personnel (see 42 U.S.C. 263b(f)(2)).

6. Establishment of quality standards for mammography equipment and practices, including QA and quality control programs (see 42 U.S.C. 263b(f)(1)(A)).

7. Standards governing recordkeeping for patient files and requirements for mammography reporting and patient notification by physicians (see 42 U.S.C. 263b(f)(1)(G)).

8. Establishment of the National Mammography Quality Assurance Advisory Committee (NMQAAC or Committee) (see 42 U.S.C. 263b(n)(1)). Among other things, NMQAAC is

required to advise FDA on appropriate quality standards for mammography facilities and accreditation bodies (see 42 U.S.C. 263b(n)(3)).

*B. History of FDA's Mammography Regulations (21 CFR Part 900)*

FDA published interim mammography regulations on December 21, 1993 (58 FR 67558 and 58 FR 67565; see also 59 FR 49808). These interim regulations established requirements for entities applying to serve as accreditation bodies and for facilities applying to obtain FDA certification to provide mammography services after October 1, 1994. FDA published comprehensive mammography quality standards in a final rule published on October 28, 1997 (62 FR 55852). Most of these regulations became effective on April 28, 1999; the remainder became effective on October 28, 2002. FDA also published a final rule on the MQSA and State certification agencies on February 6, 2002 (67 FR 5446).

*C. Need for New and Amended Regulations*

Most of the requirements in our mammography regulations are over 20 years old. As described below, major developments in understanding relating to the importance of certain breast anatomy on breast cancer risk have occurred and FDA believes these developments should be reflected in our nationwide standard. In addition, we are proposing to update our mammography regulations in response to several gaps that we have identified as we have implemented the current regulations. For example, FDA is proposing to require that both the mammography report and lay summary include basic mammography facility identification information. Technology has also advanced since the regulations were promulgated, so the proposed regulations would make changes to reflect current mammography best practices and technologies.

1. Additional Information in Mammography Reporting: Breast Density

Breast density refers to the proportion of fibroglandular tissue in the breast, as seen on a mammogram. Mammograms of breasts with higher density are harder to interpret than those of less dense breasts, because the dense tissue can obscure cancers (Ref. 9). In 2005, the Institute of Medicine (IOM) noted that breast density is a characteristic of some patients that affects the quality of mammographic interpretation (Ref. 10). In addition, since the publication of the current MQSA regulations, peer reviewed scientific research has confirmed that dense breast tissue is one of the factors that increases the chances that a woman will develop breast cancer (Refs. 11 to 15). The CDC accordingly lists dense breast tissue as one of the risk factors for breast cancer (Ref. 16). Because dense breast tissue can obscure small cancers and is also a risk factor for breast cancer, some women with dense breasts may choose, after consulting with their healthcare provider, to undergo additional screening. Additional screening of women with dense breasts can detect some additional cancers and reduce delays in treatment (Refs. 17 to 19).

On November 4, 2011, FDA convened an open public meeting of the NMQAAC to consider possible changes to the MQSA regulations. At the meeting, FDA sought input from the Committee on the potential inclusion of breast tissue density information in facility mammography reports. The Committee advised that FDA require breast density reporting in mammography reports provided to healthcare providers as well as in lay-language summaries provided to patients (Ref. 20).

The MQSA and current regulations require a mammography facility to provide a written report on each mammographic examination to the patient's healthcare provider (see 42 U.S.C. 263b(f)(1)(G)(ii)(II); § 900.12(c)(3) (21 CFR 900.12(c)(3)). The mammography facility is also required to provide a summary of the report in lay language to the patient (see 42 U.S.C. 263b(f)(1)(G)(ii)(IV); § 900.12(c)(2)). Current regulations do not require that a notification of

breast density be part of the report provided to the healthcare provider or the lay summary provided to the patient. However, there is increasing interest in breast density reporting, and States are taking action. Between 2009 and May 2018, 34 States have passed laws mandating notification of breast density (Ref. 21). These State laws impose requirements that vary from State to State. To ensure all women receive consistent breast density information from their mammograms, FDA is proposing to amend the mammography reporting requirements in § 900.12(c) to require that the written report of the results of the mammographic examination provided to the healthcare provider and the lay summary of the results provided to the patient also include information concerning patient breast density.

## 2. Classifications of Mammography Assessment

Additionally, the current categories do not account for some important clinical and mammographic scenarios, which could lead to confusing communication between interpreting physicians and referring healthcare providers, and may also lessen the usefulness of the required medical outcomes audit if these cases are incorrectly classified. Classification of the assessment of the mammogram is part of the information that a mammography facility currently is required to include in the mammography report (see § 900.12(c)(1)(iv)). Mammography facilities classify their findings regarding a mammogram using the following assessment categories: negative, benign, probably benign, suspicious, and highly suggestive of malignancy (see § 900.12(c)(1)(iv)(A)-(E)), or the assessment “incomplete: need additional imaging evaluation” (see § 900.12(c)(1)(v)). FDA is proposing to add to the current categories two new categories of final assessment (known biopsy proven malignancy and post-procedure mammograms for marker placement), and one new assessment category of incomplete (need prior mammograms for comparison). The addition of these categories would allow the mammography facility to

more precisely classify its findings (see section V.E.3 of this proposed rule and proposed § 900.12(c)(1)). In September 2006, the NMQAAC recommended adding these categories to the assessment categories used in the referring healthcare provider report (Ref. 22).

#### IV. Legal Authority

The MQSA (Pub. L. 102-539) was enacted on October 27, 1992, and is codified at 42 U.S.C. 263b (section 354 of the PHS Act). Under the MQSA, all mammography facilities, except facilities of the VA, must be accredited by an approved accreditation body and certified by FDA (or an approved State certification agency) to provide mammography services (42 U.S.C. 263b(b)(1) and (d)(1)(iv)). FDA is proposing these amendments to the mammography regulations (set forth in part 900) under section 354 of the PHS Act (42 U.S.C. 263b), and sections 519, 537, and 704(e) of the FD&C Act (21 U.S.C. 360i, 360m, and 374(e)).

#### V. Description of the Proposed Rule

##### *A. Definitions of Mammography and Mammographic Modality*

FDA is proposing to amend the definition of “mammography” to exclude computed tomography (CT) of the breast as the requirements in part 900 relating to mammography personnel qualifications and image quality are not applicable to breast CT (§ 900.2(aa)). FDA is also proposing to amend the definition of “mammographic modality” to replace “xeromammography” as an example of a modality with “full field digital mammography,” as the former is an obsolete technology (see § 900.2(z)).

##### *B. Repeated Failure of Accreditation*

FDA is proposing to add a new subsection to the code of conduct and general responsibilities requirements for accreditation bodies, which would prohibit an accreditation body from accepting an application for accreditation from a facility that has failed to become

accredited after three consecutive attempts until 1 year after the most recent failed attempt (proposed § 900.4(a)(6)(ii)).

Upon receipt of an accreditation body's decision that a facility has submitted the necessary information, FDA may issue a provisional certificate to the facility so that it can perform mammography and obtain clinical images for the purposes of ultimately meeting the requirements necessary for accreditation (and later certification). FDA's experience with MQSA program administration has shown that some facilities repeatedly receive a provisional certificate--and continue to perform mammography--but repeatedly resubmit and fail to achieve accreditation. This new subsection would prohibit an accreditation body from accepting an application for accreditation from a facility that has failed to become accredited after three consecutive attempts until 1 year after the most recent accreditation failure (proposed § 900.4(a)(6)(ii)). This would help to ensure that facilities that have repeatedly failed to meet the required quality standards will not continue to offer mammography services while in an unaccredited and provisionally certified status. FDA believes that three consecutive failures signify that a facility is not capable of performing mammography that meets the required quality standards.

### *C. Retention and Provision of Personnel Records*

Mammography personnel in all categories (interpreting physicians, radiologic technologists, and medical physicists) may work in more than one mammography facility. Each facility is required to maintain records of the training and experience supporting the qualification of each of its personnel (see § 900.12(a)(4)). If a facility worker loses his or her personal copy of these records, he or she may attempt to obtain copies from a facility where he or she works. Experience with MQSA program administration has shown that facilities have refused

reasonable requests by personnel for copies of these records. When personnel cannot obtain copies of their records to document their qualifications, they may not be able to work at additional or new facilities, which can lead to reduced public access to mammography services. FDA is proposing to amend the retention of personnel records section to require that facilities provide copies of these records to personnel upon their reasonable request (proposed § 900.12(a)(4)). It would further require that facilities that close or cease to provide mammography services make arrangements for access by personnel to these records.

#### *D. Equipment and Quality Control*

The proposed rule would amend parts of the equipment section to address digital mammography and other changes in technology that have occurred since publication of the current regulations (§ 900.12(b)).

##### 1. Digital Accessories and Unit Conversion

FDA is proposing to add a new provision that would require that facilities use only digital accessory components that were either approved or cleared by FDA specifically for mammography or approved or cleared by FDA for a use that could include mammography and that have the same equipment specifications as those approved or cleared for mammography (§ 900.12(b)(2)). All equipment must be designed for mammography. The mechanism by which it is known that equipment is designed for mammography is that it was approved or cleared by FDA for that use. This proposal clarifies that this is applicable to all equipment, including things such as monitors. This change would ensure that only those components appropriate for mammography would be used clinically.

The proposed rule would also add a provision establishing that a mammography unit that is converted from one mammographic modality to another is considered a new unit at the facility

under this part and, prior to clinical use, must undergo a mammography equipment evaluation demonstrating compliance with applicable requirements. The facility would also have to follow its accreditation body's procedures for applying for accreditation of that unit.

## 2. X-Ray Film/Printer Film

FDA is proposing to rename "X-Ray film" to "Film" and insert the phrase "For facilities using screen-film units" regarding the use of x-ray film (§ 900.12(b)(11)). The revised section also would contain an additional provision that would require that facilities using hardcopy prints of digital images for transfer, retention, or final interpretation purposes use a type of printer film designated by the film manufacturer as appropriate for this purpose and compatible with the printer being used to maintain image quality.

## 3. Quality Assurance Testing for Equipment Other Than Screen-Film

To ensure compliance with image quality standards, FDA is proposing to amend the equipment section to add a new paragraph for equipment of other modalities (proposed § 900.12(b)(16)) that would require that systems with image receptor modalities other than screen-film demonstrate compliance with quality standards by successful results of QA testing as specified in the section for quality control testing--other modalities (§ 900.12(e)(6)).

### *E. Mammography Reporting*

FDA also is proposing to amend section "Medical records and mammography reports" (§ 900.12(c)). The proposed rule would amend the mammography reporting requirements as described below (see § 900.12(c)). Our goal is to revise the mammography reporting regulations to increase the clarity of communication among mammography facilities, healthcare providers, and patients, facilitate the retrieval of mammography images, and help ensure that healthcare providers and patients are obtaining the necessary information from the report of the results of a

mammographic examination to enable a woman and her healthcare provider to make informed healthcare decisions.

## 1. Contents and Terminology

Image quality contributes to accurate interpretation of mammograms. The MQSA and implementing regulations are intended to ensure that quality images are produced. However, FDA's experience has shown that some facilities copy or digitize clinical images, and submit these copies, of lesser quality than the original images, to the interpreting physician for interpretation. This can adversely affect accuracy of interpretation. Therefore, to ensure that the interpreting physician interprets the actual images, which were performed in compliance with MQSA quality standards, FDA is proposing to change this section on content and terminology of medical records and mammography reports to require that the mammograms submitted for interpretation be presented in the mammographic modality in which they were originally produced, and not be copied or digitized (§ 900.12(c)(1)).

## 2. Facility Identification and Other Information

The existing section on content and terminology requires that a mammography facility prepare a written report of each mammographic examination performed under its certificate (§ 900.12(c)(1)). The proposed rule would add a requirement that the report include the facility name and location (at a minimum, the city, State, and ZIP code of the facility) (proposed § 900.12(c)(1)(ii)). This proposed addition would help to ensure that healthcare providers know which facility is providing the report of the results of a mammographic examination so they can follow up with the reporting facility as necessary in order to assist their patients in making informed healthcare decisions.

The existing section on communication of mammography results to the patients requires that the facility provide each patient with a summary of the report in lay language within 30 calendar days of the mammographic examination (§ 900.12(c)(2)). The proposed rule would revise this subsection to require that the lay summary include the name of the patient, and the name, address, and telephone number of the facility performing the mammographic examination. This proposed addition would help to ensure that appropriate mammography facility identification information is included in the lay summary sent to the patient. Experience has shown that inadequate facility identification information in mammography reports and lay summaries can impede communication among healthcare providers and patients and hamper the timely provision of medical care.

### 3. Mammographic Assessment Categories

Mammography facilities classify their findings regarding a mammogram using the categories listed in current categories for final assessment of findings (§ 900.12(c)(1)(iv)), and they report that classification in the written report of the results of each mammography examination sent to the healthcare provider. For each final assessment category in the current regulations, the words in quotation marks are required to be included in the medical report, while the remaining language is intended to provide explanations of the categories to promote their consistent use but is not required to be included in the medical report.

FDA is proposing to change the explanatory language associated with the “benign” assessment category to more accurately reflect and communicate the intent of this category (§ 900.12(c)(1)(iv)(B)). Currently the prescribed wording associated with this assessment is “‘Benign.’ Also a negative assessment.” FDA is proposing to change the wording of this category to “‘Benign.’ Also a normal assessment, with benign findings present, but no evidence

of malignancy (if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be explained).” The mammogram assigned this category is not truly “negative,” as it has one or more findings. However, these findings are benign, and no further evaluation or follow up is recommended. This change would promote greater consistency and accuracy in the use of the “benign” final assessment category.

These proposed changes to the reporting requirements would add three new categories (listed below) of mammographic assessment to the existing categories in the regulations (proposed § 900.12(c)(1)(iv) through (c)(1)(vi)). The addition of these categories would allow the mammography facility to more precisely classify its findings.

One proposed new category is “‘Known Biopsy Proven Malignancy.’ Reserved for known malignancies being evaluated by mammography for definitive therapy” (see proposed § 900.12(c)(1)(iv)(F)). The addition of this final assessment was recommended in the IOM report of 2005 (Ref. 10), which was commissioned by Congress to address concerns about the quality of mammography image interpretation. This recommendation was also supported by the NMQAAC in 2006 (Ref. 22). This assessment would be used when breast imaging is performed after a tissue diagnosis of cancer, but before complete surgical removal of the cancer. The category would alert providers who receive the report that the mammographic finding has already received additional evaluation, including tissue diagnosis, and is not a new finding that requires further evaluation. Additionally, the category would be relevant to the mammography medical outcomes audit, which is required under the MQSA regulations (see § 900.12(f)). For this required audit, each facility must have a system to track a mammogram that is found to be either “suspicious” or “highly suggestive of malignancy” and a process to correlate the mammographic findings with biopsy results. The “Known Biopsy Proven Malignancy” final

assessment could be used to exclude such cases from the mammography medical outcomes audit, in order to avoid counting the same cancer case more than once in an audit. FDA determined that this proposed category could be used as an alternative quality standard (see § 900.18) (Ref. 23).

The second proposed new category is “Post-Procedure Mammograms for Marker Placement” (proposed § 900.12(c)(1)(iv)(G)). The addition of this final assessment category was also supported by the NMQAAC in 2006 (Ref. 20). This category has two roles in current clinical practice. It is primarily used for a mammogram performed following a biopsy to confirm the deployment and position of a breast tissue marker. During a biopsy using a needle to withdraw tissue from a suspicious breast lesion, a marker may be placed at the site, and mammographic images are obtained to assess and document the position of the marker. If this mammogram demonstrates that the marker has not deployed or has migrated, placement of another marker may be necessary before concluding the procedure. Also, if the tissue biopsy result, when it becomes available, shows cancer and further surgery is necessary, the marker identifies the site for further surgical planning. The breast abnormality has already been found to be mammographically suspicious and warranting biopsy, and it will be definitively diagnosed by the tissue biopsy result when available, so this post-procedure mammogram does not contribute to lesion characterization, and other final assessments are not appropriate for this mammogram. The other use of this final assessment category is for a mammogram performed to document the position of a localization needle. During needle localization, a needle is positioned as a temporary marker to direct subsequent surgery for a nonpalpable lesion seen on earlier mammography. The post-procedure mammogram is performed as a guide to identify the suspicious site for the surgeon who will biopsy or excise the lesion and remove the marker

needle. FDA determined that this proposed category could be used as an alternative quality standard (see § 900.18) (Ref. 24).

FDA proposes to add a third new category, “Incomplete: Need prior mammograms for comparison,” for those examinations where no final assessment category can be assigned (proposed § 900.12(c)(1)(v)(B)). This assessment category would be reserved for examinations where comparison with prior mammograms should be performed before one of the other assessment categories is given. If this assessment category is used, a follow up report with one of the other assessment categories must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained. The addition of this assessment category was also supported by the NMQAAC in 2006 (Ref. 22). Comparison to previous examinations is sometimes required to make a final assessment. Assigning this “Incomplete: need prior mammograms” assessment as an assessment category would allow tracking of these examinations to ensure either that prior examinations are obtained and compared in a timely fashion, or, if they remain unavailable, that the current examination is given a definitive final assessment in a timely fashion. This proposed category is part of an assessment that FDA determined could be used as an alternative quality standard (see § 900.18) (Ref. 23).

#### 4. Deadlines for Provision of Lay Summary to Patient and Report to Provider

Current regulations require that if the final assessment in a mammography report is “Suspicious” or “Highly suggestive of malignancy,” the facility should make reasonable attempts to ensure that the results are communicated to the patient and healthcare provider as soon as possible (§ 900.12(c)(2) and (c)(3)(ii)). FDA proposes adding a specific timeframe for delivery of medical reports to healthcare providers and the summary written in lay language to patients whose mammograms have either of these two final assessment categories.

The proposed rule would amend communication of mammography results to patients and healthcare providers to require that, if the assessment of the mammography report is “Suspicious” or “Highly suggestive of malignancy,” the facility must communicate the results to the referring healthcare provider or a healthcare provider named by the patient, within 7 calendar days of the final interpretation of the mammographic examination but in no case later than 14 calendar days from the date of the mammographic examination, and to the patient in the summary written in lay language, within 7 calendar days of the final interpretation of the mammographic examination but in no case later than 21 calendar days from the date of the mammographic examination (§ 900.12(c)(2) and (c)(3)). FDA would require such action by the facility for these two final assessment categories because they both suggest a high possibility of malignancy. We believe that specifying a timeframe for communicating these results, instead of the open-ended “as soon as possible,” which is currently required, could lead to earlier definitive tissue diagnosis of malignancy and earlier start of treatment, and avoid, for the patient, the anxiety of a protracted waiting period.

##### 5. Breast Density Notification

Clinical practice guidelines already recommend that the interpreting physician provide breast density information in the mammography report to the referring healthcare provider (Ref. 25). Moreover, as of May 2018, facilities in 34 States are also required by State law to provide breast density information to patients (Ref. 21). Proposed § 900.12(c)(1)(vi) would require that the patient’s breast density be included in the mammography report that must be provided to the patient’s referring or named healthcare provider. Proposed § 900.12(c)(1)(vi) would establish four categories for reporting breast tissue density in the mammography report: “The breasts are almost entirely fatty.”, “There are scattered areas of fibroglandular density.”, “The breasts are

heterogeneously dense, which may obscure small masses.”, and “The breasts are extremely dense, which lowers the sensitivity of mammography.” These four categories are consistent with current clinical practice guidelines (Ref. 25).

Based on discussion with the NMQAAC in 2011 (Ref. 20), and consistent with current clinical practice (Ref. 26) as well as most State density notification laws (Ref. 27), for notification to patients, FDA has grouped these four categories of breast density into two broader groups: low density and high density. Proposed § 900.12(c)(2)(iii) and (c)(2)(iv) would require that the lay summary provided to patients identify whether the patient has low or high density breasts and include a prescribed paragraph on the significance of breast density.

FDA developed two patient density paragraphs, one intended for patients with low breast density and one for patients with high breast density with input from FDA’s Risk Communication Advisory Committee. The paragraphs contain an explanation of high breast tissue density, as well as specific topics for women to discuss with their healthcare providers.

The purpose of these proposed breast density notification requirements is to provide women and their healthcare providers with additional information regarding their mammography results and the potential limitations of those results to enable women and their healthcare providers to make informed healthcare decisions. As discussed previously, dense breast tissue increases the risk of developing breast cancer (Refs. 11 to 13). Dense breast tissue can also obscure mammographic signs of breast cancer and thus result in a delayed cancer diagnosis (Ref. 9). Women with dense breasts who receive the notification would have additional information about their own anatomy and be positioned to discuss this and make more informed healthcare choices with their healthcare providers. With knowledge of their breast density, some women may choose additional screening using technology approved by FDA, either with indications for

use specifically for dense breasts, or known to be effective for evaluating dense breasts, which could result in additional cancers detected and reduce delays in treatment. For example, a device for automated breast ultrasound has been FDA-approved for use in combination with a screening mammogram for additional breast cancer screening in women with dense breasts and a negative mammogram. One study showed that supplemental ultrasound screening in high-risk women with dense breasts resulted in the detection of 1.1 to 7.2 additional cancers per 1,000 women (Ref. 19). The detection of additional cancers has to be weighed against any increase in false positive results (Ref. 28).

#### 6. Mammography Self-Referrals

Current § 900.12(c)(2)(ii) requires that “Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated,” i.e., when necessitated by the presence of signs or symptoms of disease. However, many cases of breast cancer are identified due to an abnormality on a mammogram, in the absence of any clinical signs or symptoms. Proposed § 900.12(c)(2)(ii) adds the term “mammographically” as another indication for which facilities must maintain a system for referral to a healthcare provider. This addition would help to ensure that patients without healthcare providers and receiving mammographic examinations from a mammography facility are referred to healthcare providers when mammographically appropriate, i.e., when appropriate based on the results of the mammogram, as well as when clinically appropriate.

### *F. Recordkeeping*

#### 1. Policies to Minimize Loss of Records

Current § 900.12(c)(4)(i) requires facilities to maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than

10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law. FDA's experience has shown that, with the widespread use of electronic media for the storage of soft copy images, facilities face new technical challenges regarding maintaining the availability of current and recent mammograms. Since the loss of these images can have a significant impact on patient care, facilities must address these challenges. The proposed rule (proposed § 900.12(c)(4)(i)) would amend this section to require each facility to implement policies and procedures to minimize the possibility of loss of these records. In addition, since copying or digitizing a mammographic image can degrade the quality of the image and potentially lead to incorrect diagnoses, the proposed rule would also require that, to preserve image quality, the mammograms must be retained in retrievable form in the mammographic modality in which they were produced and cannot be produced by copying or digitizing hardcopy originals.

## 2. Transfer of Mammograms and Mammography Reports

Current § 900.12(c)(4)(ii) requires facilities, upon request by, or on behalf of, the patient, to permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly. Since delays in the transfer of these records can lead to delays in diagnosis or treatment, the FDA's proposed rule (proposed § 900.12(c)(4)(ii)) would amend this section to require facilities to release records within 15 calendar days of the facility receiving the transfer request in order to facilitate prompt patient care. Also, copying or digitizing a mammographic image can degrade the quality of the image and potentially lead to incorrect diagnoses. Therefore, to preserve image quality, the proposed rule would also require that the transferred mammograms be in the mammographic modality in which they were produced, and cannot be

produced by copying or digitizing hardcopy originals. Additionally, for digital mammograms or digital breast tomosynthesis, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically.

### 3. Provision of Copies of Mammograms and Mammography Reports

With the widespread use of digital mammography, facilities often retain the original mammogram even when releasing a copy upon the patient's request. Delays in release of these copies can lead to delays in diagnosis or treatment, so FDA is proposing to add § 900.12(c)(4)(iii), which would require that each facility that performs mammograms, upon request by, or on behalf of, the patient, provide copies of mammograms and copies of mammogram reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly, and that the release of the copies must take place within 15 calendar days of the facility receiving such a request in order to facilitate prompt patient care..

### 4. Facility Closure and Record Access

FDA is proposing to add § 900.12(c)(4)(v), which would provide that, before a facility closes or no longer provides mammography services, it must make arrangements for the continued access by patients and healthcare providers to mammograms and reports. This access may be provided by the permanent transfer of mammograms and reports to the patient or her healthcare provider or transfer of the mammograms and reports to a facility or other entity that will continue to provide access to patients and healthcare providers within the time periods specified in § 900.12(c)(4)(i). The facility must notify its accreditation body and certifying agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients as to how to obtain their records.

### *G. Mammography Medical Outcomes Audit*

As part of recordkeeping requirements, the existing MQSA regulations, § 900.12(f), require facilities to perform an audit of medical outcomes of its mammography patients, but do not specify the information to be collected or evaluated during this audit. Recently, the clinical practice community recognized that specific audit metrics are particularly relevant to continuous quality improvement at mammography facilities (Refs. 29 and 30).

Based on this industry best practice, FDA is proposing to clarify the minimum required components of the medical outcomes audit, including the calculation of three clinically significant metrics known as positive predictive value, cancer detection rate, and recall rate (see proposed § 900.12(f)(1)). The latter two metrics incorporate the accepted clinical distinction between a screening mammogram (consisting of routine views for the earlier detection of cancer in an asymptomatic woman) and a diagnostic mammogram (consisting of individualized views for the evaluation of a woman with breast symptoms, physical signs of breast disease, or abnormal findings on a screening mammogram) (Ref. 31). Calculating and tracking these three audit metrics would allow facilities and interpreting physicians to review their performance, evaluate their accuracy in detecting breast cancer, and enact quality improvement measures as necessary. As a result, FDA is proposing to revise § 900.12(f)(1) and add subparagraphs § 900.12(f)(1)(i) through (f)(1)(iii) to clarify the minimum information that must be collected during the audit, including a determination of three of the most clinically significant metrics: positive predictive value, cancer detection rate, and recall rate.

### *H. Additional Mammography Review and Patient and Referring Physician Notification*

Existing § 900.12(j) addresses AMR and PPN. It sets forth the AMR procedures, whereby FDA may require the facility to provide clinical images and other relevant information

to the accreditation body or other entity designated by FDA if FDA believes that mammography quality at the facility has been compromised and may present a serious risk to human health (§ 900.12(j)(1)). If FDA determines that the quality of mammography performed by a facility was so inconsistent with the quality standard established in § 900.12 as to present a significant risk to individual or public health, FDA may require such facility to issue a PPN to notify patients who received mammography at such facility and their referring physicians of the deficiencies and resulting potential harm, appropriate remedial measures, and other relevant information (§ 900.12(j)(2)).

Proposed revised § 900.12(j)(1) adds the State certification agency as an entity that may initiate an AMR. Proposed revised § 900.12(j)(2) would require that referring non-physician healthcare providers receive notification along with referring physicians (many patients are referred for mammography by non-physician healthcare providers), and expressly state that FDA and the State certification agency can notify patients and their providers individually or through the mass media when a facility is unable or unwilling to perform the required notification. This proposed subsection also would make clear that a PPN could be based on information discovered during the AMR or it could be based on other information. These proposals would help to assure that quality mammography services are provided and that patients and providers are informed of significant risk to individual or public health resulting from mammography that fails to meet quality standards.

*I. Additional Bases for Suspension or Revocation of a Certificate, and Ineligibility to Own or Operate After Revocation*

Revisions to § 900.14(a)(3) would expressly state that FDA and State certification agencies can suspend or revoke the certificate of a facility that fails to comply with reasonable

requests by FDA, the State certification agency, or the accreditation body for records, including clinical images for an AMR under § 900.12(j). Experience with MQSA program administration has shown that some facilities are unable or unwilling to cooperate with submissions for such requested materials. The refusal to provide records can delay identification of serious risks to human health or delay notification of significant risk to individual or public health to affected patients and their healthcare providers.

In addition, proposed § 900.14(a)(7) would state that FDA may suspend or revoke the certificate of a facility that fails to comply with reasonable requests by current or former facility personnel for records documenting their qualifications. Experience with MQSA program administration has also shown that facilities have refused reasonable requests to give copies of their records to the personnel named in the records. When personnel cannot obtain copies of their records to document their qualifications under MQSA, they may be prevented from working at additional or new facilities, which can lead to reduced public access to mammography services.

The MQSA (42 U.S.C. 263b(i)) states that upon the finding of certain acts, such as misrepresentation in obtaining a certificate, failure to comply with quality standard requirements, failure to provide certain information to FDA in response to reasonable requests, failure to permit inspection, violation of any provision of the MQSA or regulation promulgated under the MQSA, and failure to comply with a sanction, a facility's certificate may be revoked. If a facility's certificate is revoked, persons who owned or operated the facility at the time of revocation are ineligible to own or operate a mammography facility for 2 years.

FDA is also revising § 900.11(c) to correct a citation error to the MQSA and make clear that § 900.14(c) implements 42 U.S.C. 263b(i) and not 41 U.S.C. 263b(i).

## VI. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 18 months after the date of publication of the final rule in the *Federal Register*. Facilities need time to become familiar with new requirements and to add breast density reporting to their reporting systems.

## VII. Preliminary Economic Analysis of Impacts

### A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many facilities that will be affected by this rule are defined as small businesses, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before

proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

### B. *Summary of Benefits and Costs*

The proposed rule would modernize mammography regulations by incorporating current science and mammography best practices to improve the delivery of mammography services. The proposed updates include requirements on recordkeeping, reporting, and communication of results. This proposed rule also addresses procedural requirements in several areas related to quality control and management of mammography facilities.

The benefits and costs associated with this proposed rule are summarized in table 1. The quantified benefits are derived from reduced mortality and breast cancer treatment costs resulting from the breast density reporting requirements. In this analysis, we use two methods of measuring the value of reduced mortality: the value per statistical life (VSL) approach and an approach based on the value of lost quality-adjusted life years (QALY). Under the VSL approach, the estimate of annualized benefits over 10 years ranges from \$73.24 million to \$466.75 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from \$85.33 million to \$534.03 million. Under the QALY approach, the estimate of annualized benefits over 10 years ranges from \$16.27 million to \$77.23 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from \$16.27 million to \$ 61.77. Because there is uncertainty in the literature about the most appropriate method for

analyzing reduced mortality for the population affected by this proposed rule, we do not present a primary value and use estimates from both methods to create the range of values in Table 1. The high estimate in Table 1 is based on the VSL approach, which yields the higher bound estimate of the two methods. The low estimate is based on the QALY approach, which yields the lower bound estimate of the two methods. Other benefits that we are not able to quantify include improvements in the accuracy of mammography by improving quality control and records management, and effects on morbidity

The costs of the proposed rule include costs to mammography facilities to comply with the proposed requirements and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years ranges from \$34.96 million to \$60.50 million at a 7 percent discount rate with a primary value of \$47.03 million. Using a 3 percent discount rate, the annualized costs range from \$33.86 million to \$59.40 million with a primary value of \$45.92 million. The primary estimate of the present value of costs over 10 years is \$330.29 million at a 7 percent discount rate and \$391.74 million at a 3 percent discount rate.

Table 1.--Summary of Benefits and Costs in Millions 2017 Dollars Over a 10-Year Time Horizon

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$/year		\$16.27	\$466.75	2017	7%	10 years	
			\$16.27	\$534.03	2017	3%	10 years	
	Annualized Quantified					7%		
						3%		
Qualitative	Improvements in the accuracy of mammography and better management of mammography facilities.							
Costs	Annualized Monetized \$/year	\$47.03	\$34.96	\$60.50	2017	7%	10 years	
		\$45.92	\$33.86	\$59.40	2017	3%	10 years	
	Annualized					7%		

	Quantified					3%			
	Qualitative								
Transfers	Federal Annualized Monetized \$/year					7%			
						3%			
	From/ To	From:			To:				
	Other Annualized Monetized \$/year						7%		
							3%		
	From/To	From:			To:				
Effects	State, Local or Tribal Government:								
	Small Business: Annual cost per affected small entity estimated as \$357-\$623, which would represent a maximum of 2.7 percent of annual receipts								
	Wages:								
	Growth:								

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs this proposed rule would be considered a regulatory action under EO 13771.

Table 2.--EO 13771 Summary Tables in Millions 2016 Dollars Over an Infinite Time Horizon

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)
Present Value of Costs	\$615.44	\$446.14	\$804.56	\$1,378.67	\$983.65	\$1,819.96
Present Value of Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Present Value of Net Costs	\$615.44	\$446.14	\$804.56	\$1,378.67	\$983.65	\$1,819.96
Annualized Costs	\$43.08	\$31.23	\$56.32	\$41.36	\$29.51	\$54.60
Annualized Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Annualized Net Costs	\$43.08	\$31.23	\$56.32	\$41.36	\$29.51	\$54.60

### C. Summary of Regulatory Flexibility Analysis

We estimate that there are 4,585 non-hospital facilities and 4,106 hospitals that perform mammography. A minimum of 3,865 of the mammography facilities in operation for the entire

year, or 95 percent of the total, would be small. At least 382 of all hospitals with less than \$10 million in annual receipts, or 9 percent of the total, are small. The estimated one-time cost is \$4,100 to \$6,474 per facility. The estimated annual cost is \$357 to \$623 per facility. One-time costs are 26.7 percent of receipts and annual costs are 4.1 percent of receipts for the smallest diagnostic imaging centers. Based on this, we conclude that the proposed rule, if finalized, would have a significant impact on a substantial number of small entities. The proposed regulation would have smaller effects on hospitals because they provide more diversified services and tend to be larger. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 32) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>. We solicit comment about the analysis of economic impacts.

#### VIII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

#### IX. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information in part 900 have been approved under OMB control number 0910-0309. The proposed amendments to part 900 in this document necessitate revisions to OMB control number 0910-0309. A description of

the proposed amendments that necessitate revisions to the annual third-party disclosure burden is given in the *Description* section below. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's information collection provisions that are subject to review functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Mammography Facilities, Standards, and Lay Summaries for Patients

*Description:* FDA is proposing to amend its mammography reporting requirements to require that the mammography report provided to the healthcare provider and the lay summary report provided to the patient include basic mammography facility identification information and information concerning patient breast density. This action is intended to facilitate communication between mammography facilities, healthcare providers, and patients; facilitate the retrieval of mammography images; and help ensure that healthcare providers and patients obtain the necessary information from the mammography facility to enable a woman and her healthcare provider to make informed healthcare decisions. FDA also is proposing additional categories be added to the list of assessments that facilities are required to use in the mammography report. In addition, FDA is proposing to amend its requirements related to the

transfer and provision of mammography records, the transfer and provision of personnel records upon request or facility closure, and FDA notification and mammographic records access upon facility closure.

*Description of Respondents:* Respondents to this information collection are facilities that provide mammographic examinations and State certification.

*Agencies:* As of May 1, 2018, FDA internal data on facilities showed that there were 8,691 facilities certified to perform mammography. In addition to mammography-performing facilities, the regulation would also affect four State certification agencies (Ref. 33).

FDA estimates the burden of this collection of information as follows:

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours <sup>2</sup>
Provision of personnel records - 900.12(a)(4)	608	1	608	0.08 (5 minutes)	49
Transfer of personnel records by closing facilities-- 900.12(a)(4)	87	1	87	5	435
New assessment categories and breast density reporting in mammography report (one-time burden)-- 900.12(c)(1)(iv)-(c)(1)(vi)	8,691	1	8,691	23	199,893
Breast density reporting in lay summary (one-time burden)-- 900.12(c)(2)	8,691	1	8,691	11	95,601
Transfer/provision of copies of mammograms and records upon patient's request-- 900.12(c)(4)(ii) and (c)(4)(iii)	8,691	1,508	13,109,566	0.08 (5 minutes)	1,048,765

Facility closure; notification and records access-- 900.12(c)(4)(v)	87	1	87	32	2,784
Patient notification of significant risk (by State certification agency)-- 900.12(j)(2)	5	1	5	100	500
Total					1,348,027

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Columns may not sum due to rounding.

*Personnel records--§ 900.12(a)(4):* Under § 900.12(a)(4), facilities are required to maintain records of training and experience regarding personnel who work or have worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. Facilities must maintain records of personnel no longer employed by the facility at least until the next annual inspection and until FDA has determined that the facility is in compliance with the MQSA personnel requirements. FDA is not proposing any changes to these requirements. The information collection (recordkeeping) burden for this provision is currently approved under OMB control number 0910-0309.

Also under proposed § 900.12(a)(4), facilities would have to provide copies of personnel records to current or former interpreting personnel (physician, radiological technologist and medical physicist) upon their reasonable request. We estimate that there are, on average, seven interpreting personnel per facility (approximately 60,837 total). We estimate that 1 percent of these personnel (608 personnel annually) would request the records and that it would take approximately 5 minutes to provide the copies for each request.

Additionally, under proposed § 900.12(a)(4), before a facility closes or ceases to provide mammography services, it would have to make arrangements for personnel to access their MQSA personnel records. This access may be provided by the permanent transfer of these

records to the personnel or the transfer of the records to a facility or other entity that would provide access to these records. We estimate that annually 1 percent of the total facilities would close or cease to provide mammography services and that it would take each of the facilities approximately 5 hours to transfer the records.

*Medical records and mammography reports--§ 900.12(c)(1) through (c)(4):* Section 900.12(c)(1), *Contents and terminology*, sets forth the requirement for facilities to prepare a written report of the results of each mammographic examination performed under its certificate. Section 900.12(c)(1) requires that the report include patient identifying information, date of examination, facility name and location, the final assessment of findings (or classification as to why no final assessment can be made), name of the interpreting physician, and recommendations to the healthcare provider.

This proposed rule would include two additional final assessment categories and an additional classification in the mammography report and would also require an assessment of breast density in the report (proposed § 900.12(c)(1)(iv) through (c)(1)(vi)). We estimate a one-time burden for facilities to update their existing mammography reports with these new categories. Based on the Eastern Research Group (ERG), Inc.'s report, we believe this would take 23 hours per facility (Ref. 34).

Under the proposed rule, if the final assessment is “Suspicious” or “Highly suggestive of malignancy,” the facility would have to provide the report to the healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee (proposed § 900.12(c)(3)(ii)) within a specified timeframe; the current regulation states that facilities must make reasonable attempts to provide the report in such situations “as soon as possible.” The provision of the report to the healthcare provider was not included in the currently approved

information collection burden, OMB control number 0910-0309, because it was considered usual and customary practice and was part of the standard of care prior to the implementation of the regulations (see 5 CFR 1320.3(b)(2)). Provision of the mammography report to healthcare providers continues to be part of the standard of care and remains the usual and customary business practice. Therefore, these changes would not result in additional burden.

Under § 900.12(c)(2), *Communication of mammography results to the patients*, within 30 days of the mammographic examination, each facility shall provide each patient a summary of the mammography report written in lay terms. Under the proposed rule, if the final assessment is “Suspicious” or “Highly suggestive of malignancy,” the facility would have to provide the patient a summary of the mammography report within a specified timeframe (proposed § 900.12(c)(2)); the current regulation states that facilities must make reasonable attempts to provide the report in such situations “as soon as possible.” Under the proposed rule, this summary would need to include the name of the patient and name, address, and telephone number of the facility. We estimate that the proposed requirements for the lay summary to include this information would not result in a change to the currently approved information collection burden for § 900.12(c)(2).

Proposed § 900.12(c)(2) also would require facilities to provide an assessment of breast density in the lay summary. We estimate a one-time burden for facilities to update their existing lay summary reports with the breast density assessments. Based on the ERG report, we believe this would take 11 hours per facility (Ref. 34).

Also, under § 900.12(c)(2)(ii), each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated. The proposed rule would also require that the system provide referrals

when “mammographically” indicated. We estimate this proposed addition would not result in a change to the currently approved information collection burden.

The proposed requirements in § 900.12(c)(2)(iii) and (c)(2)(iv) to provide an explanation of the breast density assessment identified in § 900.12(c)(1)(vi) are not considered to be “collections of information” because the language is originally supplied by the Federal government for the purpose of disclosure to members of the public (5 CFR 1320.3(c)(2)).

Under proposed § 900.12(c)(4)(i), facilities that perform mammograms must maintain mammographic records. The proposed rule would require that facilities implement policies and procedures to minimize the possibility of record loss and would require that records be maintained in the modality in which they were produced. We estimate these proposed additions would not result in a change to the currently approved information collection burden.

Under § 900.12(c)(4)(ii), facilities shall, upon request by or on behalf of the patient, transfer or release the mammograms and copies of the patient’s reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly. Under proposed § 900.12(c)(4)(ii) and (c)(4)(iii), facilities would need to transfer original mammograms (and copies of associated reports) or provide copies of mammograms (and copies of associated reports) within a specified period of time. Copies of mammograms would need to be in the same modality in which they were produced. Moreover, for digital mammograms or digital breast tomosynthesis, the facility would have to be able to provide the recipient with original digital images electronically if the examination is being transferred for final interpretation. While the burden of maintaining records under § 900.12(c)(4) is included in the currently approved burden estimate, the currently approved burden estimate does not include the third-party disclosure burden of transferring the records. We estimate that approximately one third of patients would

request transfer or release of the records (this equals an average of approximately 1,508 requests per facility) and it would take approximately 5 minutes per request.

Under proposed § 900.12(c)(4)(v), before a facility closes or ceases to provide mammography services, it would have to make arrangements for access by patients and healthcare providers to their mammographic records. Additionally, the facility would have to notify its accreditation body and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients. We estimate that 1 percent of facilities would close on an annual basis and that it would take each facility approximately 32 hours to provide notification and access to the records.

*Quality assurance-mammography medical outcomes audit--§ 900.12(f):* Section 900.12(f)(1) requires each facility to establish a system to collect and review outcome data for all mammographic examinations performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. The proposed rule would clarify that positive predictive value, cancer detection rate, and recall rate would have to be collected during this audit. We estimate that the proposed clarifications would not result in a change to the currently approved information collection burden.

*Additional mammography review and patient and referring physician notification--§ 900.12(j):* Under § 900.12(j)(1), if FDA believes that mammographic quality at a facility has been compromised and may present a serious risk to human health, the facility must provide clinical images and other relevant information for review by the accreditation body or other entity designated by FDA. Under the proposed rule, the State certification agency may request

and then review such information. We estimate these proposed revisions would not result in a change to the currently approved information collection burden.

Under § 900.12(j)(2), when FDA has determined that the quality of mammography performed by the facility poses a significant risk to human health, a facility may be required to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians of the deficiencies and resulting potential harm, appropriate remedial measures, and other relevant information. Under the proposed rule, facilities would need to notify referring non-physician healthcare providers (along with referring physicians). We estimate this proposed revision would not result in a change to the currently approved information collection burden. Also under the proposed rule, State certification agencies (along with FDA) would have the authority to notify patients and their providers if a facility is unable or unwilling to do so. We estimate that the burden to State certification agencies would be similar to the approved burden estimate for facilities; approximately five notifications per year will take 100 hours per notification.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the title, “Mammography Facilities, Standards, and Lay Summaries for Patients (OMB control number 0910-0309)”.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule (revisions of collections approved under OMB control number 0910-0309) to OMB for review. These requirements will not be effective

until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the *Federal Register*.

#### X. Federalism

The MQSA established minimum national quality standards for mammography. The MQSA replaced a patchwork of Federal, State, and private standards with uniform Federal standards designed to ensure that all women nationwide receive adequate quality mammography services. FDA has worked very closely with State officials in developing the national standards for the MQSA program and has sought and obtained input from States at every step of the process.

FDA issued final rules implementing the MQSA on October 28, 1997 (“Quality Mammography Standards,” 62 FR 55852) and February 6, 2002 (“State Certification of Mammography Facilities,” 67 FR 5446). As required by Executive Order 13132 (August 4, 1999), FDA prepared a federalism assessment in this latter final rule and determined that the rule was consistent with the federalism principles expressed in Executive Order 13132.

The proposed amendments to the MQSA regulations, among other things, are intended to amend the requirements for reporting to healthcare providers and patients to assure that patients receive all necessary information after their mammograms, including an assessment of breast density, while not unduly burdening the mammography facility.

Although certain proposed provisions impact Federal-State relations, FDA does not believe that they impose any additional, significant burden on the States. The division of responsibilities between FDA, the States, and State agencies would not change if the proposed regulations were finalized, as these proposals would continue to provide for necessary uniformity of minimum national standards and, at the same time, provide maximum flexibility to States

administering the States as Certifier program within their State, and State agencies serving as accreditation bodies.

On November 4, 2011, FDA convened a public meeting of the NMQAAC where possible amendments to the MQSA regulations, including breast density reporting, were discussed (Ref. 18). This meeting was open to the public and time was allotted for public statements on issues of concern in the mammography field. FDA has also met and held teleconferences several times a year with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern.

The Agency also has long enjoyed a good relationship with the Conference of Radiation Control Program Directors, Inc. (CRCPD), which is the professional organization of the State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

For the reasons discussed previously, FDA believes that this proposed rule is consistent with the federalism principles expressed in Executive Order 13132.

## XI. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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#### List of Subjects in 21 CFR Part 900

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 900 is amended as follows:

#### PART 900--MAMMOGRAPHY

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

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

2. Amend § 900.2 by revising paragraphs (z), (aa)(1) and (2), and by adding new paragraph (aa)(3) to read as follows:

§ 900.2 Definitions.

\* \* \* \* \*

(z) *Mammographic modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and full field digital mammography.

(aa) \* \* \*

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures;

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter; or

(3) Computed tomography of the breast.

\* \* \* \* \*

3. Amend § 900.4 by redesignating paragraph (a)(6) as (a)(6)(i) and by adding new paragraph (a)(6)(ii).

The addition reads as follows:

§ 900.4 Standards for accreditation bodies.

(a) \* \* \*

(6)(i) \* \* \*

(ii) If a facility has failed to become accredited after three consecutive attempts, an accreditation body shall not accept an application for accreditation from the facility for a period of 1 year from the date of the most recent accreditation failure.

\* \* \* \* \*

4. In § 900.11 revise paragraph (c)(4) to read as follows:

§ 900.11 Requirements for certification.

\* \* \* \* \*

(c) \* \* \*

(4) If a facility's certificate was revoked on the basis of an act described in 42 U.S.C. 263b(i)(1), as implemented by § 900.14(a), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

5. Amend § 900.12 by:

- a. Revising paragraph (a)(4);
- b. Adding paragraphs (b)(2)(i) and (ii);
- c. Revising paragraph (b)(11);
- d. Adding paragraph (b)(16); and
- e. Revising paragraphs (c)(1) and (2), (c)(3)(ii), (c)(4), (f)(1), and (j).

The additions and revisions read as follows:

§ 900.12 Quality standards.

(a) \* \* \*

(4) *Retention of personnel records.* Facilities shall maintain records of training and experience relevant to their qualification under MQSA for personnel who work or have worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility must be maintained at least until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements. The facility shall provide copies of these personnel records to current or former interpreting physicians, radiologic technologists, and medical physicists upon their reasonable

request. Before a facility closes or ceases to provide mammography services, it must make arrangements for access by personnel to their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records.

(b) \* \* \*

(2) \* \* \*

(i) All digital accessory components shall be approved or cleared by FDA,

(A) Specifically for mammography or,

(B) For a use that could include mammography and have the same equipment specifications as those approved or cleared by FDA specifically for mammography.

(ii) A mammography unit that is converted from one mammographic modality to another is considered a new unit at the facility under this part and must, prior to clinical use, undergo a mammography equipment evaluation demonstrating compliance with applicable requirements. The facility must also follow its accreditation body's procedures for applying for accreditation of that unit.

\* \* \* \* \*

(11) *Film*. For facilities using screen-film units, the facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography. For facilities using hardcopy prints of digital images for transfer, retention, or final interpretation purposes, the facility shall use a type of film designated by the film manufacturer as appropriate for these purposes and compatible with the printer being used.

\* \* \* \* \*

(16) *Equipment--other modalities.* Systems with image receptor modalities other than screen-film shall demonstrate compliance with quality standards by successful results of quality assurance testing as specified under paragraph (e)(6) of this section.

(c) *Medical records and mammography reports--(1) Contents and terminology.* Each facility shall prepare a written report of the results of each mammographic examination performed under its certificate. The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed, and must not consist of digital images produced through copying or digitizing hardcopy original images. The mammography report shall include the following information:

- (i) The name of the patient and an additional patient identifier;
- (ii) Date of examination, facility name, and location. At a minimum, the location shall include the city, State, ZIP code, and telephone number of the facility;
- (iii) The name of the interpreting physician who interpreted the mammogram;
- (iv) Overall final assessment of findings, classified in one of the following categories:
  - (A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);
  - (B) "Benign." Also, a normal result, with benign findings present, but no evidence of malignancy (if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be explained);
  - (C) "Probably Benign." Finding(s) has a high probability of being benign;
  - (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) “Highly suggestive of malignancy:” Finding(s) has a high probability of being malignant;

(F) “Known Biopsy Proven Malignancy.” Reserved for known malignancies being mammographically evaluated for definitive therapy; and

(G) “Post-Procedure Mammograms for Marker Placement.” Reserved for a post-procedure mammogram used to confirm the deployment and position of a breast tissue marker.

(v) In cases where no final assessment category can be assigned due to incomplete work-up, one of the following classifications shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician.

(A) “Incomplete: Need additional imaging evaluation.” Reserved for examinations where additional imaging needs to be performed before an assessment category identified in paragraph (c)(1)(iv)(A) through (G) of this section can be given; or

(B) “Incomplete: Need prior mammograms for comparison.” Reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in paragraph (c)(1)(iv)(A) through (G) of this section can be given. If this assessment category is used, a follow up report with an assessment category identified in paragraph (c)(1)(iv)(A) through (E) of this section must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained.

(vi) Overall assessment of breast density, classified in one of the following categories:

(A) “The breasts are almost entirely fatty.”

(B) “There are scattered areas of fibroglandular density.”

(C) “The breasts are heterogeneously dense, which may obscure small masses.”

(D) “The breasts are extremely dense, which lowers the sensitivity of mammography.”

(vii) Recommendations made to the healthcare provider about what additional actions, if any, should be taken. All clinical questions raised by the referring healthcare provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

(2) *Communication of mammography results to the patients.* Each facility shall provide each patient a summary of the mammography report written in lay terms within 30 calendar days of the mammographic examination which shall, at a minimum, include the name of the patient, the name, address, and telephone number of the facility performing the mammographic examination and an assessment of breast density as described in paragraph (c)(1)(vi) of this section. If the assessment of the mammography report is “Suspicious” or “Highly suggestive of malignancy,” the facility shall provide the patient a summary of the mammography report written in lay language within 7 calendar days of the final interpretation of the mammograms but in no case later than 21 calendar days from the date of the mammographic examination.

(i) Patients who do not name a healthcare provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.

(ii) Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when mammographically or clinically indicated.

(iii) If the mammography report identifies the patient’s breast density as “The breasts are almost entirely fatty” or “There are scattered areas of fibroglandular density,” the lay summary shall include “Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is low,

not high. Follow the recommendations in this letter, and talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation.”

(iv) If the mammography report identifies the breast density as “The breasts are heterogeneously dense, which may obscure small masses” or “The breasts are extremely dense, which lowers the sensitivity of mammography,” the lay summary shall include “Some patients have high breast tissue density (more glands than fat in the breasts), which makes it harder to find breast cancer on a mammogram. Your breast tissue density is high. Some patients with high breast density may need other imaging tests in addition to mammograms. Follow the recommendations in this letter, and talk to your healthcare provider about high breast density and how it relates to breast cancer risk, and your individual situation.”

(3) \* \* \*

(ii) If the assessment is “Suspicious” or “Highly suggestive of malignancy,” the facility shall provide a written report of the mammographic examination, including the items listed in paragraph (c)(1) of this section, to the referring healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee of the referring healthcare provider within 7 calendar days of the final interpretation of the mammograms but in no case later than 14 calendar days from the date of the mammographic examination.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain the mammograms and mammography reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law. Facilities shall implement policies and procedures to minimize the possibility of loss of these

records. The mammograms must be retained in retrievable form in the mammographic modality in which they were produced. They cannot be produced by copying or digitizing hardcopy originals.

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly during the time specified in paragraph (c)(4)(i) of this section. Transfer of the mammograms and mammography reports must take place within 15 calendar days of the facility receiving such request. The transferred mammograms must be in the mammographic modality in which they were produced, and cannot be produced by copying or digitizing hardcopy originals. For digital mammograms or digital breast tomosynthesis, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically;

(iii) Shall upon request by, or on behalf of, the patient, provide copies of mammograms and copies of mammogram reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly during the time specified in paragraph (c)(4)(i) of this section. Release of the copies must take place within 15 calendar days of the facility receiving such request;

(iv) Any fee charged to the patients for providing the services in paragraphs (c)(4)(ii) or (c)(4)(iii) of this section shall not exceed the documented costs associated with this service; and

(v) Before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records. This access may be provided by the permanent transfer of mammographic records to the patient or her healthcare provider or the transfer of the mammographic records to a facility or other

entity that will provide access to patients and healthcare providers for the time periods specified in paragraph (c)(4)(i) of this section. The facility must notify its accreditation body and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients.

\* \* \* \* \*

(f) \* \* \*

(1) *General requirements.* For the purposes of these requirements, a mammographic examination consisting of routine views of an asymptomatic woman shall be termed a screening mammogram, while a mammographic examination consisting of individualized views of a woman with breast symptoms, physical signs of breast disease, or abnormal findings on a screening mammogram shall be termed a diagnostic mammogram. Each facility shall establish a system to collect and review outcome data for all mammographic examinations performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. In addition, for cases of breast cancer among patients imaged at the facility that subsequently become known to the facility, the facility shall promptly initiate follow up on surgical and/or pathology results and review of the mammographic examinations taken prior to the diagnosis of a malignancy. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians and, at a minimum, shall consist of a determination of the following:

(i) Positive predictive value--percent of patients with positive mammograms who are diagnosed with breast cancer within 1 year of the date of the mammographic examination.

(ii) Cancer detection rate--of the patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious,"

or “Highly suggestive of malignancy” on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within 1 year of the date of the initial screening mammogram, expressed arithmetically as a ratio per 1,000 patients.

(iii) Recall rate--percentage of screening mammograms given an assessment of “Incomplete: Need additional imaging evaluation.”

\* \* \* \* \*

(j) *Additional mammography review and patient and referring physician notification.*

(1) If FDA or the State certification agency believes that mammographic quality at a facility has been compromised and may present a significant risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA or the State certification agency, for review by the accreditation body or the State certification agency. This additional mammography review will help FDA or the State certification agency determine whether the facility is in compliance with this section and whether there is a need to notify affected patients, their referring physicians or healthcare providers, and/or the public that there is a significant risk to human health.

(2) Based on the results of the additional mammography review, the facility's failure to comply with the terms of the additional mammography review, or other information, FDA or the State certification agency may determine that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in this part as to present a significant risk to human health. FDA or the State certification agency may require such a facility to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians or healthcare providers, of the deficiencies and

resulting potential harm, appropriate remedial measures, and such other relevant information as FDA or the State certification agency may require. Such notification shall occur within a timeframe and in a manner specified by FDA or the State certification agency. If the facility is unable or unwilling to perform such notification, FDA or the State certification agency may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

6. In § 900.14, revise paragraph (a) introductory text and paragraphs (a)(3), (5), and (6), and add paragraph (a)(7) to read as follows:

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for a hearing in accordance with part 16 of this chapter, that the facility, owner, operator, or any employee of the facility:

\* \* \* \* \*

(3) Has failed to comply with reasonable requests of FDA, the State certification agency, or the accreditation body for records, information, reports, or materials, including clinical images for an additional mammography review under § 900.12(j), that FDA or the State certification agency believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

\* \* \* \* \*

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b;

(6) Has failed to comply with prior sanctions imposed by FDA or the State certification agency under 42 U.S.C. 263b(h), including a directed plan of correction or a patient and referring

physician notification; or

(7) Has failed to comply with reasonable requests of current or former facility personnel for records of their training or experience relevant to their qualification under MQSA, in violation of § 900.12(a)(4).

\* \* \* \* \*

Dated: March 21, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

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