

# 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:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule 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 issuing updates to modernize the regulations by incorporating current science and mammography best practices. These updates are intended to 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:** This rule is effective on September 10, 2024.

**ADDRESSES:** For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**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 Final Rule

Mammography is an x-ray imaging examination used to identify signs of breast cancer. For patients 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, among other things, that all patients nationwide have access to quality mammography services. The MQSA implementing regulations address, among other things, standards for accreditation bodies and certifying agencies and mammography quality standards for facilities, such as qualifications of personnel at mammography facilities, standards for mammography equipment, the content and terminology for mammography reports, the requirement to establish a quality assurance program, standards and timing for quality assurance testing, standards for clinical image quality, recordkeeping, communication of results, and clinical image review by the facility's accrediting body. Based on technology changes in mammography and our experience with the administration of the MQSA program, FDA is modernizing and updating the regulations as well as improving the information, including breast density information, provided by mammography facilities to patients and their healthcare providers. This final rule requires that the summary of the mammography report written in lay terms (“lay summary”) that is provided to patients identifies whether the patient has dense or non-dense breast tissue and includes a prescribed paragraph on the significance of breast density. The rule also establishes 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 was enacted on October 27, 1992, and is codified, as amended in 1998 and 2004, under section 354 of the Public Health Service (PHS) Act. Public Law 102-539, 2, 106 (1992), *codified as amended* at 42 U.S.C. 263b. Under the MQSA, all mammography facilities, except facilities of the Department of Veterans Affairs (VA), must be accredited by an approved accreditation body (AB) and certified by FDA (or an approved State certification agency) to provide mammography services. FDA is amending the mammography regulations established under the PHS Act, and sections of the FD&C Act.

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

FDA is making 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. Specifically, in this final rule FDA is making the following amendments:

- New and amended provisions related to technology that, among other things, update several equipment and quality control provisions in the regulations to address current technology, including digital mammography;
- Improvements that enhance enforcement that, 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 from hardcopy original images, 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 requests by FDA, the State certification agency, or the AB for records, including clinical images for an additional mammography review (AMR), or with 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 that, among other things:

- Require that the mammographic examination report include the facility name and location (at a minimum, the city, State, ZIP code, and telephone number of the facility), in order to help to ensure that healthcare providers can obtain the necessary information to enable them to assist patients 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 will allow mammography facilities to precisely classify and communicate findings;

- Add a specific, required timeframe for facilities to send mammography reports to healthcare providers and the summary written in lay terms 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 that patients and their healthcare providers can make informed healthcare decisions by;

- Retaining the two categories of density in the patient lay summary, but changing the wording from the comparative terms "high density" and "low density" to "dense" and "not dense," in order to align with clinical practice and improve clarity to the patient.

- Revising the written lay summary of the results provided to the patient to contain one of the following breast density notification statements. The non-dense breast notification (see § 900.12(c)(2)(iii) in this final rule) now states, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast

tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." The dense breast notification (see § 900.12(c)(2)(iv) in this final rule) now states, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

- Requiring that the written report of the results of the mammographic examination provided to the healthcare provider include information concerning an 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."

- 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 Final Rule*

The quantified benefits of this rule 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 \$12.99 million to \$232.69 million at a 7 percent discount rate and \$8.50 million to \$266.09 million at a 3 percent discount rate. Other benefits that we are not able to quantify include reduced cancer morbidity and improvements in the accuracy of mammography by

improving quality control and strengthening the medical audit. The costs of the final rule include costs to mammography facilities to comply with the 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 \$28.87 million to \$45.42 million at a 7 percent discount rate with a primary value of \$36.31 million. Using a 3 percent discount rate, the annualized costs range from \$27.61 million to

\$44.16 million with a primary value of \$35.05 million.

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

Abbreviation or acronym	What it means
AB .....	Accreditation Body.
ACR .....	American College of Radiology.
ACS .....	American Cancer Society.
AMR .....	Additional Mammography Review.
BICOE .....	Breast Imaging Centers of Excellence.
BI-RADS .....	Breast Imaging—Reporting and Data System.
CAD .....	Computer-Aided Detection.
CD .....	Compact Discs.
CDC .....	Centers for Disease Control and Prevention.
CDR .....	Cancer Detection Rate.
CDRH .....	Center for Devices and Radiological Health.
CFR .....	Code of Federal Regulations.
CRCPD .....	Conference of Radiation Control Program Directors, Inc..
DBT .....	Digital Breast Tomosynthesis.
DICOM .....	Digital Imaging and Communication in Medicine.
DMQS .....	Division of Mammography Quality Standards.
ERG .....	Eastern Research Group.
FDA, Agency, or we .....	Food and Drug Administration.
FD&C Act .....	Federal Food, Drug, and Cosmetic Act.
FFDM .....	Full-Field Digital Mammography.
FRIA .....	Final Regulatory Impact Analysis.
HIPAA .....	Health Insurance Portability and Accountability Act of 1996.
IP .....	Interpreting Physician.
MBI .....	Molecular Breast Imaging.
MQSA .....	Mammography Quality Standards Act of 1992.
MQSRA .....	Mammography Quality Standards Reauthorization Acts of 1998 and 2004.
MRI .....	Magnetic Resonance Imaging.
NAPBC .....	National Accreditation Program for Breast Centers.
NMQAAC .....	National Mammography Quality Assurance Advisory Committee.
OMB .....	Office of Management and Budget.
PACS .....	Picture Archiving and Communication System.
PGHS .....	Policy Guidance Help System.
PHS Act .....	Public Health Service Act.
PPN .....	Patient and Referring Physician Notification.
PPV .....	Positive Predictive Value.
QC .....	Quality Control.
QI .....	Quality Indicator.
SCA .....	State Certification Agency.
U.S.C. ....	United States Code.
USPSTF .....	U.S. Preventive Services Task Force.
VA .....	Department of Veterans Affairs.

## III. Background

According to the Centers for Disease Control and Prevention (CDC), in 2018, the most recent year for which numbers are available, over 254,000 women were diagnosed with breast cancer, and more than 42,000 women died of the disease (Ref. 1). According to the National Cancer Institute of the National Institutes of Health, in 2020, over 276,000 women were projected to be diagnosed with breast cancer, and over 42,000 women were projected to die of the disease (Ref. 2). Breast cancer is rare in men, with approximately 2,300 new cases and 500 deaths reported in the United States in 2017, according to the CDC (Ref. 3). Among women, however, breast cancer is now the most common

non-skin cancer and the second leading cause of cancer deaths after lung cancer (Ref. 4). There are also disparities in both the incidence of breast cancer, and in mortality from breast cancer, by both race and ethnicity. In 2019, the latest year for which incidence data are available, in the United States, 30,450 new cases of breast cancer were reported among Black, Non-Hispanic women, and 6,600 Black, Non-Hispanic women died of this cancer. For every 100,000 Black, Non-Hispanic women, 128 new breast cancer cases were reported and 28 Black, Non-Hispanic women died of this cancer (Ref. 1). Health disparity and equity considerations may exist as they relate to mammography practice and density

notification, and we have considered sociodemographic differences in mammography practice and outcomes. This final rule provides standard requirements that help to ensure that all patients and providers receive complete and consistent breast density information in mammography reports.

Early detection of female breast cancer, typically involving mammography, is the best means of preventing deaths that can result if the diagnosis is delayed until the onset of more advanced symptoms (Ref. 5). 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 workstation, and can, for example, be digitally magnified. Digital breast tomosynthesis also uses an electronic image receptor and a computer workstation, 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. 6).

However, as noted by the Government Accountability Office (GAO), a mammogram is among the most difficult radiographic images to interpret (Ref. 7). 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. Need for Amendments to Mammography Regulations

Most of the requirements in our mammography regulations are over 20 years old. As described below and in the proposed rule (84 FR 11669, March 28, 2019), 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 updating our mammography regulations in response to several gaps that we have identified as we have implemented the current regulations. 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 June 2021, 38 States have passed

laws mandating notification of breast density (Ref. 8). These State laws impose requirements that vary from State to State. To ensure all patients receive breast density information from their mammograms, and that such required baseline information is consistent, FDA is amending the mammography reporting requirements 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. FDA is also requiring that both the mammography report and lay summary include basic mammography facility identification information. Technology has also advanced since the regulations were issued, so the amended regulations will make changes to reflect current mammography best practices and technologies.

#### B. Summary of Comments to the Proposed Rule

In the **Federal Register** of March 28, 2019, FDA published a rule proposing amendments to the MQSA regulations. The comment period for the proposed rule closed on June 26, 2019. FDA received many comments on the proposed rule from several entities including medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. While several comments object to particular sections or subsections of the proposed rule, almost all comments voice support for the objective intent of the proposed rule, to establish updates to modernize the MQSA regulations to incorporate current science and mammography best practices.

Some comments raise concerns or request clarification regarding:

- the scope of the MQSA regulations,
- failure of facility accreditation,
- retention of personnel records,
- mammography reports (including assessment categories) and lay summaries,
- breast density notification to patients and referring providers,
- requirements for image retention, transfer of original images, and release of copies,
- the mammography medical outcomes audit,
- patient and provider notification,
- the availability and use of various imaging modalities, and
- issues related to clinical decision-making.

#### C. General Overview of the Final Rule's Changes From the Proposed Rule

FDA considered all comments received on the proposed rule and made changes, primarily for clarity and accuracy and to improve understanding of breast density notification language to healthcare providers and patients. On its own initiative, FDA is also making minor technical changes to make the withdrawal provisions clearer. The changes from the proposed rule include the following significant revisions, additions, and removals to the codified section:

- add or substitute the term “provider” or “healthcare provider” in several paragraphs in place of references to referring physician (§§ 900.2(c)(2), 900.2(k), 900.2(ii), 900.4(f)(1)(ii)(B), and 900.12(j)),
- revise language to clarify that no AB shall accept an application for accreditation from a facility that has had three consecutive failures (§ 900.4(a)(6)(ii)),
- include additional language requiring that facilities must retain personnel qualification records of former employees for at least 24 months (§ 900.12(a)(4)),
- remove the proposed term “digital accessory components” and clarify the premarket requirements for devices used in mammography (§ 900.12(b)(2)(i)),
- include additional language clarifying that the required final assessment statements are only the words or phrases in quotation marks (§ 900.12(c)(1)(iv)),
- revise the requirement that clinical findings or symptoms in a patient whose mammogram assessment is negative or benign shall be “documented and addressed,” rather than “explained” (§ 900.12(c)(1)(iv)(A) and (B)),
- correct the reference to the two categories of breast density that shall be included in the lay summary provided to the patient (§ 900.12(c)(2)),
- include additional language clarifying the deadline for sending the mammography report to a self-referred patient when the assessment is “Suspicious” or “Highly Suggestive of Malignancy” (§ 900.12(c)(2)(i)),
- include additional language clarifying the situations in which a facility must maintain a system for referring self-referred patients to a healthcare provider (§ 900.12(c)(2)(ii)),
- revise the breast density notification language that must be included in lay summaries provided to patients with non-dense and dense tissue, respectively (§ 900.12(c)(2)(iii) and (iv)),

- add language clarifying the length of time a facility is required to maintain the original mammograms and mammography reports in a permanent medical record of the patient by clarifying it is for the longer of the applicable Federal timeframes, or the mandated State or local timeframes (§ 900.12(c)(4)(i)),

- add language clarifying that a facility that ceases to perform mammography but continues to operate as a medical entity may retain, rather than transfer, its mammography records (§ 900.12(c)(4)(v)),

- add or substitute the term “patient” in place of references to “women” or “woman” (§§ 900.12(c)(4)(v) and (f)(1)),

- add the word “audit” to clarify that the use of certain terms applies to the medical outcomes audit (§ 900.12(f)(1)), and

- include an amendment changing the name of Healthcare Financing Administration to Centers for Medicare & Medicaid Services and updating the Center for Devices and Radiological Health (CDRH) office’s name (§ 900.15(d)(1)).

#### IV. Legal Authority

The MQSA (Pub. L. 102–539) was enacted on October 27, 1992, and is codified under section 354 of the Public Health Service (PHS) Act (42 U.S.C. 263b). Under the MQSA, all mammography facilities, except facilities of the VA, must be accredited by an approved AB 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 making these amendments to the mammography regulations (set forth in part 900 (21 CFR part 900)) under section 354 of the PHS Act, and sections of the FD&C Act (sections 519, 537, and 704(e); 21 U.S.C. 360i, 360nn, and 374(e)).

#### V. Comments on the Proposed Rule and FDA’s Responses

We received several sets of comments on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We received comments from medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. We describe and respond to comments in sections A through Z of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number so that FDA’s responses could be addressed by topic, instead of each

comment addressed independently, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received or considered.

##### A. General Comments on the Proposed Rule

(Comment 1) FDA received many comments that express support for the MQSA proposed rule. Some comments express support for requiring density notification to patients and for establishing a national standard for such notification. Other comments respectively express support for the changes to the assessment categories, equipment quality control (QC), and requirements related to the provision of copies of mammograms. Some comments express support for the changes to the patient and provider notification in the event of compromised mammographic quality, which may represent a serious risk to human health, including the notification of nonphysician referring healthcare providers. Another comment compliments FDA on proposing amendments to the regulations, but recommends more frequent changes to respond promptly to new information.

(Response 1) FDA appreciates the public support for the rule. FDA notes that the notification requirement regarding breast tissue density will enhance communication between patients, interpreting physicians (IP), and referring providers about this important factor in the effectiveness of mammography, and ensure that required baseline information is consistent. FDA also concludes that the other amendments to the regulations (part 900), including the changes to the equipment QC, assessment categories, provision of copies of mammograms, and notification to nonphysician healthcare providers when necessary, will also contribute to improvement in the quality of mammography and of communication about mammography between patients, IPs, and providers. Regarding the recommendation for more frequent changes, FDA notes that it continues to engage with the National Mammography Quality Assurance Advisory Committee (NMQAAC) and the professional and patient mammography communities regarding the need for changes to the regulations, but the frequency of amendments to the

regulations is based on public health need and Agency resources.

(Comment 2) Several comments express opposition to the proposed rule, including the following concerns: (1) that patients will not understand that dense tissue is a normal variant, and that the proposed breast density notification will increase their anxiety; (2) that breast cancer information to be given to a patient should be determined only by the patient’s healthcare provider, or that the new requirement places a burden on the healthcare provider; (3) that all medical tests should be interpreted by clinicians with years of training who can identify the findings that require intervention; (4) that ultrasound rather than digital breast tomosynthesis (DBT) is the method to screen for cancers that are not mammographically visible; and (5) that there is no clinical recommendation to change patient management based on density or to perform additional ultrasound and magnetic resonance imaging (MRI) for screening dense breasts, and that current evidence contradicts the suggestion that supplemental screening based on breast density reduces breast cancer mortality. The latter comment also recommends that FDA’s suggestion that additional imaging based on density alone may reduce breast cancer mortality should be deleted from the cost and benefit information of the rule.

(Response 2) FDA acknowledges the comments and responds according to the numbered topics identified in Comment 2:

(1–2) We note that breast tissue density is an important factor in mammography, both because of the masking effect of dense tissue, which limits the sensitivity of mammography (Refs. 9 to 11), and because density is an independent risk factor for the development of breast cancer (Refs. 12 to 15). FDA concludes that patients benefit from having information about their breast anatomy, and should be informed of their density so that the patient and their healthcare provider can make informed and shared decisions about the patient’s healthcare. This rulemaking provides consistent language for communicating that information, as FDA concludes that there is also a benefit from obtaining baseline information in a consistent manner.

The requirement to notify patients about their density is a baseline standard and does not constrain a healthcare provider from further discussing density with the patient. FDA has determined that the benefit of informing patients of their density

outweighs both the burden on healthcare providers to provide density information and the risk of patient anxiety. FDA also notes that the Agency received many comments in support of the proposed rule and the breast density notification to patients. FDA also notes that 38 States have passed laws mandating notification of breast density, which may mitigate any potential burden on healthcare providers in those states (Ref. 8).

(3) The MQSA provides authority to FDA to ensure quality mammography, and FDA has determined that the initial and continuing qualification requirements for IPs in § 900.12(a)(1) are sufficient to ensure that mammograms, including density observations, are interpreted by personnel with adequate training to ensure quality mammography.

(4–5) FDA acknowledges there are conflicting comments about the utility of other imaging modalities besides DBT, such as ultrasound, for supplemental screening of women with dense breasts; however, this final rule does not specify any particular supplemental imaging modality or other particular clinical management of patients with dense breasts. FDA has not indicated any particular additional steps in a patient's care based only on the mammogram, as individual situations and risk factors vary. FDA does not agree that it is appropriate to require the lay summary to include a discussion of all possible breast imaging modalities that may be more effective for some patients than mammography, which would encompass a significant amount of information that may be overwhelming and difficult for patients to interpret (see also Responses 57 and 60). We believe that it is more appropriate for the healthcare provider to discuss this information with the patient and engage in shared clinical decision-making based on the patient's individual circumstances. In this final rule, to allow patients and their healthcare providers to make shared decisions appropriate for each patient, the notification to these patients in § 900.12(c)(2)(iv) simply states, in part, "In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers," and advises the patient to discuss their individual situation with their provider (see also Response 62). FDA notes that there is conflicting evidence about the effect of supplemental screening on breast cancer mortality, including Chiu in 2010 (Ref. 16), which found that dense tissue was associated with increased mortality from breast cancer. Therefore, FDA disagrees with the

assertion that additional imaging based on breast density is not relevant, or that the mortality information should be deleted from the economic cost and benefit analysis of the rule.

(Comment 3) A comment opposes more mammography regulation, and asserts:\* that MQSA duplicates an American College of Radiology (ACR) program which "certifies" mammography facilities; that FDA dictating what IPs should say in their reports constitutes the practice of medicine; and that MQSA regulations are driving physicians out of mammography and limiting access. This comment recommends that FDA limit itself to its "original mandate" to ensure that mammography units produce quality images at a reasonable radiation dose.

(Response 3) FDA disagrees with the comment. The ACR does not certify mammography facilities. The MQSA and its implementing regulations distinguish between accreditation and certification (see 42 U.S.C. 263b(e) and (g); part 900, subparts A and C; see also Response 145). The ACR is one of several FDA-approved accreditation bodies. Accreditation, which mainly focuses on the quality of clinical images and phantom images, is one of the prerequisites for facility certification by FDA or a State certifying agency. FDA does not specify which assessment category an IP should assign to a mammogram because this is more appropriately left to the provider's interpretation in the course of clinical decision-making. However, FDA does provide for the specific phrasing of the final assessment statements, which is standardized in accordance with the MQSA (42 U.S.C. 263b(a)(3)(B)) to ensure clear consistent communication between patients, IPs, and referring healthcare providers. FDA does not track practice rates of IPs or other facility personnel, but is not aware of information showing a decrease in access to mammography services; according to MQSA national statistics (Ref. 17), from November 2003 to February 2022, there has been a 4 percent decrease in the total number of certified facilities across the United States but a 29 percent increase in the total number of mammograms performed. Therefore, FDA concludes that these amendments to the MQSA regulations are neither duplicative of the ACR program nor have the existing MQSA regulations had a negative impact on access to mammography.

#### *B. Scope of the MQSA Regulations*

(Comment 4) Several comments address the scope of the MQSA

regulations, including comments that support the objectives of the proposed rule and/or provide the following recommendations: (1) FDA's proposal should remove xeromammography from the examples of mammographic modalities, which accompany the definition provided in proposed § 900.2(z), and replace it with full-field digital mammography (FFDM); (2) FDA should remove screen-film mammography from these examples of modalities; (3) comments that FDA should also add the example of DBT as a modality; (4) that mammography IPs should also be qualified in breast ultrasound; and (5) that FDA should consider requiring mammography facilities to meet additional quality standards, such as the ACR's Breast Imaging Centers of Excellence (BICOE) program or the American Cancer Society (ACS) National Accreditation Program for Breast Centers (NAPBC), in addition to MQSA certification requirements.

(Response 4) The scope of FDA's authority over mammography facilities is established in the MQSA, and, as described in the following and organized according to the numbered topics identified in Comment 4, FDA is adopting limited changes to this rule:

(1–3) The MQSA and its implementing regulations apply only to radiological equipment used in facilities to perform mammographic modalities, which do not include breast sonography or other non-mammographic modalities (42 U.S.C. 263b(a)(5) and (6), (b)(1) and (2)). However, FDA agrees that the modality of DBT has reached wide clinical use and should be listed as an example of a mammographic modality in this rule. Xeromammography is no longer in clinical use in the United States, and screen-film mammography is in limited use. Therefore, in this final rule, FDA is revising the examples of mammographic modalities to remove xeromammography, and to list screen-film mammography, FFDM, and DBT, all of which are currently in clinical use in the United States (see § 900.2(z) in this final rule). Other modalities are covered by the requirements of the FD&C Act, and may be subject to performance standards prescribed pursuant to section 534 (Electronic Product Radiation Control (EPRC)) of the FD&C Act.

(4) FDA disagrees with the recommendation to require mammography IPs to also be qualified in breast ultrasound. As noted, the MQSA does not provide for the establishment of requirements related to breast sonography for IPs, other personnel, or facilities.

(5) FDA notes that the ACR BICOE program covers other breast imaging modalities and interventions in addition to mammography, and the ACS NAPBC covers additional breast imaging as well as other aspects of clinical breast care. Therefore, these programs are not implemented within the scope of the MQSA regulations.

(Comment 5) Several comments recommend removing the exclusion of invasive interventions for biopsy or localization in § 900.2(aa)(1) so that they are included within the scope of the MQSA regulations. A separate comment recommends that post-procedure mammograms for marker placement should not be regulated under the MQSA.

(Response 5) FDA disagrees with these comments. The MQSA was enacted by Congress in 1992 due to evidence of poor quality in mammographic imaging in the United States at that time. However, since then, the implementation of the MQSA and the widespread adoption of digital imaging technologies and other technological and QC advances have contributed to quality improvement not only in screening and diagnostic mammography, but also in interventional mammography. The majority of personnel performing interventional mammography also perform non-interventional mammography and are therefore subject to the requirements of the MQSA. Currently, FDA is not aware of information showing significant quality problems with interventional mammography in the United States. At this time, FDA concludes that it is not necessary to introduce regulations covering interventional mammography.

Unlike the targeted images of a small portion of the breast that are typically performed during localization or intervention, a post-procedure mammogram typically includes the entire breast; may be performed using general mammography equipment rather than dedicated interventional equipment; and is often logged, reported, and charged as an independent examination, separate from the interventional procedure that precedes it. Therefore, FDA concludes that this post-procedure examination should continue to meet the quality standards mandated under the MQSA regulations. As discussed in Responses 32, 38, and 39, this final rule includes the assessment statement “Post-Procedure Mammogram for Marker Placement,” which may be appropriate for such mammograms (see § 900.12(c)(1)(iv)(G)).

(Comment 6) Several comments suggest that the MQSA regulations should be expanded to cover other imaging modalities in addition to mammography, including ultrasound and MRI.

(Response 6) The MQSA was passed by Congress in 1992 in response to evidence of poor quality in mammographic imaging in the United States at that time (42 U.S.C. 263b). As we noted in Response 4, the MQSA applies only to mammographic imaging. As such, the MQSA does not provide for the establishment of requirements related to breast sonography or MRI, and the MQSA regulations have not been amended to include such modalities.

(Comment 7) A comment recommends that medical offices be required to display posters depicting breast anatomy and to distribute literature regarding breast physical examination.

(Response 7) FDA disagrees with the comment. FDA notes that the shared clinical decision-making process generally takes place between the patient and their referring healthcare provider or other clinical healthcare provider, not with the interpreting physician at the mammography facility, and therefore does not agree that there is a need to require posters of breast anatomy at mammography facilities, although facilities may choose to display patient education resources. Referring healthcare providers who order mammography studies, and are not themselves the reviewing physicians of the clinical images at issue (see 42 U.S.C. 263b(a)(8)), are not generally subject to the requirements specified in the MQSA and its implementing regulations. Clinical healthcare providers may provide such patient education resources if they choose to do so, but this recommendation is outside the scope of this final rulemaking.

#### *C. Repeated Failure To Achieve Accreditation*

(Comment 8) Several comments express concerns with the number and type of accreditation failures after which an AB may not accept a facility's application for accreditation for 1 year. One comment recommends that this provision be revised to apply to a facility that has “failed to become accredited after four consecutive failures”; another comment recommends that this be revised to apply to a facility which has “failed to become accredited after four failed accreditation cycles”; and another comment recommends that this be revised to apply to a facility that has had “three consecutive failures of

accreditation granting cycles.” Two of these comments also express concern over the effect of this provision on the timing of the AB's onsite visit to the facility to provide oversight and hands-on training.

(Response 8) FDA disagrees with these comments. The Agency believes that a facility that has failed to become accredited after three consecutive attempts should not be permitted to become accredited until it has implemented all necessary corrective actions and any other necessary changes, such as additional training or personnel changes, specific to the facility's individual situation (see § 900.4(a)(6)(ii) in this final rule). The Agency believes that the 1-year waiting period will allow the facility sufficient time to make these corrections. Regarding the terminology used for these failures, the Agency notes that the various FDA-approved ABs currently use different terms, such as “deficiency” and “failure,” for the initial failure to become accredited. Therefore, FDA concludes that the phrasing of the provision, “If a facility has failed to become accredited after three consecutive attempts,” is sufficiently clear and broad to apply to facilities accredited by any AB. Regarding the AB onsite visits to facilities, the various ABs currently have different policies for the timing of their onsite visits, each respectively approved by FDA. FDA notes that, upon publication of this final rule, the ABs can review and, if needed, revise their procedures to accommodate the change in the regulations, including to account for any procedures to address tracking the number of facility applications submitted to an AB, and submit their proposed policy changes to FDA for review and approval.

(Comment 9) Some comments recommend that facilities not be allowed to switch ABs in order to avoid this 1-year exclusion after three consecutive failed attempts at accreditation.

(Response 9) FDA agrees with this recommendation. Accordingly, we are revising § 900.4(a)(6)(ii) to state “If a facility has failed to become accredited after three consecutive attempts, no AB shall accept an application for accreditation from the facility for a period of 1 year from the date of the most recent accreditation failure.”

(Comment 10) Some comments address the situation of a facility with more than one mammography unit, of which one unit fails to receive accreditation but one or more units receive accreditation. These comments recommend either that the facility be



permitted to continue to perform mammography with the remaining accredited unit(s), or that the facility's individual situation be evaluated by the AB to determine the appropriate course of action.

(Response 10) We appreciate the comment, but note that the commenter misunderstood the proposed amendment. The provision that was proposed for revision refers to overall facility accreditation (see § 900.4(a)(6)(ii) in both the proposed and final rule) as opposed to individual unit accreditation (see §§ 900.4(e) and 900.12(e)). FDA acknowledges that some reasons for the failure of a facility to receive accreditation, such as a mechanical deficiency in a mammography unit, may be limited to that particular unit, while other reasons for failure, such as poor patient positioning, may extend to the practice of mammography throughout the entire facility. The various FDA-approved ABs have policies to address the requirements for accreditation of a facility that has multiple mammography units. The ABs also have policies regarding the circumstances, including poor quality noted on accreditation images, which may prompt an AMR to assess the overall quality of mammography at a facility. FDA believes that if a facility fails three consecutive attempts to receive accreditation, it should be subject to a 1-year waiting period to allow the facility adequate time to address issues that have prevented accreditation (see also Response 8). FDA anticipates that the ABs may review their policies and procedures, and if needed, may decide to submit revised policies and procedures to FDA (see § 900.4(a)(8)) to conform to this provision of the final rule; if the ABs do so, the Agency will review and consider the ABs' proposals.

(Comment 11) A comment recommends that a facility under its third provisional certificate have all exams double-read by a qualified IP from an accredited and certified facility, until the applying facility either fails or receives accreditation.

(Response 11) FDA disagrees with adding this requirement to the regulations. Such increased oversight of facilities with provisional certificates is not appropriate in this circumstance, considering that there are existing regulations requiring corrective action. Depending on the specific circumstances of the failure, the applying facility's AB will either have required the facility to perform corrective action after the first two failures, or will first have performed an AMR to determine the extent and

severity of the quality problems at the facility (see § 900.4(a)(1)(i)), and will have required corrective action (see §§ 900.4(a)(1)(ii) and 900.4(b)(3)). Corrective action is individualized by the AB for the specific facility, but often includes requirements for additional training for the facility personnel. Therefore, FDA concludes that the IP and other personnel will be sufficiently trained to correct the quality problems at the facility.

(Comment 12) A comment recommends clearer language about the facility's next steps, corrective action, "necessary information," and the duration of effectiveness of a provisional certificate for a facility that has had a year-long waiting period after having failed to become accredited after three consecutive attempts. The same comment recommends clearer language about FDA's action if a facility fails accreditation for a third time, and also recommends that a facility be permanently ineligible to provide mammography services after a fourth failure.

(Response 12) Regarding improving clarity about the process for reapplying for accreditation, FDA disagrees with this comment. The process is subject to the policies and procedures of each AB, and the Agency notes that the necessary information as well as the steps to apply for accreditation are clearly specified by each AB's policies and procedures (see, e.g., § 900.4(e) and (f)). We further note that the duration of effectiveness of a provisional certificate is already discussed in current § 900.11(b) and (c). Regarding the commenter's recommendation that a facility be ineligible to provide mammography services after a fourth failure, FDA concludes that a facility that has performed all required corrective action may reapply for accreditation, but notes that, in accordance with AB policies, an AB may take into account the facility's entire history and practice of mammography, such as a lack of improvement after multiple corrective actions, in considering a decision to suspend or revoke the facility's accreditation, or to revoke its application for accreditation (see § 900.4(a) and (b)). Also, the AB must notify FDA if it believes that a facility's practice of mammography may pose a serious risk to human health (see § 900.4(a)(2)). Likewise, the Agency may take into account the facility's entire history in determining that its practice poses a serious risk to human health and in considering the suspension or revocation of a facility's certificate (see § 900.14). Therefore, FDA concludes that a facility whose practice warrants

such a determination will be identified, and appropriate accreditation and/or certificate actions will be taken. Finally, as noted in Responses 8 and 10, if the ABs review their policies and procedures in light of this provision of the final rule and decide to submit revised policies and procedures to FDA (see § 900.4(a)(8)), the Agency will review and consider those policies and procedures.

#### *D. Retention and Release of Personnel Records*

(Comment 13) Several comments were submitted that recommend specifying the amount of time that a facility must retain personnel records for employees that are no longer at that facility. Some comments recommend that facilities only be required to keep the records for former employees from the time of one inspection to the time of the next annual inspection. Another comment recommends that facilities only be required to give employees their records at the time of the employees' departure. Other comments recommend that facilities be required to keep personnel records for former employees for 24 months following the departure of that employee.

(Response 13) FDA agrees that a minimum length of time should be included in the amendments to the regulations for the personnel records retention requirement. We note that previous employees may need access to these personnel records to document their MQSA qualifications to permit them to provide mammography services at other facilities. Accordingly, we conclude that former employees should have an opportunity to obtain their personnel records for a time period beyond the immediate date of their departure from a facility. After considering the comments on this requirement, we are revising and finalizing the provision as follows: "Records of personnel no longer employed by the facility must be maintained for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months" (see § 900.12(a)(4) in this final rule). FDA has made this change to the codified language to clarify that the records must be available during an inspection that can occur at any point during the 24 months after which an employee departs, which better aligns with the records retention requirement and is distinct from any FDA determination regarding compliance with the MQSA and its implementing regulations that would



otherwise occur following the next annual inspection after the employee departs. FDA is also revising the provision to distinguish and clarify the requirements for providing such records to current and former employees, as follows: “The facility shall provide copies of these personnel records to current interpreting physicians (IPs), radiologic technologists, and medical physicists upon their request. Facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.”

(Comment 14) Rather than providing records after an employee leaves, a comment recommends that facilities should require a qualifications package for each employee that would only be retained until after the first inspection following the hiring of that employee, at which point the package should be given to the employee to retain, and any continuing experience or other information would be accumulated and maintained from the time that the qualifications package is given to the employee.

(Response 14) FDA disagrees with this comment. Personnel qualifications under § 900.12(a) include both initial and continuing requirements, and both components are reviewed at the time of inspection (Ref. 18). The personnel record keeping requirements apply to facilities, not individual personnel (see 42 U.S.C. 263b(d)(1)(A)(ii)(III), (B)(ii)(II), and (g)(1)(C), and § 900.12(a)(4)). Therefore, each facility is required to document the qualifications of its personnel. Also, FDA is concerned that the comment’s recommended changes would not be as effective as the current system in maintaining the necessary documentation of qualification of a facility’s personnel.

(Comment 15) A comment recommends that FDA specify a penalty for facilities that do not adhere to the personnel records requirement.

(Response 15) FDA agrees with this comment. A facility that does not comply with the personnel records retention requirement (see § 900.12(a)(4) in this final rule) may receive a citation at the time that this failure is identified at inspection, in a manner similar to other comparable violations (Ref. 18). The totality and severity of violations identified at inspection determine the consequences for the facility.

(Comment 16) A comment recommends that facilities should only

need to provide personnel records to former employees if the employee submits the request in written format.

(Response 16) FDA disagrees with this recommendation. FDA concludes that requiring requests from former employees for their personnel records to be transmitted in writing may be overly burdensome to both facilities and former employees because it may delay how quickly a facility would receive the request, and may reduce access to mammography by delaying how quickly those records could be provided to facilities evaluating the qualifications of new personnel. FDA believes that minimizing barriers to the provision of qualification records to former employees will facilitate the hiring of these personnel at other facilities, thus preserving patient access to mammography services.

(Comment 17) A comment recommends that facilities give personnel records to personnel when the facility ceases performing mammography, and it also asks for clarification as to whether the phrase “ceases to perform mammography” refers to the facility or to specific personnel.

(Response 17) The final rule states that “Before a facility closes or ceases to perform mammography services, it must make arrangements for access by current and former personnel to their MQSA records,” and that this may be accomplished by either “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 for no less than 24 months from the date of facility closure or cessation of mammography services” (see § 900.12(a)(4)). FDA believes that these two pathways provide adequate access for personnel to their MQSA records. The primary reason that personnel may require access to their qualification records is that they are continuing to practice mammography at other facilities. Therefore, the clause “Before a facility closes or ceases to provide mammography services” (see § 900.12(a)(4) in this final rule) refers to the closure or cessation of mammography services of a facility and not to the cessation of specific personnel from practicing mammography.

(Comment 18) A comment requests that FDA provide guidance on how to demonstrate compliance with the requirement to provide access for personnel to their MQSA records when a facility closes or ceases mammography services.

(Response 18) The Agency believes that the current regulations, and the regulations being revised at § 900.12(a)(4) in this final rule, are clear on the requirements regarding personnel records for facilities that close or cease to provide mammography services. Facilities that close or cease to perform mammography services should inform their AB, which will assist them in complying with record retention obligations and other applicable MQSA requirements. (Ref. 19.)

#### *E. Digital Accessories*

(Comment 19) Several comments request that FDA provide additional clarification of the definition of a digital accessory component, or ask for clarity on whether specific equipment, such as display monitors, are included in this category.

(Response 19) FDA defines an “accessory” of a device as “A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices” (Ref. 20). Because a device accessory is a “device,” we believe the broader term “devices” is simpler and allows for a clearer understanding of the mammography regulations. In this final rule, we are revising § 900.12(b)(2)(i) for clarity, to state that “All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type and intended use.” This applies to devices used in the acquisition, processing, or display of digital mammographic images. For example, a display device used in the interpretation of digital mammographic images generally needs to have 510(k) clearance prior to being used in a mammographic facility. Not all equipment needs clearance or approval; for example, some devices, such as medical image storage devices, may be exempted from premarket notification requirements. (It is important to consult the appropriate classification regulation to determine the premarket authorization requirements.)

(Comment 20) Several comments recommend changing the effective date for the digital accessory component requirements from 18 months to 24 months.

(Response 20) FDA disagrees with the recommendation to extend the effective date to 24 months after publication of this final rule. FDA considers 18 months to be a reasonable amount of time for facilities to achieve compliance with this requirement, based on both previous experience with the 18-month effective date specified in the 1997 MQSA final rule (62 FR 55852, October

28, 1997) and the need for timely effectiveness of this rule.

(Comment 21) Other comments recommend that, for QC testing of digital accessories, in addition to the use of QC procedures in the manufacturer's manual, the proposed rule should add an option to use the ACR QC manual.

(Response 21) Alternative requirements for § 900.12 quality standards are addressed in § 900.18. The current "ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems and Supplement for Digital Breast Tomosynthesis Mammography Systems" has been approved as applicable to any facility as alternative standard #24 (Ref. 21; see also § 900.18(f)). The use of approved alternative standards such as the ACR QC manual as they relate to digital accessories remains acceptable; however, since the ACR manual may undergo future revisions, and a revision would have to undergo FDA review to determine whether it is at least as effective in ensuring quality mammography as the standard it proposes to replace, the current ACR manual is not specified in the codified section of the final rule.

(Comment 22) A comment expresses concern that a facility using displays that are not specific for mammography or for a use that could include mammography would be in violation. Another comment suggests that, if a manufacturer QC procedure exists, there is no need for FDA premarket authorization of displays, and continues that there is no need for FDA premarket authorization for equipment since there are alternative standards for QC from the ACR. A comment also asserts that the process by which FDA clears or approves displays is not transparent.

(Response 22) These comments tend to confuse two separate processes: (1) the premarket approval or clearance of a medical device as described in 21 CFR 807.81 and (2) the MQSA requirements for mammography facilities under 42 U.S.C. 263b and the implementing regulations under part 900. Medical devices are subject to FDA's medical device requirements, which may include premarket authorization. Mammography equipment must also meet MQSA regulatory requirements that govern its use in a mammography facility.

FDA premarket authorization of a display intended for use in interpreting mammography images is a premarket device requirement; however, after this final rule becomes effective, any applicable premarket authorization

requirements will also be required under the MQSA quality standards for use of the display for interpreting mammography images (see § 900.12(b)(2)(i) in this final rule). Therefore, FDA agrees with the comment that a facility interpreting mammograms using a display that has not met the applicable FDA premarket authorization requirements for use in interpreting mammography images would generally be in violation of the MQSA quality standards regulations.

The QC tests for a display are another MQSA quality standard required for use of that display for mammography interpretation (see § 900.12(e)(6)), but the existence of QC tests for a display is generally not sufficient to satisfy all FDA premarket regulatory requirements that may apply to the device. Likewise, the existence of a QC program for other mammography equipment does not generally satisfy all the premarket regulatory requirements applicable to that equipment. Regarding the comment that states there are QC procedures available from ACR, we also note that facilities that adopt the ACR QC manual for the QC of their FFDM or DBT system may not limit the use of the manual to a single piece of equipment or accessory, such as a display, while following a different QC program (such as the manufacturer's QC manual) for the mammography unit (Refs. 21 and 22), and we reiterate that the existence of a QC program does not necessarily reflect that any applicable FDA premarket authorization requirements are being met.

Regarding the comment on the clarity of FDA premarket review process for mammography displays, the premarket requirements for displays that are intended to be used in interpreting mammography images, among others, are discussed in 21 CFR 892.2050 and FDA's guidance "Display Devices for Diagnostic Radiology" (Ref. 23).

(Comment 23) A comment states that the requirement that mammograms submitted for interpretation be "presented in the mammographic modality" in which they were originally produced is unclear, and suggests that mammograms are being read on a device not intended for mammography. The comment also recommends including a statement to caution facilities that they should be aware of potential compatibility issues in their imaging/reading chain.

(Response 23) The requirement that mammograms be presented for interpretation in the mammographic modality in which they were originally produced means, for example, that screen-film mammograms must be

presented for interpretation as the original hardcopy films, and not digitized or scanned. FDA does not agree that this requirement would reasonably be interpreted to mean that mammograms are being read on equipment not intended for mammography. FDA notes that all equipment used for mammography must be specifically designed for mammography (see § 900.12(b)(2) in this final rule) and that all devices used in mammography (including displays, as discussed in Responses 19 and 22) must have met the applicable FDA premarket authorization requirements for medical devices of that type and intended use (see § 900.12(b)(2)(i) in this final rule). FDA agrees that facilities are responsible for ensuring that any equipment they use in the acquisition, processing, interpretation, retention, and retrieval of mammographic images be compatible, in order to facilitate mammography practice and to allow compliance with the record retention, transfer, and release provisions in § 900.12(c)(4) of this final rule. The Agency does not believe it is necessary to include a cautionary statement in the final rule, as facilities in the course of their practice of mammography will readily be able to determine whether their equipment is interoperable.

#### *F. Facility Identification Information in Mammography Report and Lay Summary*

(Comment 24) A comment requests clarification, in the case of a facility that is associated with a centralized entity that sends reports and summaries, as to whether the centralized entity may be the only name on the report or summary, whether an abbreviated name for the actual facility is acceptable, and whether an alias (e.g., "Doing Business As" or DBA) is required to appear on the report. The commenter also requests clarification of the required timeframe for a facility to report a name change.

(Response 24) FDA distinguishes each mammography facility based on its physical location (see 42 U.S.C. 263b(a)(3) and § 900.12(c)(1)(ii) in this final rule). Healthcare networks that offer mammography services at several locations are accredited and certified as several separate facilities. The name recognized by FDA for a facility is the name under which the facility is accredited by its AB (see § 900.11(b)). Therefore, the facility identification information in the report to the healthcare provider (see § 900.12(c)(1)(ii) in this final rule) and the lay summary sent to the patient (see § 900.12(c)(2) in this final rule) must be unique to the actual facility where the

mammogram was performed, and must include the name under which the facility is accredited and certified. A change to a facility's name must be submitted to the facility's AB, and is subsequently conveyed to FDA by the AB (see § 900.11(b)); therefore, the timeframe for reporting a name change, as well as the acceptability of an alias or DBA, are governed by the policies of the AB.

(Comment 25) A comment recommends that FDA specify whether the report identification information is required for a "consult report."

(Response 25) The commenter's reference to a "consult report" is not clear. Typically, a mammogram will be interpreted only once, and will have only a single report and a single lay summary. In some cases, a mammogram that has already been interpreted and for which a report and lay summary have been issued is subsequently presented to another IP for a repeat interpretation or "second opinion." By referencing determinations made by an "outside consultant," the commenter may either be referring to a later IP rendering such an additional opinion on an examination that has already been interpreted, or may be referring to an IP who is a contractor to a facility (rather than a facility employee) rendering the initial or sole interpretation. If the comment refers to the reinterpretation of a previously interpreted mammogram, the second (or subsequent) IP must also meet the existing personnel requirements of § 900.12(a)(1), and must separately comply with the reporting requirements of § 900.12(c) in this final rule. To help distinguish them from the original interpretation, we recommend that a second (or subsequent) report and lay summary be identified as a second opinion or similar term. If the comment refers to a report rendered by an IP who is a contractor or consultant to the facility rather than a facility employee, that IP must also meet all personnel requirements, and the report and lay summary must meet all reporting requirements.

(Comment 26) Several comments address the required identification information in the lay summary. A comment asserts that most facilities already provide facility identification in the lay summary. Another comment recommends that the patient name and the facility information be required in the lay summary. A separate comment recommends that the summary include separately both the contact information of the facility or business where a patient can request images and records, and the actual physical location where the mammography services were

provided. Another comment recommends that FDA not specify the information that is required "at a minimum," but rather specify all required information, including the facility telephone number, email address, and instructions for clear communication.

(Response 26) FDA agrees that there have been situations in which the facility information in the lay summary was inadequate. FDA concludes that the expanded requirements in § 900.12(c)(2) of the final rule will enhance communication between the facility, the patient, and the referring provider, and lead to improved patient care. Because, as noted in Response 24, FDA identifies each facility by its unique location (see § 900.12(a)(1), in both the proposed and final rule), the location of the facility where the mammogram was performed must be included in the lay summary. In response to the comment recommending that a facility's parent company information be included in the header, FDA does not agree that such additional information should be required because FDA identifies each facility by its unique location and not by any affiliation with a network or company. However, a facility may choose to include additional information about a healthcare network, affiliated site, or records storage site. In addition, FDA agrees with the recommendation that the facility telephone number be included with the lay summary, and notes that § 900.12(c)(2) of both the proposed and final rule include this requirement. Because in FDA's experience, some facilities do not have email addresses, and some others communicate through patient portals, FDA disagrees with the recommendation to require that the lay summary include an email address or instructions for clear communication between the patient and the facility. FDA notes that facilities may choose to include this additional contact information.

(Comment 27) A comment recommends that the lay summary be required to include the name of the IP, so that patients will know who is involved with their care, and if dissatisfied, can request a different IP.

(Response 27) FDA does not believe it is necessary to require the name of the IP as part of the lay summary. A facility may choose to include this information, but it is not required. The Agency notes that the lay summary is prepared after the examination has been interpreted, so adding the name of the IP to the lay summary will not intervene early enough for the patient to request a different IP. A patient who prefers a

particular IP would have to discuss such a request with the facility staff before the mammogram is interpreted. After interpretation by the IP, FDA notes that the name of the IP is included in the report to the referring provider, per § 900.12(c)(1)(iii), and the patient can request the name either from the facility or from the referring provider.

#### *G. Final and Incomplete Assessments and Lay Summaries*

(Comment 28) A comment recommends that FDA clarify the limits of the required assessment language for each mammographic assessment category, and recommends that the rule preserve the concept that the assessment statement is required, while the explanatory language is not required to be included in the mammography report.

(Response 28) For each assessment category, the required assessment statement is only the word or phrase in quotation marks (see § 900.12(c)(iv) in this final rule). As in the existing regulations, each assessment statement, identified in quotation marks, is followed by explanatory language, which is not in quotation marks; this explanatory language not in quotation marks is intended to provide an explanation of the assessment category in order to promote its consistent use, but it is not part of the assessment statement, and is not required to be included in the report to the referring healthcare provider nor in the lay summary to the patient. This format of an assessment statement in quotation marks followed by explanatory language outside the quotation marks was also used in the existing regulations, and FDA is not aware of significant confusion caused by this format. In both the proposed and final rule, § 900.12(c)(1)(iv)(A) through (G), the explanatory language is distinguished from the assessment statement by the closing quotation mark at the end of the assessment. For added clarity, in this final rule we are revising § 900.12(c)(1)(iv) to add the parenthetical clarification, "the assessment statement is only the word or phrase within the quotation marks." We are also revising § 900.12(c)(1)(iv) to replace the colon with a period within the quotation marks surrounding each assessment statement, to further clarify the distinction between the required statement and its explanatory language.

(Comment 29) A comment asserts that the negative and benign assessment categories are functionally equivalent and recommends combining them.

(Response 29) FDA disagrees with this comment. Although we acknowledge

that in most instances there may be no difference in clinical management between patients with negative mammograms and those whose mammograms show benign findings, the Agency notes that IPs often distinguish between these examinations and identify benign findings if they are present; therefore, we conclude that the negative and benign assessment categories should remain separate.

(Comment 30) A comment stated that the new “Benign” phrasing would be confusing to patients if sent to them. Another comment recommends that the verbiage explaining the term “Benign” not be required to be in the report.

(Response 30) FDA disagrees with the comment that the “Benign” phrasing would be confusing to patients. We note that the explanatory language following the word “Benign” in

§ 900.12(c)(1)(iv)(B) in this final rule is not part of the assessment statement. It is intended only to explain the category to IPs and other facility personnel, and is not required to be included in the report to the referring provider nor in the lay summary to the patient; therefore, patients are unlikely to be presented with such phrasing. We further note that even the word “Benign” need not be stated to the patient; a patient summary in lay terms of either a negative or a benign report might say, for example, “Your mammogram is normal,” “Your mammogram shows no sign of cancer,” or similar phrasing.

(Comment 31) A comment recommends that, in the parenthetical statement “if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be explained” (in proposed § 900.12(c)(1)(iv)(B)), the word “explained” should be revised to “documented.”

(Response 31) FDA agrees in part with the comment. The parenthetical statement in the explanation of the benign assessment category is intended to mirror the existing parenthetical statement in the explanation of the negative assessment category (in § 900.12(c)(1)(iv)(A)), “if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained.” However, FDA agrees with the commenter that the IP may not always be able to explain the clinical finding or symptom in a patient with a negative or benign mammogram. Furthermore, the IP may have clinical information from a patient history form or interview that is not yet known to the referring healthcare provider, and is therefore not addressed by the

subsequent requirement in proposed § 900.12(c)(1)(vii) that “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.” FDA believes that this pertinent clinical information should be documented and, if possible, explained or otherwise addressed. Therefore, the Agency concludes that these parenthetical statements should be retained, with revision as suggested, for the negative assessment category (see § 900.12(c)(1)(iv)(A)) and for the benign assessment category (see § 900.12(c)(1)(iv)(B)). As such, FDA is revising the parenthetical language in this final rule for the negative and benign categories, respectively, to state that “if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed,” and “if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed.”

(Comment 32) A comment requests confirmation that the new assessment categories are part of the alternative standard approved in 2003. Another comment requests confirmation that the “FDA-approved” equivalent wording for assessment categories is still permitted, and asserts that IPs should have the option to report equivalent language rather than the assessment statements in the regulations.

(Response 32) The new assessment statement “Post-Procedure Mammogram for Marker Placement” (§ 900.12(c)(1)(iv)(G)) is identical to alternative standard #12 approved by FDA in 2003 (Ref. 24). The new assessment statements “Incomplete: Need Additional Imaging Evaluation” (§ 900.12(c)(1)(v)(A)) and “Incomplete: Need Prior Mammograms for Comparison” (§ 900.12(c)(1)(v)(B)) are derived from alternative standard #11 approved by FDA in 2003 (Ref. 25). The statements “Incomplete: Need Additional Imaging Evaluation” and “Incomplete: Need Prior Mammograms for Comparison” represent the division of the single assessment statement in alternative standard #11 into two new assessment statements. These statements reflect FDA’s recognition that some mammograms require comparison for interpretation, while some mammograms require additional imaging to reach a final interpretation.

The only authorized assessment statements are those in the quality standards and the approved alternative standards (Refs. 22 and 24; see also §§ 900.12(c)(1)(iv) and 900.18). In

addition, as described in the MQSA Policy Guidance Help System (PGHS), FDA has acknowledged that some closely worded variations of the approved assessment statements may generally be acceptable where the particular wording does not change the meaning of the category (Ref. 26).

(Comment 33) A comment expresses concern that the reporting requirements, which seemingly would allow for an automated process of an IP selecting prepared comments that match the assessment categories, do not include an assessment statement or comment for patients with a history of breast cancer surgery who are subsequently undergoing routine screening.

(Response 33) Although FDA places requirements on the wording of the assessment statement used to describe the assessment category selected by the IP to promote clarity of communication between the IP and the referring clinical healthcare provider, we anticipate that the mammography report may include additional information about the findings of the examination, before the concluding assessment statement. FDA agrees that, after an IP examines the images, the IP may select prepared statements that in the IP’s judgment accurately describe the findings of the examination, and likewise may select the final assessment from a prepared list of the approved assessment statements. The Agency anticipates that there will be some mammograms whose findings necessitate additional nonstandard statements within the report, but the report must conclude with one of the standard approved assessment statements listed in § 900.12(c)(1)(iv)(A) through (G). As applicable to the commenter’s example, the patient’s history of cancer and prior surgery, and any relevant post-surgical findings on the images, may be described in the report, but it must conclude with a final assessment chosen from the approved statements; for example, “Benign” (see § 900.12(c)(1)(iv)(B)) or “Suspicious” (see § 900.12(c)(1)(iv)(D)). The Agency does not believe it is necessary to add a unique assessment statement for patients with the history described by the commenter, as the statements listed in § 900.12(c)(1)(iv)(A) through (G) are adequate to encompass patients who have previously had breast cancer and those who have had surgery, whether for cancer or other reasons.

(Comment 34) A comment mentions the potential limitations of a mammogram when a patient either cannot cooperate with or cannot understand instructions, and recommends that FDA add assessment categories that reflect these limitations,

including “Benign with technical limitation” and “Normal with technical limitation.” Similarly, another comment mentions the limitation of dense breast tissue and recommends that FDA add an assessment category for “Normal but dense.”

(Response 34) FDA agrees that some mammograms have technical limitations, but concludes that the limitations should be documented elsewhere in the report, not in the assessment statement. For clarity, the assessment statement should represent only the IP’s final conclusion about the results of the examination. The limitation of breast density is addressed elsewhere in this final rule (see § 900.12(c)(1)(vi)(A) through (D)). In particular, the limitations conferred by dense tissue must be stated elsewhere in the report, using the language in § 900.12(c)(1)(vi)(C) of the final rule, “The breasts are heterogeneously dense, which may obscure small masses,” or § 900.12(c)(1)(vi)(D) of the final rule, “The breasts are extremely dense, which lowers the sensitivity of mammography.”

(Comment 35) Several comments address the assessment category “Suspicious,” which the commenters erroneously refer to as a numerical category 4. These comments recommend that the use of alphanumeric subcategories 4a, 4b, and 4c be allowed, be encouraged, or be considered a legitimate option.

(Response 35) FDA disagrees with the recommendations to permit or encourage the use of alphanumeric subcategories instead of the assessment statement “Suspicious.” All the required assessment statements under the MQSA quality standards are words or phrases, not numbers. Thus, the assessment statements are not identical to the numerical codes derived from ACR’s Breast Imaging—Reporting and Data System (BI-RADS) (Refs. 26 and 27). BI-RADS is a practice guideline published by a professional society (the ACR), and is not associated with the MQSA quality standard requirements. While a numeric or alphanumeric BI-RADS assessment code in addition to the assessment statement may be used, one of the overall final assessment of findings statements as described in § 900.12(c)(1)(iv) of this final rule must appear in the report.

For example, in BI-RADS, category 4 (Suspicious) offers optional subcategories a through c, and phrases associated with each letter (4a: “Low suspicion for malignancy,” 4b: “Moderate suspicion for malignancy,” and 4c: “High suspicion for malignancy”), to further refine the level

of suspicion (Ref. 28). However, for any mammogram that would receive an ACR BI-RADS code of either 4, 4a, 4b, or 4c, the assessment statement required under the MQSA quality standards is not a number or a letter, but the word “Suspicious.” Additionally, the phrase associated with each ACR BI-RADS code 4a through 4c is not an approved alternative standard for use as an assessment statement; while the final rule does not prohibit such a statement from being included in the report, the overall final assessment statement, “Suspicious,” would be the appropriate statement to include as the final assessment category of the mammogram (Ref. 29).

(Comment 36) A comment recommends that FDA provide examples of when referral of a self-referred patient to a healthcare provider is mammographically indicated.

(Response 36) The proposed § 900.12(c)(2)(ii) stated 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 mammographically or clinically indicated.” FDA believes that such referral is indicated when the mammographic findings warrant followup imaging or intervention sooner than at a routine screening interval. Therefore, for patients who do not have a healthcare provider and whose mammogram results are either probably benign, suspicious, or highly suggestive of malignancy, referral to a provider is generally mammographically indicated. For clarity, FDA is revising this provision to state, “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, which shall include when such patients’ mammogram assessment is either probably benign, suspicious, or highly suggestive of malignancy” (see § 900.12(c)(2)(ii) in this final rule).

(Comment 37) A comment recommends that the lay summary inform the patient if risk factors such as density, pain, calcifications, discharge, and other items are identified on the mammogram.

(Response 37) FDA does not believe it is necessary to require this information in the lay summary. The facility is required to send the patient a summary of the mammography report written in lay terms (see § 900.12(c)(2) in this final rule). This final rule adds breast density notification language to the lay summary requirement, but it does not require that the lay summary mention patient symptoms or individual

mammographic findings. FDA does not believe that it is appropriate to require specific language for the wide range of breast symptoms and mammographic findings that may be identified. For example, some of the items mentioned in the comment, such as pain and discharge, cannot be identified on a mammogram. The regulations require that the mammography report to the provider address findings, clinical questions raised by the referring healthcare provider, and recommendations for additional actions, if any, (see §§ 900.12(c)(1)(iv)(A) and (B) and (vii) in this final rule). Some findings or symptoms may be present but not clinically significant. The referring healthcare provider, who receives the mammography report and is also familiar with the patient’s history and physical findings, is best positioned to discuss the case with the patient.

(Comment 38) Several comments address the proposed final assessment category “Post Procedure Mammograms for Marker Placement.” A comment asserts that the addition of an assessment category for a post-procedure mammogram is unnecessary. Another comment asserts that the post-procedure mammogram is “bundled into” the interventional procedure and does not receive an assessment. A comment requests clarification on whether a mammogram documenting a biopsy clip or marker requires documentation.

(Response 38) The assessment statement “Post Procedure Mammograms for Marker Placement” was approved as alternative standard #12 on September 17, 2003 (Ref. 24), under the mechanism described in current § 900.18 for the approval of alternatives to the MQSA quality standards in § 900.12. Since its approval in 2003, it has been available and acceptable for use as a final assessment statement. In this final rule, § 900.12(c)(1)(iv)(G), FDA is adding the nearly identical assessment statement “Post-Procedure Mammogram for Marker Placement” to the implementing regulations. The situations in which this assessment should be given to any particular mammogram are more appropriate for the IP to determine in the course of clinical decision-making. As FDA described in approval of the alternative standard, if a facility makes the post-procedure examination part of the interventional procedure instead of a separately charged examination, then the examination is not subject to the MQSA quality standard requirement and need not receive an assessment (Ref. 24). Nor would it require any report separate from the report of the

interventional procedure. However, when the post-procedure mammogram is logged or charged separately from the interventional procedure, this mammogram is a separate examination and requires a separate report.

This “Post-Procedure” assessment category is useful to distinguish examinations that simply document the localization of a known abnormality or a known marker without contributing new diagnostic information, so that these examinations are not misconstrued as showing new or additional abnormalities. The availability of a post-procedure assessment category also helps maintain the accuracy of the medical outcomes audit required under § 900.12(f). The audit requires followup for positive mammograms, defined in existing § 900.2(mm) as mammograms receiving assessments of either “Suspicious” or “Highly Suggestive of Malignancy,” but a post-procedure mammogram of a patient with a previously identified abnormality is not intended to be counted as a new positive result; this assessment category helps facilities to distinguish and exclude post-procedure mammograms from the audit.

(Comment 39) Two comments object to FDA’s mention of a “localization needle” in the explanation of one potential use for this “Post-Procedure Mammogram for Marker Placement” final assessment, since spatial localization may not always be performed with a needle, and recommends revising this explanation to “localization device” or “localization marker.” Another comment asserts that a marker may not always deploy and recommends changing the wording of the assessment statement to “Post procedure mammogram.”

(Response 39) FDA agrees that some localization devices are not needles, and is clarifying our explanation of the assessment category as follows: this category is primarily used for a mammogram performed following a biopsy to confirm the deployment and position of a breast tissue marker. The other use of this final assessment category is for a mammogram performed to document the position of a localization needle or other marker. During preoperative localization, a needle or other temporary marker may be positioned 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 needle or marker.

The post-procedure mammogram is typically performed in an attempt to localize a device, such as a needle or other tissue marker, or to determine whether the device has deployed. FDA concludes that this intention is accurately captured by the phrasing “Post-Procedure Mammogram for Marker Placement,” even in cases in which the mammogram reveals that a marker failed to deploy. FDA notes that all mammographic views obtained in a single examination are typically referred to collectively as a “mammogram,” and therefore agrees in part with the comment that recommends changing the wording of the assessment statement to the singular “Post procedure mammogram.” Accordingly, we are revising the wording of the assessment statement to the singular “Post-Procedure Mammogram for Marker Placement” (see § 900.12(c)(1)(iv)(G) in this final rule), in addition to clarifying the description as noted.

(Comment 40) One comment asserts that a lay-language summary to the patient should not be required for a mammogram performed for marker placement, because the mammogram is performed for localization rather than for diagnosis, and receiving a lay summary of such an examination may confuse the patient.

(Response 40) As discussed in Response 38, we have explained that if a facility makes the post-procedure mammogram a separately logged or charged examination rather than part of the interventional procedure, the mammogram is subject to all MQSA quality standard requirements, including a report to the referring healthcare provider and a summary of the report in lay language to the patient. The lay summary must be specific to the examination and report; for example, if the assessment statement in a report states that an examination was a post-procedure mammogram for marker placement, then the lay summary of that report should likewise mention the procedure or the marker placement, but it would not be appropriate to state that the mammogram results were abnormal, worrisome, suspicious for cancer, etc. FDA believes that a lay summary limited to discussing the fact that the mammogram was performed for localization after a procedure will not confuse a patient who has just undergone a procedure.

(Comment 41) Several comments recommend that FDA revise the assessment statement “Incomplete: Need prior mammograms for comparison” (proposed § 900.12(c)(1)(v)(B)) to replace “mammograms” with “breast imaging”

or “breast examinations,” to include other imaging modalities such as breast ultrasound.

(Response 41) FDA disagrees with this recommendation. The Agency concludes that extending the assessment statement “Incomplete: Need prior mammograms for comparison” to a comparison with other breast imaging modalities, which may have been performed at multiple different imaging facilities and centers, could impose delays in obtaining those prior examinations and issuing the final interpretation of the mammogram. As addressed in Response 4, the MQSA and FDA’s implementing regulations apply specifically to mammography facilities, so facilities where a patient’s prior mammograms were performed would have retained those examinations, pursuant to the MQSA record retention requirement (see § 900.12(c)(4)(i) in this final rule), and would presumably respond to the patient’s request to transfer them or release copies of their records, pursuant to the MQSA record release requirements (see § 900.12(c)(4)(ii) and (iii) in this final rule). In contrast, other imaging centers not subject to the MQSA quality standards are not required to release prior non-mammography imaging within these regulatory deadlines. Additionally, other imaging modalities may not provide the type of information that is directly comparable to the mammogram.

(Comment 42) A comment requests confirmation that an Incomplete assessment statement, which the commenter cites as “Category 0: Incomplete—need additional imaging evaluation and/or comparison with prior examination(s),” remains acceptable. Similarly, another comment recommends that FDA allow facilities to choose whether to separate the two Incomplete assessment categories or to keep them grouped together.

(Response 42) The first commenter’s citation of the assessment statement is incorrect on two points. As we noted in Response 35, all approved assessment statements under the MQSA quality standards are words or phrases, not numeric or alphanumeric codes, so the numeral zero is not required as part of the assessment. Also, the Incomplete assessment statement approved by FDA in 2003 as alternative standard #11 does not refer to “prior examinations,” but to “prior mammograms.” Therefore, the phrasing cited by the first commenter is not acceptable. However, we note that even after the introduction of the two Incomplete assessment statements in this final rule, alternative standard #11 remains in effect, such that the

combined assessment statement “Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison” may also be used. Therefore, FDA agrees with the second commenter that a facility may choose either to use one of the separate Incomplete assessment statements that appear in this final rule (see § 900.12(c)(1)(v)(A) and (B)), or to use the combined statement as found in alternative standard #11, which remains an approved alternative standard.

(Comment 43) A comment recommends that FDA expand and clarify its justification of the assessment category “Incomplete: Need prior mammograms for comparison” with a more evidence-based justification addressing the value of the comparison of a mammogram with prior mammograms. The proposed rule (under section V.E.3 of the Supplemental Materials) includes the statement, “Comparison to previous examinations is sometimes required to make a final assessment.” However, the comment recommends that FDA instead justify the value of comparison mammograms by using the statement, “Evidence shows that comparison with a single prior exam, and more so with multiple prior examinations, improves accuracy, including a reduction in the recall rate and an improvement in sensitivity and predictive value.”

(Response 43) The reference cited by the commenter (Ref. 30) demonstrates that comparison to two or more prior exams reduces the recall rate, and increases the cancer detection rate and a positive predictive value (PPV) known as PPV1. Although comparison to previous examinations is valuable, FDA does not believe that the recommended statement is fully supported by the cited reference. However, FDA agrees with the commenter’s broader implication that there are many benefits to interpreting a mammogram in comparison to one or more of the patient’s previous mammograms, including but not limited to improved accuracy and reduced recall rate. FDA believes that the final rule adequately reflects the value of making comparisons to previous mammograms when available.

(Comment 44) Some comments express concern about the timing of interpretation of a mammogram following an assessment of “Incomplete: Need prior mammograms for comparison.” A comment asserts that a patient may not be able to obtain prior mammograms within 30 days, and another comment asserts that the rule would permit a total of 60 days from the performance of the examination to the

final interpretation, assuming 30 days to obtain the prior examination and another 30 days to make the comparison and issue a final report, and that during that time the patient’s insurance or healthcare provider may change. One of the commenters recommends that FDA impose a total limit of 30 days from the performance of the examination to the issuance of the final report, and one recommends that FDA monitor the use and benefit of the new assessment category.

(Response 44) A facility is required to issue a report to the referring healthcare provider and a summary in lay terms to the patient no later than 30 days after the examination (§ 900.12(c)(3)(i)), and to issue a followup report no later than 30 days after issuing an initial report of “Incomplete: Need prior mammograms for comparison,” whether or not comparison views can be obtained (§ 900.12(c)(1)(v)(B) in this final rule). However, we note that these 30-day intervals are maximums, and represent baseline standards. There is no requirement that a facility wait a full 30 days for a patient to submit prior images, and likewise no requirement that a facility wait a full 30 days after receiving a prior comparison examination before issuing a final report. A facility may establish policies regarding a shorter interval to wait for prior examinations and a shorter interval in which to issue a final report after receiving comparison examinations, perhaps with exceptions for a patient’s individual situation. Therefore, FDA concludes that the reporting deadlines stated in the regulations as proposed and finalized are adequate. FDA also notes that although the two “Incomplete” assessment statements are new to the quality standards regulations, they are derived from the “Incomplete” assessment statement approved in alternative standard #11 in 2003 (Ref. 25) and in widespread use since that time. FDA is not aware of any concerns raised about the benefit of the use of this assessment category or concerns about the timing of the final report. The Agency further notes that the report is required to be sent to the healthcare provider who referred the patient for the mammogram, unless the patient informs the facility of a new or additional provider (§ 900.12(c)(3)).

(Comment 45) A comment expresses opposition to the new assessment statement “Incomplete: Need prior mammograms for comparison,” asserting that this will lead to an increase in the number of mammograms that either do not receive a final

assessment within 30 days, or do not receive one at all.

(Response 45) FDA disagrees with this comment. First, as noted in Response 44, this assessment statement is derived from one that has already been eligible for use since 2003 under the approved alternative standard #11 (Ref. 25). Furthermore, in this final rule, use of the assessment statement “Incomplete: Need prior mammograms for comparison” in § 900.12(c)(v)(B) also requires that “a followup report with an assessment category identified in paragraphs (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.” Thus, the imperative to issue a final assessment for the examination within 30 days is directly linked to the initial use of this incomplete assessment category. As noted, since the time that alternative standard #11 was approved in 2003, FDA has not become aware of any concerns raised about the timing or issuance of the final report.

#### *H. Deadlines for Mammography Reports*

(Comment 46) A comment recommends that the report to the healthcare provider and the lay summary to the patient should have the same deadline of 14 days. A separate comment recommends that screening mammograms should have a deadline for reports and lay summaries of 30 days from the date of the examination. Another comment recommends that when prior mammograms are needed for comparison, the report should have a deadline of 14 days and the lay summary a deadline of 21 days, respectively, from the receipt of the prior mammogram, not from the date of the current examination.

(Response 46) FDA disagrees with these comments. The deadline of 30 days from the date of the examination (or from the date of the initial Incomplete report, if applicable) is a maximum and a baseline standard. As noted in Response 44, facilities may choose to establish policies of shorter deadlines for releasing prior examinations and for performing comparisons to prior examinations. FDA concludes that the deadline stated in this final rule is adequate. Aside from the specific audit provisions in § 900.12(f), the MQSA and FDA’s implementing regulations do not distinguish between mammograms whose clinical role is screening or diagnosis. All examinations must meet the reporting deadlines, and the commenter’s recommendation of a 30-day deadline is generally consistent with the regulations. FDA concludes



that the deadline for the report should be linked to the date of the examination. This is because the receipt of prior comparison examinations may be unpredictable and inconsistent, and using the date of receipt of prior examinations as opposed to the date of the current examination for the reporting deadline could lead to delays in reporting.

(Comment 47) Several comments note an inconsistency between, on the one hand, the 30-day deadlines for all mammography reports (§ 900.12(c)(3)(i)) and lay summaries (§ 900.12(c)(2)), and on the other hand, the new earlier deadlines for the report of 14 days (in proposed § 900.12(c)(3)(ii)) and lay summary of 21 days (in proposed § 900.12(c)(2)) when a mammogram is interpreted as “Suspicious” or “Highly Suggestive of Malignancy.”

(Response 47) FDA agrees with the comments and acknowledges that these proposed deadlines were inconsistent with respect to deadlines calculated from the date of the mammographic examination. Accordingly, in this final rule we are revising § 900.12(c)(2) by deleting the words “but in no case later than 21 calendar days from the date of the mammographic examination,” and revising § 900.12(c)(3)(ii) by deleting the words “but in no case later than 14 calendar days from the date of the mammographic examination.” All reports and lay summaries, regardless of the assessment of the mammogram, must be sent within 30 calendar days of the examination (see § 900.12(c)(2) and (3)(ii) in this final rule). However, as noted in Response 46, this 30-day deadline is a maximum and a baseline standard. In many facilities, the interpretation and communication of the results is typically performed much sooner than at 30 days. Accordingly, we consider the within-30-day timeframe of the mammographic examination to be appropriate, except in the following circumstances: We require that, for positive mammograms (defined as mammograms with an assessment category of either suspicious or highly suggestive of malignancy (see § 900.2(mm))), the facility send both the report and the lay summary within 7 calendar days of the final interpretation of the mammogram. For these situations, the deadline for providing the lay summary is earlier than the general 30-day deadline from the date of the mammographic examination for all reports and lay summaries (see §§ 900.12(c)(2) and (c)(3)(ii) in this final rule). As discussed in the proposed rule (84 FR 11676), FDA believes such action by the facility is appropriate for these two final assessment categories because

they both indicate findings that warrant further evaluation.

We have noted an additional inconsistency, regarding the deadlines for sending a report to a “self-referred” patient who has not identified a referring healthcare provider. A self-referred patient receives both the lay summary and the mammography report. As discussed above (in this response), the timeframe for sending the lay summary to any patient, including a self-referred patient, is within 30 days of the performance of the examination, and within 7 days of interpretation if the assessment is “Suspicious” or “Highly Suggestive of Malignancy” (see § 900.12(c)(2) in this final rule). The timeframe for sending the report to the self-referred patient is within 30 days of the examination (see § 900.12(c)(2)(i) in this final rule), but the proposed rule did not specify any change in that deadline when the results are suspicious or highly suggestive of malignancy. We are now adding the statement “If the assessment of the mammography report is “Suspicious” or “Highly Suggestive of Malignancy,” the facility shall send this report to the patient within 7 calendar days of the final interpretation of the mammograms” (see § 900.12(c)(2)(i) in this final rule). This addition makes the 30-day and 7-day deadlines consistent for sending the mammography report to either the referring provider (if a patient identifies a provider) or directly to a patient who has not identified a provider.

#### *I. Breast Density Notification—General Support for Density Notification*

(Comment 48) FDA received comments that support the proposed requirements to provide information regarding breast density to both patients and their healthcare providers, with comments recommending that FDA finalize the regulations with the two categories of breast density in patient lay summaries and four categories in reports to healthcare providers as proposed.

(Response 48) FDA appreciates the public support for the density notification requirement. FDA believes that receiving consistent baseline information regarding breast density is important for both patients and their healthcare providers to make informed shared decisions, and that the respective requirements for the report and lay summary strike an appropriate balance between providing sufficient information to healthcare providers while maintaining a clear message to patients. Therefore, in this final rule, FDA is requiring that the breast density

notification use two categories of breast density in the lay summary to patients (see § 900.12(c)(2)(iii) and (iv)) and four categories in the report to healthcare providers (see § 900.12(c)(1)(vi)(A) through (D)).

(Comment 49) A comment states that the proposed rule creates a standard that is not backed by medical evidence.

(Response 49) FDA disagrees with this comment. The commenter is referring to the requirement for breast density notification. Both the proposed amendments and this final rule do not specify the further management of patients with dense tissue, only that these patients and their providers must be notified of their breast density. As discussed in Response 62, the Agency is revising the notification to patients with dense breast tissue to reflect that “In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers.” (see § 900.12(c)(2)(iv) in this final rule), which is supported by many scientific studies demonstrating increased cancer detection in dense breasts using supplemental imaging modalities (Refs. 10, 11, 31, and 32). This increased detection facilitates earlier treatment of mammographically occult cancers, and may reduce morbidity from the tumor and its treatment.

(Comment 50) Several comments recommend that the lay summary should contain simple, clear language, and several comments recommend that the density information should be placed at the top of the letter instead of following the result or assessment statement.

(Response 50) FDA agrees with the recommendation that the lay summary should contain clear language. In this final rule, both of the revised notification statements for the lay summary are below the eighth grade reading level on the Flesch-Kincaid scale. We conclude that the notification language represents a balance of understandability and accuracy (see § 900.12(c)(2)(iii) and (iv) in this final rule). However, the Agency does not agree that it is necessary to require that the breast density notification statement be placed in a specific location relative to other mammogram result information in the lay summary. We incidentally note that the lay summary is not required to include an assessment category or statement. Furthermore, given the range of mammogram results and recommendations that may need to be communicated by a facility to a patient, we conclude that it may be unduly restrictive to make this a requirement for facilities, and that it

may potentially be confusing to patients.

(Comment 51) A comment recommends that an explanation of medical terms must be included in all lay summaries.

(Response 51) FDA disagrees with the comment. We note that the language for the lay summary in this final rule excludes medical terminology that may not be understandable to a wide audience. We do not believe that it is necessary to require that an additional explanation of medical terms be included in a lay summary.

(Comment 52) A comment recommends that the lay summary include additional information about mammography and its limitations.

(Response 52) FDA disagrees with requiring this information in the lay summary. The language in this final rule for the lay summary includes the statement that “Dense tissue makes it harder to find breast cancer on a mammogram,” and FDA concludes that this statement is adequate in addressing the limitations of mammography as they relate to breast density. As is also stated in the breast density notification language (see § 900.12(c)(2)(iii) and (iv) in this final rule), FDA recommends that patients speak to their healthcare provider after receiving the lay summary, and this discussion can include more information on mammography and its limitations.

(Comment 53) A comment recommends that FDA work with individuals to improve the readability and understandability of any proposed language and describes existing breast density notification language as poor in understandability and causing confusion and misinformation.

(Response 53) The breast density notification language in this final rule is the result of discussion between clinicians, patients, and FDA. Both the notification statement to patients with non-dense breasts (see § 900.12(c)(2)(iii) in this final rule) and the notification statement to patients with dense breasts (see § 900.12(c)(2)(iv) in this final rule) are below the eighth grade reading level on the Flesch-Kincaid scale. We believe that these statements represent an appropriate balance between patient understandability and accuracy of the information conveyed. FDA cannot comment on the understandability of various State breast density notifications; however, FDA recommends that patients speak to their healthcare provider about any language that they do not understand.

(Comment 54) A comment recommends that visual aids and medical cartoons for patients with low

literacy should be included, to decrease health disparities.

(Response 54) FDA acknowledges that patients of limited literacy may need assistance with the interpretation of the lay summary. However, FDA does not believe it is necessary to require this information in the summary. The requirements for the lay summary represent baseline standards; FDA recognizes that facilities may choose to provide additional information or explanation they feel is needed by their patients. The breast density notification language in this final rule is meant to be concise and clear, and adding visual aids and medical cartoons into the lay summary may potentially distract from the primary message regarding a patient's breast density and resulting recommendations. FDA notes that the interaction between a patient and their healthcare provider presents an appropriate opportunity to address questions that a patient may have regarding the lay summary. The required language in this final rule (§ 900.12(c)(2)(iii) and (iv)) includes such a recommendation to talk to a healthcare provider.

(Comment 55) Several comments recommend that in addition to the breast density notification, FDA add patient education and a clear plan of management to the lay summary.

(Response 55) FDA disagrees with the comment. We conclude that the language in this final rule provides a foundation for patients to be informed regarding their breast density when using mammography. The intent of the lay summary being required and provided to the patient is not to serve as an exhaustive resource regarding breast disease and its management. The lay summary includes the recommendation for the patient to talk to their healthcare provider, and we note that this interaction is an appropriate opportunity for additional patient education. Regarding the recommendation that the lay summary include a clear plan of management, FDA notes that the lay summary is generated by the breast imaging facility, whereas the plan of clinical management for each individual patient will be developed by the patient and their healthcare provider, and as such, it is not appropriate for this type of information to be included in the lay summary.

(Comment 56) A comment recommends replacing the phrase, “The breasts are almost entirely fatty,” in § 900.12(c)(1)(vi)(A), with the phrase, “The breast tissue is of low density,” asserting that the former statement has

“negative connotations” to many patients.

(Response 56) FDA disagrees with the comment. FDA notes that this category, and the others in § 900.12(c)(1)(vi)(A) through (D), are already in widespread use in breast density reporting. Thus, FDA believes it would be confusing to replace the “almost entirely fatty” category with the “low density” sentence recommended by the commenter, as it would be unclear whether “low density” referred to the breast density category in § 900.12(c)(1)(vi)(A), “The breasts are almost entirely fatty,” or the density category in § 900.12(c)(1)(vi)(B), “There are scattered areas of fibroglandular density.” Additionally, the breast density assessment statement in § 900.12(c)(1)(vi)(A) is included only in the report intended for the healthcare provider, and not in the lay summary sent to the patient, so it will not be sent to patients with a referring provider. Self-referred patients will receive the lay summary as well as the report, which should help mitigate any unintended negative connotations of the report.

(Comment 57) A comment questions the benefit of the density notification and recommends that FDA should involve more individuals in the drafting of density notification language, and that this language should describe the limitations of density assessment, the risks of overdiagnosis and overtreatment such as gadolinium exposure from MRI and radiation exposure from additional mammographic evaluation, and the lack of benefit of density notification. A comment recommends adding additional language educating patients about breast density, what it means to a patient, and how patients can take extra steps to protect themselves.

(Response 57) FDA disagrees with the assertion of lack of benefit in informing patients and their healthcare providers of a patient's breast density. FDA considers it to be a benefit to inform patients about their breast anatomy. In addition, FDA considers it to be a benefit to inform patients in a consistent manner about their breast density. The language in the final rule is intended as a baseline for breast density information, which can be used by patients and their healthcare providers to help inform and guide patient care. FDA notes that the provider-patient interaction is an appropriate opportunity for further discussion of breast density and of the benefits and risks of possible further evaluation. We conclude that including too wide a range of information in the lay summary, particularly information that

may not be supported by a wide consensus in the scientific community or current information that may be subject to change with future advances in knowledge and understanding, may unnecessarily increase patient confusion and lead to reduced effectiveness of the breast density notification.

(Comment 58) A comment recommends eliminating the recommendation in § 900.12(c)(2)(iii) for patients with non-dense breast tissue to talk to their healthcare provider. Another comment recommends that patients should be directed to additional information on breast density, not just to their referring physician.

(Response 58) The Agency believes it is important for patients to have an understanding of their breast density to promote informed and shared decision making about whether supplemental screening is appropriate based on each patient's individual circumstances, and speaking with their healthcare provider is an additional opportunity to accomplish this. The final rule does not prohibit facilities or healthcare providers from providing additional information on breast density to patients; however, FDA concludes that specific additional resources on breast density should not be codified in the final rule as a requirement to be provided as part of the lay summary, particularly since these sources of information may change or become outdated.

(Comment 59) A comment asserts that there are conflicting reports of the density discussion at the 2011 NMQAAC meeting.

(Response 59) FDA disagrees with the comment. A transcript of the 2011 NMQAAC meeting is available (Ref. 33). The transcript shows there was general agreement on requiring density notification and advising patients to speak with their healthcare providers. In 2011, there was some disagreement among the members of the Committee on particular issues such as the definition of a dense breast, the degree of cancer risk conferred by dense breast tissue, and recommendations for further evaluation of patients with dense breasts. FDA notes that since 2011 there is now greater consensus in the scientific and medical practice community on the categorization of breast density and the degree of risk it confers, and also greater availability of imaging modalities for supplemental screening (Ref. 31). This final rule only recommends that patients speak with their providers, and does not make any specific recommendations for further imaging or other evaluation, which is

more appropriately reserved for the unique clinical decision-making process that takes place between a patient and their provider.

(Comment 60) A comment recommends that there be four different patient notification statements in the lay summary rather than two. A comment recommends adding detailed explanatory information regarding breasts as “dense” or “not dense,” or adding a four-category patient density notification.

(Response 60) FDA concludes that the two patient notification statements (*i.e.*, informing patients that they have “dense” breast tissue or “not dense” breast tissue) provide a clear message to patients regarding their breast density, and that generating four different categories, each with unique language in the lay summary, would potentially add confusion for some patients, as well as an increased burden on facilities. FDA concludes that the language in this final rule for the lay summaries (§ 900.12(c)(2)(iii) and (iv)) provides an adequate baseline for breast density notification to patients given that the purpose of the letter is not to serve as a complete resource for breast density information and, further, that the inclusion of more detailed information might detract from the actual notification, including by dissuading patients from reading the notice at all, given its length.

(Comment 61) A comment asserts that there is variability and limited reproducibility in the determination of dense versus non-dense breasts, and that if this variation is expressed as changing assessments, women may lose confidence in the screening mammography process.

(Response 61) FDA acknowledges that for some patients there may be some degree of variability in the determination of breast density due to interobserver and intra-observer variability. FDA notes that there have been advancements in technology (*e.g.*, density classification software devices) that may help mitigate such variability in assessment. In addition, we conclude that potential variability in density assessment does not outweigh the importance of communicating breast density to patients and their healthcare providers. FDA disagrees with the comment that patients will lose confidence in mammography if their breast density assessment changes. If a patient has any concerns regarding any aspect of the mammogram, including the breast density assessment, the patient may contact the referring provider or the mammography facility. This final rule contains requirements for

facilities regarding providing mammogram studies and reports to patients upon request (§ 900.12(c)(4)).

(Comment 62) A comment recommends that the final rule not contain the statement that some patients with high breast density may need other imaging tests in addition to mammography, as this is not supported by evidence, and may lead to false positives, overtreatment, and overdiagnosis.

(Response 62) The language in the final rule is not intended to require additional imaging evaluation for patients with dense breasts, but rather to provide a baseline of information for discussion between a patient and their healthcare provider. Accordingly, we are revising this sentence of the notification to reflect that other imaging tests in addition to a mammogram may help find cancers, as opposed to stating that some patients with dense tissue “may need” additional imaging. The notification in this final rule states, in part, that “In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers.” (see § 900.12(c)(2)(iv) in this final rule). The density notification requirement does not specify additional clinical management, but the Agency believes that the communication of breast density information is important for a patient to better understand their own situation and to facilitate joint decision-making by the patient and the healthcare provider.

(Comment 63) A comment recommends that FDA withdraw the requirement for breast density notification to patients from the final rule until better evidence is available, asserting that breast density notification will cause undue worry for women without specific actions they can take.

(Response 63) FDA disagrees with the recommendation to withdraw the requirement for breast density notification to patients. We conclude that there is already adequate support for informing patients of their breast density, and while we do not believe that it is appropriate for this final rule to contain requirements regarding specific followup imaging tests, this rule does contain the recommendation for a patient to discuss their breast density and individual situation with their healthcare provider.

(Comment 64) A comment recommends that FDA allow variation in the wording of the breast density notification in the lay summary and states that the commenter's State already requires density reporting with the use of four density categories.

Another comment states that FDA already has density wording.

(Response 64) FDA disagrees with the recommendation to allow variations in the wording of the density notification. The required breast density notification language in this final rule is intended to provide a uniform density notification; however, the final rule does not prohibit facilities from providing patients with additional information regarding breast density. FDA disagrees with the assertion that there was already density notification wording provided by FDA prior to the publication of this rule.

(Comment 65) A comment recommends that increased risk of breast cancer be included in the lay summary for patients with dense breasts, and that qualifying words such as “may” be eliminated.

(Response 65) FDA agrees with the recommendation to include a statement in the lay summary about the increased risk of breast cancer associated with dense tissue (see Response 75). We are revising the notification language in this final rule, including the sentence “Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer” (see § 900.12(c)(2)(iii) and (iv) in this final rule). The word “may” is used in the revised statement that “In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers” (see § 900.12(c)(2)(iv) in this final rule). FDA believes that this language in the lay summary is appropriate for communicating breast density information and recommendations without causing undue alarm to patients.

(Comment 66) A comment recommends adding BI-RADS density categories to the MQSA regulations.

(Response 66) We note that the breast density assessment statements in the report to the healthcare provider, as written in § 900.12(c)(1)(vi)(A) through (D) in this final rule, correspond to the wording of the density categories in the BI-RADS 5th edition (Ref. 34) (see also Response 35).

(Comment 67) A comment recommends that facilities be required to have different lay summaries, for those given to patients at “time of service” and for those that are mailed.

(Response 67) FDA does not agree that it is necessary to require facilities to have different versions of the lay summary based on when the letter is delivered to the patient. This final rule does not prohibit a facility from adopting such a practice, but the required language in § 900.12(c)(2) must

be included in any version of the lay summary.

(Comment 68) A comment specifically recommends that the lay summary make it clear to a patient whether their breast density is high or low.

(Response 68) As addressed in Responses 76 and 79, we are revising this final rule and replacing the wording of high density and low density with “dense” and “not dense,” respectively (see § 900.12(c)(2)(iii) and (iv) in this final rule). We conclude that these revised terms will be clearer to patients. FDA believes that the language in the final rule for the lay summaries is adequate and accomplishes its intent of communicating breast density information and recommendations to patients.

(Comment 69) A comment recommends that before finalizing the rule, FDA should document the benefits of breast density notification and ensure that unintended harms are avoided.

(Response 69) FDA notes that communicating breast density to patients is an important component of empowering them to make decisions regarding their healthcare, and is the primary benefit of the breast density notifications set forth in this rulemaking. As most States already have breast density notification requirements, which vary across the country (Ref. 8), FDA concludes that it is important to have a consistent baseline for the content of these notifications. Some patients with dense breast tissue and other risk factors may be advised by their providers (based on their individual risk factors) to undergo supplemental screening, such as with ultrasound, which has been shown to increase cancer detection, particularly of small and node-negative cancers (Ref. 32); this early detection may decrease morbidity from the cancers and their treatment.

(Comment 70) A comment recommends that FDA should support development of an evidence base and guidelines for care for women with dense breasts, which can then be used to develop and provide educational materials to clinical providers in providing evidence-based supplemental screening recommendations.

(Response 70) FDA disagrees with the comment. There are many existing resources, including recommendations from professional societies and a large base of literature, that already provide recommendations on care for patients with dense breasts (including, but not limited to Refs. 10, 12 to 14, 28, 31, and 33 to 37). The MQSA implementing regulations (including this final rule) are designed to ensure that patients in the

United States have access to quality mammography services.

(Comment 71) Some comments recommend that breast density notification should not be required in the lay summary sent to women in the non-dense categories, and that if FDA requires breast density notification to women in these categories, that verbiage describing the implications of having dense tissue be minimized.

(Response 71) FDA disagrees with the comment. The Agency believes that it is important to communicate information regarding breast density to patients in all density categories. FDA concludes that the language in this final rule for the lay summary for patients who have non-dense breasts (see § 900.12(c)(2)(iii)) is of an appropriate level of detail and provides context for the breast density notification.

(Comment 72) A comment asserts that the way that risk is described by statisticians and epidemiologists, for example by comparing the risk of breast cancer between women whose breast tissue is at the extremes of greatest and least density, is misleading to the average lay person.

(Response 72) FDA notes that the language in this final rule for breast density notification in the lay summary does not communicate risk information to patients in the manner in which the commenter asserts risk information is described by statisticians or epidemiologists. As addressed in Responses 68, 75, 76, and 79, we have revised the notification statements to patients with both dense and non-dense tissue to say, in part, “Dense tissue . . . raises the risk of developing breast cancer” (see § 900.12(c)(2)(iii) and (iv) in this final rule).

(Comment 73) Several comments recommend that information on next steps needs to be included with the dense tissue notification to patients. Another comment recommends that more specific recommendations be given beyond discussing breast density with a healthcare provider, that radiologists should be specific in recommending additional imaging studies, and that all possible imaging modalities that may be more effective than mammography should specifically be mentioned in the lay summary.

(Response 73) The language in this final rule for the patient lay summary for patients with dense breasts (see § 900.12(c)(2)(iv)) includes the recommendation to speak with the patient’s healthcare provider regarding breast density, breast cancer risk, and the patient’s individual situation. FDA concludes that it is not appropriate to indicate any additional steps in a

patient's care prior to this interaction and based only on the mammogram, as individual situations and risk factors vary. FDA does not agree that it is appropriate to require the lay summary to include a discussion of all possible breast imaging modalities that may be more effective for some patients than mammography, as this would require a significant amount of information that may be difficult for patients to interpret. We believe that it is more appropriate for the healthcare provider to discuss this information with the patient and engage in shared clinical decision-making based on the patient's individual circumstances. This rule does not prohibit a facility from providing further information to patients in addition to the required language in the final rule if the facility chooses to do so.

#### *J. Breast Density Notification Language*

(Comment 74) Several comments recommend deleting the phrase "more glands than fat in the breasts" from § 900.12(c)(2)(iii), asserting that it is inaccurate because: (1) the ratio of fat to glandular tissue is not always related to density on mammography due to regional variation of fat and glandular tissue as well as a fibrous tissue component; (2) fibrous tissue is distinct from glandular tissue and often accounts for the majority of the density seen on mammograms; and (3) dense breasts have more fat than dense tissue when quantified. Another comment asserts that the breast density depends upon other factors, such as the glandular tissue and stroma projecting together, the compliance of the breast under pressure of the compression paddle and the amount of fat in the macroscopic component of stroma.

(Response 74) FDA acknowledges the presence of fibrous stroma in the composition of the breast, and agrees with the comments regarding the many anatomic, technical, and other factors that contribute to mammographic breast density. We also agree with the recommended deletion. Accordingly, we have deleted the phrase "more glands than fat in the breasts" from the density notifications in § 900.12(c)(2)(iii) and (iv) of this final rule. Additionally, this final rule does not use the term "glandular tissue" in either the assessment of breast tissue density in the report to the healthcare provider (see § 900.12(c)(1)(vi)(A) through (D)) or the notification of density in the lay summary to the patient (see § 900.12(c)(2)(iii) and (iv)).

(Comment 75) Several comments recommend modifying the language in the patient lay summary in proposed

§ 900.12(c)(2)(iv) to include a statement that higher breast density raises a patient's risk of developing breast cancer.

(Response 75) FDA agrees with the comments, and notes that studies show that women with dense breast tissue do have an elevated risk of developing breast cancer (Refs. 12 to 15). Accordingly, we have added to the patient notification language in § 900.12(c)(2)(iii) and (iv) of this final rule, a statement that "Dense tissue . . . raises the risk of developing breast cancer."

(Comment 76) Several comments recommend that FDA adopt the density notification language proposed by two commenters. This language includes: (1) a revision of FDA's proposed introductory sentences beginning with "Some patients," out of concern that they will cause alarm to patients with non-dense breasts and confusion to patients with dense breasts; (2) a recommendation to include an elective option to use four density categories in States whose notification regulations require this; (3) a recommendation to substitute the term "scattered fibroglandular tissue" for the term "scattered areas of fibroglandular density" in the mammography report, to avoid patient confusion of the phrase "scattered . . . density" with tissue that is "dense"; (4) a recommendation that patients with non-dense breasts should not be advised to speak to their provider; (5) a recommendation that patients be advised to continue routine screening mammography; and (6) a recommendation to add a statement that risk factors such as density can change.

(Response 76) FDA appreciates these comments. As described in the following and organized according to the numbered topics identified in Comment 76, we are revising some of the wording in the final rule for the lay summary.

(1) We have modified the introductory language to remove the reference to "Some patients," but we disagree with the assertion that providing some basic information about density will cause alarm to patients with non-dense breast tissue or confusion to patients with dense breast tissue.

(2) As addressed in Responses 68 and 79, we have retained the two categories of density, but changed the wording from the comparative terms "high density" and "low density" to "dense" and "not dense," in order to provide a clear message to the patient. We have also corrected § 900.12(c)(2) to specify that the lay summary shall include "an assessment of breast density as described in paragraphs (c)(2)(iii) and

(iv) of this section" (*i.e.*, the two categories of "dense" and "not dense"). In States where notification using four density categories is required by State law, facilities may also provide that information to patients, but this is distinct from the notification paragraph required by this MQSA final rule.

(3) As the commenter notes, the phrase "scattered areas of fibroglandular density" is only required in the report intended for the healthcare provider, where this phrase conforms to current clinical practice and should not cause confusion to healthcare providers. One of the goals of the MQSA and its implementing regulations is ensuring clear communication between the IP and the referring provider; therefore, the report is written using medical terminology. The phrase is not required in the lay summary to the patient; therefore, we do not agree that the phrase will cause patient confusion. For all patients, whether referred by a provider or self-referred, the lay summary will only contain a clear statement that the patient's breast tissue is "dense" or "not dense." Patients who are self-referred will also receive the report, but the lay summary should help avoid confusion. Even a patient who is self-referred for a mammogram may give the report to their healthcare provider; therefore, the precision of the report should not be sacrificed in order to tailor the language to the lay patient, who will also receive a lay summary.

(4) Regarding the commenter's recommendation that FDA should remove the advice for patients whose tissue is assessed as "not dense" to discuss breast density with a healthcare provider, FDA disagrees with this recommendation, as we believe that this conversation is appropriate for patients in all density categories.

(5) In response to the recommendation to add a statement instructing patients to continue routine screening mammograms, we believe that is part of a larger discussion, including regarding screening methods and time intervals, that should take place between a patient and the patient's healthcare provider.

(6) In response to the recommendation to add a statement that breast density and other risk factors can change, FDA concludes that adding this statement in the lay summary may be confusing and may detract from the information provided regarding the current assessment of the patient's breast density.

(Comment 77) Several comments recommend that not all women should be informed of breast density risks, and that notifying all women is ineffective

and doing so may cause confusion. Another comment recommends that breast density language should only be included in lay summaries to women with dense breast tissue.

(Response 77) FDA disagrees with the comments. A primary goal of this provision of the final rule is to provide information to patients and their healthcare providers to help guide each individual patient's care. Therefore, as noted in Response 76, FDA believes that it is appropriate for patients in all density categories to discuss breast density with their healthcare providers. The intent of this final rule is to provide breast density information to all patients and their healthcare providers to help guide each patient's care.

(Comment 78) A comment recommends that patients should be encouraged to discuss their mammography findings with their physician to determine what additional tests may be beneficial in their specific circumstances.

(Response 78) FDA agrees with the comment, and concludes that the current wording in the final rule, § 900.12(c)(2)(iii) and (iv), accomplishes this.

(Comment 79) Several comments recommend using the terms "dense" and "not dense" rather than "high density" and "low density."

(Response 79) FDA agrees with this recommendation to improve clarity and reflect clinical practice. Accordingly, as noted in Responses 68 and 76, we are revising the final rule to now state, in § 900.12(c)(2)(iii), "Your breast tissue is not dense," and in § 900.12(c)(2)(iv), "Your breast tissue is dense."

(Comment 80) A comment recommends clarification on whether FDA will provide acceptable alternative breast density reporting language, and requests that FDA consider replacing the breast density notification language with a list of required key information points proposed by one commenter.

(Response 80) FDA disagrees with the comment. One of the intents of this rulemaking is to ensure that patients receive a consistent baseline of information regarding their breast density; additionally, the notification should be subject to straightforward verification during the MQSA inspection. Therefore, the Agency is not providing alternative breast density reporting language aside from that which is included in the final rule, nor changing the notification requirement from a required paragraph to a list of key points. FDA recognizes that individual States as well as facilities may choose to provide patients with additional information, beyond the

information required in this final rule, where it does not conflict with the MQSA and its implementing regulations.

(Comment 81) A comment recommends that FDA be cautious in the use of the word "normal" when referring to women with dense breasts, since dense breasts may be pathologic and should be a subject of research for disease prevention. Conversely, several comments recommend that lay summaries should state that dense breasts are not abnormal.

(Response 81) FDA agrees that it is not necessary to characterize dense breast tissue as normal or abnormal, but rather to focus on communicating whether a patient has breast tissue that is dense or not dense. In this final rule, FDA does not use the words "normal" or "abnormal" in the breast density notification statements for patients with either dense or non-dense breast tissue.

(Comment 82) A comment recommends that the lay summary should emphasize that dense breasts are common and that most women with dense breasts do not reach the clinical threshold for having an elevated risk for breast cancer.

(Response 82) FDA agrees that dense breast tissue is common; however, we disagree with the comment regarding elevated risk of cancer. We note that studies show that women with dense breast tissue do have an elevated risk of developing breast cancer (Refs. 12 to 15), and as noted in Response 75, we are revising the patient notification language (see § 900.12(c)(2)(iii) and (iv) in this final rule) to include a statement that dense tissue raises the risk of developing breast cancer.

(Comment 83) A comment recommends that FDA include recommendations to use FDA-cleared automated breast density assessment devices, and that instead of the four categories of breast density proposed for the report to the healthcare provider, breast density should be reported along a continuum based on such automated breast density devices.

(Response 83) FDA acknowledges that there are various methods for the assessment of breast density, which may include automated processes such as FDA-cleared density assessment software devices. However, the categories in § 900.12(c)(1)(vi)(A) and (D) of this final rule are consistent with the four ACR BI-RADS categories of breast composition, which are "defined by the visually estimated content of fibroglandular-density tissue within the breasts" (Ref. 34) and do not require automated assessment. The MQSA and implementing regulations do not require

the purchase or use of specific products as a condition of facility certification, and ABs may not require the purchase or use of specific equipment or software as a condition of facility accreditation (see § 900.4(a)(5)). Furthermore, not all facilities may have or be able to afford the same equipment or software, and requiring specific equipment could potentially limit access to mammography services. Finally, the four density categories in this final rule are in wide use in current clinical practice, and will be more readily understood by clinicians than a report of individual results along a continuum.

(Comment 84) A comment recommends that the lay summary specify how dense breast tissue impacts the statistical accuracy of mammography.

(Response 84) FDA disagrees with making this a requirement of the lay summary. The Agency notes that any information included in the lay summary must account for patient understandability. FDA concludes that including a discussion of statistics in the lay summary may detract from the effectiveness of the breast density notification and recommendations. Additionally, knowledge of breast conditions and disease processes is subject to change with ongoing research, and specific statistical information may become outdated and misleading. However, as noted in Response 52, we are revising the notifications to include the statement that "Dense tissue makes it harder to find breast cancer on a mammogram. . . ." (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that this language adequately conveys the existence of a masking effect of dense tissue on mammography.

(Comment 85) Several comments recommend that the lay summary use four categories for breast density, similar to the report to the healthcare provider; however, the language used in the lay summary should be written at an appropriate education level. Another comment recommends adding the word "significantly" in reports for patients with extremely dense breasts.

(Response 85) FDA does not consider it necessary to use four categories of breast density in a lay summary. In clinical practice, further management decisions are typically based on the distinction between non-dense and dense, *i.e.*, two categories, as well as on other patient risk factors. The Agency believes that the two categories for breast density in the lay summary represent an appropriate balance between patient understanding and precision of the underlying information.

We believe that using four categories rather than two in the lay summary would not be more effective in communicating breast density information, and that doing so may be confusing to patients and burdensome to facilities. As noted in Response 60, we are revising § 900.12(c)(2) to specify that the lay summary shall include “an assessment of breast density as described in paragraphs (c)(2)(iii) and (iv) of this section,” *i.e.*, the two categories of “dense” and “not dense,” and have simplified the language used in these patient notifications.

Similarly, we note that adding the word “significantly” would effectively divide the single category of dense breast tissue into two categories, and detract from the goal of providing a clear message to patients with dense breast tissue. Also, this may cause undue alarm to patients, as this term is subjective and will not be consistently interpreted by all patients. The healthcare provider will receive the report that assesses the density on a four-category scale, and can incorporate this information into their clinical recommendations to the patient.

(Comment 86) A comment recommends that when a patient views their online medical chart from their primary care physician, rather than a report that describes their breast density, the patient’s actual mammogram images should be displayed, and the patient can assess where their own density is located along a normal distribution.

(Response 86) FDA agrees that patients should be informed and empowered in the decision-making related to their healthcare. Therefore, this final rule includes the requirement for mammography facilities to directly notify patients of their breast density in the lay summary (see § 900.12(c)(2)(iii) and (iv)), not through viewing a primary care provider’s medical chart. However, we disagree with including an image display requirement for several reasons. First, the primary care physician or other referring healthcare provider may not have the mammogram images, unless the patient has requested that the images be sent to that provider (see § 900.12(c)(4)(ii) and (iii)). Also, requiring primary care physicians to display online medical charts in a specific manner is not within the scope of the MQSA; furthermore, not all patients may choose to access online charts even when these are made available. We also conclude that it is not reasonable to expect patients to assess their own breast density and generate plans for followup based on their self-assessment. Finally, we note that

providing patients with the images from their mammogram studies when requested continues to be a requirement in the final rule (see § 900.12(c)(4)(ii) and (iii)), so if patients choose to do so, they can directly obtain their mammogram images from the performing facility, without any need to use their primary care provider as an intermediary.

(Comment 87) A comment recommends that, due to the variety of recommendations for patients with dense breasts, the lay summary should include a statement to follow the recommendations in the lay summary and in the report sent to the patient’s healthcare provider.

(Response 87) The Agency finds that the notification language in this final rule for patients assessed to have dense breast tissue (see § 900.12(c)(2)(iv)) is adequate. In the course of the clinical decision-making, the referring provider will typically read and interpret the mammography report, including its recommendations, in the context of other clinical information about the patient. We also note that all patients will receive the lay summary, but most patients (except for those who are self-referred) will not receive the report that is sent to the referring healthcare provider. A referred patient would therefore not typically have the ability to independently follow the recommendations in that report.

Although the lay summary does not explicitly state that patients should follow the recommendations in the report to the patient’s healthcare provider, it does state that patients should speak with their healthcare provider. That interaction is an opportunity for the patient to receive recommendations from their healthcare provider.

(Comment 88) A comment recommends that the lay summary should encourage patients and referring providers to discuss mammogram results with the radiologist who interpreted the mammogram. Another comment recommends that patients should have the opportunity to speak with the radiologist.

(Response 88) FDA interprets the word “radiologist” to mean the IP, as the majority of qualified IPs under the MQSA and its implementing regulations are radiologists. We agree that the IP for a mammogram is a potential resource for both patients and their healthcare providers, and this final rule does not prohibit communication between these parties. However, we conclude that it is neither necessary nor practical to include a recommendation for patients and healthcare providers to discuss the

results of every mammogram with the IP. Workflow varies across facilities; many mammograms are interpreted in batches at times when the imaged patients are not present, and many mammograms are interpreted at sites other than the facilities where the images were performed. Therefore, the IP may not be readily available to speak to all patients. The recommendations to encourage all patients to discuss their results with the IP, or to require the facility to provide an opportunity for the patient to speak with the IP, are likely to cause a significant burden on IPs and facilities, and could reduce access to mammography services. Furthermore, the referring healthcare provider is likely to have a more complete knowledge of each patient’s history and risk factors than the IP, and it is therefore more appropriate for the patient to discuss their results with their provider. There is also no need for the lay summary to encourage the referring healthcare provider to discuss the results with the IP, as the provider does not receive the lay summary (but does receive the more detailed mammography report). Healthcare providers who require additional information after reading a mammography report can typically contact the IP.

(Comment 89) A comment asserts that DBT is considered supplemental to conventional mammography, and recommends that this be made clear in the notification wording, to prevent a large increase in orders for screening breast ultrasound examinations.

(Response 89) FDA disagrees with this comment. The choice of imaging modalities and the various clinical guidelines for breast cancer screening are more appropriately left to the judgment of the referring provider and the IP as part of the clinical decision-making process. However, FDA notes that many facilities that have DBT equipment use this DBT modality for primary screening of many or all of their patients, and do not reserve it only for supplemental screening. Furthermore, as noted in Response 108, with the exception of the medical outcomes audit (see § 900.12(f)(1) in this final rule), the MQSA and its implementing regulations do not distinguish between screening and diagnostic mammograms. Under the MQSA and its implementing regulations, DBT is a mammographic modality, and is subject to MQSA quality standards and requirements, including the reporting requirements. Therefore, under this final rule, the lay summary for a DBT examination, just like the lay summary for a screen-film mammogram or a full-field digital



mammogram, must include the breast density notification that is appropriate to the patient's breast tissue (see § 900.12(c)(2)(iii) and (iv)). See also Response 2.

(Comment 90) A comment recommends that, in addition to notifying patients about their breast density, the lay summary should also inform patients that ultrasound or MRI may be performed for additional screening. Another comment recommends that the lay summary should explicitly state that for women with dense breasts, it may be appropriate to consider additional imaging tests. Conversely, a comment notes that the U.S. Preventive Services Task Force (USPSTF) has not taken a definitive position regarding supplemental MRI or ultrasound.

(Response 90) In § 900.12(c)(2)(iv) of this final rule, the notification language for patients with dense breasts is being revised to include the statement that "In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers." FDA believes that this information, in addition to the recommendation to discuss breast density with a patient's healthcare provider that is also included in § 900.12(c)(2)(iv), provides a reasonable basis for the patient and the healthcare provider to determine an individual plan that takes into account that patient's breast density. FDA acknowledges that in current clinical practice, ultrasound and MRI examinations are frequently used as imaging modalities in breast evaluation; however, practice can change over time, and therefore we do not believe that it is necessary to specify these particular modalities in the lay summary, but rather, the various options may be discussed by the patient and the healthcare provider. In response to the comment recommending an explicit statement that it may be appropriate to consider additional imaging tests for women with dense breasts, FDA believes that the language in this final rule adequately communicates that other imaging tests may provide benefit in the evaluation of some patients with dense breast tissue. Finally, FDA agrees with the comment about the USPSTF. As noted above in Responses 2, 55, 62, and elsewhere, we have also not specified the further management of patients with dense breast tissue.

(Comment 91) Several comments address the grade level, literacy level, and readability of the notification wording, in general or for particular patient populations. A comment expresses concern that the wording is above the fifth grade level and may

cause misunderstanding, confusion, and fear. Another comment recommends that the breast density notification should adhere to FDA's best practices requirement to use plain language and should ensure that the readability is at or below the eighth grade level, or that FDA should explain why this notification is not subject to its general policy on risk communications, and continues that if the reading level exceeds the eighth grade level, FDA should issue a supplemental rule with modified breast density notification. Another comment asserts that the reading level recommended for U.S. women is the fifth to sixth grade level, and recommends that any prescribed language should undergo assessment with tools such as Flesch-Kincaid, Dale-Chall, or the Patient Education Materials Assessment. A similar comment recommends that the Agency should apply textual analysis tools to its proposed notification and consider how to address issues raised with understandability and readability. A comment recommends that if FDA conducted message testing, the results should be made available, and if it did not, it should undertake testing to determine whether the notification is capable of achieving its intended purpose. Another similar comment recommends that FDA should use accepted readability tools to analyze its notification language for readability and understandability, and test the notification among a diverse and representative set of mammography-eligible women, to ensure that it is clear and understandable to all women, and adequately explains all "hard" terms, particularly "breast density." Another comment recommends that the Agency should test the notification with an adequate sample of African-American and Hispanic women.

(Response 91) FDA acknowledges these comments. The notification language in this final rule is not intended to be a complete discussion of breast density, but rather to encourage further discussion between each individual patient and their healthcare provider. Readability testing was performed internally by FDA on an earlier draft of the breast density notifications, and although FDA modified the text of the breast density notification from the draft the committee reviewed, FDA incorporated the feedback it received to modify the required breast density notification statements to a lower grade reading level. Many factors, including but not limited to scientific accuracy, adequacy, and readability, were considered in

composing the final patient density notifications in this rule. As noted in several responses, in this final rule we are revising both the non-dense and dense breast notifications. The non-dense breast notification (see § 900.12(c)(2)(iii) in this final rule) now states, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." The dense breast notification (see § 900.12(c)(2)(iv) in this final rule) now states, "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation." Both of these notification statements are below the eighth grade reading level on the Flesch-Kincaid readability scale, which is the average reading level among adults. FDA believes that these notifications and their reading level appropriately balance readability with scientific accuracy and adequacy of information. The Agency also notes that the wording of the notification statements in this final rule is simpler than most of the State breast density notification statements currently used across the country, which are written at a higher reading level (see Ref. 8 for the State notification statements). The simpler language of the Federal notification statements represents a baseline national standard for density notification. FDA notes that further information about appropriate reading levels is also addressed in the response to Comment 92.

(Comment 92) Several comments discuss the research literature on public health messaging in general and breast density notification in particular. A comment recommends that FDA consider the literature on how public health messages are received. Another comment recommends that FDA acknowledge the findings of the Boston University study and other research on the readability and understandability of public health messaging. A comment encourages the Agency to consult the researchers funded by the ACS who are studying the communication of breast density information to women. Another

comment recommends that FDA should assess the State breast density notification requirements to evaluate their benefits to public health, including reviewing the existing literature, and performing an assessment either alone or in partnership with other entities.

(Response 92) FDA acknowledges these comments. We have reviewed some of the research on the readability and understandability of breast density notification, such as References 37 to 40, including the research of the Boston University group (including Refs. 42 to 44). As noted in Responses 52 and 91, FDA believes that the revised notification language in this final rule appropriately balances readability, accuracy, and adequacy, and is simpler than most of the State breast density notifications currently in effect across the country. The revised notification statements in this final rule (see § 900.12(c)(2)(iii) and (iv)) are consistent with the recommendations of most of these researchers, including that the density notification should be written at a lower grade level than most current State density notifications. The Agency agrees with the Boston University researchers (see Ref. 43) that the notification in this final rule should not be the only information a patient receives about breast density, but rather is intended to establish a consistent national baseline standard and to encourage further discussion between each individual patient and their healthcare provider.

(Comment 93) Several comments address the use of languages other than English. A comment recommends that FDA identify and require best practices for disseminating messages about breast density in multiple languages, to reduce anxiety and confusion. Another comment recommends that facilities should be urged or even required to translate the density information into the prevalent or dominant languages of their patient populations. Another comment asserts that there must be a Spanish translation, and recommends that translation into Mandarin, Hindi, or other commonly used languages should also be performed.

(Response 93) FDA acknowledges that patients of limited English literacy may need assistance with the interpretation of the lay summary. However, FDA does not believe that it is necessary to add additional language requirements for the lay summary. The MQSA and its implementing regulations establish baseline national standards. Under the current regulations, the required statements in the mammography report, such as the final assessment statement, are in English. Likewise, the required

statements on breast density that this final rule adds to the mammography report (§ 900.12(c)(1)(vi)) and the corresponding required breast density notification statements that this final rule adds to the lay summary (§ 900.12(c)(2)(iii) and (iv)) are in English. Facilities are encouraged to make every effort to communicate with their patients, and FDA recognizes that facilities may choose to provide patients with a translation of the breast density notification statement, but FDA does not believe it is practical for the Agency to regulate such translation. The English-language notification statement in this rule must be included in the lay summary regardless of any additional information or translation that a facility may elect to provide to the patient.

#### *K. Breast Density Notification and the Role of the Referring Healthcare Provider*

(Comment 94) Several comments recommend that, in addition to breast density notification, FDA should require that the report to the healthcare provider include a recommendation that the healthcare provider perform a risk assessment.

(Response 94) The reporting requirements in this final rule are intended to promote clear communication about the results of the mammogram, not to prescribe other aspects of patient care. FDA acknowledges that risk assessments may be an important component of care for some patients; however, the Agency generally defers to healthcare providers to determine when a risk assessment is appropriate for their patients, and so declines to require that such an express recommendation be included in mammography reports. As noted in several other responses, the notification statements to patients with dense or non-dense tissue both say, in part, “Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation” (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that the interaction between patients and their healthcare provider presents an appropriate opportunity for the healthcare provider to assess the patient’s individual risk factors.

(Comment 95) A comment asserts that most healthcare providers are not equipped to discuss potential options for further assessment with patients who are reported as having dense breasts.

(Response 95) FDA disagrees with this comment. Many resources related to breast density are available to healthcare providers from various sources such as

professional societies, continuing education courses, and articles in professional journals (including, but not limited to Refs. 10, 12 to 14, 28, and 31 to 37), so healthcare providers should generally be equipped to discuss with patients potential options for further assessment.

(Comment 96) A comment asserts that there is little difference between heterogeneously dense breasts and extremely dense breasts, and that there is interobserver variability in assessing breast density.

(Response 96) FDA acknowledges that in some cases there may be interobserver variability in breast density assessment (*i.e.*, different IPs may assign different density categories to the same examination). However, we note that categorizing breast density is part of the IP’s mammogram interpretation, and is not controlled by FDA. After the IP assigns a category, the final rule requires the category to be included in the mammography report, using the wording in this final rule (see § 900.12(c)(1)(vi)(A) and (D)), to promote clarity of communication between the IP and referring healthcare provider. We also note that the two categories of breast density cited by the commenter, which appear in § 900.12(c)(1)(vi)(C) and (D), respectively, as well as the other two categories in § 900.12(c)(1)(vi)(A) and (B), are already in wide use and conform to current clinical practice.

(Comment 97) A comment recommends that additional information and images regarding breast density be provided to clinicians and patients, and that FDA should consider providing, for clinicians, a reference to a specific article on breast density and the risk of interval cancer (Ref. 45).

(Response 97) FDA disagrees in part with this comment. Patients are not trained to interpret mammograms; the patient’s referring healthcare provider is best suited to explain the mammogram results to the patient and provide additional information as needed. For healthcare providers, some references are cited in this final rule (including, but not limited to Refs. 10, 12 to 14, 28, 31 to 37, and 45) and healthcare providers can also identify additional resources such as medical journal articles, continuing education courses, or practice guidelines from professional societies that are most current or most relevant to the specific situation of the healthcare provider’s patient.

*L. Format for Image Interpretation, Retention, Transfer of Original Images, and Release of Copies*

(Comment 98) A comment recommends clarification of the meaning and intent of the term “original format” as it relates to mammographic studies. Another comment recommends that digital images should not contain computer-aided detection (CAD) markings. A comment agrees with the proposed requirement to retain mammograms in the original modality in which they were obtained and not copied or digitized, and recommends that facilities be required to adhere to this requirement immediately upon publication of the rule rather than 18 months after publication of the rule.

(Response 98) We note that neither the proposed rule nor this final rule uses the phrase “original format.” The rule states that mammograms must be presented for interpretation in the “original mammographic modality” in which they were performed (see § 900.12(c)(1)), must be retained in retrievable form in the mammographic modality in which they were produced (see § 900.12(c)(4)(i)), and cannot be produced by copying or digitizing hardcopy originals (see § 900.12(c)(4)(i)). For mammographic images obtained by screen-film mammography, this means that the original films that were performed and used for interpretation must be retained, and they cannot be copied, scanned, or digitized to meet the record retention requirement. Mammographic images obtained by FFDM or DBT must be retained in digital format. In the rare situations in which FFDM images, which are produced in a digital format, are then printed and interpreted on hardcopy film, the facility may choose to retain this hardcopy print alongside the digital data, but if this hardcopy in turn is scanned or digitized, such scan cannot be the sole record of the examination that is retained. To ensure compliance with the requirement to maintain the original mammograms in § 900.12(c)(4)(i) and (ii), digital (FFDM or DBT) images must be retained such that the file format and all other characteristics of the original digital image files are preserved. Moreover, to ensure compliance with this requirement any CAD markings placed by computer software after the mammographic images are obtained, and which typically overlie and obscure portions of the image, must be removable and the images must be capable of being displayed without the CAD marks. A facility may choose to retain a set of the images with

permanent CAD marks, but this set of images alone would not meet the retention requirement. FDA does not believe that these requirements should be effective earlier than the other provisions of the rule.

(Comment 99) Several comments recommend requiring facilities to store and transfer images in Digital Imaging and Communication in Medicine (DICOM) format. A comment recommends that DICOM be required so that proprietary file formats, which receiving facilities may not be able to view, are not used.

(Response 99) FDA disagrees with these comments. Although FDA acknowledges that DICOM is currently the predominant format used for image files in medical imaging, requiring the use of a specific file format in the MQSA regulations is overly restrictive and may limit the future development of alternative formats, including formats that offer improvements.

(Comment 100) Comments were received that recommend the use of lossy compression for digital mammogram images.

(Response 100) FDA disagrees with these comments. Section 900.12(c)(4)(i) of this final rule states that a facility “Shall . . . maintain the mammograms and mammography reports in a permanent medical record of the patient” for a specified time period, and § 900.12(c)(4)(ii) states that a facility “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 this time period. Thus, the facility must retain the original mammogram, and must have it available for transfer upon request. Because lossless compression permits complete reconstruction of the image data, images undergoing such compression would be generally considered to be “original” mammograms for the purposes of § 900.12(c)(4) (this aligns with statements made by FDA in the PGHS (Refs. 46 to 48) regarding lossless compression of digital mammographic images). In contrast, images that have undergone lossy compression, which does not maintain all of the data related to the mammogram image files, would generally not be considered to be “original” mammograms for the purposes of § 900.12(c)(4). Transferring images that have undergone lossy compression would have potential consequences regarding the ability to process the digital mammogram files, and potential implications for the

visualization of both normal tissue and abnormalities that may extend beyond the subjective image quality. While we acknowledge that data storage and transfer may pose significant considerations for facilities, we do not believe there is consensus on what loss of information is acceptable while maintaining the standards to be able to review and/or transfer the original mammogram images as required in the regulations.

(Comment 101) FDA received several comments that requested clarification on the conditions by which digital mammogram files are transferred between facilities, including the permissibility of downloading images from one facility to another, digitization of comparison images, and uploading of digital mammogram images from a compact disc (CD) to a receiving facility’s picture archiving and communication system (PACS). A separate comment recommends that FDA require that mammograms be available for electronic transfer rather than by using physical media such as a CD. Another comment recommends that FDA develop a cloud-based or electronic repository of mammogram images for all MQSA-certified facilities.

(Response 101) Section 900.12(c)(4)(ii) and (iii) of this final rule address the transfer of original mammograms and release/provision of copies of mammograms, respectively. The Agency wishes to clarify its use of the terms transfer and release/provision of copies. In these regulations, “transfer” means the conveyance of the mammogram such that the sending facility no longer retains it. Screen-film examinations often are transferred; transfer of FFDM and DBT examinations is extremely rare because the original images are typically retained in the sending facility’s PACS even when copies are released upon request. In the final rule, FDA distinguishes between “interpretation” (*i.e.*, initial, repeat, or additional review of a mammogram), for which an examination must be presented in the original mammographic modality in which it was performed (see § 900.12(c)(1) in this final rule), and “comparison” (*i.e.*, using a mammogram to aid in the interpretation of another exam), which is not subject to that requirement. Under the final rule, if transfer is requested, original mammograms must be transferred in the mammographic modality in which they were produced. Also, under the final rule, for interpretation purposes (including “second opinion” or additional interpretation), digital examinations must be presented to the IP in their

original digital modality. Thus, if a facility requests an FFDM or DBT examination in order to perform a second or additional interpretation at the request of the patient or their representative, the exam must be provided in its original modality (FFDM or DBT, respectively). We note that this may be accomplished either through transfer of the original images (which is rare), following the processes described in §§ 900.12(c)(4)(ii) and (iv) of this final rule, or through the release of a digital copy, following the processes described in § 900.12(c)(4)(iii) and (iv) of this final rule. FDA recognizes that many facilities may request the release of copies of mammograms not for interpretation of the requested exam, but for comparison purposes (*i.e.*, in order to aid the interpretation of a subsequent exam); such release must follow the processes described in § 900.12(c)(4)(iii) and (iv) (see also Response 102 below).

Technical methods of either transfer or release are not prescribed by the final rule, and may include, but are not limited to the following (assuming such transfers/releases otherwise comply with applicable law): direct electronic transmission of digital mammogram files that is arranged between two facilities utilizing Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant and appropriate practices for privacy and data security; providing the requesting facility with HIPAA-compliant remote electronic access to the images in the PACS of the originating facility; the viewing of digital mammogram images located on a physical storage medium such as a CD; or the uploading of such images from a digital storage medium to a receiving facility's PACS. FDA views all of these methods as meeting the requirement to provide original digital images electronically. FDA disagrees with the comment recommending that FDA require facilities to have the capability to electronically transmit original images or copies, rather than transmit via physical media such as CD-ROM, as FDA believes such a requirement may be overly burdensome and could impact a facility's ability to operate, which could reduce patient access to mammography services. We also disagree with the recommendation that FDA should develop and maintain a repository of mammogram images performed at all MQSA-certified facilities. We note that while such a repository could facilitate image comparison between facilities, there are significant privacy concerns, and also concern for the expense and resources

required to establish and maintain such a repository. In addition, it may be excessively burdensome for facilities to participate in such a repository when facilities are already required to retain original mammogram images.

(Comment 102) A comment recommends that FDA develop a form asking if a facility is able to view hardcopy images, and a similar comment recommends that "some consideration be given for facilities that no longer have equipment suitable for viewing hardcopy images." A comment also recommends that facilities should be required to transfer 2D images and images from other breast imaging modalities only, but should not be required to transmit DBT image sets due to their file size unless specifically requested.

(Response 102) FDA disagrees with the recommendation to develop a form regarding hardcopy viewing capability. As discussed in Response 101, this final rule includes different requirements when transferring original mammograms versus when releasing copies (see § 900.12(c)(4)(ii) and (iii) of this final rule). We reiterate that, in current practice, it is very rare for any facility to transfer a digital mammogram, whether FFDM or DBT. For these digital modalities, if a comparison is sought, typically only copies are provided, while the original images are retained by the performing facility, *i.e.*, they are not transferred. The requirements in this final rule are less stringent for the release of copies than for transfer of the original examination. Either original images or exact copies of digital exams may be used for interpretation (such as a second opinion) or comparison (see § 900.12(c)(1)). Copies of screen-film examinations may be used for comparison but not for interpretation (see § 900.12(c)(1)). However, FDA does not consider film copies of screen-film examinations to be in the original mammographic modality for purposes of § 900.12(c)(1), and thus such copies may be used for comparison but not for interpretation. As noted in Response 101, a facility may provide a digitized or scanned copy of a hardcopy original, such as a scan of a screen-film mammogram, either directly or via physical storage media. Therefore, a receiving facility that cannot view a hardcopy image may request a scanned or digitized copy for comparison purposes; the original film is only required if it is being submitted for interpretation, such as a second opinion. Note that this rule does not specify any requirement for the type of images that must be included when

copies are released. Also, images from non-mammography imaging modalities are outside the scope of this rulemaking.

#### *M. Deadlines for Image Transfer and the Release of Copies*

(Comment 103) Several comments were received regarding "transfer" of comparison studies between facilities. A comment states that 15 calendar days is too long for a facility to transfer patient mammograms if a final report is required within 21 to 30 days. A comment notes that 15 calendar days is too accelerated a time for facilities to transfer large image files such as those associated with DBT image files when original images are requested for transfer. A comment agrees with requiring transfer of images within 15 days, but it recommends that FDA encourage facilities to transfer images within 7 days.

(Response 103) FDA generally disagrees with these comments. As noted in Responses 101 and 102, this rule distinguishes between transfer of original examinations and release of copies. For digital (FFDM and DBT) examinations, it is very rare to transfer the original; when comparison is sought, typically a copy is released. However, under this rule, the required timeframe is the same for either the transfer of originals or the release of copies, and therefore this response addresses both scenarios.

FDA believes that requiring the transfer of original mammogram studies, and the release of copies, within 15 calendar days of a request provides adequate time for a comparison to be made and a followup report to be issued (see § 900.12(c)(4)(ii) and (iii)), because the receiving facility will be aware of the deadline for issuing the final report, and can prioritize making the necessary comparison upon receiving the prior examination. FDA also notes that 15 days is the maximum amount of time allowed for a facility either to transfer original mammogram studies or to release copies, and is intended to be a baseline requirement, but we anticipate that the transfer or release will frequently occur in less than 15 days. FDA disagrees that 15 days is too little time for DBT studies to be transferred (or copies to be released) between facilities, despite the size of the image files, as the size of the file does not significantly affect the time required to provide electronic access to it, transmit it, or copy it. FDA believes that requiring the transfer of original examinations or the release of copies within 7 days may not allow adequate time for a facility to effect this transfer or release.

(Comment 104) A comment recommends that the 15-day requirement for the transfer of patient files be reconsidered since some records are faxed or mailed and would be difficult for a facility to track, and because there are already specific rules for medical recordkeeping, making this requirement redundant.

(Response 104) The 15-day deadline refers to the sending of (or provision of electronic access to) the requested records by the sending facility, not to their receipt by the receiving facility. FDA acknowledges that delivery time may be delayed by factors that are beyond the control of the sending facility, so the tracking time is not included in the required timeline. Given the importance of ensuring timely communication regarding final results of mammograms, FDA disagrees that a deadline for facsimile transmission or delivery of physical media is overly burdensome as to warrant the removal of this requirement from the regulations. Moreover, although there may be other applicable State and local medical recordkeeping requirements, such requirements are subject to change/ repeal and there may be no requirements in certain States/localities. FDA believes it is important that there be consistent Federal regulations that clearly specify a timeframe in which a facility is required to transfer or release patient files, as this may have a significant impact on a patient's care and management.

(Comment 105) A comment recommends that FDA provide a guidance document that explains how a facility can demonstrate compliance with the records transfer and release requirements, including the method of determining the dates at which relevant actions occur.

(Response 105) We believe the records transfer and release requirements in this final rule, including the method of determining the dates at which relevant actions occur, are sufficiently clear. If facilities have specific questions about applicability to their situation, we believe such questions would be best addressed by directing the questions to FDA's MQSA Facility Hotline or the facility's AB.

#### *N. Facility Closure and Mammography Record Retention*

(Comment 106) A comment recommends that FDA create standard forms for use by closing facilities to communicate with patients and healthcare providers. Another comment recommends that the patients of a facility that closes or ceases mammography services should be

notified, and a comment recommends defining the term "reasonable efforts" to be made in notifying affected patients.

(Response 106) Due to the variety of circumstances that may lead to the closure or cessation of mammography services at a facility, FDA believes that a standard form would not be feasible. This final rule requires that a facility that closes or ceases to provide mammography services notify its AB and certification agency of the arrangements that the facility has made, including making reasonable efforts to notify all affected patients (see § 900.12(c)(4)(v)). FDA believes this process will enable the AB and certification agency to assess the specific circumstances of the facility to help ensure that reasonable efforts are made by the facility to notify affected patients. Reasonable efforts may include, but are not limited to, sending written notification to patients using a traceable method, speaking directly to patients by telephone, or asking referring providers to reach those patients who the facility was unable to contact directly after attempting the above methods. However, FDA acknowledges the wide range of circumstances and unique factors that may be related to the reasonableness of a facility's efforts to notify all affected patients, and therefore this final rule requires the facility to discuss its notification efforts with its AB and certifying agency.

(Comment 107) A comment recommends that FDA include a requirement that before a facility closes or ceases performing mammography services, the facility must arrange for the permanent transfer of records to a facility that will provide access for at least 24 months.

(Response 107) FDA disagrees with this comment. Section 900.12(c)(4)(v) of the final regulations states that a facility that is closing or ceasing to perform mammography services must permanently transfer mammographic records to a patient or the patient's healthcare provider, or transfer the mammographic records to another facility or entity that will provide access to those records for the patient or the patient's healthcare provider for the time periods specified in § 900.12(c)(4)(i), which are longer than 24 months. Because mammography records can be of continuing value to a patient's care, the Agency believes that they should remain accessible for the same length of time whether they were performed at a facility that continues to perform mammography or whether they were performed at a facility that has closed or ceased to perform

mammography. Therefore, the time periods for retention specified in § 900.12(c)(4)(i) apply from the date of performance of the exam at the facility through the time after records are transferred from facilities that close or cease to perform mammography to another facility or entity that will provide access to patients and healthcare providers (see § 900.12(c)(4)(v) of this final rule).

FDA also believes that if a mammography facility that is part of a medical entity such as a radiology practice or hospital ceases to perform mammography, but the medical entity does not close, the medical entity may be able to continue to retain and release the mammography records in a manner consistent with the requirements in § 900.12(c)(4)(i) through (iv). Accordingly, we are revising the proposed requirement that a facility must make arrangements for access by patients and healthcare providers to their mammographic records before the facility closes or ceases to provide mammography services, in § 900.12(c)(4)(v), to add that "If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of § 900.12(c)(4)(i) through (iv), it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient."

#### *O. Mammography Medical Outcomes Audit*

(Comment 108) Several comments recommend that FDA provide additional guidance regarding the medical outcomes audit, including clarification of the definition of a positive study, specifying which method should be used to calculate the PPV, and differentiating between screening and diagnostic mammogram studies when calculating PPV. Related comments recommend the use of a patient's screening interval, which may or may not be 1 year, as the time period over which to calculate PPV, and updating the definitions of positive and negative studies in the MQSA implementing regulations to conform to the definitions in the ACR BI-RADS 5th edition (Ref. 49).

(Response 108) In § 900.2(mm), a positive mammogram is defined as a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy." This definition was used in the discussion of the metrics for the outcomes audit within § 900.12(f). The MQSA and its implementing regulations

apply to all mammograms, including those performed for either screening or diagnosis. In this final rule, only for the purposes of calculating the audit metrics, FDA has acknowledged the distinct clinical roles of screening mammography and diagnostic mammography. For clarification, in this final rule we are replacing the phrase “For the purposes of these requirements” in the medical audit outcomes provision with the phrase “For the purposes of these audit requirements” (see § 900.12(f)(1) in this final rule).

We note that the clinical practice community recognizes several different methods for calculating the PPV, including the PPV1, PPV2sc, PPV2dx, and PPV3 (Refs. 49 and 50.). Of these variants, the PPV2sc includes the outcomes of all biopsy recommendations, whether that recommendation resulted directly from a screening mammogram (a sequence that is clinically discouraged (Ref. 49) and rarely occurs in practice) or from a subsequent diagnostic mammogram performed after an abnormal screening mammogram. As stated in § 900.12(f)(1)(i) in this final rule, FDA will require facilities to calculate the PPV as the percent of patients with positive mammograms who are diagnosed with breast cancer within 1 year of the date of the mammographic examination. This metric is essentially identical to the PPV2sc used by the clinical practice community, and uses a 1-year interval like the PPV2sc. The use of this metric is considered a minimum requirement; facilities are also permitted to calculate additional PPVs using other methods if they choose to do so. However, FDA disagrees with the recommendation to adopt definitions from a particular edition of a particular clinical practice guideline, to avoid restricting the future development of mammography practice.

(Comment 109) Several comments also recommend clarification of the definition of cancer detection rate (CDR) and recommend separate calculations for CDR for screening and diagnostic mammogram studies.

(Response 109) FDA recognizes that the clinical practice community uses various methods for calculating CDR, including calculating CDR only for screening mammograms, or separately for screening and diagnostic mammograms. The CDR calculation required by this final rule (see § 900.12(f)(1)(ii) in this final rule) is a single calculation for CDR for screening mammograms. As with Response 108, regarding PPV, the calculation method for CDR in this final rule is also

considered a minimum requirement. Facilities are permitted to calculate CDR using additional methods if they choose to do so. However, FDA also notes that the PPV required by § 900.12(f)(1)(i) of this final rule is essentially equivalent to the CDR calculation for diagnostic mammograms, so by meeting the requirements of this final rule, facilities will be calculating both the CDR for screening mammograms and a value (*i.e.*, PPV) using a calculation that is essentially equivalent to the calculation done for the CDR for diagnostic mammograms.

(Comment 110) A comment states that in BI-RADS, a screening mammogram assessed as either category 0, 3, 4, or 5 (*i.e.*, Incomplete, Probably Benign, Suspicious, or Highly Suggestive of Malignancy, respectively) is considered positive, and may be suggesting that FDA adopt this approach.

(Response 110) This final rule states that recall rate will be calculated as the percentage of screening mammograms given an assessment of “Incomplete: Need additional imaging evaluation” (see § 900.12(f)(1)(iii)). We note that assigning any of the other assessments mentioned by the commenter—Probably Benign, Suspicious, or Highly Suggestive of Malignancy—to a screening mammogram is clinically discouraged (Ref. 51) and rarely occurs in practice.

(Comment 111) Several comments recommend that FDA offer further guidance on how facilities should interpret medical outcomes data and derive performance data. A comment recommends linking the medical outcomes data with cancer registries.

(Response 111) The medical outcomes audit is intended to allow each facility to assess and improve its own performance. FDA’s finalized metrics of PPV, CDR, and recall rate for the outcomes audit are minimum requirements; facilities are not restricted from calculating additional metrics if they choose to do so. Regarding the recommendation to link medical outcomes data with cancer registries, this is outside the scope of this rule, although the regulations do not prohibit facilities from adopting this practice.

(Comment 112) Comments recommend that mammograms used for localization should have no numeric value and should be excluded from medical outcomes audits.

(Response 112) FDA agrees that mammograms used for localization should be excluded from the medical outcomes audit, and the required calculations in § 900.12(f)(1)(i) through (iii) in this final rule do not include mammograms that are in this category.

As noted in Responses 38 and 108, only a mammogram that receives an overall assessment of either “suspicious” or “highly suggestive of malignancy” is defined as a positive mammogram (see § 900.2(mm)). This final rule adds the assessment category “Post-Procedure Mammogram for Marker Placement” (see § 900.12(c)(1)(iv)(G)), which may be assigned in the clinical scenario described in this comment. If a mammogram receives the assessment “Post-Procedure Mammogram for Marker Placement,” rather than the positive assessment of “suspicious” or “highly suggestive of malignancy,” then it is not a positive mammogram, and should not be counted in any audit calculations that track the outcomes of positive mammograms.

FDA also reiterates that all of the assessment statements in the MQSA regulations are comprised exclusively of words or phrases, as noted in Response 35, and do not include numeric values or codes (see § 900.12(c)(1)(iv) and (v) of this final rule); code numbers are used together with assessments in some clinical practice guidelines, such as ACR BI-RADS, but are not part of the approved assessment statements.

(Comment 113) A comment recommends maintaining the current medical outcomes audit requirements, as the comments states that additional requirements in the proposed regulations will result in inspection failures at facilities with limited resources.

(Response 113) FDA disagrees with the comment. The Agency believes that it is appropriate to provide the additional requirements for the medical outcomes audit that are included in this final rule (see § 900.12(f)(1)). The three additional metrics in this final rule are widely acknowledged in the clinical practice community and are already in wide use in mammography practices. Because all certified facilities already perform a medical outcomes audit, which for many facilities already includes these specific metrics, we believe that adding these metrics to the requirements will not be unduly burdensome. Also, we note that although MQSA inspectors will check whether each facility is performing these calculations, those inspectors generally will not document the specific values obtained by the audit.

(Comment 114) Several comments recommend additional clarification regarding the medical outcomes audit, including how it relates to annual facility inspection, how long it should be retained, and who has access to the audit.

(Response 114) During a facility's annual inspection, the inspector generally will verify that a facility has completed its medical outcomes audit during the time period for which the annual inspection is evaluating the facility, or (in the event the inspection occurs during the first 2 years of the facility's operation) will verify that the facility has established the required audit procedures and designated an audit IP (Ref. 18). This final rule requires that facilities, at a minimum, calculate the PPV, CDR, and recall rate (see § 900.12(f)(1) in this final rule), and the inspector generally will check whether these three metrics, at a minimum, have been calculated, or that the procedures for calculating them are in place, as applicable. However, FDA does not anticipate that the inspector will document the specific values obtained by the medical outcomes audit. The inspector will generally verify that the audit IP has notified each IP at the facility of their respective individual audit results and the facility's aggregate results, or, in the event the inspection occurs during the first 2 years of the facility's operation, generally will verify that the facility has established a procedure for such notification. The inspector generally will also verify that the audit IP has documented any followup actions taken, or that the facility has established a system for such documentation. Because the audit information is subject to inspection, at a minimum, the data must be retained by the facility until the MQSA inspection that covers that medical outcomes audit (see § 900.12(f)(4)). After the MQSA inspection that covers that medical outcomes audit, the facility and the audit IP may determine any ongoing utility of the medical outcomes audit data, and may elect a longer retention time if this is deemed beneficial to the facility. As noted, § 900.12(f)(3) requires that each IP be notified of that IP's respective individual audit results and the facility's aggregate results; beyond this requirement, the facility and the audit IP can determine who else, if anyone, may have access to the data.

#### *P. Patient and Referring Provider Notification*

(Comment 115) A comment recommends that FDA and the State certification agency be required to directly notify patients and providers, and that they may use mass media only if all other options for direct notification have been exhausted, for PPNs, when a facility is not able or willing to perform the PPN.

(Response 115) FDA disagrees with the comment. The Agency notes that

some facilities that have been required to perform a PPN have reported that they were unable or unwilling to do so, but the circumstances of each facility differed. This provision of the rule (see § 900.12(j)(2) of this final rule) expressly states that FDA or a State certification agency may notify the affected population if a facility is unable or unwilling to perform such notification. The requirement recommended in the comment could cause significant delays in notification of affected patients and their providers, related to both the attempt to identify all possible options and the practical considerations of performing individual notification. If a facility is unable or unwilling to perform a required PPN, FDA intends that State certification agencies and FDA will act in the manner that best serves the interests of public health and will consider the specific circumstances when selecting the method(s) for notification of patients and healthcare providers.

(Comment 116) A comment recommends that the description of non-physician healthcare providers in § 900.12(j)(2) (*i.e.*, "other healthcare providers"), in the context of PPNs, be included earlier in the final regulations.

(Response 116) FDA agrees with the comment. The reference to non-physician healthcare providers in § 900.12(j)(2) in this final rule revises this specific provision in the 1997 MQSA final rule (62 FR 55852), which previously listed only patients and their referring physicians as parties who must be notified in the event of a PPN. This revision is intended to address notification of non-physician referring providers when their patients are among the affected PPN population. However, we agree that some earlier references in the regulations to referring physicians should also be revised to use or incorporate the term "healthcare provider." In this final rule, FDA is either replacing the word "physician" with the term "provider" or "healthcare provider," or adding one of these terms in addition to "physician," in §§ 900.2(c)(2), 900.2(k), 900.2(ii), 900.4(f)(1)(ii)(B), and 900.12(j). Some other sections of the regulations already use the term "provider," and FDA believes that this term in those instances remains accurate (see §§ 900.12(c)(1)(vi), 900.12(c)(2)(i) and (ii), 900.12(c)(3), 900.12(c)(3)(i) and (ii), 900.12(c)(4)(ii)).

#### *Q. Revocation of Certification*

(Comment 117) A comment recommends using boldface text to state that a State agency that is an FDA-approved State certification agency (SCA) under the States-as-certifiers

provision may suspend or revoke a certificate.

(Response 117) FDA understands the concern for readability of the regulations; however, FDA is unable to change the typeface and font used for display and printing of regulations in the CFR, as such stylistic issues are determined by the U.S. Government Publishing Office for the entire Federal government. For clarification, part 900, subpart C ("States as Certifiers") establishes the procedures for a State to apply to become an FDA-approved SCA, and the requirements and standards for the SCA to use to ensure that all mammography facilities are adequately and consistently evaluated for compliance with quality standards at least as stringent as those established by FDA. SCAs are required to have appropriate criteria and processes for suspension and revocation of certificates and to have a process for appeals of inspection findings, enforcement actions, and adverse certification decisions (§ 900.22(d) and (e)). SCAs cannot suspend or revoke certificates under the authority in § 900.14, but instead are required to have their own process for taking such actions.

(Comment 118) A comment recommends that FDA define an operator of a facility.

(Response 118) FDA disagrees with this recommendation. The exact role, responsibilities, and title of an operator varies depending on the specific circumstances of the individual facility and operator. Operators may include the lead IP, other IPs, QC technologist, other radiologic technologists, medical physicists, or other staff, depending on the circumstances. Operators may have varied responsibilities, including but not limited to ensuring that a facility's quality assurance program meets the requirements set forth in this final rule, interpreting mammograms, evaluating the performance of mammography equipment, positioning patients for radiographic examinations, or performing other staff responsibilities at a facility.

(Comment 119) A comment recommends that a facility that has had its certificate revoked should not return to practice without probationary oversight.

(Response 119) FDA disagrees with this recommendation. Before a facility whose certificate was revoked can return to the practice of mammography, it will have to comply with all corrective actions required by its AB. Additionally, under the MQSA, when a facility's certificate is revoked, the owners and operators of the facility at



the time of the revocation may not own or operate a mammography facility for 2 years (42 U.S.C. 263b(i)(3)). At the end of those 2 years, those operators will have failed to maintain their qualifications under the MQSA and implementing regulations, and will be required to reestablish qualification, each according to the requirements for their profession (either § 900.12(a)(1)(iv) for IPs; §§ 900.12(a)(2)(iii)(D) and 900.12(a)(2)(iv)(B) for radiologic technologists; or § 900.12(a)(3)(iv) for medical physicists) before they may resume practice at a certified facility. FDA thinks that the facility and its operators will have received sufficient training and completed sufficient corrective action before they are permitted to return to practice. Furthermore, upon returning to practice, the facility and personnel again become subject to all accreditation and certification requirements of the AB and FDA (or SCA).

#### *R. Interpreting Physician Qualifications, Including Continuing Experience*

(Comment 120) Several comments were submitted regarding the continuing experience and continuing education requirements for IPs. Comments recommend: (1) increasing the number of mammographic examinations that an IP must interpret to satisfy the continuing experience requirement; (2) adding a requirement for a minimum number of diagnostic mammograms that must be read; (3) requiring continuous feedback to IPs on individual cases rather than only at the time of the annual medical outcomes audit; (4) requiring that IPs “work up” their own recalled cases; and (5) requiring that IPs at facilities with lower volumes and in low-income areas be exposed to more mammography examinations.

(Response 120) (1) Regarding the number of mammographic examinations an IP must interpret to satisfy the continuing experience requirement, although FDA acknowledges that there may be certain benefits to increasing the continuing experience requirement, this must be weighed against a potential loss in access to mammography services if IPs are unable to satisfy these increased requirements. FDA believes that the current continuing experience requirements, as described in § 900.12(a)(1)(ii), represent a reasonable balance between the goals of maintaining an IP’s ongoing ability to interpret mammograms and preserving access to mammography services at facilities across the country.

(2) Regarding an additional requirement for a minimum number of

diagnostic mammograms versus screening mammograms, FDA again believes that while there may be certain benefits with such a requirement, establishing such a requirement may adversely impact the ability of IPs who work in varied settings to meet these requirements and to continue interpreting mammogram studies, again potentially impacting access to mammography services. Furthermore, as noted in Response 108, with the exception of the outcomes audit requirements (see § 900.12(f) in this final rule), the MQSA regulations do not distinguish between mammograms performed for screening or diagnosis.

(3) Regarding the recommendation for requiring continuous feedback on individual cases to IPs, FDA notes that there is a requirement in § 900.12(i) that “[c]linical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility’s accreditation body.” To ensure compliance with such standards, facilities conduct regular periodic reviews of the image quality of samples of the images performed by each RT and the images accepted for interpretation by each IP (see Ref. 52). This is a mechanism for providing periodic image quality feedback to IPs. The Agency believes that this requirement, together with the requirement to provide IPs with outcomes feedback from the annual medical outcomes audit and the requirements for continuing education and continuing experience are reasonable and appropriate to ensure an IP’s ongoing ability to interpret mammographic examinations.

(4) Regarding the recommendation that IPs be required to work up their own recalled cases, FDA notes that workflow as well as personnel schedules vary across facilities; also, some facilities perform only screening and not diagnostic mammograms. Therefore, we believe that such a requirement would be significantly burdensome for facilities to implement, and may be both impractical and restrictive for scheduling, both for the IP and for the patient, which could lead to decreased access to mammography services.

(5) Regarding IPs at lower volume facilities or in areas with a low-income population, such IPs are required to meet the continuing experience requirements (see § 900.12(a)(2)(ii)). FDA believes that placing additional requirements on IPs at these facilities would be detrimental to these facilities’ ongoing ability to operate and provide services to their patient populations. As with other MQSA requirements, the

continuing experience requirement is a baseline national standard; the MQSA regulations do not prohibit IPs from obtaining additional experience nor facilities from requiring that their employees obtain additional experience.

(Comment 121) A comment recommends that continuing education be specifically required to be obtained through active, case-based learning, and test sets with feedback.

(Response 121) FDA disagrees with the comment, and so has not incorporated this requirement in the final rule. FDA believes that the continuing education requirements for IPs, as described in § 900.12(a)(1)(ii)(B), are appropriate and adequate to ensure the ongoing education of IPs in mammography. Adding specific requirements such as those recommended by the commenter may be overly burdensome, risking a decrease in personnel and in patient access to mammography services. FDA also notes that specific requirements for active, case-based learning and for test sets with user feedback may be confusing to IPs and facilities determining how to satisfy such requirements.

(Comment 122) A comment recommends that double-reading be required for some IPs, such as newly trained IPs, requalifying IPs, or those who do not meet benchmarks.

(Response 122) FDA disagrees with the comment, and has not added this requirement in the final rule. FDA believes that the requirements for initial qualification of IPs, as described in § 900.12(a)(1)(i), and for requalifying IPs, as described in § 900.12(a)(1)(iv), are adequate, and in both of these situations, there is already a requirement for interpretation of certain numbers of mammograms under the direct supervision of a qualified IP. The MQSA and part 900 do not contain specific benchmarks for the performance of IPs in the interpretation of mammograms, and while we note that careful review of the results of the annual medical outcomes audit may be beneficial for IPs and informative in guiding their selection of continuing education to address areas where improvement is needed, we do not agree that it is necessary to introduce a requirement for additional supervised interpretation for qualified IPs.

#### *S. Cleaning of Mammography Equipment*

(Comment 123) A comment recommends that the MQSA regulations be more specific regarding when and how mammography equipment should be cleaned.

(Response 123) FDA disagrees that more specificity is needed in these regulations regarding this issue. The regulations already describe processes that facilities must follow regarding cleaning and disinfecting mammography equipment (see §§ 900.12(e)(11)(ii) and 900.12(e)(13)). The Agency is not aware of information showing that the existing requirements have led to contamination of equipment. This final rule does not provide additional requirements beyond those already specified because we believe that these requirements are adequate in their detail regarding the cleaning and disinfecting of mammography equipment.

*T. Availability and Clinical Role of Breast Imaging Modalities, Screening Mammography Guidelines*

(Comment 124) A comment recommends that facilities should be required to offer 3D mammography (*i.e.*, DBT) and ultrasonography within 6 months of publication of this final rule; another comment recommends that facilities should be required to offer DBT within 10 years of publication of this rule; and a comment recommends that every mammography facility should be required to have at least one 3D mammography unit. A different comment suggests that a list of facilities offering advanced technologies, including 3D mammography, should be published.

(Response 124) FDA disagrees with these comments. Various devices cleared or approved by FDA are respectively capable of performing examinations using different mammographic modalities, including screen-film, FFDM, and DBT; the choice of the specific technology used to image each patient is a decision by the IP and the patient's referring healthcare provider, if any. FDA does not require facilities to offer specific equipment or particular imaging modalities. Additionally, as stated in the proposed rule, Executive Summary section I.A, the MQSA and implementing regulations are designed to ensure that all patients nationwide have access to quality mammography services, and FDA is concerned that instituting a requirement to use only more expensive technology (*e.g.*, DBT) may place a significant financial burden on facilities, potentially impacting their ability to operate, which may then reduce patient access to mammography services. Regarding the recommendation to publish a list of facilities offering 3D mammography, FDA does offer a public database of all certified facilities (Ref. 53), but the Agency thinks that

including information on the equipment at each facility would be impractical, as equipment changes at facilities may occur at irregular and potentially frequent intervals, including both the introduction and removal of equipment, which may impact the accuracy of the information in such a list.

(Comment 125) Many comments recommend the use of specific medical imaging technologies, including 3D mammography and other modalities such as ultrasound and MRI, in varying clinical situations for the examination of patients with dense breasts. Specifically, several comments recommend that women with dense breasts should either have only 3D mammography performed, or have both 3D mammography and ultrasound performed, with a comment recommending that mammography and ultrasound should be performed every 3 months, or that imaging modalities other than mammography should be used. A comment recommends that information regarding the benefits of 3D mammography be provided to patients. Conversely, another comment recommends that 3D mammography be pulled from use until additional safety and efficacy studies have been performed due to its higher radiation dose compared to 2D imaging. Another comment recommends that patients be provided with information on ultrasound and that women should be able to choose to have either a mammogram or an ultrasound.

(Response 125) FDA disagrees with incorporating these recommendations into the regulations. Certain 2D and 3D (*i.e.*, DBT) mammography equipment has been approved or cleared by FDA following FDA's review of a premarket approval application or premarket notification (510(k)) submission. The choice of particular breast imaging modalities or screening time intervals, whether for patients with dense breasts or for any other patients, is a decision for healthcare providers to make in caring for their patients. Likewise, we defer to healthcare providers on provider-patient discussions regarding use of ultrasound or other tests when caring for their patients.

(Comment 126) Several comments recommend that providers be notified of the possibility that additional imaging modalities may be needed.

(Response 126) The consideration of the benefits, risks, and uses of various tests or imaging modalities is most appropriately left to the licensed healthcare provider. We decline to incorporate this recommendation.

(Comment 127) Several comments recommend that patients be informed of

other options for breast imaging such as molecular breast imaging (MBI), ultrasound, and MRI. A comment also recommends that patients be informed that their health insurance plan may not cover these tests.

(Response 127) FDA disagrees with adding a requirement to the regulations to inform patients of other options for breast imaging, including because the options for breast imaging may change with technological advancements. The required density notification language in the final rule includes a recommendation that all patients discuss their individual situation with their healthcare provider (see § 900.12(c)(2)(iii) and (iv)), and advises patients with dense breasts that in some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers (see § 900.12(c)(2)(iv)). Insurance coverage and reimbursement are outside the scope of these regulations; furthermore, FDA is also concerned that including references to insurance coverage in the lay summary may distract from the information in the breast density notification.

(Comment 128) Several comments suggest that MBI should be recommended to patients, be added to a list of supplemental screening methods, or have information about it provided to patients.

(Response 128) FDA believes that decisions about the use of various imaging modalities, including whether or not to consider them, are more appropriate for the healthcare provider to make, as they can take into consideration their understanding of the specific patient and the patient's needs from their relationship with the patient and medical history.

(Comment 129) A comment recommends that FDA approve thermography and ultrasound used together as an alternative to mammography.

(Response 129) As we noted in various responses, the MQSA applies only to mammography activities. Accordingly, breast sonography and thermography are both outside the scope of this rulemaking and are both outside the scope of the MQSA. Additionally, FDA has issued a Safety Communication (Ref. 54) and a Consumer Update (Ref. 55) that warn that thermography is not an effective alternative to mammography, and that there is no valid scientific data to demonstrate that thermography devices, on their own or with another diagnostic test, are an effective screening tool for any medical condition, including the early detection of breast cancer. People who choose thermography instead of

mammography may miss the chance to detect breast cancer at its earliest and most treatable stages.

#### *U. Clinical Decision-Making*

(Comment 130) A comment recommends that healthcare facilities be required to arrange mammography appointments for patients on the same day that a clinical breast exam is performed. Another comment recommends that healthcare providers be required to schedule followup appointments with patients reported to have dense breasts, and a comment recommends that physicians use shared decision-making with their patients. Several comments recommend that IPs be able to assume the role of healthcare provider for a patient with no referring provider, and that the IP should be able to order additional imaging studies such as ultrasound. A comment also recommends that patients be able to self-refer for supplemental breast imaging.

(Response 130) FDA agrees that providing timely breast imaging services to patients is important. However, the scope of the MQSA is limited to the regulation of mammography facilities and their activities (see 42 U.S.C. 263b(a)(3)), as opposed to regulation of more general healthcare provider practices, such as the ordering of imaging studies or general followup with patients by their primary care physician or referring provider. Radiologist ordering of additional imaging studies and patient self-referral for imaging are both largely dependent on State or local requirements or specific facility policies and are outside the scope of this rulemaking (see also Responses 70, 89, 90, 125, and 131).

(Comment 131) A comment recommends that breast imaging centers should not refuse to perform annual mammography on patients with dense breasts. A comment recommends that facilities should interpret mammograms in real time and add ultrasound for patients with dense breasts. Another comment recommends that radiologists use all available technologies to determine breast density.

(Response 131) The MQSA regulations do not take a position on the frequency or interval for screening mammography, as these vary and FDA generally defers to healthcare providers on such matters involving clinical decision-making with their patients. Similarly, other than the requirement to issue the report and lay summary (following interpretation of the mammogram) within respectively specified time periods (see § 900.12(c)(2) and (3) in this final rule),

the timing and workflow for the interpretation itself is generally outside the scope of this rule. FDA notes that imposing a requirement to interpret examinations in real time may be overly burdensome to many facilities and may impact their ability to operate, thus reducing patient access to mammography services. The recommendation to require facilities to add ultrasound or other non-mammographic breast imaging modalities is outside the scope of authority of the MQSA, and is addressed in responses to other comments (see Responses 2, 4, 6, 41). FDA also concludes that a requirement for facilities to use all available technologies, or any particular technology, to determine breast density is overly burdensome and would unnecessarily restrict facilities both in terms of the resources and time required to acquire the equipment and to implement such a requirement. Also, the MQSA regulations do not require the use of specific devices; similarly, no AB is permitted to require the use of specific devices or products as a condition of accreditation (see § 900.4(a)(5)).

(Comment 132) Comments recommend that mammography patients should be informed of the limitations and radiation risk of mammography and asked to provide consent prior to undergoing mammography, and that patients should be informed of the risk of overdiagnosis and overtreatment of breast cancer due to screening mammography.

(Response 132) As noted in Response 131, the clinical indications used to decide when to perform a mammogram are more appropriate for the referring healthcare provider to consider. FDA notes that the healthcare provider who refers a patient for a mammogram can discuss with that patient the benefits and risks of the examination, including the implications of the potential results, and the patient and provider can utilize shared decision-making to determine whether to proceed with the examination. Additionally, although not addressed in the MQSA or its implementing regulations, a critical component of FDA premarket approval or clearance of any mammography equipment is a benefit-risk analysis that considers the radiation exposure associated with imaging with the device, among other information, before determining that the device meets the standard for approval, clearance, or marketing authorization when used according to its stated indications (Ref. 56).

(Comment 133) A comment recommends that all mammograms should be performed as screening mammography.

(Response 133) The MQSA was passed to improve the quality of mammography, regardless of the clinical scenario in which a particular mammogram is recommended or performed. With the exception of the medical outcomes audit, as discussed in § 900.12(f)(1) in this final rule, the MQSA and its implementing regulations do not distinguish between screening and diagnostic mammography. As we noted in Response 131, the choice of a screening time interval and other clinical decisions related to mammography are more appropriate for the healthcare provider in the course of clinical decision-making with the patient.

#### *V. Insurance Coverage*

(Comment 134) Many of these comments recommend the following: (1) insurance should cover all breast imaging services, including mammography, MRI, ultrasound, and breast biopsy procedures; (2) insurance should be required to reimburse for “3D breast imaging” (this term is not specific, but the commenter may be referring to DBT, which is a mammographic modality subject to MQSA); (3) insurance coverage should not be impacted by a patient having dense breasts; (4) insurance coverage should be mandated such that socioeconomic disparities in treatment and outcomes will not be worsened; (5) additional reimbursement per examination should be granted to facilities in rural and underserved areas to cover the cost of new equipment; and (6) genetic testing and patient education should be provided at no additional expense to the patient. Another comment suggests that FDA should limit the interest rate charged by equipment manufacturers for facilities that finance equipment purchases from them. Finally, several comments recommend requiring insurers, including Medicare/Medicaid, to increase reimbursement for screening mammography and to eliminate patient expense for annual mammograms for patients aged 40 to 74 years and for high-risk patients aged 25 to 40 years.

(Response 134) FDA considers the recommendations within these comments to be outside the scope of its authority to regulate under the MQSA or other authorities. We recognize that healthcare costs are a significant concern to the public. FDA recommends that patients check with their insurance company regarding coverage before

undergoing mammography examinations.

#### *W. Economic Impact of This Rule*

(Comment 135) A comment asserts that the costs associated with MQSA are high, and recommends that a less expensive way be found to encourage and mandate that facilities use “decent” equipment and personnel.

(Response 135) To the extent the comment is about the cost of the proposed rule, FDA disagrees with the comment. As discussed in the proposed rule and elsewhere in this final rule, we considered costs and benefits. We conclude that the current final rule represents an appropriate balance between costs and benefits, with the goal of improving mammography quality and the public health.

(Comment 136) One comment expresses support for the modernization of the MQSA regulations, but states that the “breast x-ray examination fee is relatively high in the proposed rules, which ranges from \$600 to \$1,800,” and recommends that the regulations provide examination methods that are less expensive than mammography.

(Response 136) FDA appreciates the commenter’s support for the regulations. We note that the commenter misunderstood the preliminary economic analysis, which estimated at between \$615.44 and \$1,819.96 the present value of the costs to each facility to implement the changes to the MQSA regulations; these costs do not represent a fee charged to a patient undergoing a mammogram. Furthermore, as we noted in Response 134, issues of insurance coverage and reimbursement are outside the scope of FDA’s authority.

(Comment 137) Several comments state that the benefits estimated in the Preliminary Regulatory Impact Analysis related to fatalities and cost savings due to density reporting are not supported by existing evidence, and that the estimates of costs of overtreatment and overdiagnosis are omitted from the analysis.

(Response 137) Recent research has shown that 7 percent to 11 percent of patients who are informed that they have dense breasts undergo supplemental ultrasound screening (Refs. 57–59). Research studies have also shown that adjunct ultrasound screening in high-risk women with dense breasts results on average in the detection between 2.75 to 3.90 additional cancers per 1,000 women (Refs. 11, 32, and 60 to 62). Because survival rates are higher for cancers detected at an earlier stage, early cancer detection due to supplemental screening such as ultrasound for women with

dense breasts may result in a reduction in cancer fatalities. We use this existing evidence to support our analysis related to quantified benefits of breast density reporting requirements. These potential outcomes are discussed qualitatively in the Final Regulatory Impact Analysis (FRIA) (Ref. 63). Additionally, the density notification requirement does not discuss additional clinical management beyond imaging. We believe that a discussion of overtreatment and overdiagnosis of cancer is outside the scope of this rulemaking, and so have not been addressed by this analysis.

(Comment 138) A comment suggests that the analysis be revised to include distributional and equity effects.

(Response 138) FDA recognizes that distributional and equity considerations may exist as they relate to mammography practice and density notification. We have revised the distribution section of the FRIA to include a qualitative discussion of sociodemographic differences in mammography practice and outcomes.

#### *X. Federalism and the Relationship Between Federal and State Breast Density Reporting Requirements*

(Comment 139) Some comments recommend that FDA clarify the relationship between Federal and State breast density requirements, and specifically: (1) whether facilities must always use the Federal breast density notification language and (2) whether the Federal breast density notification requirements preempt State requirements. If there is preemption, a comment states that FDA should consider whether it has adequate evidence to justify such preemption, consistent with Executive Order 13132 (Ref. 64). Some of the comments submitted regarding preemption seem to be addressing express preemption, whereas others seem to be addressing implied preemption.

(Response 139) With regard to the first question, all facilities providing mammography services will be required to comply with FDA’s reporting requirements, regardless of whether there are applicable State requirements. Under § 900.12(c)(1)(vi), (c)(2)(iii), and (iv), facilities must provide the breast density information specified in those regulations in mammography reports to healthcare providers and in lay summaries to patients. The regulations do not include exceptions for facilities in States with breast density reporting requirements. As discussed in Response 140, FDA believes these requirements are critical, among other things, to ensuring that patients and healthcare

providers receive accurate, complete, and understandable breast density information.

With regard to the second question, Federal law can expressly preempt State law when the text of a Federal statute explicitly manifests Congress’s intent to displace state law. Federal law also can impliedly preempt State law when Congress’s preemptive intent is implicit in the relevant Federal law’s text, structure, and purpose. Courts have identified two subcategories of implied preemption—field preemption and conflict preemption. Field preemption occurs when a comprehensive scheme of Federal regulation implicitly precludes supplementary State regulation. Conflict preemption occurs when simultaneous compliance with Federal and State law is impossible (“impossibility preemption”) or when State law poses an obstacle to the accomplishment of Federal goals (“obstacle preemption”).

Here, Congress included a preservation provision addressing State laws, which provides: “Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.” (42 U.S.C. 263b(m)). Thus, the statute preserves any State law that is “at least as stringent” as the regulations issued by FDA under the MQSA. See also 138 Cong. Rec. 33615 (October 7, 1992) (“The bill allows and encourages states to carry out the certification program requirements and to implement standards no less stringent than those of the national program.”).

Based on the preservation clause of the MQSA, FDA’s reporting requirements do not preempt State reporting requirements that are “at least as stringent” as the Federal requirements. The provisions of the MQSA, however, do not resolve which State reporting requirements, if any, that are less stringent than the Federal requirements may be subject to preemption. That analysis would be informed by the specific provisions of the State laws in question, and FDA has not undertaken a 50-state analysis of all current State breast density reporting laws. We note, however, that it is possible for a State breast density reporting law to be preempted based on these regulations. For example, if a State law theoretically were to prohibit facilities from providing a breast density notification to patients with non-dense breasts, we believe that law could be preempted because it would be impossible for facilities to comply with

both the Federal law (which requires such breast density reporting) and the State law (which forbids it). As another example, if a State were to require a breast density statement that directly contradicts or undermines a key message in FDA's breast-density reporting requirement (such as the message that "dense tissue makes it harder to find breast cancer on a mammogram," or "dense tissue . . . raises the risk of developing breast cancer,"), that State law could be preempted on the basis that it poses an obstacle to the accomplishment of FDA's goals in communicating clear, consistent, and understandable information about breast density to patients and healthcare providers.

For further discussion of this final rule and the federalism principles expressed in Executive Order 13132, please see other responses in section X.

(Comment 140) Several comments express concern with having potentially two different breast density notifications for patients and their healthcare providers, one required by Federal law and one required by State law. The comments note that different notifications could lead to patient confusion and be overly burdensome for facilities. For these and related reasons, some comments recommend that FDA include a clear statement that the Federal breast density reporting requirements preempt State requirements, while other comments recommend that FDA not require Federal breast density reporting language and allow State language to be used instead, at least in certain circumstances (e.g., so long as certain information is included in the notification). One comment proposes that FDA develop a "waiver" process to allow the State to apply to FDA to use its alternative notification.

(Response 140) FDA declines to adopt these recommendations. As previously explained, all facilities providing mammography will be required to comply with FDA's reporting requirements, regardless of whether there are applicable State requirements. As such, all patients will receive information about their breast anatomy, and this rulemaking will require consistent baseline information be provided. But the statute does not authorize FDA to categorically assert preemption over all State reporting requirements. As discussed in Response 139, Congress specifically preserved State laws that are at least as stringent as Federal law. Depending upon the circumstances, some State laws could be found to be preempted, such as less stringent State laws that make it

impossible to comply with both Federal and State requirements, or that stand as an obstacle to the accomplishment of Federal goals. FDA has not performed a State by State analysis to determine whether any specific, current State law may be subject to preemption. FDA notes that no comment proffered a State law that was asserted to be subject to preemption.

We also disagree with the recommendation that FDA does not require Federal breast density report language and allow certain State breast density language to be used alone instead. Although FDA recognizes that many States have their own breast density reporting requirements, the Agency believes that consistent national breast density reporting requirements are critical in order to ensure that: (1) breast density reporting occurs in all States and (2) patients and healthcare providers receive accurate, complete, and understandable breast density information.

First, the Agency believes it is important to ensure that patients receive a baseline set of key breast density information. Not all States currently have a breast density reporting requirement. If FDA does not require breast density reporting, in those States that also do not have reporting requirements, patients and their healthcare providers generally would not receive any breast density information, which raises significant public health concerns for all of the reasons set forth in this preamble, and the preamble to the proposed rule.

Second, even in those States that already have a breast density reporting requirement, FDA believes there is value in having a single, consistent set of FDA-required information shared with the public. FDA breast density notification language is drafted by FDA subject-matter experts, contains the information FDA believes is critical to communicate, and is drafted using easily understandable language. FDA does not have the resources to monitor all State laws, particularly as they change over time, in order to ensure that the key information is being communicated consistently and effectively to patients and providers under State law. Requiring uniform breast density reporting on a Federal level ensures that patients and providers nationwide receive the appropriate information and avoids mistakes and gaps in critical information being communicated to patients and their healthcare providers.

Regarding the comment that patients may be confused by receiving Federal and State notifications and the

recommendation that FDA should take measures to avoid such confusion, we note that in this final rule we have simplified the notification statements to patients with either non-dense or dense tissue, using concise and understandable language, and have concluded both statements with the recommendation, "Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation" (see § 900.12(c)(2)(iii) and (iv) in this final rule). We believe that the clear language and the recommendation to talk directly to the healthcare provider will minimize the likelihood of patient confusion.

Regarding the potential burden on facilities, we believe the breast density notification requirement established in this final rule is simple for mammography facilities and Agency personnel to understand and implement. Ultimately, FDA anticipates that it will be easier for both facilities and the Agency if FDA requires uniform notification language, which consists of specific language for the overall assessment of breast density in the mammography report (see § 900.12(c)(1)(vi)) and four to five lines of text in the lay summary to patients (see § 900.12(c)(2)(iii) and (iv)), as opposed to permitting State language to be used alone in certain circumstances. FDA is concerned that alternative approaches, such as requiring that specific information rather than specific statements be communicated to patients, would be complex, inefficient, and difficult to administer, and would consume unnecessary resources in the long term. Moreover, including FDA-required text in mammography reports and lay summaries will not be unduly burdensome for facilities, including because facilities will not need to expend resources in crafting their own language. Rather, facilities will have to add the FDA-required text.

(Comment 141) Several comments note that it may be difficult for States and facilities to determine if State requirements are "more stringent" than Federal requirements, and request that FDA provide input to help determine what requirements are "more stringent" than the Federal requirements.

(Response 141) As explained in Response 140, all facilities providing mammography services will be required to comply with FDA's reporting requirements, regardless of whether there are applicable State requirements. As discussed in Responses 139 and 140, FDA has not conducted a State-by-State preemption analysis or evaluated whether current State laws are more or less stringent than FDA breast density

reporting requirements. We note that FDA has defined “[m]ore stringent,” albeit in regard to language used in section 521 of the FD&C Act (21 U.S.C. 360k), as “a requirement of greater restrictiveness or one that is expected to afford those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act” (21 CFR 808.3(c)).

#### *Y. Effective Date of This Rule*

(Comment 142) A comment recommends that all provisions of the rule except the density notification should become effective 6 months after publication. Conversely, some comments assert that 18 months is an inadequate period of time for facilities to implement the new requirements under the rule. A separate comment recommends that FDA consult with equipment manufacturers regarding an appropriate implementation date.

(Response 142) FDA disagrees with these recommendations. FDA does not anticipate that facilities would be able to implement all of the requirements of this rule into facility practice within 6 months without undue hardship. Based on FDA’s experience with the effective date of the previous MQSA final rule (62 FR 55852), FDA concludes that 18 months is a practical timeframe for this final rule to take effect (see also Response 20). Regarding the recommendation to consult with equipment manufacturers, FDA notes that, beyond meeting any applicable FDA premarket authorization requirements for medical devices, the provisions of this final rule do not necessitate the design or manufacture of any new equipment by manufacturers. Moreover, all members of the public, including equipment manufacturers, had an opportunity to comment on the proposed rule. As such, recognizing that FD&C Act requirements have been, and continue to be, applicable to medical devices generally, notwithstanding the provisions in this final rule, FDA does not believe that specific consultation is warranted.

(Comment 143) Several comments recommend that the breast density notification requirements become effective earlier than 18 months after publication of the final rule, including specific recommendations for alternative timeframes of 30 days or 12 months. Another comment recommends allowing flexibility in the effective date of the breast density notification requirements due to the cost of making these changes.

(Response 143) FDA disagrees with these comments. FDA notes that breast

density notification is an important addition to the final regulations; however, we also note that facilities should be allowed adequate time to implement these requirements into their facility practice before the requirements become effective. In addition, the breast density notification requirements should not be subject to a separate scheduled effective date than other requirements in this final rule. Facilities are not precluded from including the required breast density notifications prior to 18 months if they choose to do so, and considering any applicable State requirements. Because of the importance of establishing a consistent national standard for density reporting and notification, FDA does not agree that a longer effective date of this provision is warranted. Although there may be financial considerations for a facility in transitioning to compliance with the breast density notification requirements, FDA has concluded that 18 months is an adequate amount of time to make any necessary changes.

#### *Z. Miscellaneous Comments*

(Comment 144) A comment recommends that FDA and the ACR focus on increasing the consistency and quality of MQSA inspections by inspectors.

(Response 144) The ACR and other accreditation bodies are only involved in facility accreditation, not certification or inspection. Inspection is part of the process of certification, not accreditation. FDA trains all MQSA inspectors, both FDA employees and those who are State employees that perform MQSA inspections under State contracts with the Agency. FDA sends updated information to all inspectors whenever necessary. Furthermore, other FDA staff including Radiological Health representatives and auditors oversee and provide inspectional guidance to inspectors. The Agency concludes that these existing measures already promote consistency and quality in the MQSA inspection process.

(Comment 145) A comment recommends that FDA become the sole AB, and hire some of the staff currently employed by the ACR AB.

(Response 145) FDA disagrees with this comment. The MQSA and the implementing regulations distinguish between the separate responsibilities of the ABs and the certification agencies, which include FDA and the SCAs (see 42 U.S.C. 263b(e) and (g); part 900, subparts A and C). The ACR is one of several FDA-approved ABs. FDA (or an SCA) certifies facilities, after they have satisfied all necessary prerequisites, including accreditation by an AB.

(Comment 146) A comment recommends that FDA analyze how to improve the quality of care for women through using technology to improve the quality of mammograms and the accuracy of interpretation, and recommends that random samples of mammograms from all facilities be sent to FDA radiologists for review.

(Response 146) FDA disagrees with this comment. The ABs already initially and continually assess mammographic image quality at facilities they accredit, and are required to inform FDA of equipment or practices that may pose a serious risk to human health (see § 900.4(a)). At this time, FDA believes that the regulations afford FDA adequate opportunities to investigate any such occurrences and take action as necessary (see part 900, subpart B). The AB’s responsibilities include not only reviews of the initial and renewal accreditation images, but also random image reviews of a sample of facilities accredited by the AB. The interpretation of a mammogram is a decision made by IPs, but we note that many of the MQSA regulatory requirements, including the initial and continuing qualifications for IPs and the annual medical outcomes audit, promote quality mammography practice by IPs.

(Comment 147) A comment recommends that an independent commission review the relationship between the ACR and FDA for conflict of interest.

(Response 147) FDA disagrees with this comment. The relationship between FDA and each of the ABs, including the ACR, is regulated by the MQSA and the implementing regulations and meets all applicable Federal ethics requirements (see, e.g., 18 U.S.C. 201, *et seq.*).

(Comment 148) A comment asserts that improving mammography outcomes, such as lower rates of recalls and biopsies, could justify different clinical protocols, such as a younger screening age and shorter screening interval than are currently supported by the USPSTF.

(Response 148) This comment is beyond the scope of this rulemaking. This final rule requires that each facility include recall rate and certain other metrics in the audit of its mammography medical outcomes (see § 900.12(f)(1)(i) through (iii) in this final rule), but the MQSA quality standards do not specify benchmark or target values for these metrics. This rule requires that facilities compile this information and review it internally, to encourage their own quality improvement. However, decisions on which clinical practice guidelines, if any, to follow for such things as the

recommended age range or time interval for breast cancer screening with mammography are more appropriately for the healthcare provider to make.

(Comment 149) A comment recommends that FDA propose special amendments to address “cystic fibroid breast disease,” because the commenter states that with this condition, her mammograms are more painful and are limited by the associated breast tissue density.

(Response 149) The commenter is likely describing fibrocystic change, one of many conditions that may contribute to dense breast tissue. FDA disagrees with the recommendation to propose unique amendments to address a specific clinical condition apart from the requirements at §§ 900.12(c)(1)(vi)(A) through (D) and 900.12(c)(2)(iii) and (iv) in this final rule, which, as discussed in other responses throughout this final rule, are necessary to address the limitations of mammography in the presence of dense breast tissue caused by any etiology.

(Comment 150) One commenter cites a news article that discusses a research study showing that breast cancer screening increases the detection of early-stage cancers rather than late-stage cancers.

(Response 150) The intent of the MQSA is to ensure that the practice of mammography, across the country and whenever it is recommended by clinicians, meets consistent baseline quality standards. Decisions about whether to follow any recommendations or guidelines regarding patient age or interval for screening mammography are decisions more appropriate for the patient’s clinical healthcare provider to make.

(Comment 151) One comment states only “Should be standard of care for all women.”

(Response 151) The subject of the comment is not clear. FDA notes that the MQSA requirements apply consistently to all facilities that provide mammography services. Thus, every person who undergoes mammography at a certified facility in the United States can be assured that baseline national quality standards apply. However, decisions on whether to follow clinical practice guidelines, including recommendations for screening mammography at a certain age and/or a certain time interval, and any other clinical standards of care, are more appropriately made in the course of clinical decision-making by the provider and the patient.

(Comment 152) A comment recommends that image quality must be held to the highest possible standard.

(Response 152) FDA believes the amended regulations will continue to ensure appropriate national standards for quality mammography services. We note that provisions of the MQSA and its implementing regulations, including many that are not amended in this final rule, already address image quality. These include: the role of the ABs in clinical image review and phantom image review (§ 900.4), the eight image quality attributes that must be included in AB clinical image reviews (§ 900.4(c)(2)(i) through (viii)), personnel qualifications (§ 900.12(a)), equipment requirements (§ 900.12(b)), quality assurance requirements (§ 900.12(d) through (f)), and the general requirement that clinical images must continue to comply with the image quality standards of the facility’s AB (§ 900.12(i)). We further note that some of these requirements related to the facility’s responsibility to maintain clinical image quality were highlighted by the introduction in 2017 of FDA’s Enhancing Quality Using the Inspection Program (EQUIP) initiative (Ref. 52).

(Comment 153) A comment recommends that FDA should spend \$2.5 million per year for 10 years for public service announcements, advertisements, and a website.

(Response 153) FDA disagrees with the comment. General patient outreach and education is not within the scope of this final rulemaking. The MQSA program certifies mammography facilities and is funded largely by the user fees paid by those certified facilities. However, we note that the MQSA program maintains a public website (Ref. 65), and also occasionally uses email and social media to disseminate important information about the MQSA program. FDA also notes that the HHS Office of Women’s Health, and the FDA Office of Women’s Health are each committed to advancing issues regarding women’s health and to providing health education materials through outreach activities and collaborative partnerships. Among other things, these offices use resources to maintain the programs and publish resources regarding cancer, mammography, and other relevant health issues.

(Comment 154) A comment recommends that FDA should grant \$500,000 per year for 10 years to DenseBreast-Info for webinars and its website.

(Response 154) FDA disagrees with the comment. As noted in Response 153, general patient education and outreach are not within the scope of this rulemaking. Similarly, individual grant-

making activities are also outside the scope of this rulemaking.

(Comment 155) A comment recommends that FDA name this rule in memory of an advocate for breast density notification.

(Response 155) FDA appreciates the comment. We acknowledge the important work done by advocates for breast density notification in educating the public about the significance of breast tissue density. However, we disagree with the recommendation to name this rule after any one individual. The title of the rule is based on the specific regulations being amended, but the rule is not “named.”

(Comment 156) A comment asserts that the “FDA device pathway” is very different from, and much slower than, the Center for Drug Evaluation and Research Fast Track program for drug approval.

(Response 156) FDA acknowledges the comment, but notes that the pathways for premarket review of medical devices as they relate to those of drugs are outside the scope of this rulemaking. The MQSA is found under the Public Health Service Act in Title 42 of the U.S.C., and it is implemented by DMQS in FDA’s CDRH. The authority for FDA’s regulation of drugs and medical devices is found under the FD&C Act in Title 21 of the CFR.

## VI. Effective Date and Compliance Date

This rule is effective 18 months after the date of publication in the **Federal Register**. Mammography facilities will need to be in compliance with the amended MQSA regulations in this final rule by September 10, 2024.

## VII. Economic Analysis of Impacts

### A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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). The Office of Information and Regulatory Affairs has determined that this final 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 final 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 issuing “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 \$165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

#### B. Summary and Accounting Statement

The final rule will modernize mammography regulations by incorporating current science and mammography best practices to improve the delivery of mammography services. These updates include requirements on

recordkeeping, reporting, and communication of results. This final rule also addresses procedural requirements in several areas related to quality control and management of mammography facilities.

The benefits and costs associated with this final 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. 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 life years (LY). Under the VSL approach, the estimate of annualized benefits over 10 years ranges from \$42.00 million to \$232.69 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from \$48.42 million to \$266.09 million. Under the LY approach, the estimate of annualized benefits over 10 years ranges from \$12.99 million to \$66.90 million at a 7 percent discount rate. Using a 3 percent discount rate, the annualized benefits range from \$8.50 million to \$37.96 million. Because there is uncertainty in the literature about the most appropriate

method for analyzing reduced mortality for the population affected by this final 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 LY approach, which yields the lower-bound estimate of the two methods. Other benefits that we are not able to quantify include reduced cancer morbidity and improvements in the accuracy of mammography by improving quality control and strengthening the medical audit.

The costs of the final rule include costs to mammography facilities to comply with the requirements of the regulation and costs associated with supplemental testing and biopsies resulting from the breast density requirements. The estimate of annualized costs over 10 years range from \$28.87 million to \$45.42 million at a 7 percent discount rate with a primary value of \$36.31 million. Using a 3 percent discount rate, the annualized costs range from \$27.61 million to \$44.16 million with a primary value of \$35.05 million.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN MILLIONS 2020 DOLLARS OVER A 10-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Benefits:							
Annualized Monetized \$/year .....		\$12.99	\$232.69	2020	7	10	
		8.50	266.09	2020	3	10	
Annualized Quantified .....					7		
					3		
Qualitative .....	Improvements in the accuracy of mammography and better management of mammography facilities.						
Costs:							
Annualized Monetized \$/year .....	36.31	28.87	45.42	2020	7	10	
	35.05	27.61	44.16	2020	3	10	
Annualized Quantified .....					7		
					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 \$416–\$727, which would represent a maximum of 1.2 percent of annual receipts.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN MILLIONS 2020 DOLLARS OVER A 10-YEAR TIME HORIZON—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (percent)	Period covered (years)	
Wages:							
Growth:							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 63) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

#### 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 final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are

shown in the following paragraphs with an estimate of the annual third-party disclosure burden. 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.

*Title:* Mammography Facilities, Standards, and Lay Summaries for Patients; OMB Control Number 0910–0309.

*Description:* FDA is amending its mammography reporting requirements to require that the mammography report provided to the healthcare provider and the lay summary provided to the patient include basic mammography facility identification information and information concerning patient breast density. This action is intended to facilitate communication among 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 patient and their healthcare provider to make informed healthcare decisions. FDA also is including categories be added to the list of assessments that facilities are required to use in the mammography report. In addition, FDA is amending 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 perform mammographic examinations and State certification agencies. As of July, 1, 2022, FDA internal data on facilities showed that there were 8,781 facilities certified to perform mammography (Ref. 65).

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs	Total operating and maintenance costs
Mammography medical outcomes audit—900.12(f) .....	8,781	1	8,781	16	140,496	\$2,496,452	\$5,807,650

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs	Total operating and maintenance costs
Provision of personnel records to IPs—900.12(a)(4).	615	1	615	0.08 (5 minutes) ...	49	.....	\$55,682
Transfer of personnel records by closing facilities—900.12(a)(4).	88	1	88	5 .....	440	.....	.....
New assessment categories and breast density reporting in mammography report (one-time burden)—900.12(c)(1)(iv) to (vi).	8,781	1	8,781	23 .....	201,963	\$37,166,396	.....
Breast density reporting in lay summary (one-time burden)—900.12(c)(2).	8,781	1	8,781	11 .....	96,591	6,844,077	.....
Transfer/provision of copies of mammograms and records upon patient's request—900.12(c)(4)(ii) and (iii).	8,781	1,135	9,966,435	0.08 (5 minutes) ...	797,315	.....	.....
Facility closure; notification and records access—900.12(c)(4)(v).	88	1	88	32 .....	2,816	.....	55,682

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs	Total operating and maintenance costs
Patient notification of significant risk (by State certification agency)—900.12(j)(2).	5	1	5	100 .....	500	.....	.....
Total .....	.....	.....	.....	.....	1,099,674	44,010,473	111,364

<sup>1</sup> Numbers have been rounded.

*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 IPs, radiologic technologists, or medical physicists. Facilities must maintain records of personnel no longer employed by the facility for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months.

Also, under § 900.12(a)(4), facilities shall provide copies of personnel records to current or former interpreting personnel (physician, radiological technologist and medical physicist) upon their request. We estimate that there are, on average, seven interpreting personnel per facility (approximately 61,467 total). We estimate that 1 percent of these personnel (615 personnel annually) will request the records and that it will take approximately 5 minutes to provide the copies for each request.

Additionally, under § 900.12(a)(4), facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request.

Finally, under § 900.12(a)(4), before a facility closes or ceases to provide mammography services, it will 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 will provide access to these records. We estimate that annually 1 percent of the total facilities will close or cease to provide mammography services and that it will take each of the facilities approximately 5 hours to transfer the records.

*Medical records and mammography reports—§ 900.12(c)(1) through (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 IP, and recommendations to the healthcare provider.

This final rule includes two additional final assessment categories and an additional classification in the mammography report and also requires an assessment of breast density in the report (§ 900.12(c)(1)(iv) through (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 will take 23 hours per facility (Refs. 66 and 67).

Under the final rule, if the final assessment is “Suspicious” or “Highly Suggestive of Malignancy,” the facility must provide the report to the healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee (§ 900.12(c)(3)(ii)) within a specified timeframe. 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.

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. If the final assessment is “Suspicious” or “Highly Suggestive of Malignancy,” the facility shall provide the patient a summary of the

mammography report within a specified timeframe (§ 900.12(c)(2)). The summary shall include the name of the patient and name, address, and telephone number of the facility. The requirements for the lay summary to include this information do not result in a change to the currently approved information collection burden for § 900.12(c)(2).

Section 900.12(c)(2) also requires facilities to provide an assessment of breast density (as described in § 900.12(c)(2)(iii) to (iv)) in the lay summary. We estimate a one-time burden for facilities to update their existing lay summaries with the breast density assessments. Based on the ERG report, we believe this will take 11 hours per facility (Refs. 65 and 66).

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 requirements in § 900.12(c)(2)(iii) and (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 § 900.12(c)(4)(i), facilities that perform mammograms must maintain mammographic records. The rule requires that facilities implement policies and procedures to minimize the possibility of record loss and requires that records be maintained in the modality in which they were produced.

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 § 900.12(c)(4)(ii) and (iii), facilities must 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 must be in the same modality in which they

were produced. Moreover, for digital mammograms or digital breast tomosynthesis, the facility must be able to provide the recipient with original digital images electronically if the examination is being transferred for final interpretation. We estimate that approximately one third of patients will request transfer or release of the records and it will take approximately 5 minutes per request. To calculate the estimated number of requests, we use the estimated number of screening mammograms (29,890,141) (Ref. 62) divided by 3. This results in approximately 9,963,380 requests, or an average of 1,135 requests per facility.

Under § 900.12(c)(4)(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. Additionally, 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. If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of § 900.12(c)(4)(i) through (iv), it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient. We estimate that 1 percent of facilities per year will close and that it will 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 followup on the disposition of all positive mammograms and correlation of pathology results with the IP's mammography report. The rule clarifies that positive predictive value, cancer detection rate, and recall rate must be collected during this audit.

*Additional mammography review and patient and referring provider notification—§ 900.12(j):* Under § 900.12(j)(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 must provide clinical images and other relevant information for review by the accreditation body or the State certification agency.

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 or healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and other relevant information. Also under the rule, State certification agencies (along with FDA) may notify patients and their providers if a facility is unable or unwilling to do so.

We received several comments related to the proposed rule. Descriptions of the comments and our responses are provided in section V of this final rule, Comments to the Proposed Rule and FDA's Response. Comments and responses related to the provisions that underlie the information collection are described in the following sections: V.A, regarding general comments; V.D, regarding retention and release of personnel records; V.E, regarding digital accessories; V.F, regarding facility identification information in mammography report and lay summary; V.G, regarding final and incomplete assessments and lay summaries; V.H, regarding deadlines for mammography reports; V.I, regarding breast density notification—general support for density notification; V.J, regarding breast density notification language; V.K, regarding breast density notification and the role of the referring healthcare provider; V.L, regarding format for image interpretation, retention, transfer, and release of copies; V.M, regarding deadlines for image transfer and the release of copies; V.N, regarding facility closure and mammography record retention; V.O, regarding mammography medical outcomes audit; V.P, regarding patient and referring provider notification; V.Q, regarding revocation of certification; V.X, regarding federalism and the relationship between Federal and State breast density reporting requirements; and V.Y, regarding timeframe for implementation of this rule. We have not made changes to the estimated burden as a result of the comments.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a

person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

## 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 patients 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 (Ref. 64).

This final rule amends, among other things, the requirements in the MQSA for reporting to healthcare providers and patients to ensure that patients receive all necessary information after their mammograms, including an assessment of breast density, while not unduly burdening the mammography facility.

Although certain 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 will not change as the regulations will 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. 33). 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 final rule is consistent with the federalism principles expressed in Executive Order 13132.

## XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

## XII. References

The following references marked with an asterisk (\*) 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>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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. In § 900.2, revise paragraphs (c)(2), (k), (z), and (aa)(1) and (2), add paragraph (aa)(3), and revise paragraph (ii) to read as follows:

##### § 900.2 Definitions.

\* \* \* \* \*

(c) \* \* \*

(2) Failure to send mammography reports within 30 days to the referring healthcare provider or in a timely manner to the self-referred patient; and

\* \* \* \* \*

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring healthcare provider).

\* \* \* \* \*

(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, full field digital mammography, and digital breast tomosynthesis.

(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.

\* \* \* \* \*

(ii) *Patient* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a healthcare provider or is self-referred.

\* \* \* \* \*

- 3. In § 900.4 revise paragraphs (a)(6) and (f)(1)(ii)(B) to read as follows:

##### § 900.4 Standards for accreditation bodies.

(a) \* \* \*

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

(ii) If a facility has failed to become accredited after three consecutive attempts, no accreditation body shall accept an application for accreditation from the facility for a period of 1 year from the date of the most recent accreditation failure.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(ii) \* \* \*

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

\* \* \* \* \*

- 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. In § 900.12:

■ a. Revise paragraph (a)(4);

■ b. Add paragraphs (b)(2)(i) and (ii);

■ c. Revise paragraph (b)(11);

■ d. Add paragraph (b)(16);

■ e. Revise paragraphs (c)(1) and (2), (c)(3)(ii), (c)(4), and (f)(1);

■ f. Add paragraph (f)(4); and

■ g. Revise paragraph (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 for no less than 24 months from the date of the departure of an employee, and these records must be available for review at the time of any annual inspection occurring during those 24 months. The facility shall provide copies of these personnel records to current interpreting physicians, radiologic technologists, and medical physicists upon their request. Facilities must provide personnel records to former employees if the former employees communicate their request within 24 months of the date of their departure. If it has been greater than 24 months and the facility has maintained those records, the facility must provide those records to former employees upon request. Before a facility closes or ceases to provide mammography services, it must make arrangements for access by current and former 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 for no less than 24 months from the date of facility closure or cessation of mammography services.

(b) \* \* \*

(2) \* \* \*

(i) All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type with that intended use.

(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 (the assessment statement is only the word or phrase within the quotation marks):

(A) “Negative.” Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed);

(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 documented and addressed);

(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 Mammogram 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 classification statements shall be assigned as an assessment and reasons why no final 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 paragraphs (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 paragraphs (c)(1)(iv)(A) through (G) of this section can be given. If this assessment category is used, a followup report with an assessment category identified in paragraphs (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 paragraphs (c)(2)(iii) and (iv) 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.

(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. If the assessment of the mammography report is “Suspicious” or “Highly Suggestive of Malignancy,” the facility shall send this report to the patient within 7 calendar days of the final interpretation of the mammograms.

(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, which shall include when such patients’ mammogram assessment is either probably benign, suspicious, or highly suggestive of malignancy.

(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 the statement “Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. 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 the statement “Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, 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.

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

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain the original mammograms and mammography reports in a permanent medical record of the patient for the longest of the following: a period of not less than 5 years, a period of not less than 10 years if no additional mammograms of the patient are performed at the facility, or a period, if any, mandated by State or local law. Facilities shall implement policies and procedures to minimize the possibility of loss of these records. The original 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. For digital mammograms or digital breast tomosynthesis, if the copies are being released for final interpretation purposes, the facility must be able to provide the recipient with digital images electronically;

(iv) Any fee charged to the patients for providing the services in paragraphs (c)(4)(ii) or (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 the patient's healthcare provider or the transfer of the mammographic records to a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by such other facility or entity for the remainder of the time periods specified in paragraph (c)(4)(i) of this section. If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of paragraphs (c)(4)(i) through (iv) of this section, it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient. 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 audit requirements, a mammographic examination consisting of routine views of an asymptomatic patient shall be termed a screening mammogram, while a mammographic examination consisting of individualized views of a patient 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 followup 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 followup 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."

\* \* \* \* \*

(4) The records and data required to demonstrate compliance with the requirements in paragraphs (f)(1) through (3) of this section must be retained until the annual inspection that follows the facility's analysis of that information.

\* \* \* \* \*

(j) *Additional mammography review and patient and referring provider 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 other 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 other 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 paragraphs (a) introductory text and (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 issued 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 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).

\* \* \* \* \*

■ 7. In § 900.15 revise paragraph (d)(1) to read as follows:

**§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.**

\* \* \* \* \*

(d) \* \* \*

(1) References to the Centers for Medicare and Medicaid Services in 42 CFR part 498 should be read as the Division of Mammography Quality Standards (DMQS), Center for Devices and Radiological Health, Food and Drug Administration.

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Dated: February 27, 2023.

**Robert M. Califf,**

*Commissioner of Food and Drugs.*

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