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Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency

**Guidance for Mammography Facilities,
State MQSA Contract Partners, FDA-
Approved MQSA Accreditation Bodies,
and Food and Drug Administration Staff**

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, the webpage titled "Mammography Quality Standards Act and Program", *available at* <https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program>, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20047 and complete title of the guidance in the request.

Questions

For questions about this document, contact the MQSA Hotline at 1-800-838-7715, or you can submit your questions by email to MQSAHotline@versatechinc.com.

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Guidance for Mammography Facilities, State MQSA Contract Partners, FDA-Approved Accreditation Bodies, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide FDA's enforcement policy regarding certain quality standards requirements under the Mammography Quality Standards Act of 1992 (MQSA) and also to provide general considerations to facilities that may have temporarily ceased performing mammography or that may be continuing to perform mammography while facing difficulty in complying with certain quality standards requirements during the public health emergency. The MQSA is part of United States Code Title 42 – Public Health and Welfare, and is implemented in FDA's regulations at 21 CFR part 900.

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This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

The MQSA requires, among other things, that mammography facilities obtain an MQSA certificate prior to performing mammography, submit to an annual inspection, and meet the quality standards described in 42 U.S.C. 263b(f) and the implementing regulations under 21 CFR 900.12. The quality standards include, for example, requirements for establishing and maintaining a quality assurance program, undergoing an annual medical physicist survey, and completing initial training and continuing education and experience for certain mammography personnel.

¹ Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

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On March 18, 2020, the FDA temporarily postponed domestic inspections as a result of the COVID-19 pandemic.³ As FDA prepares to resume domestic routine inspections, FDA recognizes that many mammography facilities may have been impacted by unavoidable operational challenges as a result of the COVID-19 public health emergency. For example, some mammography facilities may have been unable to schedule their annual medical physicist surveys as part of their responsibilities for ensuring compliance with the required mammography quality standards due to COVID-19 infection control measures (e.g., travel restrictions, quarantine, site closures) as a result of the public health emergency. Other healthcare facilities may have suspended elective procedures, including mammography exams, or reduced or modified their mammography operations, which could have restricted some mammography personnel from the opportunity to meet or maintain their continuing experience requirements. In addition, some mammography personnel may have been unable to complete the training required to meet initial and continuing MQSA qualification and/or education requirements because of certain closures of colleges, universities, and training facilities due to restrictions on public gatherings and physical distancing requirements. This guidance provides FDA's current thinking in response to questions received from mammography facilities about compliance with the MQSA quality standards during the COVID-19 public health emergency to help facilitate the availability of mammography services in light of operational challenges during the public health emergency.

III. Policy

This guidance provides FDA's enforcement policy and outlines general considerations in response to common scenarios and challenges faced by mammography facilities in complying with MQSA quality standards as a result of the COVID-19 public health emergency, which FDA believes will help facilitate the availability of mammography services. The policy and scenarios provided below pertain to the mammography facility quality standards requirements under the MQSA (21 CFR 900.12), including facility surveys, maintaining personnel qualifications, and other quality standards requirements. The policy concerning the annual survey by a medical physicist is under Part A, and the policies concerning other requirements, such as the Mammography Equipment Evaluation (MEE), are under Part B. This policy does not apply to compliance with other requirements under the MQSA and FDA has not changed its policies related to compliance with those requirements.

A. Facilities that have been unable to schedule a timely annual medical physicist survey due to the public health emergency

Under the MQSA and its implementing regulations, at least once a year each mammography facility is required to undergo an on-site survey performed by an MQSA-qualified medical physicist, or by an individual under the direct supervision of an MQSA-qualified medical physicist (see 21 CFR 900.12(e)(9)). During the COVID-19 public health emergency, certain travel restrictions between states and within states may have occurred, preventing some medical physicists from reaching facilities and delaying the performance of the required annual survey. In a guidance entitled "[Mammography Facility Surveys, Mammography Equipment Evaluations, and Medical Physicist requirements under](#)

³ For updates on [MQSA Inspection Information related to COVID-19](https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/mqsa-inspection-information-related-covid-19) see FDA's website at <https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/mqsa-inspection-information-related-covid-19>.

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[MQSA](#),”⁴ FDA indicated that MQSA inspectors are instructed that the facility meets this annual requirement if, at the time of inspection, the most recent survey was conducted within 14 months of the previous survey and within 14 months of the current inspection. The COVID-19 public health emergency has created an unavoidable scenario where some facilities may have found it difficult to undergo an annual on-site survey due to COVID-19 infection control measures, and FDA anticipates that medical physicists may have a large backlog of facility surveys to complete once these control measures are lifted.

In light of anticipated difficulties facilities may encounter in scheduling their annual medical physicist survey due to the COVID-19 public health emergency, FDA generally does not intend to object to a facility’s completion of the annual survey requirement (see 21 CFR 900.12(e)(9)) beyond the time period of “[a]t least once a year” where the facility has ensured that mammography unit(s) are surveyed as soon as possible, ideally within six months of the 14-month date calculated from the date of their previous survey,⁵ and has documented and/or submitted certain information related to the delay and the public health emergency. The details of this policy are provided in the table below (Table 1).

Facilities that temporarily ceased performing mammography, and have since resumed, should be aware that they are required to be inspected at least annually under the MQSA (42 U.S.C. 263b(g)(1)), and are subject to the annual survey requirement discussed above (21 CFR 900.12(e)(9)(i)). Compliance with the survey requirement is generally assessed during the annual inspection.

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mammography-facility-surveys-mammography-equipment-evaluations-and-medical-physicist-qualification>.

⁵ FDA has previously stated that facilities meet the annual survey requirement in 21 CFR 900.12(e)(9) when the most recent survey was conducted within 14 months of the previous survey and within 14 months of the current inspection (see FDA’s guidance entitled “[Mammography Facility Surveys, Mammography Equipment Evaluations, and Medical Physicist Qualification Requirements under MQSA](#).”)

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Table 1 – Annual On-Site Medical Physicist Survey Policy

<p style="text-align: center;">Facilities that Temporarily Ceased Performing Mammography in Response to the COVID-19 Public Health Emergency, and have since resumed, and Have Not Been Able to Schedule the Annual Medical Physicist Survey</p>	<p style="text-align: center;">Facilities that Continued to Perform Mammography During the COVID-19 Public Health Emergency and Have Not Been Able to Schedule the Annual Medical Physicist Survey</p>
<p>If the facility temporarily ceased performing mammography in response to the COVID-19 public health emergency, and has since resumed, then FDA generally does not intend to object to a delayed completion of the annual survey requirement where the facility:</p> <ul style="list-style-type: none"> • Documents the time period that the facility was temporarily closed and presents that information to the inspector during the facility’s MQSA inspection; <p>AND COMPLETES THE SURVEY AS SOON AS POSSIBLE, IDEALLY:</p> <ul style="list-style-type: none"> • Have the mammography unit surveyed within six months of the 14-month date calculated from the date of the last annual (full) medical physicist survey that was completed. 	<p>If the facility continued to perform mammography, and/or operated at a reduced or modified capacity in response to the COVID-19 public health emergency, and the facility has not been able to schedule a medical physicist survey due to COVID-19 restrictions, then FDA generally does not intend to object to a delayed completion of the annual survey requirement where the facility:</p> <ul style="list-style-type: none"> • Documents the circumstances that resulted in the facility’s inability to schedule a medical physicist survey within 14 months of the last annual survey and presents that information to the inspector during the facility’s MQSA inspection; <p>AND COMPLETES THE SURVEY AS SOON AS POSSIBLE, IDEALLY:</p> <p>Have the mammography unit surveyed within six months of the 14-month date calculated from the date of the last annual (full) medical physicist survey that was completed.</p>

FDA is aware that some facilities may not have had an annual survey in the last 20 months, as discussed in the policies above. Those facilities are encouraged to contact the MQSA Hotline as soon as possible to discuss their facility’s planned survey timeframes. FDA intends to review these instances on a case by case basis to determine if there are any concerns with a facility’s proposed survey timeframe. FDA expects that the facility will take any appropriate corrective action(s) if there are concerns with the facility’s proposed timeframe.

In the future, if facilities continue to face difficulty in meeting the survey requirements even six months after the 14-month date, such facilities are encouraged to contact the MQSA Hotline. To help address any concerns with the facility’s survey timeframes, FDA may request that the facility provide FDA with documentation of its failed attempts to schedule the medical physicist survey, including

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explanations of the circumstances that prevented the facility from completing the survey in a timely manner. FDA intends to review such information on a case by case basis and if there continue to be concerns with a facility's survey timeframes, FDA expects that the facility will take any appropriate corrective action(s) if there are concerns with the facility's proposed timeframe.

Finally, FDA is aware that there may be facilities that have not had an annual survey for more than 20 months, have been in an inactive operational status for an extended period of time (e.g., 6 months) in response to the COVID-19 public health emergency and continue to be in that status, and still intend to resume practicing mammography. As part of a facility's best practices, these facilities can contact the MQSA Hotline, and may be encouraged to have the unit(s) surveyed prior to resuming patient imaging to ensure that the long period of inactivity and any lack of routine preventative maintenance has not compromised the equipment functionality.

B. Facilities that continue to operate and face difficulty in complying with other quality standards due to circumstances out of their control

FDA recognizes that during the COVID-19 public health emergency, many mammography facilities may have had to shift resources to respond to the public health emergency, including cancelling planned travel for training, moving review workstations off-site due to the public health emergency and scheduling medical physicist mammography equipment evaluations (MEEs) after the move has become impractical or impossible due to COVID-19 related travel restrictions, and delaying other program assessments due to reductions in personnel and operations.

In light of these unavoidable challenges due to the COVID-19 public health emergency, FDA generally does not intend to object to the continued operation of facilities that have faced difficulty in complying with certain aspects of the quality standards when these facilities do not create an undue risk to patient safety or mammography quality and where the facility had no control over the events and actions that led to the non-compliance. To help evaluate the non-compliance, FDA may request that facilities provide certain information and documentation to the inspector, such as: (i) details of the events that led to the noncompliance, (ii) any dates of noncompliance, (iii) an explanation of why the noncompliance could not be avoided, (iv) any steps taken by the facility to identify alternative resources or providers, and (v) a written statement confirming that the facility will ensure compliance with the quality standards as soon as possible after the relevant COVID-19 restrictions are lifted (e.g., by placing personnel under requalification, or performing the missed assessment).

Examples of noncompliance that FDA currently believes may have been due to the COVID-19 public health emergency and for which FDA believes that noncompliance by facilities generally would not create an undue risk to patient safety or mammography quality include:

- (1) Failure of mammography personnel to meet the continuing education requirements under 21 CFR 900.12(a) due to cancellation of courses/meetings related to the COVID-19 public health emergency (see 21 CFR 900.12(a)(1)(ii)(B), 21 CFR 900.12(a)(2)(iii) and 21 CFR 900.12(a)(3)(iii)). Note that the new modality training requirement under the MQSA is not subject to this enforcement policy as new modality training can be conducted through "Peer to Peer" training with an individual who has received 8 hours of new modality training in the

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specific modality that the trainee is seeking training for (see 21 CFR 900.12(a)(1)(ii)(C), 21 CFR 900.12(a)(2)(ii)(C), and 21 CFR 900.12(a)(3)(iii)(C));

(2) Failure of mammography personnel to meet continuing experience requirements under 21 CFR 900.12(a) due to reduced patient volumes or modified operations during the COVID-19 public health emergency (see 21 CFR 900.12(a)(1)(ii)(A), 21 CFR 900.12(a)(2)(iv) and 21 CFR 900.12(a)(3)(B));

(3) Failure of a facility to have a MEE performed when a review workstation was moved to a remote location due to the COVID-19 public health emergency (see 21 CFR 900.12(e)(10)); or

(4) Failure by a facility to meet certain aspects of MQSA quality assurance requirements performed under the Enhancing Quality Using the Inspection Program (EQUIP) initiative due to staffing absences or facility closures related to COVID-19 (see e.g., 21 CFR 900.12(d)(1)(ii)(A), 21 CFR 900.12(d)(2), and 21 CFR 900.12(i)).⁶

Examples of circumstances that FDA currently believes generally would create an undue risk include:

- (1) Mammography examinations interpreted or performed, or equipment surveyed, by personnel that do not meet MQSA initial qualification requirements (see 21 CFR 900.12(a)(1)(i), 21 CFR 900.12(a)(2)(i) and (ii), and 21 CFR 900.12(a)(3)(i) or (ii));
- (2) Use of equipment not designed for mammography to perform mammography (see 21 CFR 900.12(b)(1));
- (3) Failure to perform an initial MEE after installing a new mammography unit or image processor (see 21 CFR 900.12(e)(10));
- (4) Failure to perform an MEE after the change or repair of a major component of a mammography unit or image processor (see 21 CFR 900.12(e)(10));
- (5) Failure to perform an MEE after a mammography unit or image processor is disassembled and reassembled at the same or a new location (see 21 CFR 900.12(e)(10));
- (6) The use of mammography equipment whose quality control test results fell outside of the action limits and for which corrective action was not completed within the required timeframe (see 21 CFR 900.12(e)(8)); or
- (7) The failure of facilities to meet recordkeeping requirements (21 CFR 900.12(c)(4)), including facilities that have permanently ceased performing mammography.

⁶ More information about the EQUIP initiative is available on FDA's website at <https://www.fda.gov/radiation-emitting-products/mqsa-insights/equip-first-year>.

C. Facilities that have questions regarding accreditation or Accreditation Body activities and requests

During the COVID-19 public health emergency, facilities should continue to communicate with their FDA-Approved Accreditation Body (AB) regarding accreditation activities. The ABs have protocols in place for continued performance of AB accreditation duties and responsibilities and to process inquiries from mammography facilities, including the processing of accreditation applications, personnel and equipment changes, AB required Corrective Action Plans, and facility closures.

Facilities that permanently cease performing mammography due to the COVID-19 public health emergency should follow their AB's procedures for facility closures.