and, subject to the provisions of § 416.1435, accepts as evidence any documents that are material to the issues; may stop the hearing temporarily and continue it at a later date if the administrative law judge finds that there is material evidence missing at the hearing or one or more variables outside of our control, such as audio quality or video quality, materially affects the hearing; and may reopen the hearing at any time before the administrative law judge mails a notice of the decision in order to receive new and material evidence. For purposes of this section, materially affects means prevents the hearing from proceeding. The administrative law judge may decide when the evidence will be presented and when the issues will be discussed.

■ 15. In § 416.1450, revise paragraph (a) and the second and third sentences in paragraph (e) to read as follows:

§ 416.1450 Presenting evidence at a hearing before an administrative law judge.

(a) *The right to appear and present evidence.* Any party to a hearing has a right to appear before the administrative law judge, in the manner set forth in § 416.1436, to present evidence and to state their position. A party may also make their appearance by means of a designated representative, who may make their appearance in the manner set forth in § 416.1436.

* * * * *

(e) * * * If they are unable to appear with you in the same manner as you, they may appear as prescribed in § 416.1436(c)(2). Witnesses called by the administrative law judge will appear in the manner prescribed in § 416.1436(c)(2). * * *

* * * * *

■ 16. In § 416.1476, revise paragraph (c) to read as follows:

§ 416.1476 Procedures before the Appeals Council.

* * * * *

(c) *Oral argument.* You may request to appear before the Appeals Council to present oral argument in support of your request for review. The Appeals Council will grant your request if it decides that your case raises an important question of law or policy or that oral argument would help to reach a proper decision. If your request to appear is granted, the Appeals Council will tell you the time and place of the oral argument at least 10 business days before the scheduled date. The Appeals Council will determine whether your appearance will be by audio, agency video, online video, or in person as set forth in § 416.1436. The Appeals Council will determine whether any other person relevant to the proceeding will appear by audio, agency video, online video, or in person as set forth in § 416.1436(c)(2).

[FR Doc. 2024–18591 Filed 8–23–24; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. FDA–2013–N–0134]

Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide.'' The Mammography Quality Standards Act of 1992 (MQSA) final rule amended FDA's regulations to address, among other things, standards for accreditation bodies, certifying agencies, mammography equipment, quality assurance testing, and clinical image quality, as well as to require certain breast density information be provided by mammography facilities to patients and their healthcare providers. The small entity compliance guide (SECG) is intended to help small entities comply with the MQSA final rule.

DATES: August 26, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2013–N–0134 for ''Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the SECG entitled ''Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Preetham Sudhaker, Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–5911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 10, 2023 (88 FR 15126), FDA issued a final rule to update the mammography regulations that were issued under the MQSA and the Federal Food, Drug, and Cosmetic Act.[1] The final rule, amending 21 CFR 900.1 through 900.25, becomes effective September 10, 2024. FDA has prepared this SECG to assist small entities in complying with the requirements established in FDA regulations as they apply to mammography facilities.

This level 2 guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB Control No.
900; Form FDA 3422	Mammography Quality Standards	0910–0309

III. Electronic Access

Persons interested in obtaining a copy of the SECG may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007024 and complete title to identify the guidance you are requesting.

Dated: August 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19059 Filed 8–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0712]

Special Local Regulation; Marine Events Within the Eleventh Coast Guard District-San Diego Bayfair

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the San Diego Bayfair special local regulation on the waters of Mission Bay, California from September 13, 2024, through September 15, 2024. This special local regulation is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulation in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 9, will be enforced from 6 a.m. until 6 p.m., each day from September 13, 2024, through September 15, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Shelley Turner, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email *D11MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.1101, Table 1

[1] The Office of the Federal Register has published this document under the category ''Rules and Regulations'' pursuant to 1 CFR 5.9(b). The Office of the Federal Register's categorization is solely for purposes of publication in the **Federal Register** and does not change the nature of the document and is not intended to affect its validity, content, or intent. See 1 CFR 5.1(c).