Compliance Guidance

The Mammography Quality Standards Act Final Regulations
Quality Assurance Documentation

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Finder at 301-594-3332.

Additional Copies

World Wide Web/CDRH/mammography home page at http://www.fda.gov/cdrh/mammography or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1494. Then follow the remaining voice prompts to complete your request.
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Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the Federal Register. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999.

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1 This document is intended to provide guidance. It represents the Agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.
Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration’s (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.
PROVIDING LAY SUMMARIES AND MAMMOGRAPHY REPORTS

Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

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

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

Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for providing lay summaries and mammography reports to their patients and health care providers?

Answer: In order to meet the requirements for providing lay summaries and mammography reports, facilities can either:

1. Demonstrate that:

   • the facility is notifying patients and health care providers of positive examinations as soon as possible (as guidance, within 5 and 3 business days respectively). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in logs. In the case of written communication, see next two bulleted items.

   • the facility is providing written mammography reports. This may be done by having copies of the mammography report available within 30 days of the examination (positive mammography reports should be available within 3 business days).

   • the facility is providing written lay summaries. This may be done by having copies of the lay summary available within 30 days of the examination (positive lay summaries should be available within 5 business days). If the facility does not keep copies of the patients’ lay summaries, it may document such communication in the mammography report, or in logs, or by stating in the
facility’s Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames.

OR

2. Provide written documentation describing the procedure for:

- providing (sending or giving) the written lay summary to patients within 30 days of the examination.

- providing the mammography report to the health care provider (or the patient, if self referred) within 30 days of the examination.

- communicating the results of positive (suspicious or highly suggestive of malignancy) examinations to patients and health care providers as soon as possible (as guidance, within 5 and 3 business days respectively). This communication may be verbal or written. If verbal, it must be followed by a written lay summary and mammography report provided within 30 days of the examination.

DEALING WITH CONSUMER COMPLAINTS

Each facility shall: (1) Establish a written and documented system for collecting and resolving consumer complaints; (2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received; (3) Provide consumers with adequate directions for filing serious complaints with the facility’s accreditation body if the facility is unable to resolve a serious complaint to the consumer’s satisfaction; (4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for dealing with consumer complaints?

Answer: To meet the requirements for dealing with consumer complaints, facilities must provide written documentation that describes their system for recording, maintaining, and resolving patients’ complaints. The documentation must include the instructions that are, or would be, provided to patients describing how to proceed with referral of serious unresolved complaints to the accreditation body. The documentation must also include the procedures that are, or would be used by the facility to report serious unresolved complaints to their accreditation body.

- If the facility has received serious complaints after 4/28/99, it must be able to produce records indicating that they are following their system and are maintaining the serious complaint for 3 years.
PERFORMING THE MEDICAL AUDIT

Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician’s findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of malignancy.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for the medical outcomes audit program?

Answer: For facilities that have had positive examinations, the medical outcomes audit program requirements can be met by demonstrating to the MQSA inspector that the facility has obtained, or attempted to obtain, pathology results for their positive cases (and cases of breast cancer among patients imaged at the facility that subsequently became known to the facility) and has performed appropriate analyses annually. The reviewing interpreting physician(s) must be identified.

For facilities that have not had positive examinations, the medical outcomes audit program requirements can be met by providing written documentation describing how the facility’s medical audit system would follow-up on positive cases (and any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility), would correlate pathology results with the interpreting physician’s findings and would perform appropriate analyses annually. The reviewing interpreting physician(s) must be identified.

DEALING WITH BREAST IMPLANT PATIENTS

Mammographic procedure and techniques for mammography of patients with breast implants. Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam. Except where contraindicated, or unless modified by a physician’s directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for dealing with patients with breast implants?

Answer: The requirements for dealing with patients with breast implants can be met by:

1. demonstrating to the MQSA inspector that the facility has asked its patients whether they have breast implants. This may be done by showing patient information forms that have this question answered.
2. having written procedures for inquiring, prior to the mammographic examination, whether the patient has breast implants.

PROCEDURES FOR INFECTION CONTROL

Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control?

Answer: To meet the MQSA requirements for infection control, the facility must:

1. provide written documentation that describes the infection control procedures used by the facility. If reference material is cited in the facility’s description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply with applicable Federal, State and local regulations as well as manufacturer’s recommendations.

2. have logs or charts indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials.

SPECIFIC PERSONNEL RESPONSIBILITIES

Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for assigning responsibilities to quality assurance personnel?

Answer: Facilities must provide the following documentation:

1. The names of the lead-interpreting physician, medical physicist(s), quality control technologist(s), reviewing interpreting physician(s) and any other facility personnel with delegated quality assurance responsibilities.

2. A statement of their respective responsibilities.