The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #7; Guidance for Industry and FDA

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This document modifies and updates guidance appearing in the Policy Guidance Help System.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For purposes of this document, additions to the Policy Guidance Help System (PGHS) are shown as highlighted text while deletions are shown by strikethroughs. Note: Questions and answers that are currently in the PGHS and are not being modified are not included in this document. For questions regarding the use or interpretation of this guidance contact Charles Finder at (301) 594-3332 or by email caf@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at:
http://www.fda.gov/cdrh/mammography, or through CDRH Facts-On-Demand. You may either send a fax request to (301) 443-8818 to receive a hard copy of the document, or send an e-mail request to GWA@CDRH.FDA.GOV to request hard or electronic copy. Please use the document number (1436) to identify the guidance you are requesting.

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #7

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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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Background

The Mammography Quality Standards Act was signed into law 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) or by an approved State certification body. The authority to approve accreditation bodies, State certification 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. The FDA compiled all final guidance related to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at: www.fda.gov/cdrh/mammography/robohelp/start.htm

This compliance guidance document serves to update the Policy Guidance Help System.

Guidance information is periodically updated. Individuals wishing to get automatic notification of such updates may subscribe to our E-mail ListServ by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman.

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.

Accreditation and Certification

Accreditation and Certification Overview

Citation:

900.11(a) General. After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in section 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

^+Question 11: Our radiology group has two mammography units at the same location. Can each unit be accredited by a different accreditation body (dual accreditation)?^-

^+Yes, units located at the same site can be accredited by different accreditation bodies (dual accreditation). Some of the downsides to dual accreditation include the increased cost and paperwork associated with dealing with two accreditation bodies and having to undergo two MQSA inspections (because each separately accredited unit would be considered a different MQSA certified facility). ^-

^+While there are downsides related to dual accreditation, there is at least one situation where a group might decide to have its units dual accredited. For example, suppose a facility already has a film-screen unit accredited by a State accreditation body. The facility then purchases an FFDM unit but the only body that accredits that unit is the ACR. The facility has two options. It can either drop its State accreditation and have both units accredited by ACR (both units are now part of one MQSA certified facility) or proceed with dual accreditation and keep its film-screen unit accredited by the State and have its FFDM unit accredited by the ACR (each unit is now its own MQSA certified facility). In the case of this dual accreditation, FDA would allow these two facilities to be grouped for MQSA inspection billing purposes to reduce the cost.^-

^+Question 12: Now that FDA has approved an FFDM accreditation body, do we have to have our FFDM unit accredited? ^-

^+If your State accreditation body or ACR has received FDA approval to accredit your specific model FFDM unit, then you must have your unit accredited by one of those bodies. If neither your State accreditation body nor ACR has received FDA approval to accredit your specific model FFDM unit, then you must have FDA extend your film-screen certification to cover your FFDM unit before you can use it clinically. ^-

^+Question 13: We have been using our FFDM unit under FDA's film-screen certification extension policy. Now that there is an accreditation body for our model FFDM unit, what do we need to do to have the unit accredited? We were keeping our

old film-screen-unit just to be eligible for the certification extension policy. Do we still need to keep this film-screen unit?^-

^+Your facility must follow the accreditation body's procedures for accreditation of your model FFDM unit. The facility may continue to operate its FFDM unit under FDA's film-screen certification extension policy while it applies for and proceeds through the accreditation process. Once you have started the accreditation process, you no longer are required to keep your film-screen unit.^-

^+Question 14: We have been operating our FFDM unit under FDA's film-screen certification extension policy by linking our unit with a film-screen facility at a different location. Now that an accreditation body has been approved for our FFDM model unit, must we become accredited and certified as our own independent facility?^-

^+Yes. You must become accredited and certified as your own independent facility. Once you have received your MQSA provisional certificate, you can sever your links with the film-screen facility.^-

^+Question 15: Which FFDM units can be accredited by which accreditation bodies? ^-

^+The General Electric 2000D FFDM unit can be accredited by the American College of Radiology as of February 15, 2003. ^-

Full Field Digital Mammography (FFDM) Certification

Discussion:

Until ^+an^- accreditation ~~*+bodies are prepared*-~~ ^+body has been approved^- to accredit ^+your specific model^- full field digital mammography (FFDM) ^+unit^- ~~*+units*-~~, FDA ~~*+has implemented a*-~~ ^+will continue its^- process for extending the certification of an already certified screen-film facility to include ^+these specific model^- FFDM units. Until otherwise notified by FDA, a facility with an FFDM unit ^+ (that does not have a have a corresponding approved accreditation body) ^- will be exempt from the MQSA accreditation requirement but must request FDA to extend its screen-film certification to cover its FFDM unit. Requests for FFDM certification extension need to supply all the information listed in the document MQSA Facility Certification Requirements For Use Of Full Field Digital Mammography (FFDM) and should be forwarded to:

Dr. Kish Chakrabarti
Division of Mammography Quality and Radiation Programs
FDA/CDRH/OHIP
1350 Piccard Drive, HFZ-240, Room 230B
Rockville, MD 20850
Phone : 301-594-3332 or 3313
Fax : 301-594-3306

After a decision has been reached, you will receive either a Letter of Acceptance or a Letter of Denial for your FFDM unit(s). If you receive a Letter of Acceptance, your FFDM unit will be added to your certificate and you may begin to use it for clinical examinations. Your facility must maintain its accreditation status for at least one screen-film unit in order to maintain its certification status when utilizing an FFDM unit. Your facility is also subject to an annual onsite MQSA inspection of its FFDM unit at the same time its screen-film unit(s) is/are being inspected.

If you receive a Letter of Denial, we will work with you to resolve the problems preventing your acceptance.

Question 1: Does a facility have to have its FFDM unit accredited?

~~*+Until notified by the FDA, facilities with FFDM units are exempt from MQSA accreditation requirements. However, you must obtain FDA's extension of your MQSA screen film certification to cover the FFDM unit before you can use it clinically. *-~~
^+If your State accreditation body or ACR has received FDA approval to accredit your specific model FFDM unit, then you must have your unit accredited by one of those bodies. If neither your State accreditation body nor ACR has received FDA approval to accredit your specific model FFDM unit, then you must have FDA extend your film-screen certification to cover your FFDM unit before you can use it clinically. ^-

Question 7: Which FFDM units have been approved by FDA?

FDA's Office of Device Evaluation has approved the following FFDM units for commercial use:
GE Senographe 2000D (approval date: 1/28/00)
Fischer Imaging SensoScan (approval date: 9/25/01)
Lorad Digital Breast Imager (approval date: 3/15/02)
^+Hologic/Lorad Selenia FFDM System (approval date: 10/02/02) ^-

~~***+Question 9: What will happen when the accreditation bodies start to accredit FFDM units?*-***~~

~~*+Once the accreditation bodies begin accrediting your specific model of FFDM unit, your facility will have to apply to and go through the AB's accreditation process, similar to what you would have to do for screen film units. During this transition period, your facility can continue to use the FFDM unit. Because of the different technologies used by FFDM unit manufacturers, the accreditation bodies may have to develop different programs for the different types of units. As a result, it is likely that not all FFDM unit types will be accredited at the same time. For example, if an AB implements a program to accredit the GE Senographe 2000D but not other types of units, then facilities having this GE unit have to get them accredited. Facilities having other types of FFDM units will not have to get them accredited until an accreditation process is implemented for their unit. However, the facility will be able to continue to use their unit under FDA's FFDM certification extension policy. *-~~

^+Question 9: Which FFDM units can be accredited by which accreditation bodies?^-

^+Answer: The General Electric 2000D FFDM unit can be accredited by the American College of Radiology as of February 15, 2003. ^-

^+Question 10: We have been using our FFDM unit under FDA's film-screen certification extension policy. Now that there is an accreditation body for our model FFDM unit, what do we need to do to have the unit accredited? We were keeping our old film-screen-unit just to be eligible for the certification extension policy. Do we still need to keep this film-screen unit? ^-

^+Your facility must follow the accreditation body's procedures for accreditation of your model FFDM unit. The facility may continue to operate its FFDM unit under FDA's film-screen certification extension policy while it applies for and proceeds through the accreditation process. Once you have started the accreditation process, you no longer are required to keep your film-screen unit. ^-

^+Question 11: We have been operating our FFDM unit under FDA's film-screen certification extension policy by linking our unit with a film-screen facility at a different

***location*. Now that an accreditation body has been approved for our FFDM model unit, must we become accredited and certified as our own independent facility? ^-**

^+Yes. You must become accredited and certified as your own independent facility. Once you have received your MQSA provisional certificate, you can sever your links with the film-screen facility. ^-

^+Question 12: Our radiology group has two mammography units at the same location. Can each unit be accredited by a different accreditation body (dual accreditation)? ^-

^+Yes, units located at the same site can be accredited by different accreditation bodies (dual accreditation). Some of the downsides to dual accreditation include the increased cost and paperwork associated with dealing with two accreditation bodies and having to undergo two MQSA inspections (because each separately accredited unit would be considered a different MQSA certified facility). ^-

^+While there are downsides related to dual accreditation, there is at least one situation where a group might decide to have its units dual accredited. For example, suppose a facility already has a film-screen unit accredited by a State accreditation body. The facility then purchases an FFDM unit but the only body that accredits that unit is the ACR. The facility has two options. It can either drop its State accreditation and have both units accredited by ACR (both units are now part of one MQSA certified facility) or proceed with dual accreditation and keep its film-screen unit accredited by the State and have its FFDM unit accredited by the ACR (each unit is now its own MQSA certified facility). In the case of this dual accreditation, FDA would allow these two facilities to be grouped for MQSA inspection billing purposes to reduce the cost. ^-

Application to an Accreditation Body

Citation:

900.11(b)(1)(i)(ii): Application.

(1) Certificates.

(i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

Question 9: A facility moves or relocates and the address on its MQSA certificate is no longer correct. Is the MQSA certificate still valid?

Your MQSA certificate is still valid. However, when a facility moves or relocates, it must notify its accreditation body. ^+The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations. ^- The accreditation body will direct the facility regarding any additional information and/or testing that it may require. The accreditation body will then inform FDA or the Certifying State of the facility's new address. ^+FDA will no longer issue replacement certificates for address changes. At the time of the next renewal, FDA-issued MQSA certificates will be issued with the facility name only. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding replacement of MQSA certificates.^-

~~*+ FDA or the Certifying State will then issue a new MQSA certificate to the facility reflecting the new address. The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations. *-~~

~~*+Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate. *-~~

Definition of Certificate

Citation:

900.2(h) Certificate means the certificate described in section 900.11(a).

Question 4: A facility moves or relocates and the address on its certificate is no longer correct. Is the MQSA certificate still valid?

Your MQSA certificate is still valid. However, when a facility moves or relocates, it must notify its accreditation body. The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations. The accreditation body will direct the facility regarding any additional information and/or testing that it may require. The accreditation body will then inform FDA or the Certifying State of the facility's new address. ^+FDA will no longer issue replacement certificates for address changes. At the time of the next renewal, FDA-issued MQSA certificates will be issued with the facility name only. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding replacement of MQSA certificates. ^- ~~*+FDA or the Certifying State will then issue a new MQSA certificate to the facility reflecting the new address. *-~~

~~*+Until the new MQSA certificate is received, the facility must prominently display its original MQSA certificate. The expiration date of the new MQSA certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new MQSA certificate arrives, the original MQSA certificate should not be displayed. The facility should file or destroy the original MQSA certificate after it receives the new MQSA certificate. *-~~

Definitions

Accreditation Body

Citation:

900.2(a) Accreditation body or body means an entity that has been approved by FDA under section 900.3(d) to accredit mammography facilities.

Discussion:

Currently, the FDA-approved accreditation bodies are:

American College of Radiology (ACR)
State of Arkansas
State of California
State of Iowa
State of Texas

^+Currently, the^- ~~*+The*-~~ state accreditation bodies may accredit only those facilities that are located in their respective states.

Related Topics:

~~*+**General Requirements for Accreditation and Certification***-~~

^+Authorization^-

Citation:

^+900.2 (bbb) Authorization means obtaining approval from FDA to utilize new or changed State regulations or procedures during the issuance, maintenance, and withdrawal of certificates by the certification agency^-

Certificate

Citation:

900.2(h) Certificate means the certificate described in section 900.11(a).

Discussion:

After October 1, 1994, ^+all mammography facilities are required to have an MQSA^- ~~a~~ certificate issued by FDA ^+or the Certifying State^- ~~*+is required for lawful operation of all*-~~ ^+to legally perform^- mammography ~~*+facilities*-~~. To obtain ~~a~~ ^+an MQSA^- certificate from FDA ^+or the Certifying State^- , facilities are required to be accredited by an approved accreditation body or other entity, as designated by FDA, and to meet the quality standards as published in 900.12.

By law, ~~*+FDA*-~~ ^+MQSA^- certificates must be prominently displayed ~~*+in all patient reception areas*-~~ where they can be viewed by mammography ^+patients^- ~~*+examinees*-~~.

Question 1: Where does a facility with more than one patient~~/examinee~~ reception area display its ^+MQSA^- certificate?

~~*+FDA*-~~ ^+MQSA^- certification is facility based. Therefore, if a facility has more than one patient reception area, it may request an additional ^+MQSA^- certificate for each reception area from FDA. All ^+MQSA^- certificates issued to a facility will share that facility's unique 6-digit identification number. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request ~~*+the*-~~ additional ^+MQSA^- certificates. ^+Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates. ^-

Question 2: Can a facility with a ~~+large*-~~ Spanish-speaking population get a Spanish-language ^+MQSA^- certificate?*

FDA will issue an additional ^+MQSA^- certificate translated into Spanish for those facilities serving a Spanish-speaking population for each patient reception area. The Spanish-language ^+MQSA^- certificate(s) and the English-language ^+MQSA^- certificate(s) must both be prominently displayed where they can be viewed by mammography ~~*+examinees*-~~ ^+patients^-. Contact the FDA MQSA Facility Hotline at 1-800-838-7715 to request a Spanish-language ^+MQSA^- certificate. ^+Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding additional MQSA certificates. ^-

Question 3: A facility has changed its name but has the same owner, personnel, and equipment. Is the ^+MQSA^- certificate still valid even though the facility name is different?

^+Your MQSA certificate is still valid. However, when^- ~~*+When*-~~ a facility changes just its name, it must notify its accreditation body even though it still has the same owner, personnel, and equipment. ~~*+Once the facility has complied with the accreditation body's requirements, the*-~~ ^+The^- accreditation

body will ^+then^- inform FDA ^+or the Certifying State^- of the facility's new name. FDA ^+or the Certifying State^- will then issue a new ^+MQSA^- certificate to the facility.
Until the new ^+MQSA^- certificate is received, the facility must prominently display its original ^+MQSA^- certificate. The expiration date of the new ^+MQSA^- certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new ^+MQSA^- certificate arrives, the original ^+MQSA^- certificate should not be displayed. The facility should file or destroy the original ^+MQSA^- certificate after it receives the new ^+MQSA^- certificate.

Question 4: A facility moves or relocates and the address on its ^+MQSA^- certificate is no longer correct. Is the ^+MQSA^- certificate still valid?

^+Your MQSA certificate is still valid. However, when^- ~~*+When*-~~ a facility moves or relocates, it must notify its accreditation body. ^+The facility is reminded that any mammography unit or processor that is disassembled and reassembled at the same or different location must have a mammography equipment evaluation. Any failures of a regulatory requirement found during the mammography equipment evaluation must be corrected before that piece of equipment is used for patient examinations. ^- The accreditation body will direct the facility regarding any additional information and/or testing that it may require. ~~*+Once those requirements are satisfied, the*-~~ ^+The^- accreditation body will ^+then^- inform FDA ^+or the Certifying State^- of the facility's new address. ^+FDA will no longer issue replacement certificates for address changes. At the time of the next renewal, FDA-issued MQSA certificates will be issued with the facility name only. Facilities with State issued MQSA certificates should check with their State agencies for their policies regarding replacement of MQSA certificates. ^- ~~*+FDA will then issue a new certificate to the facility reflecting the new address. *-~~
~~*+Until the new certificate is received, the facility must prominently display its original certificate. The expiration date of the new certificate will be the same as the original since the facility has not been reaccredited or recertified. After the new certificate arrives, the original certificate should not be displayed. The facility should file or destroy the original certificate after it receives the new certificate. *-~~

Question 5: What should a facility do if it closes or decides that it will no longer provide mammography services?

~~*+The facility should contact its accreditation body and inform it that the facility is no longer practicing mammography. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.*-~~ ^+Before a facility permanently stops performing mammography, it should do the following: ^-

^+1. Inform its accreditation body that it will no longer be performing mammography;
2. Notify its State radiation control program;
3. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. The

facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine if their requirements are more stringent. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography, may choose to keep the patients' medical records rather than transfer them to another facility (unless the patient requests such a transfer). ^-

^+If option 3 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise. ^-

^+Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate. ^-

^+Due to the fact that some facilities have not followed the above recommendations, FDA has received inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that a facility that plans to stop performing mammography notify its Certifying Agency of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to: ^-

^+FDA/CDRH/OHIP/DMQRP^-

^+Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850^-

^+Facilities certified by States may send the above information to: ^-

^+State of Iowa
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th Street, Suite D
Des Moines, IA 50309
515-281-3478^-

^+State of Illinois
Office of Radiation Safety
Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704
217-785-9974^-

Question 6: Our facility has several patient waiting areas. Can I photocopy our facility ^+MQSA^- certificate and place copies in each area?

While the Statute requires that the original ^+MQSA^- certificate be prominently displayed, the photocopying of the ^+MQSA^- certificate so that it may be displayed in additional areas is not prohibited. However, we recommend that facilities wishing to display their MQSA certificate in several different areas obtain additional ^+MQSA^- certificates (at no charge) by contacting FDA at 1-800-838-7715 or writing to: FDA MQSA Program, P.O. Box 6057, Columbia, MD 21045~~-*+6057*-~~. Facilities with State-issued MQSA certificates should check with their ^+Certifying^- State ~~*+agencies*-~~ for their policies regarding additional ^+MQSA^- certificates. Facilities are reminded that, at a minimum, they must have the original ^+MQSA^- certificate displayed even if they choose to display additional copies of the ^+MQSA^- certificate. Mobile facilities must have at least one original ^+MQSA^- certificate displayed whenever the mobile unit is performing mammography.

Related Topics:

~~*+General Requirement for Accreditation and Certification *-~~

Certification

Citation:

900.2(i) Certification means the process of approval of a facility by FDA ^+or a certification agency^- to provide mammography services.

Related Topics:

~~*+~~**~~General Requirement for Accreditation and Certification~~** ~~*-~~

^+Certification Agency^-

Citation:

^+900.2 (zz) Certification agency means a State that has been approved by FDA under Sec. 900.21 to certify mammography facilities. ^-

Direct Supervision of Interpreting Physicians

Citation:

900.2(o)(1): Direct Supervision means that: During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records.

Discussion:

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the physician being supervised are corrected before harm is done to the patients.

The supervising interpreting physician does not have to be present when the physician being supervised makes ~~*+their*-~~ ^+his or her^- initial interpretation. ^+However, the supervising physician must review and, if necessary, correct the final interpretation before it is given to the patient. ^-

When the physician being supervised reads previously interpreted mammographic examinations, these interpretations must still be reviewed, discussed and confirmed or corrected by a supervising interpreting physician. This must be done even if the supervised physician's interpretation agrees with the previous interpretation and/or the interpretation of the supervising interpreting physician. If mammographic examinations are being read retrospectively under direct supervision, the usual requirement that the multireading be done before the patient receives her results is waived.

When mammographic examinations are read prospectively under direct supervision, at a minimum, the qualified supervising interpreting physician must sign the report.

Physicians working to meet one or more of the initial qualifications ~~*+are still considered physicians in training*-~~ and ^+those in the requalification process^- must continue to read under direct supervision until all ~~*+initial qualifications*-~~ ^+requirements^- have been meet.

Question 2: During annual MQSA inspections, mammography personnel are sometimes found to not meet one or more of the personnel qualifications. May this individual (interpreting physician) continue to lawfully provide mammography services to the facility?

While an individual's qualifications are still under evaluation, that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the ^+initial^- personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the ^+initial^- qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.

^+Personnel who fail to meet a continuing requirement must also go under direct supervision as stated above. However, FDA may allow for a limited time exception to this rule when the imposition of direct supervision on the person failing to meet the continuing requirement would result in the facility having to cease providing mammography services. ^-

Question 4: What does it mean for a physician to be under the direct supervision of a qualified interpreting physician? Does the supervising physician have to sit next to the physician being supervised when he or she reads and interprets the film? Whose name goes on the report, the supervising physician or the physician being supervised?

The supervising physician need not be present during initial reading and interpretation. Direct supervision for an interpreting physician means that during the joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. The physician being supervised ~~*+should*-~~ ^+must^- not provide final results to patients or referring physicians without prior confirmation from the supervising physician. Since each mammography report must be signed by a qualified interpreting physician, the name of the supervising interpreting physician must be on the report as the interpreting physician.

Direct Supervision of RTs and MPs

Citation:

900.2(o)(2): Direct Supervision means that: During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Question 3: What does it mean to be under the direct supervision of a qualified medical physicist?

For the physics survey and/or ^+mammography^- equipment evaluation, direct supervision means that the supervisor (if the supervision is done after 4/28/99, the supervising medical physicist must have qualified under the Master's or higher pathway) is present to observe and correct, as needed, the performance of the supervisee. This requires that the supervisor be in the room during the performance of the individual equipment tests to assure that any mistakes made by the supervisee are corrected before the test is completed. The supervisor must review any calculations made from, and any conclusions drawn from the test results, before those results are provided to the facility.

Furthermore, when conducting a physics survey, the supervisor and supervisee must jointly review the QC program records. The supervisor does not have to be present when the supervisee initially reviews the QC program records. However, the supervisor must review, discuss, confirm, and if necessary, correct the findings made by the supervisee prior to either the initial or final survey report being issued.

The goal of direct supervision is to provide reasonable assurance that any mistakes made by the supervisee are corrected before the QC program review or tests are completed.

Question 4: During annual MQSA inspections, mammography personnel are sometimes found to not meet one or more of the personnel qualifications. May this individual (medical physicist, radiologic technologist) continue to lawfully provide mammography services to the facility?

While an individual's qualifications are still under evaluation, that individual may continue to provide mammography services to the facility in his or her area. Once it has been determined that an individual DOES NOT meet one or more of the ^+initial^- personnel qualifications (e.g., a "No" answer has been entered in response to one or more of the ^+initial^- qualification questions), that individual may lawfully provide mammography services to the facility only under the direct supervision of a fully qualified individual. The direct supervision must continue until such time as the individual meets the qualifications, at which time he/she may resume working independently.

^+Personnel who fail to meet a continuing requirement must also go under direct supervision as stated above. However, FDA may allow for a limited time exception to this rule when the imposition of direct supervision on the person failing to meet the continuing requirement would result in the facility having to cease providing mammography services. ^-

Question 6: In a radiology training program with a mammography curriculum, would the facility be ~~*+in non-compliance*-~~ ^+non-compliant^- for letting student technologists show competency in performing mammography on live patients?

No. As long as the facility is ~~*+FDA*-~~ ^+MQSA^- certified, there is nothing in the MQSA or FDA's regulations that will interfere with training in mammography. Student technologists can receive classroom and practical training in a variety of ways. Student technologists who do not yet meet the requirements established under MQSA may perform actual examinations as part of the training so long as another technologist who does meet the MQSA requirements is present in the room to supervise (i.e. direct supervision) and, if necessary, corrects the student in the conduct of the examination.

Question 8: What are the required minimum qualifications for the supervisor of an individual who is performing surveys to meet the initial experience requirement or to requalify after failing to meet the continuing experience requirement?

The surveys performed to meet the initial experience and requalification requirements for the medical physicist must be performed under the direct supervision of a medical physicist who meets all the initial qualification and continuing qualification requirements (described in 900.12(a)(3)(i) and (iii)). NOTE: Medical physicists who qualify under the alternative initial qualification route ^+ (commonly known as the bachelors degree route), ^- section 900.12(a)(3)(ii), cannot provide supervision of surveys performed for the purpose of meeting the initial experience requirement or reestablishing the continuing experience requirement.

Levels of Non-Compliance (^+Observations^- ~~*+Findings*-~~)

Discussion:

~~*+Since the early days of MQSA inspections under the interim rule, FDA has adopted and used a three-tier system of inspection findings and has assigned three corresponding non-compliance levels as defined below:~~

~~Level 1 (L1). Level 1 is the most serious. It indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography services performed at the facility. FDA reviews each L1 finding, and if confirmed, the facility receives a Warning Letter (WL) requiring a response from the facility within 15 working days regarding the necessary corrective action(s).~~

~~Level 2 (L2). In the absence of L1 findings, a Level 2 finding indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. An L2 finding usually requires a response from the facility within 30 days regarding the necessary corrective action(s).~~

~~Level 3 (L3). In the absence of L1 and L2 findings, Level 3 findings indicate that the facility meets all major MQSA requirements with only minor problems. While the facility is expected to correct each non-compliance found in an MQSA inspection as soon as possible regardless of its level, it is not required to send a written response to FDA concerning a Level 3 non-compliance. Corrective actions regarding these are usually checked during the next annual inspection.~~

~~Based on inspection experience to date and feedback from the States and the mammography community, FDA has re-evaluated the finding level assignments to be implemented under the final rule and is intending: (1) to implement a new set of finding levels corresponding to new inspection questions, and (2) to restructure some of the existing finding levels in order to reflect a more realistic approach. *-~~

^+FDA has classified each adverse inspection observation into one of three category levels. A **Level 1** observation indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography performed at the facility. A **Level 2** observation indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. A **Level 3** observation indicates that the facility meets all major MQSA requirements with only minor problems. Adverse inspection observations are placed into a category level based on FDA's assessment of how the observation may affect the quality of mammography. The category level is also used to determine how the facility should respond to the observation. Identical observations found during two consecutive inspections are identified as repeats. ^-

Key Words:

^+Observations^- ~~*+Findings*-~~, **Noncompliance**, **Level 1**, **Level 2**, **Level 3**

Mammographic Modality

Key Words/Related Topics
Citation:

900.2(z) Mammographic Modality means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

Discussion:

Question 1: Are spot compression, magnification, and implant imaging considered mammographic modalities?

No. A mammographic modality is a technology for radiography of the breast, such as screen-film mammography, ^+full field digital mammography,^- and xeromammography. Spot compression and magnification are techniques used with a mammographic modality, but are not to be considered separate mammographic modalities in and of themselves. Implant imaging represents an application of a mammographic modality to patients with breast implants.

^+Question 4: Is Full Field Digital Mammography (FFDM) considered a mammographic modality? ^-

^+Yes. FFDM is a technology for radiography of the breast and, therefore, is a mammographic modality. Until fairly recently, FFDM was classified as an investigational use of mammography and thus was exempted from the MQSA requirements. However, FFDM units produced by a growing number of manufacturers have now been approved by FDA for commercial distribution. Such approved units are subject to the MQSA requirements. However, those FFDM units that are not yet cleared for commercial distribution are still viewed as investigational units and continue to be exempt from the MQSA requirements. ^-

^+Mobile Mammography Unit^-

^+Mobile Mammography Unit means a mammography x-ray unit located in a vehicle (truck, van, etc.) that is driven from one location to another to perform mammography. These units may be fixed in a vehicle such as a van or a truck, or may be portable (i.e., can be wheeled-off the van and moved into a site). Mobile units usually go to locations where patients would not normally get mammograms. Note: many stationary facilities have mammography units that are equipped with wheels so they can be easily moved from one room to another. Such units are not considered mobile mammography units. ^-

MQSA

Citation:

900.2(gg) MQSA means the Mammography Quality Standards Act.

Discussion:

MQSA also includes ~~*+the*-~~ ^+all^- Mammography Quality Standards Reauthorization ~~*+Act*-~~ ^+Acts^-

^+Performance Indicators^-

Citation:

^+900.2 (aaa) Performance indicators mean the measures used to evaluate the certification agency's ability to conduct certification, inspection, and compliance activities. ^-

Traceable to a National Standard

Citation:

900.2(xx) Traceable to a national standard means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within +/- 3 percent of the national standard in the mammography energy range.

Discussion

~~*+Question 4: If a calibration laboratory met the proficiency test requirement in the final regulations before April 28, 1999 (the effective date of the final regulations), will that test "count" after April 28, 1999? Similarly, if an air kerma measuring instrument was calibrated in accordance with the final regulations before April 28, 1999, will that calibration "count" after April 28, 1999? *-~~

~~*+Yes, to both questions, so long as the permitted maximum time periods are not exceeded. If the proficiency test or calibration was successfully completed before April 28, 1999, in accordance with the terms of the final regulations, the test or calibration will not have to be repeated simply because the new regulations have become effective. The repetition of the proficiency test can wait until up to two years after the last test and the repetition of the calibration can wait until up to two years after the last calibration or until after the next repair, whichever comes first. *-~~

Question ^+4^-~~*+5*-~~: A physicist utilizes a calibration laboratory <u>after</u> it has been notified by the National Institute of Standards and Technology (NIST) that it has failed its latest proficiency test. Can those ~~*+calibrated instrument*-~~ ^+instruments calibrated by that laboratory^- be used for MQSA evaluations?

No. Instruments calibrated by a laboratory ^+<u>after</u>^- the laboratory has been notified that it failed NIST's proficiency test ~~*+can not*-~~ ^+cannot^- be used for MQSA evaluations.

^+Within^-

^+Discussion: ^-

^+When used in the context of numerical or time specific MQSA regulatory limits, the word "within" is intended to include the limit itself. For example, the "Kilovoltage peak (kVp) accuracy and reproducibility" requirement states that "The kVp shall be accurate within +/- 5 percent of the indicated or selected kVp.....". This means that if the indicated kVp is 20 and the measured kVp is 19.0, the unit is compliant with this regulation. Similarly, the "Communication of mammography results to the patients" requirement states that "Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. This means that if a facility performs a mammogram on March 1 and sends the lay summary out on March 31, the facility is compliant with this regulation. ^-

Equipment

Compression Paddle

Citation:

900.12(b)(8)(ii)(A)(B)(C)(D)(E): Compression Paddle.

(A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

Discussion:

Question 7: Who is responsible for performing the compression paddle deflection test? How often should this test be performed and by what method?

^+When the mammography unit is initially placed in service or if the entire compression system is replaced, the medical physicist must perform the compression paddle deflection test as part of the mammography equipment evaluation. This test should also be performed periodically throughout the life of the unit or when an old full field compression paddle is replaced with a new one. Periodic testing and testing of a new full field compression paddle may be done by a radiologic technologist or other qualified person but should be performed in consultation with the medical physicist. ^-

~~*+The regulations do not specify a frequency or designate a specific individual to perform testing for this requirement; however, the facility is responsible for ensuring the mammography equipment meets MQSA requirements. FDA has left both the test procedures and frequency to the discretion of the facility. Such conformance would be verified under the equipment evaluation performed by the medical physicist when the equipment is initially placed in service or when there is a major repair involving this component. It should also be verified periodically throughout its useful life. *~~ ^+The frequency of periodic testing should be established with reference to the manufacturer's maintenance^- specifications and the use considerations (wear and tear) unique to the facility. If the excessive deflection of the compression paddle is identified during ~~*+an*~~ ^+a mammography^- equipment evaluation, it must be repaired before the ~~*+unit*~~ ^+paddle^- is used on patients. If the facility identifies the problem at any other time, it should be repaired as soon as possible because this problem may compromise clinical image quality. Manufacturers may specify procedures and frequency for testing the compression paddles in their maintenance instructions and adherence to these recommendations should normally be adequate; however the responsibility for compliance still remains with the facility.

One acceptable method for performing the compression paddle deflection test is:

1. If the mammographic unit does not have a read-out of compression force, cover the bucky with a towel and place a bathroom scale on the towel.
2. In order to prevent measuring deflection of the image receptor support (bucky) or the scale, place a support plate on top of the scale or directly on the towel if a scale is not used. The support plate should be made of a rigid material (e.g., acrylic sheet) that is large enough to completely cover either the scale or bucky.
3. Place the test object on the support plate with its base along the chest wall edge of the compression plate. Examples of test objects include: compressible foam materials (e.g. T-200 Minicel foam (10 X 18 cm for the 18 X 24 cm paddle and 14 X 22 cm for the 24 X 30 cm paddle, thickness of 4 to 6 cm) or tennis or rubber balls taped together in the shape of an equilateral triangle (3 balls for the 18 X 24 cm paddle and 6 balls for the 24 X 30 cm paddle)
4. Apply a compression force of 111 newtons (25 pounds).
5. Measure the distance of each corner of the paddle from the support plate.
6. Subtract the smallest distance from the largest distance to determine the deflection. The difference must be 1.0 cm or less to pass the test.

Paddles designed not to be flat and parallel to the breast support table during compression should not be evaluated using the procedure described above, but rather must meet the manufacturer's design specifications and maintenance requirements.

Focal Spot Selection

Citation:

900.12(b)(7)(i),(ii),(iii): Focal spot selection.

(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

Question 1: For x-ray systems with multiple focal spot sizes and target materials that are automatically selected by the system, how is it possible for the system to indicate the selected focal spot or target material before the exposure is taken?

^+When focal spot size and/or target material are automatically selected by the system, the system must show the pre-exposure values that are set either by the technologist, by the unit, or by default. Once the exposure has been completed, the system must then display the focal spot size and/or target material actually used during the exposure. ^- ~~*+When used in the automatic mode the system cannot show before the exposure, the actual values used during the exposure, but some values must exist before the exposure can begin. These pre-exposure values are set either by the technologist, by the unit, or by default. *-~~ The unit must indicate these pre-exposure values, either on the unit or at the operator position, prior to the exposure and then indicate the actual values used during the exposure, as required in 900.12(b)(7)(iii). The indication must be clear and legible and can be achieved in any manner that provides the required information in an unambiguous fashion.

General Equipment Requirement

Citation:

900.12(b)(2): General. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to 1010.2 of this chapter as meeting the applicable requirements of §1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

Question 1: Are all regulated mammography units in the facility required to be accredited and, if so, what documentation is necessary to establish that this has been done?

Yes. The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed ~~*+an*-~~ ^+a mammography^- equipment evaluation and that the application for accreditation of the unit has been submitted. There are three cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation ^+such as written verification from a repair service that repairs will take longer^-), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an experimental one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. The requirements for accreditation of these units is dependent on the rules of the facility's accreditation body. Note that under both 1) and 2) the unit still must have passed an equipment evaluation and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.

Question 2: Is there an exemption or "grandparenting" for equipment currently in use?

No. The final regulations do not include any "grandparenting" provisions for using ~~*+non-conforming*-~~ x-ray equipment ^+that does not meet the regulations^- after the effective dates. You should note that not all equipment and/or equipment quality control requirements become effective on the same date. Equipment that meets all effective requirements may be used until any requirements that it does not meet actually go into effect.

Image Receptor Sizes

Citation:

900.12(b)(4)(i),(ii),(iii): Image receptor sizes.

(i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptors.

Question 3: ^+When doing magnification mammography, can^- ~~*+Can*-~~ a facility keep the grid in place but position the cassette on top of the patient support (to prevent the grid from interfering with the image) and ^+still^- meet the ^+requirement for doing magnification procedures with the grid removed^- ~~*+intent of the regulation*-~~?

Yes, however, under these conditions the system must still be capable of providing magnification within the ~~*+specified*-~~ range ^+of 1.4 to 2.0^-. A facility meets the requirement if it has a written procedure for (or can demonstrate that the system has the capability of) conducting mammography with and without a grid between the image receptor and the x-ray source and such a practice does not cause the system to fail any other applicable requirement. A medical physicist may be consulted regarding the appropriateness of the technique.

^+Question 6: Our mammography unit has a single image receptor holder that can accommodate both the 24 X 30 cm and 18 X 24 cm image receptors, but has only one size grid. Is that acceptable? ^-

^+No. Each mammography system must be equipped to allow operation with both referenced image receptor sizes AND be provided with moving grids matched to each image receptor size provided with the system. Having a system equipped with only a single size moving grid, even if the device is capable of accepting both size cassettes, would not meet the requirements. ^-

Light Fields

Citation:

900.12(b)(5): For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

Question 1: ^+Does FDA have^- ~~+Are there*-~~ illumination requirements applicable to the collimator light on mammography x-ray systems? If so, do they apply to all systems?*

If the system is equipped with a light source to show the approximate size of the x-ray field or for positioning of the breast and this light passes through the x-ray beam-limiting device (collimator), then ^+your system must have a^- ~~*+effective April 28, 1999 the above*-~~ minimum light output ^+of 160 lux^- ~~*+requirement is applicable to that system*-~~. The regulation only specifies this requirement if such a collimator-light field combination is provided. ~~*+The requirement is applicable to all such systems in use on that date or installed on or after that date. *-~~

Question 2: Who is responsible for performing the light beam test? How often should it be tested and by what method?

^+When the mammography unit with a light beam that passes through the collimator is initially placed in service, the medical physicist must perform the light beam test as part of the mammography equipment evaluation. This test should also be performed periodically throughout the life of the unit or when an old bulb is replaced with a new one. Periodic testing and testing of a new bulb may be done by a radiologic technologist, repair person, or other qualified person but should be performed in consultation with the medical physicist. ^-

^+The frequency of periodic testing should be established with reference to the manufacturer's maintenance specifications and the use considerations (wear and tear) unique to the facility. If the light beam fails during a mammography equipment evaluation, it must be repaired before the light beam is used on patients. If the facility identifies the problem at any other time, it should be repaired as soon as possible. ^-

~~*+The regulations do not specify a frequency or designate a specific individual to perform testing for the light illuminance requirement. However, the facility is responsible for ensuring the mammography equipment meets MQSA requirements. Such conformance would be verified under the equipment evaluation performed when the equipment is initially placed in service and should be verified periodically throughout its useful life. The verification period should be established with reference to the manufacturer's maintenance specifications and the use considerations (wear and tear) unique to the facility. Anytime the facility or its personnel become aware of suspected problems with the equipment through its use or normal visual checks, the conformance of the equipment should be checked and repair or replacement should be achieved within the times specified under 900.12(e)(8)(ii) but always within 30 days of verifying the problem. *-~~
Manufacturers may specify procedures and frequency for testing the light illuminance in their maintenance instructions and adherence to these recommendations should normally be adequate; however, the responsibility for compliance still remains with the facility.

Some recommended testing specifications for the average illuminance are found in 21 CFR 1020.31(d)(2)(ii), where it states "The average illuminance shall be based upon the measurements made in the approximate center of each quadrant of the light field." The test must be conducted at the maximal SID or one meter, whichever is less, and should compensate for the ambient light usually present during clinical examinations. Instrumentation used should be appropriate for the purpose. Since this might require special test equipment ^+not usually available in the facility^-, FDA suggests that the facility add it to the list of items to be examined by the physicist during the ^+annual physics^- survey.

Magnification

Citation:

900.12(b)(6)(i),(ii): Magnification.

(i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

Question ^+3^- ~~+1*-~~: In 900.12(b)(6)(i) what does the phrase "available for use by the operator" mean?*

^+X-ray systems used for noninterventional^- ~~*+Noninterventional*-~~ problem-solving mammography ~~*+x-ray systems*-~~ are required to have the capability for magnification "available for use by the operator," meaning that any necessary magnification devices must be present with such units to allow operator access to, and to facilitate the use of, magnification procedures. The decision on whether to use the magnification still rests with the facility.

Question 2: A facility's x-ray unit has two magnification attachments that provide a magnification of 1.5 or 2.2, depending on which attachment is used. Other values specified in the regulation cannot be achieved using that unit. Must a facility purchase new attachments to cover the range, and does it mean that magnification at the 2.2 level must be discontinued?

No. The requirement is that the x-ray unit provide "at least one magnification value" ~~*+from*-~~ ^+in^- the ~~*+specified*-~~ range ^+of 1.4 to 2.0^- (in this case, the 1.5 ^+meets the requirement^-). The regulation does not prohibit the presence or use of ~~*+other*-~~ ^+additional^- magnification settings.

Question ^+1^- ~~+3*-~~: Must all mammographic units have magnification capabilities?*

The requirement to provide magnification capabilities is limited to those units used to perform noninterventional problem-solving mammography. The requirement does not apply to units used only for normal screening procedures. "Noninterventional problem-solving mammography" means noninvasive mammographic procedures requiring techniques beyond those used in standard screening of asymptomatic patients.

Motion of Tube Image Receptor Assembly

Citation:

900.12(b)(3)(i),(ii): Motion of tube-image receptor assembly.

(i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

~~***+Question 3: What motion requirements must the tube-image receptor assembly meet? *-***~~

~~*+There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power interruption. *-~~

Question ^+3^-+4*-: How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)?*

The amount of acceptable motion is dependent on the circumstances in each facility and should be evaluated on an individual basis. The intent of this regulation is to assure patient safety during power interruptions. Facilities should evaluate their machines to determine if the amount of gantry motion during power interruptions is sufficient to allow their typical patient to fall, be twisted, or be pulled from the position that they were placed in by the technologist to such an extent that injury could occur. If such injury could reasonably occur, the regulation has not been met.

Question ^+4^-+5*-: Could you clarify what is meant by the statement that the mechanism "shall not fail in the event of power interruption"?*

This means that if the power to the x-ray system is unexpectedly terminated during an examination, the tube-image receptor assembly will not move without operator intervention. This requirement is intended to provide additional safety for the patient in the event of power interruption during an examination and to prevent patient injury that might occur if the assembly moves.

The system must prevent motion until the operator determines that such motion is acceptable. Depending on the circumstances in each facility, the time required for the operator to safely remove the patient from the unit may vary. Therefore, the length of time required for the system to remain locked in place will also vary. However, removing the patient from the unit can usually be accomplished in a minute or less. Note: systems that lack built-in mechanisms to prevent unintended gantry motion may meet the requirement using external battery backup or mechanical mechanisms that prevent unintended motion for the amount of time it takes to remove the patient from the machine.

+Question 6: What motion requirements must the tube-image receptor assembly meet? *-

*+There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power interruption. *-

+Question 7: How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)? *-

*+The amount of acceptable motion depends on the circumstances in each facility and should be evaluated on an individual basis. The intent of this regulation is to assure patient safety during power interruptions. Facilities should evaluate their machines to determine if the amount of gantry motion during power interruptions is sufficient to allow their typical patient to fall, be twisted, or be pulled from the position that they were placed in by the technologist to such an extent that injury could occur. If such injury could reasonably occur, the regulation has not been met. *-

+Question 8: Our mammography unit has a single image receptor holder that can accommodate both the 24 X 30 cm and 18 X 24 cm image receptors, but has only one size grid. Is that acceptable? *-

*+No. Each mammography system must be equipped to allow operation with both referenced image receptor sizes AND be provided with moving grids matched to each image receptor size provided with the system. Having a system equipped with only a single size moving grid, even if the device is capable of accepting both size cassettes, would not meet the requirements. *-

Prohibited Equipment

Citation:

900.12(b)(1): Regulations published under §1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements. (1) Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supercedes the implied acceptance of such systems in 1020.31(f)(3) of this chapter.

Question 1: Must mammography units that are used exclusively for special interventional purposes (localization, biopsy, specimen radiography, and/or research) be accredited? Must a facility that performs mammography only for such special purposes be accredited and certified?

Accreditation of such units is not required at this time. Although these procedures do involve radiography of the breast, ^+they currently are excluded from MQSA regulation. ^- ~~*+the current state of knowledge does not permit the development of acceptable quality standards for these procedures, nor are there mechanisms for review of the clinical images that result from these procedures. *-~~

Therefore, a mammography unit that is used exclusively for special purposes need not be included in the accreditation application. Similarly, personnel who are involved only with such special purpose mammography may also be excluded from the accreditation application.

However, an accredited and certified facility that has a mammography unit dedicated solely to these special purpose uses must be prepared to provide the MQSA inspector with proper attestation ^+or documentation^- that such equipment and personnel are used only for these special purposes.

Note that any X-ray units or personnel involved even occasionally in routine screening or diagnostic mammography must meet the MQSA quality standards. These units must be included in the accreditation process and covered under the ^+MQSA^- certificate.

~~*+Health Care Financing*-~~ ^+Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) ^- Information

~~*+Health Care Financing Administration*-~~ ^+Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) ^- Process versus MQSA Accreditation & Certification Process

Discussion:

Question 1: How does the ^+CMS (formerly^- HCFA^+)^- process relate to the certification and accreditation process?

^+CMS (^-HCFA^+)^- has revised its regulations so that since October 1, 1994, a facility that meets the MQSA quality standards has been considered as meeting the ^+CMS (^-HCFA^+)^- requirements related to quality. ^+CMS (^-HCFA^+)^- also accepts MQSA inspections in lieu of conducting its own inspections. Thus, as long as a facility has a certificate under MQSA, ^+CMS (^-HCFA^+)^- will reimburse it for Medicare covered screening and diagnostic mammography examinations. ^+CMS (^-HCFA^+)^- will not reimburse ^+a facility^- ~~*+facilities*-~~ that ~~*+do~~ ^+does^- not have an MQSA certificate. The amount and frequency of reimbursement will still be governed by the ^+CMS (^-HCFA^+)^- regulations and facilities will still need to use their ^+CMS (^-HCFA^+)^- provider number.

To receive reimbursement from ^+CMS (^-HCFA^+)^-, the facility must also submit the FDA or Certifying State facility ID number as it appears on ~~*+it's*-~~ ^+its^- certificate to ^+CMS (^-HCFA^+) with its^- ~~*+and~~ ~~it's*-~~ request for reimbursement.

Key Words:
^+**CMS**^-**, HCFA, Medicare,**