

Compliance Guidance

**The Mammography Quality
Standards Act Final Regulations
Inspection Questions**

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**U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Inspection Support Branch
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 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 [1495]. Then follow the remaining voice prompts to complete your request.

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Compliance Guidance¹

The Mammography Quality Standards Act

Final Regulations Inspection Questions

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.

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 questions and data-entry fields that follow correspond to version 3.1 of the software program used in the MQSA inspection procedures under the final regulations. They were developed with input from the States through the CRCPD Working Group, the National Mammography Quality Assurance Advisory Committee, the American College of Radiology, and others in the mammography community. The questions are consistent with the final regulations published in the Federal Register on October 28, 1997 and with the MQSA re-authorization which was signed by the President on 10/9/98.

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.

**Mammography Quality Standards Act (MQSA)
V 3.1 Inspection Questions under the Final Regulations**

1.0 Equipment Registration – for entering calibration data regarding inspection equipment.

2.0 Facility Inspection Download – for importing, prior to an inspection, any existing facility information from FDA’s database.

3.0 Facility Inspections

List (of facilities with inspections downloaded for view, edit, or new)

Facility

Address (*info about current facility address*)

Inspection

3.0 Facility Inspections - Facility

(Certificate) **expiration date** (mm/dd/yyyy)

(Certificate) **Displayed?** (y/n)

Operating with a valid certificate? (y/n)

(Facility) **Identification**

Name ----- **ID #** ----- **CFN #** ----- **EIN #** -----

Facility Category

Non Federal

Federal (*check one*)

Air Force

Army

Bureau of Prisons

Indian Health Service

Navy

VA

Facility Type (*check one*)

Breast Clinic

Health Agency

Hospital – Radiology Dept.

Hospital – Non Radiology Dept.

Mobil Unit

Multiple Specialty Practice

Other

Private Practice – Internal Medicine

Private Practice – OB GYN

Private Practice – Radiology

Private Practice – Surgery
Private Practice – Other

3.0 Facility Inspections - Inspection

Inspector Name & ID # -----
Date (*of inspection*) m/dd/yyyy
Accomplishing (FDA) District -----
Inspection Time (on-site & other) (hours) xx.x
Travel Time (hours) xx.x

Annual Inspection Type

Basic
Joint Audit
Mentored

Accompanying Inspector -----
(*only for joint Audit and Mentored*)

Regulation Enforcement (Interim, Final) -----
Software Version: -----

3.1 Aliases – other names by which the facility may be known

3.2 Additional Sites – other sites where the facility provides mammography services

3.3 Contacts

3.3.1 Facility Accreditation Contact
3.3.2 Facility Inspection Contact
3.3.3 Compliance Contact
3.3.4 Billing Contact

3.4 Related Equipment – for updating inspection equipment calibration data

3.5 Units – List (*if more than one*)

Unit #
Room Name or number
X-ray unit still in use (*Use Status*)
Manufacturer
Model
Image Receptor Type

3.5 Units - Information

X-Ray unit #	-----
<i>(pre-filled with data supplied by the accreditation body)</i>	
X-Ray Unit Room Name or Number	-----
Serial Number	-----
X-ray unit still in use <i>(evaluation status)?</i>	(y/n/t/r)
<i>["t" for "temporarily out of service", "r" for "evaluate records only"]. If "t" or "r":</i>	
<i>(Date)</i> Removed from service	(mm/dd/yyyy)
Manufacturer <i>(Code)</i>	-----
Model <i>(Code)</i>	-----
Manufacture Date -	(mm/dd/yyyy)
Is the unit mobile (van, truck,...)?	(y/n)
Image Receptor (IR) Type <i>(pre-filled)</i>	(F/X/D)
<i>[F: Film/screen, X: Xeromammography, D: Digital]</i> If the answer is D, then:	
Display Method	(M/L/O)
<i>[Monitor/Laser film/Other]- allows multiple options</i>	

3.5 Units - Evaluation

X-Ray unit designed for mammography?	(y/n)
Does x-ray system include the following?	(y/n)
- Image Receptors for 2 sizes?	(y/n)
- Moving Grids for 2 sizes?	(y/n)
- Compression Paddles for 2 sizes?	(y/n)
- Post-Exposure Display in AEC mode for focal spot?	(y/n/x)
- Post-Exposure Display in AEC mode for target material?	(y/n/x)
X-Ray unit accredited? <i>[p: pending, x: not applicable]</i>	(y/n/p/x)
Is this a new* unit? <i>[* New: in clinical use for less than a year]</i>	(y/n)
Mammo Equip. Evaluation <i>(by medical physicist)</i> Done ?	(y/n/x)

3.5 Units - Screen-Film *(info)*

Film Manufacturer <i>(Code)</i>	-----
Film Type <i>(Code)</i>	-----
Screen Manufacturer <i>(Code)</i>	-----
Screen Type <i>(Code)</i>	-----

3.5.1 Collimation Assessment

Source to Image Distance (SID) (cm)	---.
Source to Patient Support Distance (SPSD) (cm)	---.
X-ray field /IR Misalignment [l/r/n] (cm)	---.
<i>(3 separate fields for: left, right, nipple)</i>	
X-ray field /IR Misalignment [chest wall] (cm)	---.

IR/Paddle alignment

Is paddle image on the film?	(y/n)
Compression paddle / chest wall edge of IR (cm)	---.

3.5.2 Dose Estimate

Technique Factors

Target/filter (Mo/Mo, Mo/Rh, Other) ----
 Focal Spot to Patient Support (cm) ---.-
 Mode (Auto [mAs, kVp, or full] /Manual) ----

Pre-Exposure SETTINGS (if indicated)

kVp --- mAs ---- Time --- Density (*setting*) ---

Cassette Variability

	C. ID	mAs	Exposure (mR)	Exposure Time (ms)
Cassette # 1	----	----	----	----
Cassette # 2	----	----	----	----
Cassette # 3	----	----	----	----

Beam Quality (HVL)

Settings

KVp ----

mAs ----

Exposure Values (mR) (*measured*)

0.0 mmAl ----

0.1 mmAl ----

0.2 mmAl ----

0.3 mmAl ----

0.4 mmAl ----

0.5 mmAl ----

Summary Results

ESE (mR) ----

C.O.V. (*reproducibility*) ----

Beam Quality (HVL) (mmAl) ----

Mean Glandular Dose (MGD) (mRad) ----

3.5.3 Phantom Image Quality Evaluation

Image #1

Background Density (0.0-4.0) X.XX

of Fibers (0-6) X

of Fiber Artifacts (0 or 1) X

of Speck Groups (integer, 0-5) X

of Specks in last group (integer, 2-6) X

of Speck Artifacts (integer, 0-6) X

of Masses (0-5) X

of Mass Artifacts (0 or 1) X

Net Scores		Compliance
Fibers	---	pass/fail
Specks	---	pass/fail
Masses	---	pass/fail

If image # 1 passes, the test is completed. Otherwise, the same data for image # 2 must be entered.

3.6 Processors

List (*if more than one*)

Information

Processor

Status (Evaluate all, Hold, Evaluate records only)	-----
Number	-----
Room name or number	-----
Site	-----
Type (Primary, Back-up)	----
Manufacturer (<i>Code</i>)	----
Model (<i>Code</i>)	----

Developer

Manufacturer (<i>Code</i>)	----
Type (<i>Code</i>)	----
Processing Cycle (Standard, Extended)	----

Evaluation (*STEP Test*)

Ref. Step #	xx.y
Base+Fog	y.zz

	Lower Step #	Lower Step Den.	Higher Step #	Higher Step Den.
Strip 1	xx	-.--	xx+1	-.--
Strip 2	xx	-.--	xx+1	-.--
Strip 3	xx	-.--	xx+1	-.--
Strip 4	xx	-.--	xx+1	-.--

Test Result (Processing Speed) = ---- (pass/fail)

3.7 Darkrooms

List (*if more than one*)

Information

Status (Evaluate all, Hold, Evaluate records only)	-----
Room name or number	-----
Site Name	-----

Evaluation	
Border Visible?	(y/n)
Unfogged Area O.D.	y.zz
Fogged Area O.D.	y.zz
Fog Density (<i>calculated</i>)	y.zz

3.8 Quality Assurance Program

Sites – defaults to facility’s name if there are no additional sites	
Evaluate (double click next to site’s name to evaluate)	-----
Site (<i>name</i>)	-----
Do the QA records include the following?	(y/n)
- QA Personnel Assigned (lead I.P., QC tech., med. physicist)?	(y/n)
- Technique Tables/Charts?	(y/n)
- Written S.O.P.’s for QC tests (with acceptable limits for each)?	(y/n)
- S.O.P. for infection control?	(y/n)
- S.O.P. for handling consumer complaints?	(y/n)

3.9 Quality Control

3.9.1 Processor Performance QC

Processors (<i>list</i>)	
Type (<i>primary or back-up</i>)	----
Number	----
Room Name	----
Manufacturer	----
Model	----
Site	----

Evaluation	
Processor QC Records	
Worst/Sampling Month/Yr.	mm/yyyy
# days processed mammograms (in worst mo.)	dd
# of processing days without recorded data(#)	dd
Calculated % for not recording (<i># not recorded/# processed</i>)	---
# of consecutive processing days missed (12 months. 2 different mo. ok)	dd
# of days/yr. operated out-of-limits [MD, DD:±0.15. B+F: 0.03]	dd
C/A Documented?	(y/n/x)
Fixer Retention QC adequate? (<i>quarterly</i>)	(y/n)
- Done at the required frequency?	(y/n)
- C/A (30 days) Documented?	(y/n/x)

3.9.2 Phantom Image QC (weekly)

Units (list - excluding units not in use since previous inspection)

Number	----
Room name or number	----
Manufacturer	----
Model	----
Mobile	----
Image receptor type	----

Evaluation

- **Number of operating weeks missing** xx
(in worst consecutive 12-week period)
- **C/A** (before further exams) **documented?** (score, BD, contrast) (y/n/x)
- **Other phantom QC records/test conditions adequate?** (y/n)
 - Image taken at clinical ($\pm 1\text{kVp}$) setting? (y/n)
 - $\text{BD} > \text{or} = 1.20$ (y/n)

For mobile units (van, truck,..):

- Performance verification after each move? (y/n)

3.9.3 Compression QC adequate? (semi-annually)

(list of units as in phantom image QC)

- Done at the required frequency? (y/n)
- C/A (before further exams) Documented? (y/n/x)

3.9.4 Repeat Analysis QC adequate? (quarterly)

(list of sites to evaluate -if applicable- as in QA records)

- Done at the required frequency? (y/n)
- Evaluation done (cause of repeats determined for changes $> \pm 2\%$)? (y/n)
- C/A (30 days) Documented (when a given repeat % changes by $> \pm 2\%$)? (y/n/x)

3.9.5 Screen-Film Contact QC adequate? (semi-annually)

(list of sites to evaluate -if applicable- as in QA records)

- Done at the required frequency? (y/n)
- All mammography cassettes in use tested? (y/n)
- 40-Mesh copper test tool used? (y/n)
- C/A (before further exams) Documented? (y/n/x)

3.9.6 Darkroom Fog QC adequate? (semi-annually)

(list of darkrooms to evaluate as in QA records)

- Done at the required frequency? (y/n)
- Background Density $> \text{or} = 1.20$? (y/n/x)
- C/A (before further exams) Documented? (y/n/x)

3.9.7 Digital Mammography QC

Manufacturer recommended QC procedures followed? (y/n)

If “Monitor” only was checked for display mode:

- Monitor QC done per manufacturer’s recommendation? (y/n)

If “Laser film” or “Other” was checked for the display mode, then:

- Manufacturer recommended procedures used? (y/n)

3.10 Medical Physicist’s Survey

List (of all units except those not in use since the previous inspection)

Information

Survey report available? (y/n/c/x)

(“c”: claimed items)

Date of previous survey (mm/dd/yy)

Date of current survey (mm/dd/yy)

Survey conducted or supervised by -----

Action taken (if called for in Report)? (y/n/x)

Overall Evaluation

Rules conducted under (Interim - for surveys < 4/28/99, Final – otherwise) -----

Survey Complete? (computed answer) (y/n)

(answer would be “yes” only if all items in parts 1 and 2 below are answered “yes”)

3.10.1 Survey Report Part 1

Part 1 Complete? (computed answer) (y/n)

Focal Spot Size/Resolution Measurement (y/n)

- Done for all clinically used focal spots? (y/n)

- Numerical results given? (y/n)

AEC Performance

- Reproducibility (mAs) (y/n)

- Numerical results given? (y/n)

- Performance Capability (y/n)

- Done for 2, 4, and 6 cm at typical kVp(s)? (y/n)

- Numerical results given? (y/n)

Dose (including entrance air kerma reproducibility) (y/n)

- Exposure & HVL at same clinical kVp? (y/n/u)

- RMI156 or equivalent phantom? (y/n/u)

- Numerical results given? (y/n)

Phantom Image	(y/n)
- Done at the kVp normally used clinically?	(y/n)
- RMI156/equivalent phantom?	(y/n/u)
- 3 object scores given?	(y/n)
Artifact Evaluation	(y/n)
QC Tests - New Modalities (if applicable)	
(y/n/x)	
3.10.2 Survey Report Part 2	
Part 2 Complete? (<i>computed answer</i>)	(y/n)
Pass/fail list	(y/n)
Recommendations for failed items	(y/n/x)
Physicist's Evaluation of Technologist's QC Tests	(y/n)
- Processor QC? [for each processor]	(y/n)
- Phantom image? [for each x-ray unit]	(y/n)
- Repeat analysis?	(y/n)
- Analysis of fixer retention? [for each processor]	(y/n)
- Darkroom fog? [for each darkroom]	(y/n)
- Screen-film contact? [for all cassettes]	(y/n)
- Compression? [for each x-ray unit]	(y/n)
Collimation	(y/n)
X-Ray Field - Light Field	(y/n/x)
X-Ray Field - Image Receptor Alignment	(y/n)
Compression Device Edge Alignment	(y/n)
kVp Accuracy	(y/n)
- Done at these 3 clinical kVps?	(y/n)
(lowest measurable, most often used, <u>highest</u> available)	
- Numerical results given?	(y/n)
kVp Reproducibility	(y/n)
- Done at the kVp most commonly used clinically?	(y/n)
- Numerical results given?	(y/n)
Beam Quality (HVL) Measurement	(y/n)
- Done at the kVp most commonly used clinically?	(y/n)
- Numerical results given?	(y/n)
Uniformity of Screen Speed [for all cassettes used]	(y/n)
- Numerical results given?	(y/n)
Radiation Output	(y/n)

Decompression

(y/n/x)

3.11 Personnel

List

- Status (Evaluate, Hold)
- Type (Interpreting Physician, Technologist, Medical Physicist)
- Last Name
- First Name
- Middle Initial
- Full name

3.11.1 Interpreting Physicians

List (*if more than one*)

Information

- Status (Evaluate, Hold)
- Lead interpreting physician** [] – *one only may be checked*
- Name xxx** [FIRST, M.I., LAST] (caps, separate fields)
- UPIN**

Evaluation

Rules qualifying under (interim, final) [*select one*]

If you selected the interim rules:

- Initial qualifications under interim rules met?** (prior to 4/28/99) (y/n/c)
- Licensed? (y/n/c)
- Certified or 2 months training? (y/n/c)
- 40 CME hours (y/n/c)
- Initial experience adequate? (240 exams/6 months) (y/n/c)

If you selected the final rules:

- Initial qualifications met?** (y/n/c)
- Licensed? (y/n/c)
- Certified or 3 months training? (y/n/c)
- 60 category I CME hours? (y/n/c)
- Initial experience adequate? (240 exams/6 months) (y/n/c)

Date completed initial requirements mm/dd/yyyy

New modality training (8 hours) (if applicable) (y/n/c/x)

Continuing experience

Continuing experience adequate? (960 exams/24 months) (y/n/c/x)

If "n", then:

Number of exams in 24 months yyy

Continuing education

CME credits adequate? (15/36 m) (y/n/c/x)
If “n”, then:
 Number of CME’s in 36 months zzz

3.11.2 Technologists

List (*if more than one*)

Information

Status (Evaluate, Hold)

Name yyy [FIRST, M.I., LAST] (caps, separate fields)

Evaluation

Rules qualifying under (interim, final) [*select one*]

If you selected the interim rules:

Initial qualifications under interim rules met? (prior to 4/28/99) (y/n/c)

- Licensed or certified (y/n/c)

- Training specific to mammography (y/n/c)

If you checked the final rules:

Initial qualifications met? (y/n/c)

- Licensed OR Certified? (y/n/c)

- 40 supervised hours of training adequate? (y/n/c)

Date completed initial requirements mm/dd/yyyy

- **New modality training** (8 hrs.) (if applicable) (y/n/c/x)

- **Continuing experience adequate?** [200 exams/24months] (y/n/c/x)

Continuing education

CEU credits adequate? (15/36 months) (y/n/c/x)

If “n”, then :

Number of CEU’s in 36 months xxx

3.11.3 Medical Physicists

List (*if more than one*)

Information

Status (Evaluate, Hold)

Name zzz [FIRST, M.I., LAST] (caps, separate fields)

Evaluation

Degree qualifying under (Masters or higher, Bachelors, None) [*select one*]

If you selected “Masters (or higher)”:

Initial qualifications met? (y/n/c)

- Certified or state licensed/approved? (y/n/c)

- Masters degree in a physical science? [w/20 sem. hrs. in physics] (y/n/c)
- 20 contact hours of training in surveys? (y/n/c)
- Experience in conducting surveys? (1facility & 10 units) (y/n/c)

If you selected "Bachelors":

- Alternative initial qualifications met before 4/28/99?** (y/n/c)
- Certified or state licensed/approved? (y/n/c)
- Bachelor's degree in a physical science [w/10 sem. hrs in physics] (y/n/c)
- (physical science: physics, chemistry, engineering, radiation science)*
- 40 contact hrs. training in surveys (after Bachelors) (y/n/c)
- Experience in conducting surveys (after Bachelors) (1facility & 20 units) (y/n/c)

Date completed initial requirements mm/dd/yyyy

-New modality training (8 hours) (if applicable) (y/n/c/x)

Continuing experience adequate? (2 facilities & 6 units/24months) (y/n/c/x)

Continuing Education

CME Credits/year adequate? (15/36 months) (y/n/c/x).

If "n", then :

Number of CME's in 36 months **xxx**

3.11.4 Personnel – Summary

Evaluation

For all personnel categories:

Required documents available? (y/n/x)

3.12 Medical Records

Site List (if applicable)

Evaluation

System (to communicate results) adequate? (y/n)

System to provide medical reports within 30 days? (y/n)

(to referring health care providers and or self-referred patients)

System to provide lay summaries within 30 days? (y/n)

(to all patients)

System to communicate serious cases ASAP? (y/n)

(Serious: suspicious or highly suggestive cases)

Random written reports

Number of random written reports reviewed	----
Number with assessment categories <i>(Assessment categories: negative, benign, probably benign, suspicious, highly suggestive of malignancy, incomplete: need additional imaging evaluation)</i>	----
Number with qualified interpreting physician identification	----

3.13 Medical Audit and Outcome Analysis

Site List (if applicable)

Evaluation

- ALL positive mammograms entered in system? (y/n/x)
- Biopsy results present (or attempt to get) (y/n/x)
- Is there a designated reviewing interpreting physician? (y/n/x)

The next 3 questions will not result in citations until 4/28/2001

- Analysis done annually? (y/n/x)
- Done separately for each individual? (y/n/x)
- Done for the facility as a whole? (y/n/x)