MQSA Facility Certification Extension Requirements for Digital Breast Tomosynthesis (DBT) System

NOTE 1: Under MQSA, each manufacturer's Digital Breast Tomosynthesis system is currently considered a separate new mammographic modality, and the personnel requirements for new modality training apply.

NOTE 2: In order to use the tomosynthesis portion of the unit, the facility must apply to FDA to have its certificate extended to include that portion of the unit. **The certification extension only applies to the DBT portion of the unit.** The facility must have the 2D portion of the unit accredited by one of the accreditation bodies already approved to accredit the 2D portion.

Requirements:

1. **FFDM-DBT system Manufacturer's name: _____**

2. **Facility Status Information**

   a. Facility Name and FDA Facility ID Number

   b. FDA Certificate Expiration Date

   c. Current Accreditation Body for the 2D unit

   d. Accreditation Expiration Date

   e. Facility Contact Person for DBT unit

   f. Contact Person's Title

   g. Contact Person's Telephone, Fax, E-mail

   h. Facility Address

   i. Facility Owner

3. **DBT Unit Identification**

   a. Machine Manufacturer

   b. Machine Model

   c. Year of Manufacture

   d. Serial Number

   e. Accreditation Body Unit Number

4. **DBT Digital Image Receptor Identification (if interchangeable)**

   a. Receptor Manufacturer

   b. Receptor Model

   c. Year of Manufacture

   d. Serial Number (if applicable)

5. Final Interpretation Review Monitor Identification (if soft copy display is available)

a. Monitor Manufacturer

b. Monitor Model

c. Year of Manufacture

d. Serial Number

6. Phantom Identification

a. Phantom Manufacturer

b. Phantom Model

7. Submit either a hardcopy or softcopy 3D phantom image. Softcopy CD or DVD must be in DICOM Format. **(Failure to include a 3D phantom image will delay review of the application).**

8. Personnel Qualifications

a. Interpreting Physicians who are qualified to interpret DBT mammograms (see Qualified Personnel)

b. Radiological Technologists who are qualified to perform DBT mammography examinations and the manufacturer recommended quality assurance tests (see Qualified Personnel)

c. Medical Physicists who are qualified to perform equipment evaluations and/or surveys of DBT mammography units (Qualified Personnel)

9. *Complete Detailed* report of Mammography Equipment Evaluation (MEE) (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the request for use approval**) must be included when submitting application.**

a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:

(1) Prohibited Equipment

(2) Specifically Designed for Mammography

(3) Motion of Tube-Image Receptor Assembly

(4)(iii) Removable Grid (if applicable to the DBT system used) (5) Beam Limitation and Light Fields

(6) Magnification

(7) Focal Spot Selection

(8) Compression

(9) Technique Factor Selection and Display

(10) Automatic Exposure Control

b. The results of quality control tests as required under the following sections of the MQSA final regulations 21CFR 900.12(e):

(4)(iii) Compression Device Performance

(5)(i) Automatic Exposure Control Performance (if applicable to the DBT system used) (5)(ii) Kilovoltage Peak Accuracy and Reproducibility

(5)(iii) Focal Spot Condition (Resolution) (5)(iv) Beam Quality and Half-Value Layer

(5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the DBT system used) (5)(vi) Dosimetry

(5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment

(5)(ix) System Artifacts

(5)(x) Radiation Output

(5)(xi) Decompression (or alternative standards allowed for these requirements) (6) Quality Control Tests – Other Modalities (Facilities must perform all DBT manufacturer recommended quality control tests including the medical physicist's tests for Soft Copy Display system)

c. The results of the phantom image quality tests, including a sample image

d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action

e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable

f. Date of the MEE

g. Name and address of the physicist(s) who performed the MEE

10. DBT Manufacturer's Quality Control Program

a. Name of the Quality Control Manual

b. Year published

c. Revision number, if not the original

d. Printing number, if not the original

11. Signature of facility contact person for the DBT unit

Qualified Personnel

Interpreting Physicians

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DBT MAMMOGRAMS

List the current interpreting physicians who:

(1) Meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.*

_____

_____

_____

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Radiologic Technologists

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DBT MAMMOGRAMS

List the current radiologic technologists who:

(1) Meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.*

_____

_____

_____

_____

*Supporting documentation for these requirements will be checked during annual MQSA inspections.

Medical Physicists

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM DBT SURVEYS

List the current medical physicists who:

(1) Meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.*

_____

_____

_____

*Supporting documentation for these requirements will be checked during annual MQSA inspections.

Lead Interpreting Physician Attestation to Staff Personnel Qualifications

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____

Print Name _____

Date _____/_____/_____