

Each radiologic technologist who performs mammography at this facility must meet the attached FDA requirements and complete one copy of Section I. **This includes temporary and part time technologists currently working at the facility.** Please print or type. You may photocopy this form, but retyped versions will not be accepted. Original, electronic or faxed signatures are required and considered legally binding for this document. Stamped signatures are not acceptable. Signature dates must be within one year from the date of application. **Please complete all sections; an incomplete application will delay your accreditation.**

PRIVILEGED and CONFIDENTIAL • PEER REVIEW

Code of Virginia 8.01-581.17

SECTION I • PERSONNEL • RADIOLOGIC TECHNOLOGIST

1. Name _____
 Last name First name MI Degree

2. Initial qualifying date (earliest date qualified to conduct mammography. Radiologic technologists qualifying prior to the MQSA Interim Rules should check "prior to October 1, 1994.):

prior to October 1, 1994 or specify date after October 1, 1994 _____ / _____
 mo year

INITIAL QUALIFICATIONS

3. Certification/Licensure:

Certification		Licensure	
Registry	Expiration Date		
American Registry of Radiologic Technologists (ARRT)		Are you licensed to perform general radiographic procedures in a state? (if applicable)	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
ARRT Certification in Advanced Qualifications in Mammography			
American Registry of Clinical Radiography Technologists			

4. Formal mammography education: complete **ONLY** the column that pertains to you

Initially qualified under MQSA to perform mammography prior to April 28, 1999		Initially qualified under MQSA to perform mammography on or after April 28, 1999	
Have you completed at least 40 contact hours of training specific to mammography? (must be documented if obtained after October 1, 1994)	<input type="checkbox"/> ¹ No	Have you completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
	<input type="checkbox"/> ² Yes	Did this training include training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
		Have you performed a minimum of 25 examinations under the direct supervision of a qualified individual?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes

5. **New modalities:** Have you received at least eight hours of training in another mammography modality before beginning to use that modality?
(e.g., full-field digital mammography, including computed radiography)

- ¹ No ² Yes

CONTINUING EXPERIENCE

6. **How many mammographic examinations have you performed over the previous 24-month period?** *enter a number* _____
(include mammograms performed at this **and** other facilities, if you work for multiple sites)

If less than 200 mammographic examinations have been performed, are you in the process of requalifying?

- ¹ No ² Yes

CONTINUING EDUCATION

7. **Have you earned at least 15 continuing education units in a 36-month period?**

- ¹ No ² Yes

If you answered "No", are you in the process of requalifying?

- ¹ No ² Yes

I certify that the information provided in Section I is true and correct.

Executed on _____
Date

Signature of Radiologic Technologist

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 900
Quality Mammography Standards
Subpart B—Quality Standards and Certification

Sec. 900.12 Quality standards.

- (a) **Personnel.** The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:
- (2) **Radiologic technologists.** All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:
- i. **General requirements.**
 - (A) Be licensed to perform general radiographic procedures in a State; or
 - (B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and
 - ii. **Mammography requirements.** Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:
 - (A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;
 - (B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and
 - (C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams; and
 - iii. **Continuing education requirements.**
 - (A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.
 - (B) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.
 - (C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.
 - (D) **Requalification.** Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.
 - (E) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

iv. Continuing experience requirements.

- (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.
- (B) **Requalification.** Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

- (4) Retention of personnel records.** Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.