

Each radiologist (interpreting physician) who interprets mammograms for this facility must meet the following FDA requirements and complete one copy of Section G. **This includes locum tenens and part time radiologists currently working at the facility.** Please print or type. You may photocopy this form for multiple radiologists, but retyped versions will not be accepted. **Signatures** may be original or faxed. Stamps or electronic signatures are unacceptable. 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 G • PERSONNEL • RADIOLOGIST (INTERPRETING PHYSICIAN)

- Name _____

Last name	First name	MI	Degree
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- ACR Membership ID#: (optional) _____
- Initial qualifying date** (earliest date qualified to do mammography, usually the date you completed your residency. For example, a radiologist finishing a residency in June 1999 who met the initial experience and training requirements and passed the oral boards at the first possible opportunity, June 1999, would have an initial qualifying date of June 1999. Interpreting physicians qualifying prior to the MQSA Interim Rules should check "prior to October 1, 1994."):
 prior to October 1, 1994 or specify date (mo/yr) after October 1, 1994 _____

INITIAL QUALIFICATIONS

- Board certification or training: complete **ONLY** the column that pertains to you

Board Certification in Diagnostic Radiology (complete all that apply)		If NOT board certified AND you initially qualified under MQSA to interpret mammograms <i>prior to April 28, 1999</i>	If NOT board certified AND you initially qualified under MQSA to interpret mammograms <i>on or after April 28, 1999</i>
Board	Year Granted		
American Board of Radiology		Do you have two months of full-time documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection? <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	Do you have three months of full-time documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection? <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
American Osteopathic Board of Radiology			
Royal College of Physicians and Surgeons of Canada			

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

Initially qualified under MQSA to interpret mammograms <i>prior to April 28, 1999</i>		Initially qualified under MQSA to interpret mammograms <i>on or after April 28, 1999</i>	
Do you have 40 hours Category I CME in mammography prior to meeting your initial requirements? (must be documented if obtained after October 1, 1994)	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	Do you have 60 hours documented Category I CME in mammography (at least 15 of which must have been acquired in the three years immediately prior to meeting your initial requirements)?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes

6. Initial experience: complete *ONLY the column* that pertains to you

Initially qualified under MQSA to interpret mammograms prior to April 28, 1999		Initially qualified under MQSA to interpret mammograms on or after April 28, 1999		Initially qualified under MQSA to interpret mammograms on or after April 28, 1999, AND you became board certified at your first possible opportunity	
Have you interpreted mammograms from the exams of 240 patients (under direct supervision if obtained after October 1, 1994) within a six-month period <i>at any time prior to your qualifying date?</i>	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	Have you interpreted mammograms from the exams of 240 patients under direct supervision within the six months <i>immediately prior to your qualifying date?</i>	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	Have you interpreted mammograms from the exams of 240 patients under direct supervision in any six months <i>within the last two years of your residency?</i>	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes

7. New modalities: Have you received at least eight hours of training in another mammography modality before beginning to use that modality?

¹ No ² Yes, full-field digital mammography

CONTINUING EXPERIENCE

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

If less than 960 interpretations, are you in the process of requalifying?

¹ No ² Yes

CONTINUING EDUCATION

9. Have you earned at least 15 Category I CME in a 36-month period?

¹ No ² Yes

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

¹ No ² Yes

RELEASE:

I join in the request and consent to the American College of Radiology conducting such a survey and rendering a report and findings through the College. I also hereby release and forever discharge for myself, my heirs, executors, administrators, successors and assigns the American College of Radiology, its directors, officers, members, agents, volunteers and employees from and against any and all claims, suits, damages, losses, expenses (including attorneys' fees), and liabilities by reason of, arising out of, or related to participation in the aforesaid survey of the practice(s) of mammography as covered by this application, and the making of any report, statement, or recommendation or failure to make a report, statement, or recommendation with respect to the aforesaid practice of mammography, including but not limited to any such claims or other matters based on alleged or actual negligence, antitrust, misconduct, defamation, personal injury, or economic loss, and any actions that may be taken by others as a result of the survey when such actions performed by or on behalf of the ACR are done in good faith and without malice in connection with conducting this survey. Further, I agree to fully cooperate with the American College of Radiology in its accreditation survey, including to consent to an on-site visit, if desired by the American College of Radiology.

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

Executed on _____
 Date

 Signature of Radiologist (Interpreting Physician)

 Print Name of Radiologist (Interpreting Physician)

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:

(1) **Interpreting physicians.** All physicians interpreting mammograms shall meet the following qualifications:

(i) **Initial qualifications.** Unless the exemption in paragraph (a)(1)(iii)(A) of this section applies, before beginning to interpret mammograms independently, the interpreting physician shall:

(A) Be licensed to practice medicine in a State;

(B)

- (1) Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or
- (2) Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section;

- (C) Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and
- (D) Unless the exemption in paragraph (a)(1)(iii)(B) of this section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(ii) **Continuing experience and education.** All interpreting physicians shall maintain their qualifications by meeting the following requirements:

- (A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic 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) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical 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. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and
- (C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

- (D) Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

(iii) Exemptions.

- (A) Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.
- (B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

(iv) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

- (A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall:
 - (1) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or
 - (2) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.
 - (3) The interpretations required under paragraph (a)(1)(iv)(A)(1) or (a)(1)(iv)(A)(2) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.
- (B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

- (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.