

Each medical physicist who provides medical physicist services at this facility must meet the attached FDA requirements and complete one copy of Section H. 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 the most recent medical physicist's Annual Survey report. Please complete all sections; an incomplete application will delay your accreditation.

PRIVILEGED and CONFIDENTIAL • PEER REVIEW

Code of Virginia 8.01-581.17

SECTION H • PERSONNEL • MEDICAL PHYSICIST

1. Name _____
 Last name First name MI Degree
2. ACR Membership ID#: (optional) _____
3. Initial qualifying date (earliest date qualified to do mammography physics. Medical physicists 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

4. Do you meet FDA requirements for initial qualifications for medical physicists? complete ONLY the column that pertains to you

FDA Requirements	Initial Qualifications (Master's degree or higher)	Alternative Initial Qualifications must have met before April 28, 1999 (Bachelor's degree)
Qualified as a medical physicist under FDA's interim regulations and retained that qualification by maintenance of the active status of licensure, approval, or certification?	<i>Not applicable</i>	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
Board Certified by either (1) the American Board of Radiology in Diagnostic Radiological Physics (alone or combined with another subspecialty), Radiological Physics, Roentgen Ray or Gamma Ray Physics or X-Ray and Radium Physics or (2) the American Board of Medical Physics in Diagnostic Imaging Physics?	American Board of Radiology _____ Year American Board of Medical Physics _____	American Board of Radiology _____ Year American Board of Medical Physics _____
State licensed?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
State approved?	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
Meet the following degree requirement in a physical science from an accredited institution?	<i>Master's degree or higher</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<i>Bachelor's degree obtained before training and initial experience</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
Have no less than the following semester hours or equivalent of college undergraduate or graduate level physics?	<i>20 semester hours or equivalent</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<i>10 semester hours or equivalent</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
Have the following contact hours of documented specialized training in conducting surveys of mammography facilities?	<i>20 hours</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<i>40 hours</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes
Have experience conducting surveys of at least one mammography facility and the following number of mammography units? (No more than one survey of a specific unit within a period of 60 days may be counted towards the total mammography unit survey requirement. If experience was acquired after April 28, 1999, it must be under the direct supervision of a qualified medical physicist).	<i>10 units</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes	<i>20 units</i> <input type="checkbox"/> ¹ No <input type="checkbox"/> ² Yes

5. New Modalities: Have you received at least eight hours of training in surveying units of a new mammography modality before independently performing surveys? (e.g., full-field digital mammography, including computed radiography)

1 No 2 Yes

CONTINUING EXPERIENCE

6. How many mammography facilities and units have you surveyed over the previous 24-month period?

facilities _____ units _____

If less than 2 facilities and 6 units, 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 H is true and correct.

Executed on _____
Date

Signature of Medical Physicist

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:
- (3) **Medical physicists.** All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:
- (i) **Initial qualifications.**
- (A) Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and
- (B)
- (1) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;
- (2) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and
- (3) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section; or
- (ii) **Alternative initial qualifications.**
- (A) Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and
- (B) Prior to the April 28, 1999, have:
- (1) A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,
- (2) Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,
- (3) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
- (iii) **Continuing qualifications.**
- (A) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist 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 inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

- (B) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units 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 shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.
- (C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(iv) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications, as follows:

- (D) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.
- (E) Medical physicists who fail to meet the continuing experience requirement of paragraph (a)(3)(iii)(B) of this section shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(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.