

Facility Regulations – NMQAAC April 19, 2004

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

1 education credits in each mammographic modality used by the interpreting
2 physician in his or her practice; and

3 (C) Before an interpreting physician may begin independently interpreting
4 mammograms produced by a new mammographic modality, that is, a
5 mammographic modality in which the physician has not previously been trained,
6 the interpreting physician shall have at least 8 hours of training in the new
7 mammographic modality.

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

11 (iii) Exemptions.

12 (A) Those physicians who qualified as interpreting physicians under paragraph
13 (a)(1) of this section of FDA's interim regulations prior to April 28, 1999, are
14 considered to have met the initial requirements of paragraph (a)(1)(i) of this
15 section. They may continue to interpret mammograms provided they continue to
16 meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the
17 continuing experience and education requirements of paragraph (a)(1)(ii) of this
18 section.

19 (B) Physicians who have interpreted or multi-read at least 240 mammographic
20 examinations under the direct supervision of an interpreting physician in any 6-
21 month period during the last 2 years of a diagnostic radiology residency and who
22 become appropriately board certified at the first allowable time, as defined by an
23 eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this
24 section.

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

29 (A) Interpreting physicians who fail to meet the continuing experience
30 requirements of paragraph (a)(1)(ii)(A) of this section shall:

31 (1) Interpret or multi-read at least 240 mammographic examinations under
32 the direct supervision of an interpreting physician, or

33 (2) Interpret or multi-read a sufficient number of mammographic
34 examinations, under the direct supervision of an interpreting physician, to bring
35 the physician's total up to 960 examinations for the prior 24 months, whichever is
36 less.

37 (3) The interpretations required under paragraph (a)(1)(iv)(A)(1) or
38 (a)(1)(iv)(A)(2) of this section shall be done within the 6 months immediately prior
39 to resuming independent interpretation.

40 (B) Interpreting physicians who fail to meet the continuing education
41 requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient
42 number of additional category I continuing medical education credits in
43 mammography to bring their total up to the required 15 credits in the previous 36
44 months before resuming independent interpretation.

45 (2) Radiologic technologists. All mammographic examinations shall be performed by
46 radiologic technologists who meet the following general requirements, mammography
47 requirements, and continuing education and experience requirements:

48 (i) General requirements.

49 (A) Be licensed to perform general radiographic procedures in a State; or

50 (B) Have general certification from one of the bodies determined by FDA to
51 have procedures and requirements adequate to ensure that radiologic
52 technologists certified by the body are competent to perform radiologic
53 examinations; and

54 (ii) Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic
55 technologist under paragraph (a)(2) of this section of FDA's interim regulations of
56 December 21, 1993, or completed at least 40 contact hours of documented training

1 specific to mammography under the supervision of a qualified instructor. The hours of
2 documented training shall include, but not necessarily be limited to:

3 (A) Training in breast anatomy and physiology, positioning and compression,
4 quality assurance/quality control techniques, imaging of patients with breast
5 implants;

6 (B) The performance of a minimum of 25 examinations under the direct
7 supervision of an individual qualified under paragraph (a)(2) of this section; and

8 (C) At least 8 hours of training in each mammography modality to be used by
9 the technologist in performing mammography exams; and

10 (iii) Continuing education requirements.

11 (A) Following the third anniversary date of the end of the calendar quarter in
12 which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were
13 completed, the radiologic technologist shall have taught or completed at least 15
14 continuing education units in mammography during the 36 months immediately
15 preceding the date of the facility's annual MQSA inspection or the last day of the
16 calendar quarter preceding the inspection or any date in between the two. The
17 facility will choose one of these dates to determine the 36-month period.

18 (B) Units earned through teaching a specific course can be counted only once
19 towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the
20 course is taught multiple times during the previous 36 months.

21 (C) At least six of the continuing education units required in paragraph
22 (a)(2)(iii)(A) of this section shall be related to each mammographic modality used
23 by the technologist.

24 (D) Requalification. Radiologic technologists who fail to meet the continuing
25 education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a
26 sufficient number of continuing education units in mammography to bring their
27 total up to at least 15 in the previous 3 years, at least 6 of which shall be related
28 to each modality used by the technologist in mammography. The technologist
29 may not resume performing unsupervised mammography examinations until the
30 continuing education requirements are completed.

31 (E) Before a radiologic technologist may begin independently performing
32 mammographic examinations using a mammographic modality other than one of
33 those for which the technologist received training under paragraph (a)(2)(ii)(C) of
34 this section, the technologist shall have at least 8 hours of continuing education
35 units in the new modality.

36 (iv) Continuing experience requirements.

37 (A) Following the second anniversary date of the end of the calendar quarter in
38 which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were
39 completed or of April 28, 1999, whichever is later, the radiologic technologist
40 shall have performed a minimum of 200 mammography examinations during the
41 24 months immediately preceding the date of the facility's annual MQSA
42 inspection or the last day of the calendar quarter preceding the inspection or any
43 date in between the two. The facility will choose one of these dates to determine
44 the 24-month period.

45 (B) Requalification. Radiologic technologists who fail to meet the continuing
46 experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a
47 minimum of 25 mammography examinations under the direct supervision of a
48 qualified radiologic technologist, before resuming the performance of
49 unsupervised mammography examinations.

50 (3) Medical physicists. All medical physicists conducting surveys of mammography
51 facilities and providing oversight of the facility quality assurance program under paragraph (e) of
52 this section shall meet the following:

53 (i) Initial qualifications.

54 (A) Be State licensed or approved or have certification in an appropriate
55 specialty area by one of the bodies determined by FDA to have procedures and

1 requirements to ensure that medical physicists certified by the body are
2 competent to perform physics survey; and

3 (B)(1) Have a masters degree or higher in a physical science from an
4 accredited institution, with no less than 20 semester hours or equivalent (e.g., 30
5 quarter hours) of college undergraduate or graduate level physics;

6 (2) Have 20 contact hours of documented specialized training in conducting
7 surveys of mammography facilities; and

8 (3) Have the experience of conducting surveys of at least 1 mammography
9 facility and a total of at least 10 mammography units. No more than one survey of
10 a specific unit within a period of 60 days can be counted towards the total
11 mammography unit survey requirement. After April 28, 1999, experience
12 conducting surveys must be acquired under the direct supervision of a medical
13 physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of
14 this section; or

15 (ii) Alternative initial qualifications.

16 (A) Have qualified as a medical physicist under paragraph (a)(3) of this section
17 of FDA's interim regulations and retained that qualification by maintenance of the
18 active status of any licensure, approval, or certification required under the interim
19 regulations; and

20 (B) Prior to the April 28, 1999, have:

21 (1) A bachelor's degree or higher in a physical science from an accredited
22 institution with no less than 10 semester hours or equivalent of college
23 undergraduate or graduate level physics,

24 (2) Forty contact hours of documented specialized training in conducting
25 surveys of mammography facilities and,

26 (3) Have the experience of conducting surveys of at least 1 mammography
27 facility and a total of at least 20 mammography units. No more than one survey of
28 a specific unit within a period of 60 days can be counted towards the total
29 mammography unit survey requirement. The training and experience
30 requirements must be met after fulfilling the degree requirement.

31 (iii) Continuing qualifications.

32 (A) Continuing education. Following the third anniversary date of the end of the
33 calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of
34 this section were completed, the medical physicist shall have taught or
35 completed at least 15 continuing education units in mammography during the 36
36 months immediately preceding the date of the facility's annual inspection or the
37 last day of the calendar quarter preceding the inspection or any date in between
38 the two. The facility shall choose one of these dates to determine the 36-month
39 period. This continuing education shall include hours of training appropriate to
40 each mammographic modality evaluated by the medical physicist during his or
41 her surveys or oversight of quality assurance programs. Units earned through
42 teaching a specific course can be counted only once towards the required 15
43 units in a 36-month period, even if the course is taught multiple times during the
44 36 months.

45 (B) Continuing experience. Following the second anniversary date of the end
46 of the calendar quarter in which the requirements of paragraph (a)(3)(i) or
47 (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later,
48 the medical physicist shall have surveyed at least two mammography facilities
49 and a total of at least six mammography units during the 24 months immediately
50 preceding the date of the facility's annual MQSA inspection or the last day of the
51 calendar quarter preceding the inspection or any date in-between the two. The
52 facility shall choose one of these dates to determine the 24-month period. No
53 more than one survey of a specific facility within a 10-month period or a specific
54 unit within a period of 60 days can be counted towards this requirement.

55 (C) Before a medical physicist may begin independently performing
56 mammographic surveys of a new mammographic modality, that is, a

1 mammographic modality other than one for which the physicist received training
2 to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must
3 receive at least 8 hours of training in surveying units of the new mammographic
4 modality.

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

10 (A) Medical physicists who fail to meet the continuing educational
11 requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient
12 number of continuing education units to bring their total units up to the required
13 15 in the previous 3 years.

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

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

27
28 (b) Equipment. Regulations published under Secs. 1020.30, 1020.31, and 900.12(e) of this
29 chapter that are relevant to equipment performance should also be consulted for a more
30 complete understanding of the equipment performance requirements.

31 (1) Prohibited equipment. Radiographic equipment designed for general purpose or
32 special nonmammography procedures shall not be used for mammography. This prohibition
33 includes systems that have been modified or equipped with special attachments for
34 mammography. This requirement supersedes the implied acceptance of such systems in Sec.
35 1020.31(f)(3) of this chapter.

36 (2) General. All radiographic equipment used for mammography shall be specifically
37 designed for mammography and shall be certified pursuant to Sec. 1010.2 of this chapter as
38 meeting the applicable requirements of Secs. 1020.30 and 1020.31 of this chapter in effect at the
39 date of manufacture.

40 (3) Motion of tube-image receptor assembly.

41 (i) The assembly shall be capable of being fixed in any position where it is designed to
42 operate. Once fixed in any such position, it shall not undergo unintended motion.

43 (ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall
44 not fail in the event of power interruption.

45 (1) Image receptor sizes.

46 (i) Systems using screen-film image receptors shall provide, at a minimum, for
47 operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

48 (ii) Systems using screen-film image receptors shall be equipped with moving grids
49 matched to all image receptor sizes provided.

50 (iii) Systems used for magnification procedures shall be capable of operation with the
51 grid removed from between the source and image receptor.

52 (5) Light fields. For any mammography system with a light beam that passes through the
53 x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux
54 (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is
55 less.

56 (6) Magnification.

1 (i) Systems used to perform noninterventional problem solving procedures shall have
2 radiographic magnification capability available for use by the operator.

3 (ii) Systems used for magnification procedures shall provide, at a minimum, at least
4 one magnification value within the range of 1.4 to 2.0.

5 (7) Focal spot selection.

6 (i) When more than one focal spot is provided, the system shall indicate, prior to
7 exposure, which focal spot is selected.

8 (ii) When more than one target material is provided, the system shall indicate, prior to
9 exposure, the preselected target material.

10 (iii) When the target material and/or focal spot is selected by a system algorithm that is
11 based on the exposure or on a test exposure, the system shall display, after the
12 exposure, the target material and/or focal spot actually used during the exposure.

13 (8) Compression. All mammography systems shall incorporate a compression device.

14 (i) Application of compression. Effective October 28, 2002, each system shall provide:

15 (A) An initial power-driven compression activated by hands-free controls
16 operable from both sides of the patient; and

17 (B) Fine adjustment compression controls operable from both sides of the
18 patient.

19 (ii) Compression paddle.

20 (A) Systems shall be equipped with different sized compression paddles that
21 match the sizes of all full-field image receptors provided for the system.
22 Compression paddles for special purposes, including those smaller than the full
23 size of the image receptor (for "spot compression") may be provided. Such
24 compression paddles for special purposes are not subject to the requirements of
25 paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

26 (B) Except as provided in paragraph (b)(8)(ii)(C) of this section, the
27 compression paddle shall be flat and parallel to the breast support table and shall
28 not deflect from parallel by more than 1.0 cm at any point on the surface of the
29 compression paddle when compression is applied.

30 (C) Equipment intended by the manufacturer's design to not be flat and parallel
31 to the breast support table during compression shall meet the manufacturer's
32 design specifications and maintenance requirements.

33 (D) The chest wall edge of the compression paddle shall be straight and
34 parallel to the edge of the image receptor.

35 (E) The chest wall edge may be bent upward to allow for patient comfort but
36 shall not appear on the image.

37 (9) Technique factor selection and display.

38 (i) Manual selection of milliampere seconds (mAs) or at least one of its component
39 parts (milliampere (mA) and/or time) shall be available.

40 (ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in
41 mA and exposure time in seconds or the product of tube current and exposure time in
42 mAs) to be used during an exposure shall be indicated before the exposure begins,
43 except when automatic exposure controls (AEC) are used, in which case the technique
44 factors that are set prior to the exposure shall be indicated.

45 (iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak
46 (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

47 (10) Automatic exposure control.

48 (i) Each screen-film system shall provide an AEC mode that is operable in all
49 combinations of equipment configuration provided, e.g., grid, nongrid; magnification,
50 nonmagnification; and various target-filter combinations.

51 (ii) The positioning or selection of the detector shall permit flexibility in the placement of
52 the detector under the target tissue.

53 (A) The size and available positions of the detector shall be clearly indicated at
54 the X-ray input surface of the breast compression paddle.

55 (B) The selected position of the detector shall be clearly indicated.

1 (iii) The system shall provide means for the operator to vary the selected optical
2 density from the normal (zero) setting.

3 (11) X-ray film. The facility shall use X-ray film for mammography that has been
4 designated by the film manufacturer as appropriate for mammography.

5 (12) Intensifying screens. The facility shall use intensifying screens for mammography
6 that have been designated by the screen manufacturer as appropriate for mammography and
7 shall use film that is matched to the screen's spectral output as specified by the manufacturer.

8 (13) Film processing solutions. For processing mammography films, the facility shall use
9 chemical solutions that are capable of developing the films used by the facility in a manner
10 equivalent to the minimum requirements specified by the film manufacturer.

11 (14) Lighting. The facility shall make special lights for film illumination, i.e., hot-lights,
12 capable of producing light levels greater than that provided by the view box, available to the
13 interpreting physicians.

14 (15) Film masking devices. Facilities shall ensure that film masking devices that can limit
15 the illuminated area to a region equal to or smaller than the exposed portion of the film are
16 available to all interpreting physicians interpreting for the facility.

17

18 (c) Medical records and mammography reports—

19 (1) Contents and terminology. Each facility shall prepare a written report of the results of
20 each mammography examination performed under its certificate. The mammography report shall
21 include the following information:

22 (i) The name of the patient and an additional patient identifier;

23 (ii) Date of examination;

24 (iii) The name of the interpreting physician who interpreted the mammogram;

25 (iv) Overall final assessment of findings, classified in one of the following categories:

26 (A) "Negative:" Nothing to comment upon (if the interpreting physician is
27 aware of clinical findings or symptoms, despite the negative assessment, these
28 shall be explained);

29 (B) "Benign:" Also a negative assessment;

30 (C) "Probably Benign:" Finding(s) has a high probability of being benign;

31 (D) "Suspicious:" Finding(s) without all the characteristic morphology of breast
32 cancer but indicating a definite probability of being malignant;

33 (E) "Highly suggestive of malignancy:" Finding(s) has a high probability of
34 being malignant;

35 (v) In cases where no final assessment category can be assigned due to incomplete
36 work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an
37 assessment and reasons why no assessment can be made shall be stated by the
38 interpreting physician; and

39 (vi) Recommendations made to the health care provider about what additional actions,
40 if any, should be taken. All clinical questions raised by the referring health care provider
41 shall be addressed in the report to the extent possible, even if the assessment is negative
42 or benign.

43 (2) Communication of mammography results to the patients. Each facility shall send each
44 patient a summary of the mammography report written in lay terms within 30 days of the
45 mammographic examination. If assessments are "Suspicious" or "Highly suggestive of
46 malignancy," the facility shall make reasonable attempts to ensure that the results are
47 communicated to the patient as soon as possible.

48 (i) Patients who do not name a health care provider to receive the mammography
49 report shall be sent the report described in paragraph (c)(1) of this section within 30 days,
50 in addition to the written notification of results in lay terms.

51 (ii) Each facility that accepts patients who do not have a health care provider shall
52 maintain a system for referring such patients to a health care provider when clinically
53 indicated.

54 (3) Communication of mammography results to health care providers. When the patient
55 has a referring health care provider or the patient has named a health care provider, the facility
56 shall:

1 (i) Provide a written report of the mammography examination, including the items listed
2 in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no
3 later than 30 days from the date of the mammography examination; and

4 (ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make
5 reasonable attempts to communicate with the health care provider as soon as possible,
6 or if the health care provider is unavailable, to a responsible designee of the health care
7 provider.

8 (4) Recordkeeping. Each facility that performs mammograms:

9 (i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain
10 mammography films and reports in a permanent medical record of the patient for a period
11 of not less than 5 years, or not less than 10 years if no additional mammograms of the
12 patient are performed at the facility, or a longer period if mandated by State or local law;
13 and

14 (ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily
15 transfer the original mammograms and copies of the patient's reports to a medical
16 institution, or to a physician or health care provider of the patient, or to the patient
17 directly;

18 (iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of
19 this section shall not exceed the documented costs associated with this service.

20 (5) Mammographic image identification. Each mammographic image shall have the
21 following information indicated on it in a permanent, legible, and unambiguous manner and
22 placed so as not to obscure anatomic structures:

23 (i) Name of patient and an additional patient identifier.

24 (ii) Date of examination.

25 (iii) View and laterality. This information shall be placed on the image in a position near
26 the axilla. Standardized codes specified by the accreditation body and approved by FDA
27 in accordance with Sec. 900.3(b) or Sec. 900.4(a)(8) shall be used to identify view and
28 laterality.

29 (iv) Facility name and location. At a minimum, the location shall include the city, State,
30 and zip code of the facility.

31 (v) Technologist identification.

32 (vi) Cassette/screen identification.

33 (vii) Mammography unit identification, if there is more than one unit in the facility.
34

35 (d) Quality assurance--general. Each facility shall establish and maintain a quality assurance
36 program to ensure the safety, reliability, clarity, and accuracy of mammography services
37 performed at the facility.

38 (1) Responsible individuals. Responsibility for the quality assurance program and for
39 each of its elements shall be assigned to individuals who are qualified for their assignments and
40 who shall be allowed adequate time to perform these duties.

41 (i) Lead interpreting physician. The facility shall identify a lead interpreting physician
42 who shall have the general responsibility of ensuring that the quality assurance program
43 meets all requirements of paragraphs (d) through (f) of this section. No other individual
44 shall be assigned or shall retain responsibility for quality assurance tasks unless the lead
45 interpreting physician has determined that the individual's qualifications for, and
46 performance of, the assignment are adequate.

47 (ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the
48 facility shall:

49 (A) Follow the facility procedures for corrective action when the images they
50 are asked to interpret are of poor quality, and

51 (B) Participate in the facility's medical outcomes audit program.

52 (iii) Medical physicist. Each facility shall have the services of a medical physicist
53 available to survey mammography equipment and oversee the equipment-related quality
54 assurance practices of the facility. At a minimum, the medical physicist(s) shall be
55 responsible for performing the surveys and mammography equipment evaluations and

1 providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this
2 section.

3 (iv) Quality control technologist. Responsibility for all individual tasks within the quality
4 assurance program not assigned to the lead interpreting physician or the medical
5 physicist shall be assigned to a quality control technologist(s). The tasks are to be
6 performed by the quality control technologist or by other personnel qualified to perform
7 the tasks. When other personnel are utilized for these tasks, the quality control
8 technologist shall ensure that the tasks are completed in such a way as to meet the
9 requirements of paragraph (e) of this section.

10 (2) Quality assurance records. The lead interpreting physician, quality control
11 technologist, and medical physicist shall ensure that records concerning mammography
12 technique and procedures, quality control (including monitoring data, problems detected by
13 analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety,
14 protection, and employee qualifications to meet assigned quality assurance tasks are properly
15 maintained and updated. These quality control records shall be kept for each test specified in
16 paragraphs (e) and (f) of this section until the next annual inspection has been completed and
17 FDA has determined that the facility is in compliance with the quality assurance requirements or
18 until the test has been performed two additional times at the required frequency, whichever is
19 longer.
20

21 (e) Quality assurance--equipment--

22 (1) Daily quality control tests. Film processors used to develop mammograms shall be
23 adjusted and maintained to meet the technical development specifications for the mammography
24 film in use. A processor performance test shall be performed on each day that clinical films are
25 processed before any clinical films are processed that day. The test shall include an assessment
26 of base plus fog density, mid-density, and density difference, using the mammography film used
27 clinically at the facility.

28 (i) The base plus fog density shall be within + 0.03 of the established operating level.

29 (ii) The mid-density shall be within <plus-minus> 0.15 of the established operating
30 level.

31 (iii) The density difference shall be within <plus-minus> 0.15 of the established
32 operating level.

33 (2) Weekly quality control tests. Facilities with screen-film systems shall perform an
34 image quality evaluation test, using an FDA-approved phantom, at least weekly.

35 (i) The optical density of the film at the center of an image of a standard FDA-accepted
36 phantom shall be at least 1.20 when exposed under a typical clinical condition.

37 (ii) The optical density of the film at the center of the phantom image shall not change
38 by more than <plus-minus> 0.20 from the established operating level.

39 (iii) The phantom image shall achieve at least the minimum score established by the
40 accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec.
41 900.4(a)(8).

42 (iv) The density difference between the background of the phantom and an added test
43 object, used to assess image contrast, shall be measured and shall not vary by more
44 than <plus-minus> 0.05 from the established operating level.

45 (3) Quarterly quality control tests. Facilities with screen-film systems shall perform the
46 following quality control tests at least quarterly:

47 (i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per
48 square cm.

49 (ii) Repeat analysis. If the total repeat or reject rate changes from the previously
50 determined rate by more than 2.0 percent of the total films included in the analysis, the
51 reason(s) for the change shall be determined. Any corrective actions shall be recorded
52 and the results of these corrective actions shall be assessed.

53 (4) Semiannual quality control tests. Facilities with screen-film systems shall perform the
54 following quality control tests at least semiannually:

55 (i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05
56 when a mammography film of the type used in the facility, which has a mid-density of no

1 less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film
2 is placed on the counter top emulsion side up. If the darkroom has a safelight used for
3 mammography film, it shall be on during this test.

4 (ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40
5 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

6 (iii) Compression device performance.

7 (A) A compression force of at least 111 newtons (25 pounds) shall be
8 provided.

9 (B) Effective October 28, 2002, the maximum compression force for the initial
10 power drive shall be between 111 newtons (25 pounds) and 200 newtons (45
11 pounds).

12 (5) Annual quality control tests. Facilities with screen-film systems shall perform the
13 following quality control tests at least annually:

14 (i) Automatic exposure control performance.

15 (A) The AEC shall be capable of maintaining film optical density within <plus-
16 minus> 0.30 of the mean optical density when thickness of a homogeneous
17 material is varied over a range of 2 to 6 cm and the kVp is varied appropriately
18 for such thicknesses over the kVp range used clinically in the facility. If this
19 requirement cannot be met, a technique chart shall be developed showing
20 appropriate techniques (kVp and density control settings) for different breast
21 thicknesses and compositions that must be used so that optical densities within
22 <plus-minus> 0.30 of the average under phototimed conditions can be produced.

23 (B) After October 28, 2002, the AEC shall be capable of maintaining film
24 optical density (OD) within <plus-minus> 0.15 of the mean optical density when
25 thickness of a homogeneous material is varied over a range of 2 to 6 cm and the
26 kVp is varied appropriately for such thicknesses over the kVp range used
27 clinically in the facility.

28 (C) The optical density of the film in the center of the phantom image shall not
29 be less than 1.20.

30 (ii) Kilovoltage peak (kVp) accuracy and reproducibility.

31 (A) The kVp shall be accurate within <plus-minus> 5 percent of the indicated
32 or selected kVp at:

33 (1) The lowest clinical kVp that can be measured by a kVp test device;

34 (2) The most commonly used clinical kVp;

35 (3) The highest available clinical kVp, and

36 (B) At the most commonly used clinical settings of kVp, the coefficient of
37 variation of reproducibility of the kVp shall be equal to or less than 0.02.

38 (iii) Focal spot condition. Until October 28, 2002, focal spot condition shall be
39 evaluated either by determining system resolution or by measuring focal spot
40 dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by
41 determining the system resolution.

42 (A) System Resolution.

43 (1) Each X-ray system used for mammography, in combination with the
44 mammography screen-film combination used in the facility, shall provide a
45 minimum resolution of 11 Cycles/millimeter (mm) (line-pairs/mm) when a high
46 contrast resolution bar test pattern is oriented with the bars perpendicular to the
47 anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the
48 bars are parallel to that axis.

49 (2) The bar pattern shall be placed 4.5 cm above the breast support
50 surface, centered with respect to the chest wall edge of the image receptor, and
51 with the edge of the pattern within 1 cm of the chest wall edge of the image
52 receptor.

53 (3) When more than one target material is provided, the measurement in
54 paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal
55 spot for each target material.

1 (4) When more than one SID is provided, the test shall be performed at SID
2 most commonly used clinically.

3 (5) Test kVp shall be set at the value used clinically by the facility for a
4 standard breast and shall be performed in the AEC mode, if available. If
5 necessary, a suitable absorber may be placed in the beam to increase exposure
6 times. The screen-film cassette combination used by the facility shall be used to
7 test for this requirement and shall be placed in the normal location used for
8 clinical procedures.

9 (B) Focal spot dimensions. Measured values of the focal spot length
10 (dimension parallel to the anode cathode axis) and width (dimension
11 perpendicular to the anode cathode axis) shall be within the tolerance limits
12 specified in Table 1.

13
14
15
16 Table 1

Focal Spot Tolerance Limit			
Nominal Focal Spot Size (mm)	Maximum Measured Dimensions		
	Width(mm)		Length(mm)
0.10	0.15	0.15	0.15
0.15	0.23	0.23	0.23
0.20	0.30	0.30	0.30
0.30	0.45	0.45	0.65
0.40	0.60	0.60	0.85
0.60	0.90	0.90	1.30

17
18 (iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of
19 Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to
20 the mammographic range, are shown in Table 2. Values not shown in Table 2 may be
21 determined by linear interpolation or extrapolation.

22
23
24 Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

25
26 (v) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for
27 both air kerma and mAs shall not exceed 0.05.

28 (vi) Dosimetry. The average glandular dose delivered during a single cranio-caudal
29 view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0
30 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique
31 factors and conditions used clinically for a standard breast.

32 (vii) X-ray field/light field/image receptor/compression paddle alignment.

33 (A) All systems shall have beam-limiting devices that allow the entire chest
34 wall edge of the x-ray field to extend to the chest wall edge of the image receptor
35 and provide means to assure that the x-ray field does not extend beyond any
36 edge of the image receptor by more than 2 percent of the SID.

37 (B) If a light field that passes through the X-ray beam limitation device is
38 provided, it shall be aligned with the X-ray field so that the total of any
39
40

1 misalignment of the edges of the light field and the X-ray field along either the
2 length or the width of the visually defined field at the plane of the breast support
3 surface shall not exceed 2 percent of the SID.

4 (C) The chest wall edge of the compression paddle shall not extend beyond
5 the chest wall edge of the image receptor by more than one percent of the SID
6 when tested with the compression paddle placed above the breast support
7 surface at a distance equivalent to standard breast thickness. The shadow of the
8 vertical edge of the compression paddle shall not be visible on the image.

9 (viii) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the
10 facility shall be tested and the difference between the maximum and minimum optical
11 densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

12 (ix) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free
13 sheet of homogeneous material large enough to cover the mammography cassette and
14 shall be performed for all cassette sizes used in the facility using a grid appropriate for
15 the cassette size being tested. System artifacts shall also be evaluated for all available
16 focal spot sizes and target filter combinations used clinically.

17 (x) Radiation output.

18 (A) The system shall be capable of producing a minimum output of 4.5 mGy air
19 kerma per second (513 milli Roentgen (mR) per second) when operating at 28
20 kVp in the standard mammography (moly/moly) mode at any SID where the
21 system is designed to operate and when measured by a detector with its center
22 located 4.5 cm above the breast support surface with the compression paddle in
23 place between the source and the detector. After October 28, 2002, the system,
24 under the same measuring conditions shall be capable of producing a minimum
25 output of 7.0 mGy air kerma per second (800 mR per second) when operating at
26 28 kVp in the standard (moly/moly) mammography mode at any SID where the
27 system is designed to operate.

28 (B) The system shall be capable of maintaining the required minimum radiation
29 output averaged over a 3.0 second period.

30 (xi) Decompression. If the system is equipped with a provision for automatic
31 decompression after completion of an exposure or interruption of power to the system,
32 the system shall be tested to confirm that it provides:

33 (A) An override capability to allow maintenance of compression;

34 (B) A continuous display of the override status; and

35 (C) A manual emergency compression release that can be activated in the
36 event of power or automatic release failure.

37 (6) Quality control tests--other modalities. For systems with image receptor modalities
38 other than screen-film, the quality assurance program shall be substantially the same as the
39 quality assurance program recommended by the image receptor manufacturer, except that the
40 maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems
41 in paragraph (e)(5)(vi) of this section.

42 (7) Mobile Units. The facility shall verify that mammography units used to produce
43 mammograms at more than one location meet the requirements in paragraphs (e)(1) through
44 (e)(6) of this section. In addition, at each examination location, before any examinations are
45 conducted, the facility shall verify satisfactory performance of such units using a test method that
46 establishes the adequacy of the image quality produced by the unit.

47 (8) Use of test results.

48 (i) After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this
49 section, the facility shall compare the test results to the corresponding specified action
50 limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits;
51 or, for post-move, preexamination testing of mobile units, to the limits established in the
52 test method used by the facility.

53 (ii) If the test results fall outside of the action limits, the source of the problem shall be
54 identified and corrective actions shall be taken:

55 (A) Before any further examinations are performed or any films are processed
56 using a component of the mammography system that failed any of the tests

1 described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(ii), (e)(4)(iii), (e)(5)(vi),
2 (e)(6), or (e)(7) of this section;

3 (B) Within 30 days of the test date for all other tests described in paragraph (e)
4 of this section.

5 (9) Surveys.

6 (i) At least once a year, each facility shall undergo a survey by a medical physicist or
7 by an individual under the direct supervision of a medical physicist. At a minimum, this
8 survey shall include the performance of tests to ensure that the facility meets the quality
9 assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of
10 this section and the weekly phantom image quality test described in paragraph (e)(2) of
11 this section.

12 (ii) The results of all tests conducted by the facility in accordance with paragraphs
13 (e)(1) through (e)(7) of this section, as well as written documentation of any corrective
14 actions taken and their results, shall be evaluated for adequacy by the medical physicist
15 performing the survey.

16 (iii) The medical physicist shall prepare a survey report that includes a summary of this
17 review and recommendations for necessary improvements.

18 (iv) The survey report shall be sent to the facility within 30 days of the date of the
19 survey.

20 (v) The survey report shall be dated and signed by the medical physicist performing or
21 supervising the survey. If the survey was performed entirely or in part by another
22 individual under the direct supervision of the medical physicist, that individual and the
23 part of the survey that individual performed shall also be identified in the survey report.

24 (10) Mammography equipment evaluations. Additional evaluations of mammography
25 units or image processors shall be conducted whenever a new unit or processor is installed, a
26 unit or processor is disassembled and reassembled at the same or a new location, or major
27 components of a mammography unit or processor equipment are changed or repaired. These
28 evaluations shall be used to determine whether the new or changed equipment meets the
29 requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall
30 be corrected before the new or changed equipment is put into service for examinations or film
31 processing. The mammography equipment evaluation shall be performed by a medical physicist
32 or by an individual under the direct supervision of a medical physicist.

33 (11) Facility cleanliness.

34 (i) The facility shall establish and implement adequate protocols for maintaining
35 darkroom, screen, and view box cleanliness.

36 (ii) The facility shall document that all cleaning procedures are performed at the
37 frequencies specified in the protocols.

38 (12) Calibration of air kerma measuring instruments. Instruments used by medical
39 physicists in their annual survey to measure the air kerma or air kerma rate from a mammography
40 unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The
41 instrument calibration must be traceable to a national standard and calibrated with an accuracy of
42 <plus-minus> 6 percent (95 percent confidence level) in the mammography energy range.

43 (13) Infection control. Facilities shall establish and comply with a system specifying
44 procedures to be followed by the facility for cleaning and disinfecting mammography equipment
45 after contact with blood or other potentially infectious materials. This system shall specify the
46 methods for documenting facility compliance with the infection control procedures established
47 and shall:

48 (i) Comply with all applicable Federal, State, and local regulations pertaining to
49 infection control; and

50 (ii) Comply with the manufacturer's recommended procedures for the cleaning and
51 disinfection of the mammography equipment used in the facility; or

52 (iii) If adequate manufacturer's recommendations are not available, comply with
53 generally accepted guidance on infection control, until such recommendations become
54 available.
55

1 (f) Quality assurance-mammography medical outcomes audit. Each facility shall establish and
2 maintain a mammography medical outcomes audit program to followup positive mammographic
3 assessments and to correlate pathology results with the interpreting physician's findings. This
4 program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of
5 mammograms.

6 (1) General requirements. Each facility shall establish a system to collect and review
7 outcome data for all mammograms performed, including followup on the disposition of all positive
8 mammograms and correlation of pathology results with the interpreting physician's
9 mammography report. Analysis of these outcome data shall be made individually and collectively
10 for all interpreting physicians at the facility. In addition, any cases of breast cancer among women
11 imaged at the facility that subsequently become known to the facility shall prompt the facility to
12 initiate followup on surgical and/or pathology results and review of the mammograms taken prior
13 to the diagnosis of a malignancy.

14 (2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later
15 than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999,
16 whichever date is the latest. This audit analysis shall be completed within an additional 12 months
17 to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will
18 be conducted at least once every 12 months.

19 (3) Audit interpreting physician. Each facility shall designate at least one interpreting
20 physician to review the medical outcomes audit data at least once every 12 months. This
21 individual shall record the dates of the audit period(s) and shall be responsible for analyzing
22 results based on this audit. This individual shall also be responsible for documenting the results
23 and for notifying other interpreting physicians of their results and the facility aggregate results. If
24 followup actions are taken, the audit interpreting physician shall also be responsible for
25 documenting the nature of the followup.

26
27 (g) Mammographic procedure and techniques for mammography of patients with breast
28 implants.

29 (1) Each facility shall have a procedure to inquire whether or not the patient has breast
30 implants prior to the actual mammographic exam.

31 (2) Except where contraindicated, or unless modified by a physician's directions, patients
32 with breast implants undergoing mammography shall have mammographic views to maximize the
33 visualization of breast tissue.

34
35 (h) Consumer complaint mechanism. Each facility shall:

36 (1) Establish a written and documented system for collecting and resolving consumer
37 complaints;

38 (2) Maintain a record of each serious complaint received by the facility for at least 3 years
39 from the date the complaint was received;

40 (3) Provide the consumer with adequate directions for filing serious complaints with the
41 facility's accreditation body if the facility is unable to resolve a serious complaint to the
42 consumer's satisfaction;

43 (4) Report unresolved serious complaints to the accreditation body in a manner and
44 timeframe specified by the accreditation body.

45
46 (i) Clinical image quality. Clinical images produced by any certified facility must continue to
47 comply with the standards for clinical image quality established by that facility's accreditation
48 body.

49
50 (j) Additional mammography review and patient notification.

51 (1) If FDA believes that mammography quality at a facility has been compromised and
52 may present a serious risk to human health, the facility shall provide clinical images and other
53 relevant information, as specified by FDA, for review by the accreditation body or other entity
54 designated by FDA. This additional mammography review will help the agency to determine
55 whether the facility is in compliance with this section and, if not, whether there is a need to notify

1 affected patients, their physicians, or the public that the reliability, clarity, and accuracy of
2 interpretation of mammograms has been compromised.

3 (2) If FDA determines that the quality of mammography performed by a facility, whether
4 or not certified under Sec. 900.11, was so inconsistent with the quality standards established in
5 this section as to present a significant risk to individual or public health, FDA may require such
6 facility to notify patients who received mammograms at such facility, and their referring
7 physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate
8 remedial measures, and such other relevant information as FDA may require. Such notification
9 shall occur within a timeframe and in a manner specified by FDA.