### LCB File No. R033-06

# PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

**Authority.** NRS 457.065

**Section 1.** Chapter 457 of NAC is hereby amended by changing the provisions set forth in Section 2 to 44 inclusive of this regulation.

**Section 2.** NAC 457.235 is hereby amended to read as follows:

NAC 457.235 "Health Division" defined. "Health Division" means the Health Division of the Department of *Health and* Human Resources.

**Section 3.** NAC 457.285 is hereby amended to read as follows:

NAC 457.285 Adoption of publications by reference.

- 1. The State Board of Health hereby adopts by reference the provisions of:
- [1](a). Mammography Quality Control, in the form most recently published by the American College of Radiology, Committee on Quality Assurance in Mammography [(1992)], unless the Board gives notice that the most recent revision is not suitable for this State pursuant to subsection 2. A copy of this publication may be obtained at a cost of \$75 from the American College of Radiology, 1891 Preston White Drive, Reston, Virginia 22091, at website http://www.acr.org/s\_acr/sec.asp?CID=589&DID=14253, or by telephone at (703) 648-8900.
- [2](b). [Mammography A User's Guide, National Council on Radiation Protection, Report No. 85. A copy of this publication may be obtained at a cost of \$25 from NCRP Publications, 7910 Woodmont Ave., Suite 1016, Bethesda, Maryland 20814.] A Guide to Mammography and Other Breast Imaging Procedures, National Council on Radiation Protection Report No. 149. A copy of this publication may be obtained at the cost of \$110 from NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095, at telephone (800)229-2652 (Ext, 25) or at website http://NRCPpublications.org.
- (c). The standards developed under the Mammography Quality Standards Act in the form most recently published as found in Title 21, Code of Federal Regulations, Section 900 (21 CFR 900), unless the Board gives notice that the most recent revision is not suitable for this State pursuant to subsection 2. A copy of this publication may be obtained by way of the FDA Mammography website found at www.fda.gov/cdrh/mammography/, from the U.S. Government Printing Office for \$58.00 at http://www.gpoaccess.gov/, via phone at 888-293-6498, or at U.S. Government Printing Office, 732 North Capital Street NW, Washington, DC 20401.
- 2. The State Board of Health will review each revision of the publications adopted by reference pursuant to subsection 1 to ensure its suitability for this State. If the Board determines that a revision is not suitable for this State, the Board will hold a public hearing to review its determination within 6 months after the date of the publication of the revision and

give notice of that hearing. If, after the hearing, the Board does not revise its determination, the Board will give notice within 30 days after the hearing that the revision is not suitable for this State. If the Board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 1.

### **Section 4.** NAC 457.299 is hereby amended to read as follows:

NAC 457.299 Requirements for approval of applications for certificates for machines and mammographer's certificates.

- 1. The Health Division shall approve an application for a certificate for a machine or an application for a mammographer's certificate if it determines that:
- (a) The applicant has the training and experience required to conduct mammography pursuant to the provisions of NAC 457.200 to 457.480, inclusive;
- (b) The applicant has complied with any applicable requirements pursuant to NAC 457.200 to 457.480, inclusive; and
- (c) If the applicant is applying for a certificate for a machine, the equipment, facilities and procedures which the applicant proposes to use are adequate to minimize any danger to the public health or safety.
- (d) If there is no known certificate for a machine currently issued by the Health Division to another owner, lessee or other responsible person for that same mammography machine and the application is submitted by a single applicant/corporate entity.
- 2. If the applicant held a certificate for a machine issued by the Health Division or by the appropriate agency in another jurisdiction and the certificate was revoked or the holder of the certificate was found to have committed a violation of a regulation relating to public health or safety which the Health Division determines to be significant, the Health Division shall not issue a certificate for a machine or a mammographer's certificate to the applicant.

**Section 5.** NAC 457.300 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(c)(5), 900.12(d)(1) and 900.12(f)

NAC 457.300 Program for quality assurance: Establishment, maintenance and review; list of authorized mammographers required; operation of machine without mammographer's certificate prohibited. The operator of a facility shall:

- 1. Establish and maintain a program of quality assurance for each machine and all other equipment at the facility used for mammography *in accordance with the requirements found in 21 CFR 900*.
  - 2. Ensure that:
  - (a) The performance of the equipment is monitored;
- (b) The results of monitoring are analyzed to determine if there are any problems requiring correction:
- (c) The necessary corrective action is taken whenever the results of a test for quality assurance indicate that such action is required; and
- (d) If necessary corrective action is taken, the action is taken before any mammography is performed on the patient.

- 3. [At least annually, conduct a review of the effectiveness of the program and prepare a written report of the review. The operator shall ensure that a copy of the most recent report is available for inspection at the facility.
- 4.] Prepare and maintain a list which includes the name of each mammographer who is authorized to operate any machine which is under the operator's control.
- [5]4. Except as otherwise provided in NAC 457.355, not allow a person who does not hold a mammographer's certificate to operate a machine under the operator's control.
- [6]5. If the facility for mammography has more than one machine, ensure that a [number which identifies the machine] unique machine identifier is included in the information which appears on the edge of the film as it is exposed.
- 6. Ensure all quality assurance or quality control records are kept until the next annual inspection has been completed and the Health Division has determined that the facility is in compliance or until the tests have been performed two additional times at the required frequency, whichever is longer.

**Section 6.** NAC 457.305 is hereby amended to read as follows: Changes to incorporate CFR 900.12(d)(1) and 900.12(i).

NAC 457.305 Manual for quality assurance: Preparation and contents. The operator of a facility shall prepare or cause to be prepared a manual for quality assurance for the facility *and shall allow adequate time for the performance of all quality assurance duties*. The manual must include:

- 1. The name, position and a statement of the qualifications and duties of each person at the facility who is responsible for:
  - (a) Supervising the performance of mammography;
  - (b) Performing tests for quality assurance; or
  - (c) Repairing or maintaining machines.

This information may be included in an attachment to the manual.

- 2. Detailed provisions for a program of quality assurance for the image receptor and image processing systems of any [xeroradiographic machine] non screen-film system at the facility [.] that must:
  - (a)Be substantially the same as recommended by the manufacturer.
  - (b) This program must b Be approved by the Health Division before it is put into effect.
- 3. Detailed provisions for a program of quality assurance for the image receptor and film processing systems of any machine at the facility that uses a [film and screen] screen-film image receptor. These provisions must:
  - (a) Specify the tests for quality assurance that are required to be performed at the facility.
- (b) Establish the frequency with which each such test is to be performed and the range of acceptable results for each test.
- (c) Specify the procedure to be followed if the result of any test is not within the acceptable range.

The program established pursuant to this subsection must provide for the performance of tests for quality assurance in accordance with the requirements of NAC 457.420 to 457.480, inclusive, or,

if the operator of the facility has elected to comply with those standards, the alternative standards described in NAC 457.405.

- 4. A copy of any form required to be used in connection with a test for quality assurance.
- 5. Information concerning the cleaner recommended by the manufacturer of any screen used with a machine in the facility.

### **Section 7.** NAC 457.310 is hereby amended to read as follows:

NAC 457.310 Maintenance of records: Generally; tests for quality assurance; signature and initial cards; number of films used for patients.

- 1. The operator of a facility for mammography shall ensure that records are maintained in the manner provided by NAC 457.200 to 457.480, inclusive. The records must be kept at the facility and must be reasonably accessible to any representative of the Health Division.
- 2. Each record of a test for quality assurance must set forth the date on which the test was performed and the name or initials of the person who performed the test.
- 3. A signature or initial card must be kept with the records maintained pursuant to subsection 1 to assist in identifying each person who signs or initials those records. The card must contain the full name in type or print of each person who signs or initials the records maintained at the facility and:
- (a) If it is a signature card, the legal signature of each person who signs the records maintained at the facility; or
- (b) If it is an initial card, the initials of each person who initials the records maintained at the facility.
- 4. The operator of a facility for mammography shall ensure that the number of films or projections used for each patient is recorded on the patients' log.
- 5. Each record for quality assurance shall be made and evaluated immediately after the test is completed. If the results exceed the action limits, corrective action shall be completed, verified, and documented before any patients are examined or patient images are processed.

### **Section 8.** NAC 457.312 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(c)(4) and 900.12(i).

NAC 457.312 Maintenance of records: Retention of records; availability to patients.

- 1. Each facility for mammography shall maintain [each mammogram and accompanying records of a patient in a permanent medical record for the patient:
- (a) For at least 5 years if a subsequent mammogram is performed on the patient at the facility; or
- (b) For at least 10 years if no subsequent mammogram is performed on the patient at the facility.
- 2. A patient may request:
- (a) Custody of her records and mammograms; or
- (b) That her records and mammograms be transferred permanently to a responsible provider of care.] patient records as required in 21 CFR 900.

2. Facilities with digital mammography machines must be capable of printing or providing patients, their representative or other physicians with hard copy images of primary interpretation quality.

**Section 9.** NAC 457.313 is hereby amended to read as follows: Changes to incorporate CFR 900.12(c).

NAC 457.313 Maintenance of records: Written reports of mammograms required.

[1.The operator of a facility shall ensure that a written report of the results of each mammogram is prepared. The report must:

- (a) Be sent to the patient's responsible provider of care not later than 7 working days after the mammogram is performed;
- (b) Be signed by the person who interpreted the mammogram; and
- (c) Include a summary of the results of the mammogram written in clear and concise language.
- 2. A copy of the report must be included in the record of the patient.]

The operator of a facility shall ensure that all:

- 1. Mammograms have a preliminary interpretation within 7 working days of the exam. The interpreting physician must contact the patient's responsible provider of care at the time he/she interprets the mammogram for all positive mammograms or those that need additional workup or evaluation.
  - 2. Mammography records and reports are as required in 21 CFR 900.

**Section 10.** NAC 457.315 is hereby amended to read as follows: Changes to incorporate CFR 900.12(e)(12)

NAC 457.315 Maintenance of records: Repair or calibration of equipment used to perform test for quality assurance.

- [1.] A record must be made of any repair or calibration of the equipment used to perform a test for quality assurance [. The record must include the following information:
- (a) The date of the repair or calibration.
- (b) A description of the criteria used in the repair or calibration.
- (c) The name of the person performing the repair or calibration and, if he is not employed by the facility for mammography, the name of his employer.
- 2. Records maintained pursuant to this section must be kept for not less than 3 years.] in accordance with 21 CFR 900.

**Section 11.** NAC 457.320 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(e).

NAC 457.320 Maintenance of records: Information relating to machine.

[1.] A record must be maintained[, for each machine at the facility, of the following information relating to the machine:

- (a) Any evaluation of the performance of the machine.
- (b) Testing performed in connection with the acceptance of the machine before its placement into operation.
- (c) Any test performed to verify the safe operation of the machine.
- (d) Any test for quality assurance:
  - (1) Required by NAC 457.420 to 457.480, inclusive; or
- (2) Conducted pursuant to the alternative standards described in NAC 457.405.
- 2. Records relating to any maintenance or repair of the machine must be retained for not less than 3 years if the maintenance or repair could affect the quality of the images produced by the machine or the exposure of patients to radiation.] demonstrating the maintenance of all mammography related equipment as required in 21 CFR 900.

**Section 12.** NAC 457.325 is hereby amended to read as follows: Changes to incorporate CFR 900.12(d)(2)

NAC 457.325 [Film] *Image* processing *or printing* systems: [Use of control charts and control films; records; analysis of film; identification number for machine.] () The operator of a facility shall:

- 1. Use control charts and control films to ensure the proper functioning of the film processing system of each machine. The operator shall retain the control charts and control films for not less than 1 year.
- 2. Prepare a record of any maintenance, repair or cleaning of the film processing system and of any replacement of chemicals. The operator shall retain the record for not less than 1 year.
- 3. At least quarterly, analyze the film to determine the amount of fixer which is retained on the film. The amount of fixer which is retained on the film must not exceed 0.05 grams per square meter.] document all maintenance, quality assurance and quality control of image processing or printing equipment as required in 21 CFR 900.

**Section 13.** NAC 457.330 is hereby amended to read as follows: Changes to incorporate CFR 900.12(e)

NAC 457.330 Control chart: Required information. The following information must be plotted, evaluate and corrective action completed and verified before any patients are examined or films processed each day that mammography is conducted, on a control chart:

- 1. The values obtained from the daily exposure and processing of sensitometric strips.
- 2. The exposure time or mAs and the number of objects visible in the image of the breast phantom in each [monthly] test of image quality.
- 3. A description of any change in operating conditions made as the result of a test for quality assurance.
  - 4. The operating levels and control limits for each test for quality assurance performed.

**Section 14.** NAC 457.335 is hereby amended to read as follows: Changes to incorporate CFR 900.12(a)(4)

NAC 457.335 Inspection of facility and required records. The operator of a facility for mammography shall:

- 1. Allow an employee or other representative of the Health Division to inspect the facility at any reasonable time.
- 2. Make available to an employee or other representative of the Division any record required to be maintained pursuant to NAC 457.200 to 457.480, inclusive.
- 3. Make available to an employee or other representative of the division any record required demonstrating satisfaction of the regulations, to include worker schedules and/or payroll records to demonstrate who worked each day mammography was performed.

**Section 15.** NAC 457.340 is hereby amended to read as follows:

Changes to incorporate

CFR 900.12(e)(5)(vi)

NAC 457.340 Physician who supervises operation of machine: Duties. The physician who supervises the operation of a machine at a facility for mammography shall:

- 1. Prepare a manual of procedures for the operation of the machine.
- 2. Review and update the manual as required, or at least every [6]12 months. A *signed and dated* record of the review and update must be prepared and kept at the facility.
- [3. Observe and prepare a record of the performance of each mammographer at the facility to ensure that he performs his duties in accordance with the manual of procedures described in this section and in compliance with the requirements of NAC 457.200 to 457.480, inclusive. The observation must be conducted within 1 month after the mammographer begins his employment at the facility and at least every 6 months thereafter.
- 4. Ensure that each mammographer at the facility has successfully completed the training required by NAC 457.350 and is the holder of a mammographer's certificate.
- 5. Ensure that all records of training required by NAC 457.200 to 457.480, inclusive, are maintained at the facility.
- 6. Ensure that the machine is registered with the Health Division and that a certificate for the machine has been issued and is in force.
- 7. Ensure that all required documents of registration, certificates and credentials are prominently posted in the facility.
- 8. Ensure that the mean glandular dose for one contact craniocaudal view of a 4.5 centimeter (1.8 inch) compressed breast, composed of 50 percent adipose and 50 percent glandular tissue, does not exceed:
- (a) One hundred millirads (1 milligray) for a film and screen mammogram made without the use of an anti-scatter grid;
- (b) Two hundred millirads (2 milligrays) for a film and screen mammogram made with the use of an anti-scatter grid; or
- (c) Four hundred millirads (4 milligrays) in the case of a xeroradiograph.
- Ê For the purposes of this subsection, the mean glandular dose must be calculated as provided in Mammography—A User's Guide, National Council on Radiation Protection, Report No. 85.
- 9. Ensure that magnification mammography is performed only on a machine having a microfocal spot size of not more than 0.2 millimeter.

- 10. Ensure that any mammogram performed at the facility is performed only on a machine identified by the manufacturer as designed for mammography.
- 11. Ensure that the name of the referring or responsible provider of care of each patient on which a mammogram is to be taken, is entered in the records of the facility before the mammogram is performed.]

**Section 16.** NAC 457.345 is hereby amended to read as follows: Changes to incorporate CFR 900.12(a)(1)

NAC 457.345 Interpreter of mammograms: Requirements for certification of machine; qualifications; duties; continuing education.

- 1. A person who is employed or retained by a facility for mammography to interpret mammograms must comply with the requirements of this section as a prerequisite to the issuance or renewal of any certificate for a machine located at the facility.
  - 2. The person:
  - (a) Must be a physician licensed pursuant to chapter 630 or 633 of NRS; and
- (b) [Must, except as otherwise provided in this paragraph, have received not less than 40 hours of continuing medical education in mammography. The Health Division shall waive this requirement if the person furnishes to the Division evidence that he has completed a period of residency which included not less than 40 hours devoted to mammography.
- 3. In addition to meeting the requirements of subsection 2, the person must:
- (a) Submit proof satisfactory to the Health Division that he:
- (1) Is certified by the American Board of Radiology or the American Osteopathic Board of Radiology; or
- (2) Has successfully completed not less than 2 months of training in the interpretation of mammograms that includes instruction in medical radiation physics, the effects of radiation and protection from radiation, and an examination in each of these subjects; and
- (b) Have interpreted at least 240 mammograms:
  - (1) During the 6 months immediately preceding his employment at the facility; or
- (2) Under the supervision of a person who is qualified to interpret mammograms pursuant to this section.
- 4. A person who complies with the requirements of subsections 2 and 3 must thereafter:
- (a) Interpret or review not less than 480 mammograms each year.
- (b) Maintain a record of each patient in whom cancerous or potentially cancerous tissue is detected. The record must include, for each such patient, information concerning the result of any biopsy performed.
- (c) Furnish to the Health Division evidence that he has received not less than 15 hours of continuing medical education in mammography during the preceding 3 years. Continuing education received in compliance with the provisions of this paragraph must be approved in writing by the Division or a national or regional organization approved by the Division. Evidence of continuing education must include a certificate of completion issued by the sponsoring organization. The certificate must include:
  - (1) The name of the person;
    - (2) The number of hours of credit relating to mammography earned by the person; and

(3) The name of the representative of the sponsoring organization who signed the certificate.] Meet the requirements for an interpreting physician found in 21 CFR 900.

### **Section 17.** NAC 457.347 is hereby amended to read as follows:

NAC 457.347 Interpreter of mammograms: Temporary employment at other facilities.

- 1. A person who is employed or retained by a facility for mammography to interpret mammograms pursuant to NAC 457.345 may interpret mammograms at another facility for mammography for not more than 60 days each year if:
- (a) He has obtained written authorization from the operator of the facility where he will be temporarily interpreting mammograms; and
- (b) The facility where he will be temporarily interpreting mammograms maintains a copy of the current certificate for a machine issued by the Health Division to the facility where the person is regularly employed or retained, that identifies the person who will interpret mammograms at that facility, and a copy of all credentials demonstrating the temporary interpreting physician's qualifications are current.
- 2. The facility where he will be temporarily interpreting mammograms must verify the temporary interpreting physician's credentials are current at the start of each period of temporary employment.
- [2.]3. The facility where a person is temporarily interpreting mammograms shall retain a copy of the written authorization and the certificate described in paragraph [(b) of subsection] 1 for at least 2 years after the person ceases to interpret mammograms at that facility.

**Section 18.** NAC 457.350 is hereby amended to read as follows: Changes to incorporate CFR 900.12(a)(2)

NAC 457.350 Mammographer: Qualifications. A person who desires to [apply for a mammographer's certificate] work as a mammographer in Nevada must be certified in general radiography by the American Registry of Radiologic Technologists, or by another organization approved [in writing] by the Health Division, and [must] hold a valid Nevada mammographers credential.[:

- 1. Hold a certificate of advanced qualifications in mammography issued by the American Registry of Radiologic Technologists, or by another certifying organization approved in writing by the Health Division; To obtain a Nevada mammographers credential, the radiological technologist must make application to the Nevada State Health Divison, Radiological Health Section, and provide the required documentation to show the technologist meets the requirements found in 21 CFR 900.
- [2. Have received not less than 40 classroom hours of instruction from a person who is certified to provide training to mammographers pursuant to NAC 457.357 in a program of instruction relating to mammography which meets the requirements of NAC 457.355;
- 3. Have received not less than 40 classroom hours of instruction in radiologic technology in a program of instruction relating to mammography which meets the requirements of NAC 457.355 and is accredited by a national or regional accrediting organization; or

4. Have received not less than 40 hours of continuing education in mammography approved by an organization or agency which is approved by the Division, including, without limitation, the American College of Radiology or the American Society of Radiologic Technologists.]

**Section 19.** NAC 457.355 is hereby amended to read as follows: Changes to incorporate CFR 900.12(a)(2)

NAC 457.355 Program of instruction in mammography: Approval; required instruction.

- 1. A program of instruction in mammography that is undertaken to meet the requirements for issuance of a mammographer's certificate must be approved by the Health Division, *provide at least 40 contact hours specific to mammography* and comply with the provisions of this section.
  - 2. The program must include instruction in:
  - (a) The anatomy and physiology of the female breast, with instruction in the following topics:
    - (1) Mammary glands.
    - (2) External anatomy.
    - (3) Subdivision for localization.
    - (4) Retromammary space.
    - (5) Central portion.
    - (6) Cooper's ligament.
    - (7) Vessels, nerves and lymphatics.
    - (8) Breast tissue.
  - (b) The classification of breast tissue.
- (c) The epidemiology of the breast, methods of detecting breast cancer and sources of information relating to epidemiology of the breast.
- (d) The effects of adjustments relating to the setting of the exposure timer, current and voltage.
  - (e) The positioning of the breast for mammography, with instruction in:
    - (1) The following positions:
      - (I) Craniocaudal.
      - (II) Medial lateral oblique.
      - (III) Axillary.
      - (IV) Lateral.
      - (V) Mediolateral.
      - (VI) Lateromedial.
      - (VII) Exaggerated angled craniocaudal.
      - (VIII) Craniocaudal without compression.
      - (IX) "Cleopatra" or 30° oblique.
      - (X) Coned or spot compression.
      - (XI) Lateral oblique.
      - (XII) "Coathanger" or displaced.
      - (XIII) Modified craniocaudal.
      - (XIV) Modified mediolateral oblique.
      - (XV) Other positions as required.
    - (2) Magnification.
    - (3) Errors in positioning.

- (4) Special techniques for mammography of the postoperative breast and the augmented breast.
  - (5) Special radiographic techniques for breast localization and specimen radiography.
  - (f) The evaluation and critique of mammograms, with instruction in the following topics:
    - (1) Criteria for determining the quality of images.
    - (2) The scanning of images.
    - (3) The detection of pathology.
    - (4) Benign and malignant lesions.
    - (5) Mass lesion borders.
    - (6) Calcifications.
  - (g) The biological effects of radiation and protection from radiation.
  - (h) The techniques and methods of quality assurance.
  - (i) The methods of breast imaging other than mammography.
- 3. A person who is enrolled in a program of instruction in mammography pursuant to this section shall not operate a machine for mammography unless a mammographer is present while that person operates the machine and is able to stop the procedure for performing the mammogram at any time.

### **Section 20.** NAC 457.360 is hereby amended to read as follows:

### NAC 457.360 Mammographer: Duties. A mammographer shall:

- 1. Perform each of his assigned duties correctly and conscientiously.
- 2. Stand behind a protective barrier whenever X rays are being produced during mammography.
  - 3. Wear on his torso the monitoring device assigned to him during all working hours.
  - 4. Use optimum techniques of exposure.
  - 5. Use optimum techniques for the processing of images.
- 6. Follow the standing orders and policies for repeated exposures established for the facility at which he is employed.
- 7. Correctly determine what views are required, based on a written protocol, and position patients properly.
  - 8. Limit the size of the X-ray field to the area of clinical interest.
  - 9. Instruct each patient clearly to avoid movement by the patient.
- 10. Use appropriate compression with due consideration to the particular circumstances of each case.
- 11. Handle films, cassettes for holding film and [xeroradiographic plates carefully] other image receptors for mammography to eliminate artifacts.
  - 12. Post his mammographer's certificate where it can be seen by patients.
  - 13. Record his full name on the record of each patient.
- 14. Ensure that his name or initials are included in the information which appears on the edge of each film as it is exposed.
- 15. Sign or initial the patients' log to indicate each patient upon whom he performed mammography.
- 16. Indicate in the space located after his signature or initials in the patients' log, the number of films used for each patient.

### **Section 21.** NAC 457.365 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(c)(4)

NAC 457.365 Mammographer: Prohibited acts. A mammographer shall not:

- 1. Perform mammography except under the supervision of a physician who is licensed pursuant to chapter 630 or 633 of NRS and meets the requirements of NAC 457.345.
- 2. Except as otherwise authorized by the Health Division pursuant to NAC 459.554, perform mammography without a prescription or order from the patient's referring or responsible provider of care. The mammographer shall post a copy of the authorization of the Health Division in a conspicuous place near the machine.
  - 3. Use any machine unless there have been established for the facility for mammography:
- (a) Written standing orders concerning the number and type of views to be taken of each patient; and
- (b) A policy governing the repetition of exposures in any case where the image obtained from the first exposure is inadequate.
  - 4. Make a diagnosis based on any mammogram.
- 5. Operate a machine without having been trained to operate that machine safely and effectively.
- 6. Report a diagnosis to a patient, except that the mammographer may provide the patient with [a copy of a] the mammogram or a copy of the report by the physician who interprets the mammogram, or both, without any comment to the patient concerning the contents of the mammogram or report.
- 7. Touch the breast of any patient, except as required to position the patient for mammography or to obtain clinical information to assist the physician who supervises the operation of the machine in arriving at a diagnosis.
  - 8. Routinely hold the patient or the image receptor during an exposure.

### **Section 22.** NAC 457.370 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(a)(2)(iii)(B)

NAC 457.370 Mammographer: Renewal of certificate; continuing education.

- 1. A mammographer who desires to renew his mammographer's certificate must submit to the Health Division *proof of a current credential in general radiography and* an application for renewal. The application must be received by the division not less than 30 days before the expiration of the certificate.
- 2. Each mammographer must, as a condition of renewal, furnish to the Health Division evidence that he has received not less than 15 hours of continuing medical education in mammography during the preceding 3 years (36 months). Passing the ARRT or equivalent in mammography after receiving the Nevada Mammographer Certification will not be recognized as meeting the continuing education requirements in this section. Continuing education received in compliance with the provisions of this subsection must be approved [in writing] by the division or a national or regional organization approved by the division, including, without limitation, the American College of Radiology or the American Society of Radiologic

Technologists. Evidence of continuing education must include a certificate of completion issued by the sponsoring organization. The certificate must include:

- (a) The name of the person;
- (b) The number of hours of credit relating to mammography earned by the person; [and]
- (c) The name of the representative of the sponsoring organization who issued the certificate [...]; and
  - (d) The date of the training.
- 3. Continuing education units earned through teaching or attending a specific course can be counted only once towards the 15 required by this section, even if the course is taught or attended multiple times during the previous 3 years (36 months).

### **Section 23.** NAC 457.375 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(b) and 900.12(e)(5(iv)

NAC 457.375 Design and use of machine.

- [1.] A machine, including its X-ray system and its image receptor system and its components, must [be designed for mammography and may be used only for that purpose.
- 2. The X-ray machine must permit the use of a combination of target, filter and peak tube potential appropriate to the performance of mammography.
- 3. If used with a film and screen image receptor, the useful beam must have a half-value layer, measured with the device for compression in the beam, which is not less than the value of (kVp/100) and not more than the value of (kVp/100 + 0.10) in units of millimeters of aluminum, as expressed in the following equation:

 $kVp/100 + 0.10 > HVL^{3}kVp/100$ .

- 4. A machine must be equipped with a means of immobilizing and compressing the breast so that a force of not less than 25 pounds and not more than 40 pounds can be achieved. The compression device must have a straight contour along its posterior surface.
- 5. For the film routinely used by a facility for mammography, the combination of focal spot size, source-image receptor distance and magnification must produce a radiograph having a resolution of not less than 12 cycles per millimeter.
- 6. A machine that uses a film and screen image receptor must:
- (a) Permit the use of an anti-scatter grid designed for mammography. The operator of a facility shall ensure that at least one anti-scatter grid for each size of cassette for holding film is located near the machine.
- (b) Be equipped with automatic exposure control.
- 7. A machine must indicate or provide a means for determining the number of mAs resulting from each mammogram made with automatic exposure control. The provisions of this subsection apply only to a machine that is placed into service, or as to which a transfer of ownership or control occurs, on or after December 31, 1992.
- 8. As used in this section, "useful beam" has the meaning ascribed to it in NAC 459.528.] meet the standards found in 21 CFR 900 and be approved for mammography by the U.S. Food and Drug Administration.

**Section 24.** NAC 457.390 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(b)(12) and 900.12(e)(4)(ii)

NAC 457.390 [Use of film and screen i] I mage receptor: Required equipment. [If any machine at a] A facility for mammography [uses a film and screen image receptor, the following equipment] must [be] maintain[ed] at the facility, properly calibrated and in good working order:

- 1. A breast phantom capable of depicting:
- (a) A mass having a width of 0.5 millimeter or less;
- (b) A calcification having a diameter of 0.24 millimeter or less; and
- (c) Fibers of nylon or similar material having a width of 0.75 millimeter or less.
- 2. A wire mesh contact tool designed for use in mammography with a 40 mesh (40 wires per inch) copper screen, for facilities using screen-film imaging.
- 3. A thermometer accurate to  $\pm$  0.5°F. A thermometer containing mercury must not be used, for facilities using screen-film imaging.
- 4. A sensitometer that generates blue or green light, as appropriate to the type of film used at the facility, with a reproducibility of  $\pm$  0.04 log exposure, *for facilities using screen-film imaging*.
- 5. A densitometer accurate to  $\pm$  0.02 optical density and having a range of 0.00 to 3.5 optical density, *for facilities using screen-film imaging*.
- 6. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

**Section 25.** NAC 457.395 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(e)(4)(i)

NAC 457.395 Darkroom: Prohibited activities; cleanliness; safelight.

- 1. A person shall not smoke or eat in the darkroom of a facility for mammography.
- 2. The darkroom must be kept reasonably free of dust.
- 3. Counter tops and the feed tray of any film processing equipment must be cleaned daily before any film is handled or processed.
  - 4. Hands must be clean and dry when touching a film.
- 5. A darkroom safelight must be equipped with an appropriate combination of filter and bulb. Information concerning the required combination must be prominently posted in the darkroom *area*.

**Section 26.** NAC 457.400 is hereby amended to read as follows:

Changes to incorporate

CFR 900.12(e)

NAC 457.400 Mandatory performance of tests.

- 1. [Regardless of whether an election is made by the operator of a facility for mammography to comply with the alternative standards described in NAC 457.405, the following t] Tests for quality assurance found in 21 CFR 900 must be performed whenever any component of the X-ray machine is repaired or replaced, and before the machine is used for mammography.
  - 2. If the repair or replacement affects:
  - (a) Image quality, the test described in NAC 457.425 must be performed.
- (b) The accuracy or consistency of operation of the exposure timer or automatic exposure control, the test described in NAC 457.450 must be performed.
  - (c) Milliampere-seconds linearity, the test described in NAC 457.460 must be performed.
- (d) The accuracy of the kilovolt peak indicated by the machine [, the test described in NAC 457.455 must be performed].
- (e) The skin entrance exposure or glandular tissue dose<del>[, the test described in NAC 457.465 must be performed]</del>.
  - (f) Focal spot size, the test described in NAC 457.470 must be performed.
  - (g) Half-value layer, [the test described in NAC 457.475 must be performed].

## **Section 27.** NAC 457.405 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(e)

NAC 457.405 Frequency of mandatory tests; optional compliance with alternative standards.

- 1. Except as otherwise provided in subsection 2, the operator of a facility for mammography shall ensure that the tests for quality assurance [described in NAC 457.420 to 457.480, inclusive.] are performed [:
- (a) Daily, monthly, quarterly, semiannually or annually, as provided in those sections;
- (b) At the time any equipment subject to testing is placed into service; and
- (c) Whenever any such equipment is repaired or replaced.
- 2. In lieu of complying with the requirements of NAC 457.420 to 457.480, inclusive, the operator of a facility may elect to comply with the standards of testing for quality assurance contained in Mammography Quality Control, American College of Radiology, Committee on Quality Assurance in Mammography (1992). If he makes the election authorized by this subsection, the operator shall comply with these alternative standards.]
- 3.An operator shall state:
- (a) In the manual prepared pursuant to NAC 457.305; and
- (b) In any application for issuance or renewal of a certificate for a machine,

Ê whether he has elected to comply with the requirements of NAC 457.420 to 457.480, inclusive, or the alternative standards described in subsection 2.] as stated in 21 CFR 900.

### **Section 28.** NAC 457.410 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(a)

NAC 457.410 Qualification of persons to perform tests.

[1. The daily tests for quality assurance described in NAC 457.420 may be performed by any person trained in the processing of radiographic film.

- 2. The monthly tests for quality assurance described in NAC 457.425 and 457.430 may be performed only by:
- (a) A radiologic technologist certified by the American Registry of Radiologic Technologists or another body or agency approved by the Health Division;
- (b) A medical physicist;
- (c) A health physicist; or
- (d) A person having qualifications substantially equivalent to those of a medical physicist or health physicist, as determined by the Health Division.
- 3. The annual tests for quality assurance described in NAC 457.445 to 457.480, inclusive, may be performed only by a person described in paragraph (b), (c) or (d) of subsection 2.
- 4. A person described in paragraph (b), (c) or (d) of subsection 2 must, as a prerequisite to the performance of any test referred to in subsection 2 or 3, obtain training and continuing medical education approved by the Health Division in:
- (a) The performance of tests for quality assurance in mammography; and
- (b) Diagnostic X-ray physics.] Individuals performing testing must meet the qualifications as stated in 21 CFR 900.

#### Section 29. NAC 457.415 is hereby amended to read as follows:

Changes to incorporate

CFR 900.12(e)

NAC 457.415 Applicability of provisions to fixed and mobile equipment.

- [1. Except as otherwise provided in this section and in NAC 457.420 to 457.480, inclusive, the provisions of those sections apply to all equipment used for mammography, regardless of whether the equipment is fixed or mobile.
- 2. In the case of mobile equipment, the tests for quality assurance provided for in:
- (a) NAC 457.450 to 457.465, inclusive, must be performed at least quarterly.
- (b) NAC 457.470 and 457.475 must be performed at least semiannually.] Fixed and mobile mammography equipment must meet the requirements stated in 21 CFR 900.

#### Section 30. NAC 457.420 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(b) and 900.12(e)

### NAC 457.420 Test of film processing equipment.

- 1. A test of film processing equipment used for mammography must be performed each day that the equipment is in operation, before any clinical films are processed.
- 2. The test must include a check, using a thermometer, of the temperature of the developer and fixer used in the processing equipment. A thermometer containing mercury must not be used for this purpose. The temperature of these solutions must be that recommended in writing by the manufacturer of the film, the solutions or the processing equipment. The recommendation followed at the facility must be prominently posted near the processing equipment.
- 3. A sensitometric strip must be exposed and processed as part of the test, with the same film used for mammography. Using a densitometer, the person performing the test shall determine and record:

- (a) The speed step having an optical density closest to 1.20. The control limits for this value are  $\pm 0.15$ .
- (b) The control index or density difference between the step having a density closest to, but not higher than, 2.20 and the step having a density closest to, but not less than, 0.45. The control limits for this value are  $\pm$  0.15.
- (c) The base plus fog, or the optical density of the unexposed area of the strip. This value must not exceed 0.25.
- 4. A check of the rate of chemistry replenishment must be made as part of the test.] as stated in 21 CFR 900.
- 2. The results of the tests must be recorded, plotted, evaluated and acted upon immediately after the test is completed and before any patient's films are processed. If the results are not within the action limits, corrective action must be completed and verified as successful before any patient films are processed.

**Section 31.** NAC 457.425 is hereby amended to read as follows: Changes to incorporate CFR 900.12(e)(2)

### NAC 457.425 Test of image quality.

- 1. [Except as otherwise provided in this subsection, t] The operator of a facility for mammography shall ensure that [monthly] tests of image quality [is] are performed using a breast phantom [meeting the requirements of NAC 457.390. In the case of mobile mammography equipment, such a test must be performed each time the equipment is moved, but at least monthly.
- 2. The image of the breast phantom obtained in performing the test must be compared to the image of the same phantom obtained at the time the certificate for the machine was issued or most recently renewed, or the X-ray tube for the machine was replaced, whichever is later. The person performing the test shall compare the detail and resolution of the two images to ensure that they are consistent and evaluate the images to determine the presence of artifacts. If an artifact is present, the person who performs the test shall remove the artifact and record its presence.
- 3. The person who performs the monthly test of image quality shall conduct the test at the kVp and density control settings for a breast of thickness and density which corresponds to the breast phantom.
- -4. The optical density of the center of the breast phantom must be not less than 1.05 and not more than 1.60 and must not vary by more than  $\pm$  0.20. The exposure time or mAs must not vary by more than  $\pm$  15 percent from one phantom image exposure to another.
- 5. The number of fibers, specks or masses detected in each group must not decrease by more than 0.50 when viewed by the same person under optimal conditions.] as required in 21 CFR 900.

**Section 32.** NAC 457.435 is hereby amended to read as follows: Changes to incorporate CFR 900.12(e)(3)

NAC 457.435 Analysis of rejected mammograms. — [1. The operator of a facility shall ensure that an analysis of all rejected mammograms is performed at least quarterly. Each such mammogram taken during the preceding quarter must be analyzed to determine the reason for rejection.

- 2. The rejected mammograms must be categorized as having been rejected because of:
- (a) An error in machine operating parameters;
- (b) Motion by the patient;
- (c) An error in positioning;
- (d) An error in processing the image; or
- (e) A reason other than one described in paragraphs (a) to (d), inclusive.
- 3. Each action which is taken to correct an error must be recorded in the report of the review prepared pursuant to NAC 457.300.] The operator of a facility for mammography shall ensure that rejected mammograms are evaluated as required in 21 CFR 900.

**Section 33.** NAC 457.445 is hereby amended to read as follows:

Changes to incorporate CFR 900.12(b), 900.12(d) and 900.12(e)

NAC 457.445 Verification of safe operating condition of machine; records.

- 1. Before any machine is placed into service, *following major repairs* and at least annually thereafter, it must be examined to verify that it is in safe operating condition.
  - 2. The examination must:
- (a) Include a test of the image quality of the machine pursuant to NAC 457.425; and
- (b) B]**b**e made by[:
- (1) A a medical physicist; as stated in 21 CFR 900.
  - [(2) A health physicist; or
- (3) A person having qualifications substantially equivalent to those of a medical physicist or health physicist, as determined by the Health Division.]
- 3. The person making the examination shall make a written record of his findings and submit
- (a) The record to the operator of the facility; and
- (b) A copy of the record to the Health Division, within 30 days after the examination.
- 4. If the operator of the facility does not receive the written record within the period prescribed in subsection 3, he shall remove the machine from service until he receives the record.

[5. The Health Division shall review the report.]

The following sections, 34 through 44, are replaced by references to CRF 900.12(b) and 900.12(e) as found above in NAC 457.315, 457.320, 457.330, 457.340, 457.375, 457.390, 457.395, 457.400, 457.405, 457.415, 457.420, 457.425, 457.435 and 457.445.

**Section 34.** NAC 457.380 is hereby amended to read as follows (DELETED)

[NAC 457.380 Limitation on transmission of primary beam through image receptor support.

1. The transmission of the primary beam through any image receptor support provided by the manufacturer of a machine must be limited so that exposure to radiation, as measured 5

centimeters from any accessible surface beyond the plane of the support, is not more than 0.1 milliroentgens (25.8 nC/kg) for each activation of the X-ray tube.

- 2. For the purposes of this section:
- (a) Exposure must be measured with the machine operated at the minimum source-image receptor distance for which it is designed.
- (b) Compliance must be determined:
- (1) At the maximum rated peak tube potential for the machine in kVp and at the maximum rated product of tube current and exposure time in mAs for that peak tube potential.
- (2) By an average of measurements taken over an area 100 square centimeters in size and not more than 20 centimeters in length, width or height.
- 3. The provisions of this section apply only to a machine manufactured after September 5, 1978.]

### **Section 35.** NAC 457.385 is hereby amended to read as follows (DELETED)

[NAC 457.385 Use of special attachment for mammography.

- 1. Whenever any special attachment for mammography is used on a machine, the machine must be provided with a beam limiting device so that, at any given source image receptor distance, the X ray field at the plane of the image receptor does not extend beyond any edge of the receptor except the edge adjacent to the chest wall of the patient. The X-ray field must not extend beyond this edge by more than 1 percent of the source-image receptor distance.
- 2. The edge of the compression paddle which touches the chest of the patient must be aligned just beyond the edge of the chest wall of the image receptor with a tolerance of not more than +1 percent of the source image receptor distance.
- 3. If the beam-limiting device and image receptor support device are designed to immobilize the breast during an exposure, the source-image receptor distance used during the procedure must not exceed the maximum distance for which the beam-limiting device is designed.
- 4. Each image receptor support used on a machine must indicate, with clear and permanent markings, the maximum size of the receptor for which it is designed.
- 5. As used in this section, "beam-limiting device" has the meaning ascribed to it in NAC 459.414.]

### **Section 36.** NAC 457.430 is hereby amended to read as follows: DELETE

[NAC 457.430 Inspection and cleaning of screen.

- 1. Any screen used with a machine must be kept free of artifacts.
- 2. Except as otherwise provided in this subsection, each screen must be cleaned at least weekly with the cleaner recommended by the manufacturer of the screen. Before any mammogram is taken, a screen used with a mobile mammography machine must be inspected, and if necessary, cleaned each time the machine is moved.]

### **Section 37.** NAC 457.440 is hereby amended to read as follows: DELETE

[NAC 457.440 Miscellaneous tests and examinations. Except as otherwise provided in this section, the following tests and examinations must be performed at least semiannually:

- 1. A test of film-screen contact for each screen used in the facility for mammography. The test must be:
- (a) Completed before a screen is used and every 6 months thereafter.
- (b) Performed by using a contact tool designed for use in mammography.

- (c) In the case of mobile mammography equipment, performed at least monthly.
- Ê Any screen which has an area that is more than 1 centimeter of poor contact or at least three small areas, each of which is less than 1 centimeter of poor contact, must be removed from service immediately.
- 2. A test of each machine's device for compression. The test must be performed in the manual and power modes, if the machine is so equipped, using:
- (a) A push-pull force gauge; or
- (b) A flat bathroom scale having an accuracy of ± 2 percent, in accordance with the procedure prescribed in Mammography Quality Control, American College of Radiology, Committee on Quality Assurance in Mammography (1992).
- È A written record of the method of testing used must be made and kept at the facility. The force of compression in the manual or power mode must be at least 25 pounds, but not more than 40 pounds. In the case of mobile mammography equipment, such a test must be performed each time the equipment is moved, and at least semiannually.
- 3. A test of each machine's mechanism for releasing compression.
- 4. A visual examination of the adequacy of film storage at the facility.
- 5. A visual examination of the condition of the masking on each viewbox and of the uniformity of lighting provided by each viewbox used for mammography at the facility. The operator of the facility shall conduct the examination each week. If the operator replaces a bulb used in a viewbox, he shall replace all the bulbs in the viewbox at that time with bulbs of the same type and color.
- 6. A test of the integrity of the darkroom of the facility, using film exposed by a sensitometer. Immediate corrective action must be taken if a level of exposure of film caused by light entering the darkroom has an optical density of more than 0.05.]

### **Section 38.** NAC 457.450 is hereby amended to read as follows: DELETE

[NAC 457.450 Test of exposure timer and automatic exposure control.

- 1. An annual test must be performed of:
- (a) The exposure timer or automatic exposure control of each machine; or
- (b) Both the exposure timer and automatic exposure control on any machine that is equipped with both.

È using a breast phantom and a digital timer, mAs meter or ion chamber. In the case of mobile mammography equipment, the test must be performed at least quarterly.

- 2. The person who performs the test shall:
- (a) Operate the machine at a commonly used setting;
- (b) Take at least four but not more than six exposures; and
- (c) Ensure that the coefficient of variation of the exposures does not exceed 0.05.
- 3. An automatic exposure control system which is operated at a normal setting must maintain a constant film optical density of not less than 1.10 and not more than 1.50 to within ±0.30 of the average over the kVp range used for phantoms with a thickness of not less than 2 centimeters and not more than 6 centimeters.
- 4. If a machine cannot comply with the requirements set forth in subsection 3, the operator of the facility shall post a chart which sets forth the methods for altering the kVp and density control settings as a function of breast thickness and densities to produce optical densities that are within ±0.30 under phototimed conditions. The operator shall post the chart in a conspicuous place near the machine.]

### **Section 39.** NAC 457.455 is hereby amended to read as follows: DELETE

[NAC 457.455 Test of accuracy of indicated kilovolt peak.

- 1. An annual test of the accuracy of the kilovolt peak indicated by a machine must be performed using a kVp meter or kVp cassette.
- 2. The person who performs the test shall ensure that the actual kVp is maintained as specified by the manufacturer of the machine, but does not vary from the indicated kVp by more than 5 percent. The kVp must be able to be reproduced and have a coefficient of variation which is not more than 0.02.]

### **Section 40.** NAC 457.460 is hereby amended to read as follows: DELETE

[NAC 457.460 Test of mAs linearity.

- 1. An annual test of mAs linearity must be performed using:
- (a) An ion chamber, in the case of a machine equipped with an exposure timer; or
- (b) A digital timer, in the case of a machine equipped with automatic exposure control.
- 2. The person who performs the test shall ensure that the average ratio of exposure to the indicated milliampere seconds product (mR/mAs) obtained at any two consecutive tube current settings does not differ by more than their sum, multiplied by 0.10.]

### **Section 41.** NAC 457.465 is hereby amended to read as follows: DELETE

[NAC 457.465 Test of glandular tissue dose.

- 1. An annual test of glandular tissue dose must be performed using an ion chamber or one or more thermoluminescent dosimeters calibrated for mammography.
- 2. Measurements of estimated skin entrance exposure must be made as provided in Mammography—A User's Guide, National Council on Radiation Protection, Report No. 85.
- 3. The glandular dose must be calculated from the measured skin entrance exposure. The technique settings must be those used for making an image of a 4.5 centimeter compressed breast in the craniocaudal projection and the point of measurement must be 4.5 centimeters from the surface of the anti-scatter grid or cassette, as the case may be.]

### **Section 42.** NAC 457.470 is hereby amended to read as follows: DELETE

[NAC 457.470 Test of focal spot size.

- 1. An annual test of focal spot size must be performed using a star pattern test tool or a slit or pinhole camera. If a star pattern test tool is used, a written record must be made of the target and tilt angles.
- 2. If a machine uses a film and screen image receptor, the focal spot size:
- (a) Must not exceed 0.7 millimeter, in the case of contact mammography.
- (b) Must not exceed 0.2 millimeter, in the case of magnification mammography.
- 3. For a xeroradiographic machine, the focal spot size must not exceed 0.7 millimeter.
- 4. The person who performs the test shall make a record of the method used to determine focal spot size.]

### **Section 43.** NAC 457.475 is hereby amended to read as follows: DELETE

[NAC 457.475 Test of half-value layer.

1. An annual test of half value layer must be performed to ensure hardness of the X-ray beam. The tools required for the test are an aluminum half value layer set and an ion chamber.

-2. If a machine uses a film and screen image receptor, the half value layer, measured at the most commonly used mammographic kilovoltage, must be not less than the value of (kVp/100) and not more than the value of (kVp/100 + 0.10) in units of millimeters of aluminum, as expressed in the following equation:

 $kVp/100 + 0.10 > HVL^{3}kVp/100.$ 

3. For a xeroradiographic machine, the half-value layer, measured at 50 kVp, must be at least 1.2 millimeters aluminum equivalent.]

### **Section 44.** NAC 457.480 is hereby amended to read as follows: DELETE

[NAC 457.480 Test of uniformity of screen speed.

- 1. The operator of a facility shall ensure that an annual test of the uniformity of screen speed is performed by using the film normally used for mammography, a phantom breast and a densitometer. The test must include an evaluation to determine the presence of artifacts. If an artifact is present, the person performing the test shall remove the artifact and record its presence.
- 2. The optical density of each film in the center of the image of the phantom must produce a density whose ratio is not less than 0.90 and not more than 1.10 when compared to the average density of all screens of that type which are used for mammography.
- 3. The density of any single image must not vary by more than  $\pm 0.15$  from the average density of all cassettes for holding film of that size. The difference between the maximum and minimum optical densities must not exceed 0.30.
- 4. Any combination of a cassette for holding film and a screen which exposes film resulting in a film optical density that varies from the average by more than 0.15 must be removed from service immediately.
- 5. The operator of a facility shall ensure that a record of the tests and maintenance conducted for each image receptor is prepared and maintained.]