ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R033-06

Effective June 28, 2006

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1-35, NRS 457.065.

A REGULATION relating to mammography; revising provisions governing the operation of a radiation machine for mammography; revising provisions governing persons who operate a radiation machine for mammography; and providing other matters properly relating thereto.

Section 1. NAC 457.200 is hereby amended to read as follows:

457.200 As used in NAC 457.200 to **[**~~457.480,~~**]** ***457.445,*** inclusive, unless the context otherwise requires, the words and terms defined in NAC 457.205 to 457.280, inclusive, have the meanings ascribed to them in those sections.

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

457.235 "Health Division" means the Health Division of the Department of ***Health and*** Human **[**~~Resources.~~**]** ***Services.***

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

457.285 ***1.*** The State Board of Health hereby adopts by reference the provisions of:

[~~1.~~**]** ***(a) The*** *Mammography Quality Control* **[**~~,~~**]** ***Manual,*** American College of Radiology, Committee on Quality Assurance in Mammography **[**~~(1992).~~**]** ***, in the form most recently published, 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~~**]**

$57.50 from the American College of Radiology, ~~[1891 Preston White Drive, Reston, Virginia 22091.~~

~~2. Mammography A User's Guide,]~~ ***P.O. Box 533, Annapolis Junction, Maryland 20701, at the Internet address http://www.acr.org or by telephone at (800) 227-7762.***

(b) Report No. 149 - A Guide to Mammography and Other Breast Imaging Procedures, National Council on Radiation Protection ***.*** ~~[, Report No. 85.]~~ A copy of this publication may be obtained at a cost of ~~[$25]~~ ***$110*** from NCRP Publications, 7910 Woodmont Ave., Suite ~~[1016,]~~ ***400,*** Bethesda, Maryland 20814 ~~[.]~~ ***, at the Internet address http://www.ncrppublications.org or by telephone at (800) 229-2652 (ext. 25).***

(c) 21 C.F.R. Part 900, adopted pursuant to the Mammography Quality Standards Act, in the form most recently published, 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 from the Superintendent of Documents, P.O. Box 371954, Pittsburgh, Pennsylvania 15250-7954, for the price of $13. This publication is also available, free of charge, from the Government Printing Office at the Internet address http://www.gpoaccess.gov/cfr/index.html.

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 the State. If the Board determines that the revision is not suitable for this State, it will hold a public hearing to review its determination and give notice of that hearing within 6 months after the date of the publication of the revision. If, after the hearing, the Board does not revise its determination, the Board will give notice that the revision is not suitable for this State within 30 days after the hearing. If the Board does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 1.

Sec. 4. NAC 457.290 is hereby amended to read as follows:

457.290 The Health Division may, upon application or on its own initiative, grant such exemptions, exceptions or variances from the requirements of NAC 457.200 to ~~[457.480,]~~ ***457.445,*** inclusive, as it determines will not result in any undue hazard to public health and safety or property.

Sec. 5. NAC 457.293 is hereby amended to read as follows:

457.293 1. A holder of a certificate or an applicant for a certificate who has reason to believe that an action taken by the Health Division pursuant to NAC 457.200 to ~~[457.480,]~~ ***457.445,*** inclusive, is incorrect or based on inadequate knowledge may, within 10 business days after receiving notice of the action, request an informal discussion with the employee responsible for the action and the immediate supervisor of the employee.

2. If the informal discussion does not resolve the problem, the aggrieved person may, within 10 business days after the date scheduled for the informal discussion, submit a written request to the Bureau for an informal conference. The informal conference must be scheduled for a date, place and time mutually agreed upon by the aggrieved person and the Bureau, except that the informal conference must be held no later than 60 days after the date on which the Bureau received the request.

3. Except as otherwise provided in subsection 4, the determination of the Bureau resulting from the informal conference cannot be appealed and is the final remedy available to the aggrieved person.

4. An applicant for or holder of a certificate issued pursuant to NAC 457.200 to ~~[457.480,]~~ ***457.445,*** inclusive, who is aggrieved by an action of the Health Division relating to the denial of an application for or renewal of such a certificate, the withdrawal, suspension or revocation of

such a certificate or the assessment of an administrative fine may appeal that action in accordance with NAC 439.300 to 439.395, inclusive, after exhausting the informal procedures set forth in this section, except that the Bureau may waive the informal procedures, or any portion thereof, by giving written notice to the aggrieved person.

5. As used in this section, "Bureau" means the Bureau of Health Protection Services of the Health Division or its successor.

Sec. 6. NAC 457.299 is hereby amended to read as follows:

457.299 1. ~~[The]~~ ***Except as otherwise provided in subsection 2, 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,]~~ ***457.445,*** inclusive;

(b) The applicant has complied with any applicable requirements pursuant to NAC 457.200 to ~~[457.480,]~~ ***457.445,*** inclusive; and

(c) ~~[If]~~ ***In addition to the requirements of paragraphs (a) and (b), if*** the applicant is applying for a certificate for a machine ~~[, the]~~ ***:***

(1) The equipment, facilities and procedures which the applicant proposes to use are adequate to minimize any danger to the public health or safety ~~[.]~~ ***;***

(2) A certificate for that machine is not currently issued to another owner, lessee or other responsible person; and

(3) The applicant is one person or 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.

Sec. 7. NAC 457.300 is hereby amended to read as follows:

457.300 The operator of a facility shall:

1. Establish and maintain a program of quality assurance ***in accordance with the provisions of 21 C.F.R. § 900.12*** for each machine and all other equipment at the facility used for mammography.

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]~~ ***unique*** machine ***identifier*** is included in the information which appears on the edge of the film as it is exposed.

6. Ensure that all quality assurance and quality control records are kept until:

(a) The next annual inspection has been completed and the Health Division has determined that the facility is compliant; or

(b) The tests for quality assurance have been performed two additional times at the required frequency and are within the applicable control limits,

➥ whichever is longer.

Sec. 8. NAC 457.305 is hereby amended to read as follows:

457.305 ***1.*** The operator of a facility shall prepare or cause to be prepared a manual for quality assurance for the facility. The manual must include:

~~[1.]~~ ***(a)*** The name, position and a statement of the qualifications and duties of each person at the facility who is responsible for:

~~[(a)]~~ ***(1)*** Supervising the performance of mammography;

~~[(b)]~~ ***(2)*** Performing tests for quality assurance; or

~~[(c)]~~ ***(3)*** Repairing or maintaining machines.

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

~~[2.]~~ ***(b)*** Detailed provisions for a program of quality assurance for the image receptor and image processing systems of any ~~[xeroradiographic machine]~~ ***system that is not a screen-film system*** at the facility. This program must be ~~[approved]~~ ***:***

(1) Substantially the same as recommended by the manufacturer.

(2) Approved by the Health Division before it is put into effect.

~~[3.]~~ ***(c)*** 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)]~~ ***(1)*** Specify the tests for quality assurance that are required to be performed at the facility.

~~[(b)]~~ ***(2)*** Establish the frequency with which each such test is to be performed and the range of acceptable results for each test.

~~[(c)]~~ ***(3)*** 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]~~ ***paragraph*** 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.]~~ ***457.445, inclusive.***

(d) A copy of any form required to be used in connection with a test for quality assurance.

~~[5.]~~ ***(e)*** Information concerning the cleaner recommended by the manufacturer of any screen used with a machine in the facility.

2. The operator of a facility shall ensure that adequate time is allocated for the performance of quality assurance duties.

Sec. 9. NAC 457.310 is hereby amended to read as follows:

457.310 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,]~~ ***457.445,*** 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 of a test for quality assurance must be made and evaluated immediately upon completion of the test. If the results are not within the control limits, corrective action must be completed, verified and documented in accordance with the provisions of 21 C.F.R. § 900.12.

Sec. 10. NAC 457.312 is hereby amended to read as follows:

457.312 1. Each facility for mammography shall maintain ~~[each mammogram and accompanying]~~ ***the*** 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.~~**]** ***accordance with the provisions of 21 C.F.R. § 900.12.***

2. Each facility for mammography that has a digital mammography machine must be capable of printing or providing a hard copy image of primary interpretation quality to a patient, the representative of a patient or a physician.

Sec. 11. NAC 457.313 is hereby amended to read as follows:

457.313 ~~**[**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~~**]** ***:***

1. Each mammogram has a preliminary interpretation 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.~~**]**

2. For each mammogram that indicates cancerous or potentially cancerous tissue, the responsible provider of care of the patient is contacted at the time the preliminary interpretation is complete;

3. For each mammogram that otherwise indicates the need for additional workup or evaluation which prevents the written report from being sent to the responsible provider of care of the patient within 7 working days, the responsible provider of care is contacted at the time the preliminary interpretation is complete; and

4. Mammography records and reports comply with the provisions of 21 C.F.R. § 900.12.

Sec. 12. NAC 457.315 is hereby amended to read as follows:

457.315 ~~[1. A record must be]~~ ***The operator of a facility shall ensure that a record is*** 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.]~~ ***be made and maintained in accordance with the provisions of 21 C.F.R. § 900.12.***

Sec. 13. NAC 457.320 is hereby amended to read as follows:

457.320 ~~[1. A]~~ ***At each facility for mammography, 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.~~] ***documenting the maintenance of all equipment used for mammography at the facility in accordance with the provisions of 21 C.F.R. § 900.12.***

Sec. 14. NAC 457.325 is hereby amended to read as follows:

457.325 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 the imaging processing system of each machine used at the facility for mammography and the printing equipment used at the facility for mammography in accordance with the provisions of 21 C.F.R. § 900.12.***

Sec. 15. NAC 457.330 is hereby amended to read as follows:

457.330 ***1.*** The following information must be plotted ***and evaluated*** on a control chart ~~[:~~ ~~1.~~] ***in accordance with the provisions of 21 C.F.R. § 900.12:***

(a) The values obtained from the daily exposure and processing of sensitometric strips.

~~[2.]~~ ***(b)*** 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.]~~ ***(c)*** A description of any change in operating conditions made as the result of a test for quality assurance.

~~[4.]~~ ***(d)*** The operating levels and control limits for each test for quality assurance performed.

2. If the information obtained pursuant to subsection 1 is not within the applicable control limits, corrective action must be completed and verified before any patients are examined or films are processed.

Sec. 16. NAC 457.335 is hereby amended to read as follows:

457.335 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 ***Health*** Division any record required to be maintained pursuant to NAC 457.200 to ~~[457.480,]~~ ***457.445,*** inclusive.

3. Make available to an employee or other representative of the Health Division any record required to demonstrate compliance with applicable laws and regulations, including, without limitation, the work schedules of persons who are employed or retained by the facility for mammography and the records indicating the persons who worked each day that mammography was performed at the facility.

Sec. 17. NAC 457.340 is hereby amended to read as follows:

457.340 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 record of the review and update must be ~~[prepared]~~ ***:***

(a) 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.~~

~~➥ 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.~~~~]~~

(b) Signed and dated by the physician.

Sec. 18. NAC 457.345 is hereby amended to read as follows:

457.345 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.~~~~]~~ ***satisfy the qualifications for an interpreting physician set forth in 21 C.F.R. § 900.12(a)(1).***

Sec. 19. NAC 457.347 is hereby amended to read as follows:

457.347 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.

2. ***The facility where a person is temporarily interpreting mammograms must:***

(a) Verify that the person is qualified as an interpreting physician at the start of each period of temporary employment; and

(b) Maintain documentation which demonstrates that the person is qualified as an interpreting physician.

3. The facility where a person is temporarily interpreting mammograms ~~[shall]~~ ***must*** 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.

Sec. 20. NAC 457.350 is hereby amended to read as follows:

457.350 ***1.*** 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 ~~[:~~

~~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;~~

~~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.]~~ ***hold a valid mammographer's certificate.***

2. A person who desires to work as a mammographer in Nevada may obtain a mammographer's certificate by applying to the Radiological Health Section of the Bureau of Health Protection Services of the Health Division. An applicant must:

(a) Satisfy the requirements of NRS 457.183; and

(b) Provide documentation satisfactory to the Health Division that the applicant meets the requirements of 21 C.F.R. § 900.12(a)(2).

Sec. 21. NAC 457.355 is hereby amended to read as follows:

457.355 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 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 program of instruction in mammography must provide to each person who is enrolled in the program at least 40 contact hours of training specific to mammography.***

4. 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.

Sec. 22. NAC 457.360 is hereby amended to read as follows:

457.360 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]~~ ***other image receptors for mammography*** carefully 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.

Sec. 23. NAC 457.365 is hereby amended to read as follows:

457.365 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.

Sec. 24. NAC 457.370 is hereby amended to read as follows:

457.370 1. A mammographer who desires to renew his mammographer's certificate must submit to the Health Division an application for renewal. The application must ~~[be]~~ ***:***

(a) Be received by the Division not less than 30 days before the expiration of the certificate ~~[.]~~ ***; and***

(b) Include documentation which establishes that the mammographer possesses a current credential in general radiography.

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 ***immediately*** preceding ~~[3 years.]~~ ***36 months.*** Continuing education received in compliance with the provisions of this subsection must be approved ~~[in writing]~~ by the ***Health*** Division or a national or regional organization approved by the ***Health*** 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 dates on which continuing education was received; and***

(d) The name of the representative of the sponsoring organization who issued the certificate.

3. The Health Division will not recognize a mammographer's certification by the American Registry of Radiologic Technologists, or the equivalent, obtained after receipt of his mammographer's certificate, as meeting the continuing education requirements of subsection 2.

4. Continuing education hours earned through providing instruction or attending a specific course may be counted only once toward the 15 hours of continuing medical education in mammography required by subsection 2, even if the course is taught or attended more than once during the 36-month period.

Sec. 25. NAC 457.375 is hereby amended to read as follows:

457.375 ~~[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:~~

~~$$kVp/100 + 0.10 > HVL \geq kVp/100.$$~~

~~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 requirements set forth in 21 C.F.R. § 900.12 and must be approved for mammography by the United States Food and Drug Administration.***

Sec. 26. NAC 457.390 is hereby amended to read as follows:

457.390 ~~[If any machine at]~~

1. The operator of a facility ~~[for mammography uses a film and screen image receptor,]~~ ***shall ensure that*** the following equipment ~~[must be]~~ ***is*** maintained at the facility ~~[,]~~ ***and is*** properly calibrated and in good working order:

~~[1.]~~ ***(a)*** A breast phantom capable of depicting:

~~[(a)]~~ ***(1)*** A mass having a width of 0.5 millimeter or less;

~~[(b)]~~ ***(2)*** A calcification having a diameter of 0.24 millimeter or less; and

~~[(c)]~~ ***(3)*** Fibers of nylon or similar material having a width of 0.75 millimeter or less.

~~[2.]~~ ***(b) For a facility using screen-film imaging:***

(1) A wire mesh contact tool designed for use in mammography ~~[.~~ ~~3.]~~ ***with a 40 mesh copper screen.***

(2) A thermometer accurate to ± 0.5°F. A thermometer containing mercury must not be used.

~~[4.]~~ ***(3)*** A sensitometer that generates blue or green light, as appropriate to the type of film used at the facility, with a reproducibility of ± 0.04 log exposure.

~~[5.]~~ ***(4)*** A densitometer accurate to ± 0.02 optical density and having a range of 0.00 to 3.5 optical density.

2. A facility for mammography must use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography and must use film that is matched to the spectral output of the screen as specified by the manufacturer.

Sec. 27. NAC 457.395 is hereby amended to read as follows:

457.395 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. Countertops 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 or the area surrounding the*** darkroom.

Sec. 28. NAC 457.400 is hereby amended to read as follows:

457.400 ~~[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 tests]~~ ***Tests*** for quality assurance must be performed ***pursuant to 21 C.F.R. § 900.12*** whenever any component of the X-ray machine is repaired or replaced, and before the machine is used for mammography ~~[.~~

~~2. If]~~ ***if*** the repair or replacement affects:

~~[(a)]~~ ***1.*** Image quality ***.*** ~~[, the test described in NAC 457.425 must be performed.~~

~~(b)]~~ ***2.*** 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)]~~ ***3.*** Milliampere-seconds linearity **.** ~~[, the test described in NAC 457.460 must be performed.~~

~~(d)]~~ ***4.*** The accuracy of the kilovolt peak indicated by the machine **.** ~~[, the test described in NAC 457.455 must be performed.~~

~~(e)]~~ ***5.*** The skin entrance exposure or glandular tissue dose **.** ~~[, the test described in NAC 457.465 must be performed.~~

~~(f)]~~ ***6.*** Focal spot size **.** ~~[, the test described in NAC 457.470 must be performed.~~

~~(g)]~~ ***7.*** Half-value layer **.** ~~[, the test described in NAC 457.475 must be performed.]~~

Sec. 29. NAC 457.410 is hereby amended to read as follows:

457.410 ~~[1. The daily tests]~~ ***Tests*** for quality assurance ~~[described in NAC 457.420 may]~~ ***must*** 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.~~**]** ***a person who meets the qualifications set forth in 21 C.F.R. § 900.12(a).***

Sec. 30. NAC 457.415 is hereby amended to read as follows:

457.415 ~~[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]~~ ***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.~~**]** ***, must comply with the requirements of 21 C.F.R. § 900.12.***

Sec. 31. NAC 457.420 is hereby amended to read as follows:

457.420 1. A test of film processing equipment used for mammography must be performed ***pursuant to 21 C.F.R. § 900.12 for*** each day that the equipment is in operation ~~[,]~~ ***and*** 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 ± 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 ± 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.~~**]** ***results of the tests performed pursuant to subsection 1 must be recorded, plotted on a control chart, evaluated and acted upon immediately after the test is completed and before any clinical films are processed. If the results are not within the applicable control limits, corrective action must be completed and verified as successful before any clinical films are processed.***

Sec. 32. NAC 457.425 is hereby amended to read as follows:

457.425 **[**~~1. Except as otherwise provided in this subsection, the~~**]** ***The*** operator of a facility **[**~~for mammography~~**]** shall ensure that **[**~~a monthly test~~**]** ***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 ± 0.20. The exposure time or mAs must not vary by more than ± 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.~~] ***pursuant to 21 C.F.R. § 900.12.***

Sec. 33. NAC 457.435 is hereby amended to read as follows:

457.435 ~~[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.]~~ ***pursuant to the provisions of 21 C.F.R. § 900.12.***

Sec. 34. NAC 457.445 is hereby amended to read as follows:

457.445 1. Before any machine is placed into service and at least annually thereafter, ~~[it]~~ ***the machine*** must be examined to verify that it is in safe operating condition. ***An examination must also be made after a major repair to a machine.***

2. The examination ***required by subsection 1*** must ~~[:~~

~~(a) Include a test of the image quality of the machine pursuant to NAC 457.425; and~~

~~(b) Be]~~ ***be*** made by ~~[:~~

~~(1) A]~~ ***a*** medical physicist ***.*** ~~[;~~

~~(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]~~ ***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.]~~

Sec. 35. NAC 457.380, 457.385, 457.405, 457.430, 457.440, 457.450, 457.455, 457.460, 457.465, 457.470, 457.475 and 457.480 are hereby repealed.

TEXT OF REPEALED SECTIONS

457.380 Limitation on transmission of primary beam through image receptor support. (NRS 457.065)

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.

457.385 Use of special attachment for mammography. (NRS 457.065)

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.

457.405 Frequency of mandatory tests; optional compliance with alternative standards. (NRS 457.065)

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,

➥ 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.

457.430 Inspection and cleaning of screen. (NRS 457.065)

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.

457.440 Miscellaneous tests and examinations. (NRS 457.065) 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.

➥ 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).

➥ 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.

457.450 Test of exposure timer and automatic exposure control. (NRS 457.065)

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,

➥ 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.

457.455 Test of accuracy of indicated kilovolt peak. (NRS 457.065)

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.

457.460 Test of mAs linearity. (NRS 457.065)

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.

457.465 Test of glandular tissue dose. (NRS 457.065)

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.

457.470 Test of focal spot size. (NRS 457.065)

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.

457.475 Test of half-value layer. (NRS 457.065)

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:

$$kVp/100 + 0.10 > HVL \geq kVp/100.$$

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

457.480 Test of uniformity of screen speed. (NRS 457.065)

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 ±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.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R033-06

The State Board of Health adopted regulations assigned LCB File No. R033-06 which pertain to chapter 457 of the Nevada Administrative Code on June 16, 2006.

Notice date: 4/10/2006 **Date of adoption by agency:** 6/16/2006
Hearing date: 6/16/2006 **Filing date:** 6/28/2006

INFORMATIONAL STATEMENT

1. A description of how public comment was solicited, a summary of public response, and an explanation how other interested persons may obtain a copy of the summary.

   Comment was solicited from the regulated community, in that each mammography facility was sent a copy of the proposed regulations and the small business impact questionnaire. Additionally, all known interested persons were provided with copies of the proposed regulations. Notice of proposed changes were sent to all Bureau offices, main county libraries and facilities on the Health Division listing for posting of proposed regulations. All the above were notified by direct mailing of scheduled workshops. Notice of proposed workshop was published in the Reno Gazette-Journal on May 12, 2006 and the Las Vegas Review-Journal on May 15, 2006. Public workshop was held at 10:00 a.m. on May 30, 2006, by videoconference between Bureau of Licensure and Certification, 1550 East College Parkway, Suite 158, Carson City, Nevada and Bureau of Licensure and Certification, 4220 South Maryland Parkway, Suite 810, Las Vegas, Nevada

2. The number of persons who:

   (a) Attended the hearing;

   No one appear at the Board of Health meeting to testify on the regulations.

   10 members of the regulated community attended the workshop and had questions, comments and suggestions about three specific proposed changes to the regulations. Based upon the comments received at the workshop, changes were submitted to LCB and are included in the second revised proposed regulation R0033-06.

   These changes pertain to the proposed regulations are as follow:

   (1) Section 9, NAC 457.310(5) was reworded to state that corrective actions are to be completed in accordance with 21 CFR 900.12. This allows sufficient time to ensure proper corrective action, without adversely impacting of patient care and the quality of the image.

(2) Section 15, NAC 457.330(1) was reworded to replace reference to daily quality assurance activities with "in accordance with 21 CFR 900.12" because some of the quality assurance activities are required weekly, monthly and quarterly instead of daily.

(3) Section 16, NAC 457(3) had the word "payroll" removed. This allows the facility to demonstrate who conducted mammography by whatever records are appropriate.

(b) Testified at each hearing:

No one appear at the Board of Health meeting to testify on the regulations.

and

10 members of the regulated community attended the workshop and had questions, comments and suggestions about three specific proposed changes to the regulations. Based upon the comments received at the workshop, changes were submitted to LCB and are included in the second revised proposed regulation R0033-06.

(a) Submitted to the agency written statements.

Three individuals submitted written statements in the form of small business impact responses. Two of these comments addressed proposed changes to NAC 457.313. The comments were the basis for changes made to NAC 457.313 before the workshop was held.

3. A description of how comment was solicited from affected businesses, a summary of their response, and an explanation how other interested persons may obtain a copy of the summary.

Comment was solicited from the affected businesses in that all mammography facilities were mailed copies of the proposed changes and copies of the small business impact questionnaire and they were advised by direct mail of the time, date and location of the workshop.

A total of five (5) businesses responded with comments pertaining to the proposed changes to the regulations:

Two businesses stated that the changes would have no impact on their business.

Three businesses identified the following:

(a). One facility stated that the changes would result in less time on paperwork and more time with patients, because of fewer rules to follow.

(b). Two facilities identified problems with the way the changes in NAC 457.313 were worded.

Following review of these comments, the wording in NAC 457.313 was modified with the approval of the regulated businesses. This change was incorporated prior to the workshop and copies of the modified proposal were sent to all regulated facilities and to all known interested persons.

(c). One facility stated that the changes in NAC 457.305 will require the facility to block out time to ensure quality control tests are completed in accordance with the regulatory requirements.

4. If the regulation was adopted without changing any part of the proposed regulation, a summary of the reasons for adopting the regulation without change. The statement should also explain the reasons for making any changes to the regulation as proposed.

Changes to the regulation incorporated comments from the regulated community which will ensure health and safety to the public while allowing the facility the flexibility in how they notify primary providers of care when additional workup is required.

5. The estimated economic effect of the regulation on the business which it is to regulate and on the public. These must be stated separately, and in each case must include:

(a) Estimated economic effect:

(1) Regulated businesses: Should be positive in that by adopting 21 CFR 900 by reference, Nevada is adopting the federal rules the regulated businesses must follow, resulting in less confusion and less time checking for compliance to two sets of regulations.

(2) Public: Should be positive in that with fewer rules to follow, the businesses can concentrate on providing quality mammography services.

(b) Immediate and long term effects:

(1) Regulated businesses: Both immediate and long term effects should be a streamlined operation resulting in better patient flow and lower overhead by limiting the regulatory requirements.

(2) Public: Both immediate and long term effects should be a streamlined operation resulting in better patient flow and no identifiable increase in cost to the consumer.

6. The estimated cost to the agency for enforcement of the proposed regulation,

Estimated cost to the agency for enforcement of the proposed regulations is no change.

7. A description of any regulations of other state or government agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the regulation overlaps or duplicates a federal regulation, name the regulating federal agency.

   The regulations overlap 21 CFR 900, known to the regulated industry as the Mammography Quality Standards Act (MQSA), which is under the U.S. Food and Drug Administration. MQSA was passed in to law by the federal government in 1994, two years after Nevada initiated regulation of mammography under NAC 457.

8. The regulation includes provisions which are more stringent than a federal regulation which regulates the same activity, a summary of such provisions.

   (a) NAC 457.299 requires that a single person or corporate entity be responsible for each mammography machine.

   (b) NAC 457.310(5) specifically states that test for quality assurance be completed and evaluated immediately after the tests and corrective action verified as adequate within the required timeframe before the equipment is used if corrective action must be taken.

   (c) NAC 457.313 requires that each mammogram have a preliminary interpretation not later than 7 working days after the mammogram is performed. If the mammogram indicates cancer or possible cancer, the patient's responsible provider of care is to be contacted by the facility at the time the preliminary interpretation is completed. If the mammogram requires additional workup and the evaluation can not be completed within the 7 working days after the initial examination, the facility is to contact the provider.

   (d) NAC 457.370 states that Nevada will not recognize a mammographer passing the American Registry of Radiological Technologists, or equivalent, mammographer examination as meeting the continuing educations requirements. This is because the examination only verifies the training already recognized by Nevada in issuing the individual a Nevada mammographer credential.

   (e) NAC 457.420 specifically states that test for film processing equipment completed, charted and evaluated immediately after the tests and corrective action verified as adequate within the required timeframe before the equipment is used if corrective action must be taken.

9. If the regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

   There are no fee changes included.