

# PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

## LCB File No. R113-12

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

**NAC 457 is hereby amended by adding thereto the provisions set forth as sections 1 to 5, inclusive, of this regulation.**

**NAC 457 is hereby amended as follows:**

**Sec.1 NAC 457.290 is hereby amended to read as following:**

NAC 457.290 Granting of exemptions, exceptions or variances from requirements. (NRS 457.065) 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 457.445, inclusive, as it determines will not result in any undue hazard to public health and safety or property.

1. Exemption may be granted by the Division for a mammographic machine used in conjunction with radiation therapy under the following conditions:

- a. The machine is not FDA certified for mammography examinations;*
- b. The machine is not ACR (American College of Radiology) accredited;*
- c. The machine is operated by a person holding a mammographer's certificate of authorization in the state of Nevada, and*
- d. The registrant follows the policies and procedures set forth by the Health Division.*

2. *Exemption may be granted by the division for a mammographic machine used for biopsy, pathologic area localization and/or tissue radiography under the following conditions:*

- a. The machine is not FDA certified for mammography examinations;*
- b. The machine is not ACR accredited;*
- c. The machine is operated by a person holding a mammographer's certificate of authorization in the State of Nevada; and*
- d. The registrant follows the policies and procedures set forth by the Health Division.*

**Sec.2 NAC 457. 300 is hereby amended to read as following:**

NAC 457.300 Quality assurance and control: General requirements. (NRS 457.065) 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. 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. *In order to prepare such a list, the registrant will maintain records, to support the list, of the mammographers' credentials to include but not limited to:*

*a) Copy of the individual's current ARRT (American Registry of Radiologic Technologists) card, verified thru the ARRT and dated and signed by a supervisor on the copy, with the notation "Original viewed and verified".*

*b) Copy of the individual's current Nevada Certificate of Authorizaton to operate a mammography machine and noted on the copy signed and dated by a supervisor that it was verified thru the State or copied and noted on the copy signed and dated by a supervisor "Original viewed".*

*c) Copies of current Continuing Education Units certificates with the notation on the copy signed and dated by a supervisor, "Original viewed".*

*d) Copy of training on digital mammography or other training as necessary under FDA or Nevada required training. This copy is to have noted on it, "Original viewed" and signed and dated by a supervisor.*

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.

5. If the facility for mammography has more than one machine, ensure that a 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.3 NAC 457. 350 is hereby amended to read as following:**

NAC 457.350 Mammographer: Requirements for certification. (NRS 457.065, 457.183)

1. A person who desires to work as a mammographer in Nevada must be certified in general radiography by the American Registry of Radiologic Technologists, or by another organization approved by the Health Division, and must 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).

*(c) Provide the current employer's name and address; and*

*(d) Attest by signing the application that any change in employment will be reported to the Health Division, and that not reporting the change will render the certificate void.*

*3. Upon issuance of the certificate by the Division, after requirements have been satisfied and verified, the original certificate is to be posted at the place of employment visible and accessible to all clients. Should the holder of the certificate be employed at more than one*

*facility, the holder will need to apply to the Division for a duplicate original to post at each facility. A fee of \$25 will be charged by the Division for each additional duplicate original and each shall be clearly marked by the Division as “Duplicate Original to be used in the place of the Original”.*

**Sec.4 Chapter 457 of NAC is hereby amended by adding thereto a new section to read as follows:**

***Mammography Instructor Qualifications: To be a qualified mammography instructor, a person is required to hold a certification in mammography from any state or a professional certification from the American Registry of Radiologic Technologists in Mammography or meet the Mammography Quality Standards Act requirements, as defined in 21 CFR Part 900, if a physicist.***

**Sec.5 NAC 457. 370 is hereby amended to read as following:**

NAC457.370 Mammographer: Renewal of certificate; continuing education. (NRS 457.065. 457.183)

1. A mammographer who desires to renew his or her mammographer’s certificate must submit to the Health Division an application for renewal. The application must:

(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.

*(c) Include social security number for credential verification.*

*(d) Include birth date for credential verification.*

2. Each mammographer must, as a condition of renewal, furnish to the Health Division evidence that he or she has received not less than 15 hours of continuing medical education in mammography during the immediately preceding 36 months. Continuing education received in compliance with the provisions of this subsection must be approved 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;

(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 or her 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.