ADOPTED REGULATION OF THE

STATE BOARD OF HEALTH

LCB File No. R184-08

Effective May 7, 2010

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

AUTHORITY: §§1-4, NRS 457.065.

A REGULATION relating to mammography; prescribing the grounds for the denial of renewal or the suspension or withdrawal of a certificate of authorization for the operation of a radiation machine for mammography or for a certificate of authorization for a radiation machine for mammography; revising the duties of mammographers and the physicians who supervise the operation of a machine at a facility for mammography; and providing other matters properly relating thereto.

Section 1. Chapter 457 of NAC is hereby amended by adding thereto a new section to read as follows:

In addition to the grounds for disciplinary action set forth in chapter 457 of NRS, the Health Division may deny an application for renewal of a certificate or withdraw or suspend a certificate if the holder of the certificate, owner, lessee or other responsible person:

1. Violates the provisions of this chapter, chapter 457 of NRS, or any other applicable state or federal laws or regulations;

2. Permits an employee, who is under the supervision of the holder of the certificate, owner, lessee or other responsible person, to violate the provisions of this chapter, chapter 457 of NRS, or any other applicable state or federal laws or regulations;

3. Fails or refuses to cooperate with the Health Division during an investigation or inspection;

4. Fails or refuses to comply with a written request from the Health Division, the United States Food and Drug Administration or any applicable local or national accreditation body for records, reports or other materials;

5. Provides false or misleading or otherwise inaccurate information on an application for a certificate or for renewal of a certificate;

6. Has been disciplined by any applicable federal agency, local or national accreditation body or has otherwise been found by the Health Division to have committed unprofessional conduct, including, without limitation, a violation of the code of ethics or professional code of conduct of the federal agency or accreditation body; or

7. Held a certificate issued by the Health Division or by the appropriate agency in another jurisdiction and the certificate was withdrawn, revoked, terminated or suspended.

Sec. 2. NAC 457.200 is hereby amended to read as follows:

457.200 As used in NAC 457.200 to 457.445, inclusive, ***and section 1 of this regulation,*** 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. 3. 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 12 months. A record of the review and update must be:

(a) Prepared and kept at the facility.

(b) Signed and dated by the physician.

3. Comply with the standards for protection against radiation set forth in NAC 459.320 to 459.664, inclusive, and the requirements of NAC 459.780 to 459.794, inclusive.

4. Notify the Health Division of any violation of this chapter or chapter 459 of NAC within 30 days after the date on which he discovers the violation.

Sec. 4. 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 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.

17. Comply with the standards for protection against radiation set forth in NAC 459.320 to 459.664, inclusive, and the requirements of NAC 459.780 to 459.794, inclusive.

18. Notify the Health Division of any violation of this chapter or chapter 459 of NAC within 30 days after the date on which he discovers the violation.

HEALTH DIVISION
BUREAU OF HEALTH CARE QUALITY AND COMPLIANCE
RADIATION CONTROL PROGRAM
APRIL 16, 2010
LCB FILE # R184-08 & # R185-08

INFORMATION STATEMENT PER NRS 233B.066

R184-08
A regulation relating to mammography; prescribing the grounds for the denial of renewal or the suspension or withdrawal of a certificate of authorization for the operation of a radiation machine for mammography or for a certificate of authorization for a radiation machine for mammography; revising the duties of mammographers and the physicians who supervise the operation of a machine at a facility for mammography; and providing other matters properly relating thereto.

R185-08
A regulation relating to radioactive material; regulating the possession or transfer of radium-226 and americium-241; adopting by reference certain federal regulations; requiring the registration of any new X-ray system, including fees to be paid; regulating the operation, maintenance and use of therapeutic X-ray systems to include electronic brachytherapy systems; setting forth the training requirements and duties of authorized users, authorized medical physicists for electronic brachytherapy and certain radiation safety officers; requiring a registrant who uses a therapeutic X-ray system to provide annual safety training for that system; setting forth proper operating procedures, including various safety and calibration checks, for facilities with therapeutic X-ray systems; requiring a registrant to establish and maintain a quality management program and a quality assurance program; setting forth the requirements which must be followed by operators of portable equipment which is hand-held; revising certain exemptions in the handling of by-product material for certain licensees; revising certain provisions to include exempt quantities of radioactive materials; setting forth certain procedures for the production of radioactive drugs, including reporting to the Health Division of the Department of Health and Human Services; requiring certain annual reports regarding exposure to radioactive material; repealing certain provisions relating to medical uses of radiation; and providing other matters properly relating thereto.

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.**

   - **How public comment was solicited:**

   Pursuant to NRS.233B.0608 (2) (a), BHCQC consulted with owners and officers of all small businesses that are likely to be affected by the proposed regulation via telephone and written correspondence.

Comment was solicited from the regulated community, in that each radioactive material licensee, X-ray registrant and mammography technologist 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 December 23, 2008 and January 20, 2010 and in the Las Vegas Review-Journal and Las Vegas Sun on December 22, 2008 and January 22, 2010. Public workshops were held at 9.00 a.m. on January 29, 2009 and February 25, 2010, 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.

- **Summary of Response**

Public Workshop 2009:

Four individuals expressed concerns during the public workshop that were subsequently addressed by Dr. Ed Sweeten, Radiation Physicist, and Radiation Control Program.

No comments were received by mail or telephone, aside from comments in the Small Business Impact Questionnaire.

The Radiation Control Program estimates that there are approximately 1,600 unique entities holding x-ray registrations and approximately 193 unique entities holding radiological material licenses. The Radiation Control Program estimates that approximately 1,300 of these X-ray registrants qualify as State of Nevada small businesses and approximately 149 radiological materials license holders qualify as small businesses.

In accordance with NRS 233B.0608, the RCP sent a five question survey to potentially affected parties of its proposed regulatory changes. To clarify the data collected from the small business impact survey, the results have been summarized in the table below.

Two hundred twenty-five (225) Small Business Impact Questionnaires (SBIQ) were received. One hundred eighty-two (182) of those were from small businesses as defined in NRS 233B. Fifty-six (56) of them had comments written in the questionnaire. The rest answered just yes or no.

Small Business Impact Survey Questions	Yes	No	Did Not Answer	Total Responses
Will a specific regulation have an adverse economic effect upon your business?	50	107	25	182
Will the regulation(s) have any beneficial effect upon your business?	4	152	26	182
Do you anticipate any indirect adverse effects upon your business?	35	116	31	182
Do you anticipate any indirect beneficial effects upon you business?	4	148	31	182

1. 50 (27%) respondents to the SBIQ indicated the proposed regulation would have an adverse economic impact on their business.

2. 4 (2%) respondents to the SBIQ indicated the proposed regulation would have a beneficial economic impact on their business.

3. 35 (19%) respondents to the SBIQ indicated the proposed regulation would have an indirect adverse effect on their business.

4. 4 (2 %) respondents to the SBIQ indicated the proposed regulation would have an indirect beneficial effect on their business.

5. 16 (9%) gave no indication of any adverse or beneficial impact on their businesses.

No changes were made to the proposed regulations which were based on public comment received.

Public Workshop 2010

No comments were received by mail or telephone, aside from comments in the Small Business Impact Questionnaire. No comments were received during the Public Workshop.

The Radiation Control Program estimates that there are approximately 2,400 unique entities holding X-ray registrations and approximately 220 unique entities holding radiological material licenses. The Radiation Control Program estimates that approximately 2,000 of these X-ray registrants qualify as State of Nevada small businesses and approximately 170 radiological materials license holders qualify as small businesses.

In accordance with NRS 233B.0608, the RCP sent a five question survey to potentially affected parties of its proposed regulatory changes.

- **Questions asked in the Small Business Impact Questionnaire:**

2. Will a specific regulation have an adverse economic effect upon your business?
3. Will the regulation(s) have any beneficial effect upon your business?
4. Do you anticipate any indirect adverse effects upon your business?
5. Do you anticipate any indirect beneficial effects upon your business?

To clarify the data collected from the small business impact survey, the results have been summarized in the table below.

214 Small Business Impact Questionnaires (SBIQ) were received.
178 of those were from small businesses as defined in NRS 233B.0382.
77 of them had comments written in the questionnaire.
The rest answered just yes or no.

Small Business Impact Survey Questions	Yes	No	Did Not Answer	Total Responses
Will a specific regulation have an adverse economic effect upon your business?	52	100	26	178
Will the regulation(s) have any beneficial effect upon your business?	5	101	72	178
Do you anticipate any indirect adverse effects upon your business?	35	97	46	178
Do you anticipate any indirect beneficial effects upon you business?	4	128	46	178

1. 52(29%) respondents to the SBIQ indicated the proposed regulation would have an adverse economic impact on their business.
2. 5 (3%) respondents to the SBIQ indicated the proposed regulation would have a beneficial economic impact on their business.
3. 35 (19%) respondents to the SBIQ indicated the proposed regulation would have an indirect adverse effect on their business.
4. 4 (2 %) respondents to the SBIQ indicated the proposed regulation would have an indirect beneficial effect on their business.

No changes were made to the proposed regulations based on public comment received.

- **How other interested persons may obtain a copy of the summary:**

A summary of the response can be obtained by contacting:
Dorothy Rink
Radiation Control Program, Bureau of Health Care Quality and Compliance
4150 Technology Way, Suite 300, Carson City, Nevada 89706
Telephone: 775-687-7550

2. The number of persons who:

(a) Attended the hearing:

Six members of the regulated community attended the Public Workshop in 2009 and four of them commented. The comments were subsequently addressed by Dr. Sweeten and Larry Boschult of the Radiation Control Program.
Seven members of the regulated community attended the Public Workshop in 2010. No comments were received.

(b) Testified at each hearing:

Four people sought clarifications in the 2009 Public Workshop. No comments were received during the 2010 Public Workshop. No changes were made to the proposed regulations based on any comments.

(c) Submitted to the agency written statements:

No comments were received by mail in 2009, except for the response to the Small Business Impact Questionnaire. Twenty-seven percent (27%) indicated an adverse economic impact. No comments were received by mail in 2010, except for the responses to the Small Business Impact Questionnaire. Twenty-nine percent (29%) indicated that the regulations would have an adverse effect. No changes were made to the proposed regulations based on these responses.

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 regulated community, such that each radioactive material licensee, X-ray registrant and mammography technologist 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.

2009

1. 50 (27%) respondents to the SBIQ indicated the proposed regulation would have an adverse economic impact on their business.

2. 4 (2%) respondents to the SBIQ indicated the proposed regulation would have a beneficial economic impact on their business.

3. 35 (19%) respondents to the SBIQ indicated the proposed regulation would have an indirect adverse effect on their business.

4. 4 (2 %) respondents to the SBIQ indicated the proposed regulation would have an indirect beneficial effect on their business.

6. 16 (9%) gave no indication of any adverse or beneficial impact on their businesses.

2010

1. 52(29%) respondents to the SBIQ indicated the proposed regulation would have an adverse economic impact on their business.

2. 5 (3%) respondents to the SBIQ indicated the proposed regulation would have a beneficial economic impact on their business.

3. 35 (19%) respondents to the SBIQ indicated the proposed regulation would have an indirect adverse effect on their business.

4. (2 %) respondents to the SBIQ indicated the proposed regulation would have an indirect beneficial effect on their business.

No changes were made to the proposed regulations based on public comment received.

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 and suggestions made by the Legislative Counsel Bureau and the U.S Nuclear Regulatory Commission were incorporated into the drafting of these regulations. Public comment received did not justify any change. The Nevada State Board of Health adopted them as they were without seeking any additional changes.

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) Both adverse and beneficial effects; and

(b) Both immediate and long term effects.

(a) Adverse and Beneficial Effects:

On Regulated Businesses:

There are no proposed increases in fee and no anticipated adverse effects. A better regulatory framework contributes to greater compliance with the U.S NRC,

decreasing the probability of audit findings and consequently heightened oversight.

On the Public:

Indirectly ensures better safety. No anticipated adverse effects.

(b) Immediate and Long Term Effects:

On Regulated Businesses:

Both immediately and in the long run, this will lead to increased awareness, control and security in working with radiation and radioactive materials.

On the Public:

A good regulatory framework leads to increased safety for the public, contributing to the greater good in the short term and in the long term.

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

No additional expense anticipated.

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.

No overlap or duplication.

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

Does not include provisions that are more stringent than federal regulations for the same activity.

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.

No increases in fee.

10. If the proposed regulation is likely to impose a direct and significant economic burden upon a small business or directly restrict the formulation, operation or expansion of a small business. What methods did the agency use in determining the impact of the regulation on a small business?

The proposed regulations neither impose a burden on nor restrict the formation, operation or expansion of a small business. The agency used the output from Small Business Impact Questionnaires and Public Workshops to arrive at this conclusion.

SMALL BUSINESS IMPACT STATEMENT - 2010

PROPOSED AMENDMENTS TO NAC 457 and NAC 459

The Bureau of Health Care Quality and Compliance (BHCQC) has determined that the proposed amendments should not impose a direct and significant economic burden upon a small business or directly restrict the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B.0382 as a "business conducted for profit which employs fewer than 150 full-time or part-time employees."

This small business impact statement complies with the requirements of NRS 233B.0609.

1. A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Pursuant to NRS.233B.0608(2)(a), BHCQC has consulted with owners and officers of all small businesses that are likely to be affected by the proposed regulation via telephone and written correspondence.

Comment was solicited from the regulated community, in that each radioactive material licensee, x-ray registrant and mammography technologist 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 January 20, 2010 and the Las Vegas Review-Journal and Las Vegas Sun on January 22, 2010. Public workshop will be held at 9.00 a.m. on February 25, 2010, 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.

Summary of Response

No comments were received by mail or telephone, aside from comments in the Small Business Impact Questionnaire.

The Radiation Control Program estimates that there are approximately 2400 unique entities holding x-ray registrations and approximately 220 unique entities holding radiological material licenses. The Radiation Control Program estimates that approximately 2000 of these x-ray registrants qualify as State of Nevada small businesses and approximately 170 radiological materials license holders qualify as small businesses.

In accordance with NRS 233B.0608, the RCP sent a five question survey to potentially affected parties of its proposed regulatory changes.

Questions asked in the Small Business Impact Questionnaire:

2. Will a specific regulation have an adverse economic effect upon your business?
7. Will the regulation(s) have any beneficial effect upon your business?
8. Do you anticipate any indirect adverse effects upon your business?
9. Do you anticipate any indirect beneficial effects upon your business?

To clarify the data collected from the small business impact survey, the results have been summarized in the table below.

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No changes were made to the proposed regulations which were based on public comment received.

A summary of the response can be obtained by contacting:

Dorothy Rink
Radiation Control Program
Bureau of Health Care Quality and Compliance
4150 Technology Way, Suite 300
Carson City, Nevada 89706
Telephone: 775-687-7550
Fax: 775-687-7552
drink@health.nv.gov

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation both adverse and beneficial effects and both direct and indirect effects.

Estimated economic effect:

Regulated Businesses:

There is no imposition of new fees. However, there is an extension of the existing fee structure and a clarification relating to the fees imposed.

The fee for expedited review of licenses may be completely avoided by filing an application for timely renewal of the license 30 days before the date of expiration set forth on the license. The RCP sends out a reminder 60 days prior to the expiration date. (Sec.59 – NAC 459.200)

There is an extension of the existing fee structure to cover new technology. The existing fee category is appropriate and adequate for this technology. (Sec.30)

There is a clarification relating to each location of use representing a separate general licensee and thus requiring a separate registration and fee. (Sec.63 – NAC 459.218)

Public:

No anticipated economic increase to the public.

Beneficial Effects:

Regulated businesses:

The expedited review fee will ensure equity and fairness to all licensees. Staff will be able to justify spending time on renewals that do not come in 30 days prior to the expiration date. Business will proceed without interruption.

The extension of existing fee to cover new technology ensures that all licensees are treated fairly..

Public:

Having clear regulations to deal with every contingency ensures the uninterrupted conduct of business, saving time and taxpayer money.

3. A description of the methods that BHCQC considered to reduce the impact of the proposed regulation on small businesses and statement regarding whether the agency actually used those methods.

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608(2)(b)(1), the agency considered simplifying the proposed regulation.

The majority of the provisions are required to be either verbatim or substantially similar to the regulations of the U.S. Nuclear Regulatory Commission in order to maintain compatibility with their program in accordance with the Governor's signed agreement.

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608 2 (b) (2), the agency considered establishing different standards of compliance for a small business.

The majority of the provisions are required to be either verbatim or substantially similar to the regulations of the U.S. Nuclear Regulatory Commission in order to maintain compatibility with their program in accordance with the Governor's signed agreement

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608(2) (b) (3), the agency considered modifying a fee or fine set forth in the regulation so that a small business is authorized to pay a lower fee or fine.

There are no fines included in the proposed changes to NAC 459. Fees established are less than those of the U.S. Nuclear Regulatory Commission. No separate fee for small business is proposed by these regulation revisions.

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

Estimated cost to the agency for enforcement of the proposed regulations is minimal.

5. Total amount BHCQC expects to collect from any fees and the manner in which the money will be used.

No anticipated increase.

6. An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

No duplicative or more stringent provisions than federal, state or local standards regulating the same activity are proposed in these regulation revisions.