

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Division of Public and Behavioral Health

Helping people. It's who we are and what we do.



November 13, 2019

### **MEMORANDUM**

To: Dr. Jon Pennell, Chairperson

State Board of Health

Dr. Jeffery Murawsky, Vice -Chair

State Board of Health

From: Lisa Sherych, Secretary

State Board of Health

Re: Consideration and adoption of proposed regulation LCB File No. R021-18RP3,

Amendments to Nevada Administrative Codes 457 and 459.

#### PURPOSE OF AMENDMENTS

The proposed regulations amend and modify existing language to make regulations more clear, current and compatible with the intent and scope of the Radiation Control Program (RCP). Introduction of new language which aids the RCP to carry out its regulatory role more effectively. Present regulations that need to be adopted as soon as possible, in order to maintain compliance with the requirements of the U.S. Nuclear Regulatory Commission (NRC). Repeals redundant and / or outdated regulations.

# **SUMMARY OF CHANGES TO THE NAC**

The proposed addition/change of regulations to NAC 457 and NAC 459 in LCB File No. R021-18RP3 include provisions for:

- The proposed amendment to (NAC 457.295) Section 1 of this regulation increases the fee for the issuance or renewal of a mammographer's certificate from \$88 to \$200.
- Existing regulations require each facility for mammography that has a digital mammography machine to be capable of printing or providing hard copies of images to certain persons. The proposed amendment to (NAC 457.312) Section 2 of this regulation provides the alternative of being capable of providing images in any other manner approved by the Division.
- Existing law requires the owner, lessee or other person responsible for a radiation machine for mammography that was used to perform mammography to provide to a patient who undergoes mammography a certain statement and a notice concerning the patient's breast density. (NRS 457.1857) Existing regulations require such owner, lessee or other person to provide a similar notice concerning the patient's breast density. The proposed amendment to (NAC 457.313) Section 3 of this regulation removes the requirement to provide a notice concerning the patient's breast density from existing regulations because the requirement already exists in existing law.

- Sections 5-12 of this regulation set forth requirements for the operation of invasive intervention radiation machines that are used to perform federally exempt radiography.
- Existing regulations provide various requirements concerning or involving the control console of radiation machines, X-ray machines and particle accelerators. (NAC 459.154, 459.166, 459.5934, 459.746, 459.748) Sections 11, 18, 21, 27, 29 and 30 of this regulation expand the scope of existing regulations to include such control consoles or any other assembly approved by the Division of Public and Behavioral Health of the Department of Health and Human Services.
- Section 14 of this regulation revises provisions relating to exemptions from existing regulations governing the control of radiation for certain carriers with regard to transporting and storing sources of radiation in the regular course of carriage for another or storage incident thereto.
- Section 19 of this regulation revises the time limit before which a registrant is required to file his or her application for renewal of a registration certificate for a radiation machine or to install, service or repair radiation machines and pay the appropriate fee to avoid expiration of the registration certificate while the status of the registration certificate is pending with the Division.
- Section 20 of this regulation authorizes the Division to charge \$25 for a duplicate registration certificate for a radiation machine or for the person installing, servicing or repairing radiation machines.
- Section 22 of this regulation revises the requirements for a license for radioactive material from which certain quantities of source material are exempt.
- Sections 15, 23 and 32 of this regulation revise provisions which adopt by reference certain federal regulations.
- Section 24 of this regulation makes certain changes to the provisions relating to certain general licenses.
- Existing regulations require each licensee and registrant to make or cause to be made surveys of areas. Existing regulations authorize the Division of Public and Behavioral Health of the Department of Health and Human Services to exempt a licensee or registrant from making such surveys of areas if the Division determines that the exemption will not result in a significant risk to public health and safety. (NAC 459.337) Section 25 of this regulation requires the Division to evaluate the survey of areas made by a licensee or registrant to determine if a significant risk to public health or safety exists. Section 25 additionally authorizes the Division to require the licensee or registrant to make an additional survey of areas if: (1) the conditions under which the previous survey was made have changed; and (2) the Division determines that such a change may result in significant risk to public health and safety.
- Section 26 of this regulation: (1) revises the requirement relating to the periodic measurements of the exposure rate limits for fluoroscopic X-ray systems; and (2) exempts such an X-ray system from certain requirements if the X-ray system is used, at any time, for radiation therapy simulation.
- Section 31 of this regulation makes a technical change.
- Existing regulations set forth the time limit for a person to file an appeal with a hearing officer to contest proposed disciplinary action by the Division. Specifically, existing regulations require a request for an appeal to be received by the Administrator within 10 business days after the date on which the appellant received notice of the proposed disciplinary action. (NAC 439.346) Section 33 of this regulation makes conforming changes.

# POSSIBLE OUTCOME IF PROPOSED AMENDMENT IS NOT APPROVED

NAC 457 and 459 regulations are for the health and safety of Nevadans. Updating, adding new and repealing regulations assures that the public and the regulated community are safe when in the presence of ionizing radiation. Compatibility with the Title 10, Code of Federal Regulations is a requirement of the U.S. NRC for agreement states such as Nevada. If the proposed amendment is not approved these protections could be compromised.

# **PUBLIC COMMENT RECEIVED**

A Small Business Impact Questionnaire was sent to registrants and licensees. A Small Business Impact Summary was prepared based upon the returned questionnaires. Staff has determined that there is no impact on small businesses in the state of Nevada.

A Public Workshop was conducted on October 28, 2019. No written or verbal comment was received from the public.

# **STAFF RECOMMENDATION**

Staff recommends that the State Board of Health adopt the proposed amended regulations to NAC 457 Cancer and NAC 459 Hazardous Materials in LCB File No. R021-18RP3 as presented.

# **PRESENTER**

Adrian Howe, Manager, Radiation Control Program, Division of Public and Behavioral Health.

#### THIRD REVISED PROPOSED REGULATION OF

#### THE STATE BOARD OF HEALTH

#### LCB File No. R021-18

August 14, 2019

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

AUTHORITY: §1, NRS 439.150, 457.065, 457.183 and 457.184; §2, NRS 457.065; §§3-17, 19, 21-24 and 26-33, NRS 459.201; §§18 and 20, NRS 439.150 and 459.201; §25, NRS 459.030 and 459.201.

A REGULATION relating to health; increasing the fee for a mammographer's certificate and establishing a late payment fee; revising certain requirements for digital mammography machines; removing the requirement to provide a notice concerning a patient's breast density from existing regulations; prescribing the requirements for the operation of invasive intervention radiation machines that are used to perform radiography which is exempt from the requirements of the federal regulations adopted pursuant to the Mammography Quality Standards Act of 1992, as amended; prescribing the qualifications for persons who operate invasive intervention radiation machines to perform such federally exempt radiography; prescribing the fee for obtaining a duplicate registration certificate for a radiation machine or for a person installing, servicing or repairing radiation machines; revising provisions governing a license or registration authorizing the possession and use of radioactive materials; revising provisions governing surveys of areas; revising requirements concerning X-ray systems; specifying requirements concerning linearity for certain devices; and providing other matters properly relating thereto.

#### **Legislative Counsel's Digest:**

Existing law requires the State Board of Health to adopt certain regulations for the administration of chapter 457 of NRS which relates to cancer, including, without limitation, regulations concerning the operation of radiation machines for mammography. (NRS 457.065)

Existing law provides that a mammographer's certificate expires 3 years after the date on which it was issued unless it is renewed before that date. Existing law requires the Division of Public and Behavioral Health of the Department of Health and Human Services to charge a fee for the issuance and renewal of a mammographer's certificate that is calculated to cover the administrative costs directly related to the process of issuing a certificate or to the renewal of a certificate. (NRS 457.183) Existing regulations require the Division to charge and collect a fee of \$88 for the issuance or renewal of a mammographer's certificate. (NAC 457.295) **Section 1** of this regulation increases the fee for the issuance or renewal of a mammographer's certificate

from \$88 to \$200. **Section 1** additionally establishes that if the renewal fee is not received before the expiration of the 3 years, the person whose mammographer's certificate expired shall stop operating a radiation machine for mammography on the date his or her mammographer's certificate expires. If the person wishes to renew his or her certificate, the person must submit to the Division within 5 days after the expiration of the mammographer's certificate an application for renewal, the \$200 renewal fee and a fee for late payment of \$100 per mammographer's certificate.

Existing regulations require each facility for mammography that has a digital mammography machine to be capable of printing or providing hard copies of images to certain persons. (NAC 457.312) **Section 2** of this regulation provides the alternative of being capable of providing images in any other manner approved by the Division.

Existing law requires the owner, lessee or other person responsible for a radiation machine for mammography that was used to perform mammography to provide to a patient who undergoes mammography a certain statement and a notice concerning the patient's breast density. (NRS 457.1857) Existing regulations require such owner, lessee or other person to provide a similar notice concerning the patient's breast density. (NAC 457.313) **Section 3** of this regulation removes the requirement to provide a notice concerning the patient's breast density from existing regulations because the requirement already exists in existing law.

Existing law requires the State Board of Health to adopt regulations for the: (1) general or specific licensing of persons to receive, possess or transfer radioactive materials, or devices or equipment utilizing such materials, including, without limitation, for the amendment, suspension or revocation of such licenses; (2) licensing and regulation of by-product materials, source materials, special nuclear materials and other radioactive materials, including radioactive waste; and (3) control of other sources of ionizing radiation. (NRS 459.201) Existing law further provides that the Division is designated as the state radiation control agency, and is authorized to take all action necessary or appropriate to carry out the provisions of NRS 459.010 to 459.290, inclusive, which govern the control of radiation by the State. (NRS 459.020)

The federal regulations adopted pursuant to the Mammography Quality Standards Act of 1992, as amended, exempt "[r]adiography of the breast performed during invasive interventions for localization or biopsy procedures" from the requirements of the federal regulations. (21 C.F.R. § 900.2(aa)(1)) **Sections 5-12** of this regulation set forth requirements for the operation of invasive intervention radiation machines that are used to perform federally exempt radiography.

Specifically, **section 7** of this regulation requires an applicant for a registration certificate for an invasive intervention radiation machine to submit to the Division documentation evidencing that each person who will operate the invasive intervention radiation machine to perform federally exempt radiography satisfies the requirements set forth in **section 8** of this regulation. **Section 9** of this regulation sets forth the duties of the registrant for an invasive intervention radiation machine with regard to ensuring the safe operation of each such machine for which the Division has issued a registration certificate. **Section 10** of this regulation sets forth the process for conducting examinations of an invasive intervention radiation machine to determine whether the machine is operating in accordance with the specifications of the manufacturer of the machine and whether the machine satisfies the requirements of certain

standards set forth in the federal regulations adopted pursuant to the Mammography Quality Standards Act. Section 11 of this regulation requires the posting of a copy of the techniques chart for each examination performed on a patient with an invasive intervention radiation machine. Section 12 of this regulation prohibits, with certain limited exceptions, the use of an invasive intervention radiation machine to perform screening or diagnostic mammography services. Section 12 provides that an invasive intervention radiation machine may be used to perform screening or diagnostic mammography services if the registrant for the machine: (1) revokes his or her current registration; and (2) applies for and receives a valid certificate of authorization to use the machine to perform screening or diagnostic mammography services. Sections 13, 16 and 17 of this regulation make conforming changes.

Existing regulations provide various requirements concerning or involving the control console of radiation machines, X-ray machines and particle accelerators. (NAC 459.154, 459.166, 459.5934, 459.746, 459.748) **Sections 11, 18, 21, 27, 29 and 30** of this regulation expand the scope of existing regulations to include such control consoles or any other assembly approved by the Division of Public and Behavioral Health of the Department of Health and Human Services.

**Section 14** of this regulation revises provisions relating to exemptions from existing regulations governing the control of radiation for certain carriers with regard to transporting and storing sources of radiation in the regular course of carriage for another or storage incident thereto.

**Section 19** of this regulation revises the time limit before which a registrant is required to file his or her application for renewal of a registration certificate for a radiation machine or to install, service or repair radiation machines and pay the appropriate fee to avoid expiration of the registration certificate while the status of the registration certificate is pending with the Division.

**Section 20** of this regulation authorizes the Division to charge \$25 for a duplicate registration certificate for a radiation machine or for the person installing, servicing or repairing radiation machines

**Section 22** of this regulation revises the requirements for a license for radioactive material from which certain quantities of source material are exempt.

Sections 15, 23 and 32 of this regulation revise provisions which adopt by reference certain federal regulations.

**Section 24** of this regulation makes certain changes to the provisions relating to certain general licenses.

Existing regulations require each licensee and registrant to make or cause to be made surveys of areas. Existing regulations authorize the Division of Public and Behavioral Health of the Department of Health and Human Services to exempt a licensee or registrant from making such surveys of areas if the Division determines that the exemption will not result in a significant risk to public health and safety. (NAC 459.337) **Section 25** of this regulation requires the Division to evaluate the survey of areas made by a licensee or registrant to determine if a significant risk to public health or safety exists. **Section 25** additionally authorizes the Division

to require the licensee or registrant to make an additional survey of areas if: (1) the conditions under which the previous survey was made have changed; and (2) the Division determines that such a change may result in significant risk to public health and safety.

**Section 26** of this regulation: (1) revises the requirement relating to the periodic measurements of the exposure rate limits for fluoroscopic X-ray systems; and (2) exempts such an X-ray system from certain requirements if the X-ray system is used, at any time, for radiation therapy simulation.

**Section 28** of this regulation provides certain requirements regarding linearity for certain devices used to control exposures.

**Section 31** of this regulation makes a technical change.

Existing regulations set forth the time limit for a person to file an appeal with a hearing officer to contest proposed disciplinary action by the Division. Specifically, existing regulations require a request for an appeal to be received by the Administrator within 10 business days after the date on which the appellant received notice of the proposed disciplinary action. (NAC 439.346) **Section 33** of this regulation makes conforming changes.

### **Section 1.** NAC 457.295 is hereby amended to read as follows:

- 457.295 1. Except as otherwise provided in subsection 2, the Division shall charge and collect the following nonrefundable fees:
  - (a) For the issuance or renewal of a certificate for a machine, \$551.
  - (b) For the issuance or renewal of a mammographer's certificate, [\$88.] \$200.
- (c) For the issuance of a duplicate mammographer's certificate for posting at multiple facilities for mammography pursuant to NAC 457.360, \$25.
- (d) For the issuance or renewal of a certificate to provide training to mammographers pursuant to NAC 457.357, \$100.
- 2. If a payment was made in error, the Division will refund the fee collected pursuant to subsection 1, after deducting an amount calculated to cover the administrative costs directly related to issuing the refund.

- 3. A mammographer's certificate expires 3 years after the date on which it was issued unless it is renewed before that date. If the fee for renewal of a mammographer's certificate that is charged pursuant to subsection 1 is not received before the date on which the mammographer's certificate expires, the person whose mammographer's certificate expired shall:
- (a) Stop operating the radiation machine for mammography on the date his or her mammographer's certificate expires; or
- (b) Submit to the Division not later than 5 days after his or her mammographer's certificate expires:
  - (1) An application for a renewal of his or her mammographer's certificate;
- (2) The fee for renewal of a mammographer's certificate that is charged pursuant to subsection 1; and
  - (3) A fee for late payment of \$100 per mammographer's certificate.
  - **Sec. 2.** NAC 457.312 is hereby amended to read as follows:
- 457.312 1. Each facility for mammography shall maintain the records of a patient in 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, *or providing an image in any other manner approved by the Division*, of primary interpretation quality to a patient, the representative of a patient or a physician.
  - **Sec. 3.** NAC 457.313 is hereby amended to read as follows:
  - 457.313 1. The operator of a facility shall ensure that:

- (a) Each mammogram has a preliminary interpretation not later than 7 working days after the mammogram is performed;
- (b) 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;
- (c) 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
  - (d) Mammography records and reports comply with the provisions of 21 C.F.R. § 900.12.
- 2. If a patient undergoes mammography, the owner, lessee or other person responsible for the radiation machine used to perform the mammography shall ensure that [each written] the report and, if applicable, the notice required pursuant to NRS 457.1857 are provided [pursuant to 42 U.S.C. § 263b(f)(1)(G)(ii)(IV) includes a statement of the category of the patient's breast density as required pursuant to NRS 457.1857 and a statement in substantially the following form:

Early detection of cancer is very important. Although mammography is one of the most accurate methods for early detection, not all cancers are found through mammography.

Diagnosis by mammography may be limited by factors including, but not limited to, prior surgery, breast implants and breast density. Dense breast tissue is relatively common and is found in 40 percent of women. The presence of dense tissue makes it more difficult to detect cancer in the breast and may be associated with an increased risk of breast cancer.

We are providing this information to raise your awareness of this important factor and to encourage you to discuss dense breast tissue and other breast cancer risk factors with your health care providers. Together, you can decide the appropriate schedule for your personal mammograms and whether any additional screenings should be considered because of your breast density or other breast cancer risk factors. Early detection of cancer is important and far outweighs any risk associated with a radiographic procedure. A report of your mammography results was sent to your physician.] to the patient.

- **Sec. 4.** Chapter 459 of NAC is hereby amended by adding thereto the provisions set forth as sections 5 to 12, inclusive, of this regulation.
  - Sec. 5. "Exempt radiation machine" means a radiation machine that is:
- 1. Exempt, pursuant to the provisions of 21 C.F.R. § 900.2(aa)(1), from the Mammography Quality Standards Act of 1992 (MQSA), Public Law 102-539, as amended; and
- 2. Used to perform any procedure not governed by chapter 457 of NRS or NAC, including, without limitation, performing federally exempt radiography.
- Sec. 6. "Federally exempt radiography" means radiography of the breast which is performed during invasive interventions for localization or biopsy procedures and which is exempt, pursuant to the provisions of 21 C.F.R. § 900.2(aa)(1), from the requirements of the federal regulations adopted pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, as amended.
- Sec. 7. 1. In addition to any other requirements for obtaining a registration certificate for an invasive intervention radiation machine issued by the Division pursuant to NAC

- 459.156, an applicant for such a registration certificate must submit to the Division documentation evidencing that each person who will operate the invasive intervention radiation machine to perform federally exempt radiography satisfies the requirements set forth in section 8 of this regulation.
- 2. As part of the notification required pursuant to NAC 459.162, the registrant for an invasive intervention radiation machine shall notify the Division if:
- (a) A person for whom documentation was submitted pursuant to subsection 1 will no longer be operating the invasive intervention radiation machine to perform federally exempt radiography; or
- (b) A person for whom documentation was not submitted pursuant to subsection 1 will be operating the invasive intervention radiation machine to perform federally exempt radiography. The registrant must retain documentation evidencing that the person who will operate the invasive intervention radiation machine to perform federally exempt radiography satisfies the requirements set forth in section 8 of this regulation and provide the documentation to the Division upon request.
- Sec. 8. A person is qualified to operate an invasive intervention radiation machine to perform federally exempt radiography if the person:
  - 1. Is currently certified by the American Registry of Radiologic Technologists;
- 2. Has a current certificate of authorization to operate a radiation machine for mammography issued by the Division pursuant to NRS 457.183; or
  - 3. *Has*:

- (a) Documentation evidencing that the person received training which consisted of performing at least five hands-on procedures using the type of invasive intervention radiation machine for which registration is sought while supervised by a person who:
  - (1) Satisfied the qualifications set forth in subsection 1 or 2;
- (2) Was trained in the operation of the type of invasive intervention radiation machine for which registration is sought by a person who satisfied the qualifications set forth in subsection 1 or 2;
- (3) Was trained in the operation of the type of invasive intervention radiation machine for which registration is sought by a person who received training which consisted of performing at least five hands-on procedures using the type of invasive intervention radiation machine for which registration is sought while supervised by a person who was trained pursuant to subparagraph (2); or
- (4) Was trained in the operation of the type of invasive intervention radiation machine for which registration is sought by a person who received training which consisted of performing at least five hands-on procedures using the type of invasive intervention radiation machine for which registration is sought while supervised by a person who was trained pursuant to subparagraph (1), (2) or (3); or
- (b) If the training was received before March 8, 2017, completed an attestation, approved by the Division, which states that the person performed at least five hands-on procedures using the type of invasive intervention radiation machine for which registration is sought.
   → The hands-on procedures described in this subsection must have included the proper use
- and operation of the compression device of the type of invasive intervention radiation machine for which registration is sought.

- Sec. 9. The registrant for an invasive intervention radiation machine shall:
- 1. Establish and maintain policies and procedures to ensure the safe operation of each invasive intervention radiation machine for which the Division has issued a registration certificate to the registrant pursuant to NAC 459.156. The policies and procedures established pursuant to this subsection must require that tests of an invasive intervention radiation machine are performed in accordance with the frequency required and consistent with the requirements of the manufacturer of the radiation machine.
  - 2. Ensure that:
- (a) The results of the tests required by subsection 1 are analyzed to determine if there are any problems requiring correction;
- (b) The necessary corrective action is taken whenever the results of a test for quality assurance indicate that such action is required; and
- (c) If necessary corrective action is taken, the action is taken before the radiation machine is used to perform any examination on a patient.
- 3. Ensure that a medical physicist who satisfies the qualifications set forth in 21 C.F.R. § 900.12(a)(3) performs:
- (a) Surveys in accordance with the frequency and requirements described in 21 C.F.R. § 900.12(e)(9) and which include the testing described in 21 C.F.R. § 900.12(e)(4)(iii) and (e)(5)(xi); and
  - (b) The examinations required by section 10 of this regulation.
- 4. Ensure that records of the tests required by subsection 1, the surveys required by subsection 3 and the examinations required by section 10 of this regulation are retained until the Division authorizes disposal of the records.

- Sec. 10. 1. An invasive intervention radiation machine must be examined to verify that the invasive intervention radiation machine is operating in accordance with the specifications of the manufacturer of the invasive intervention radiation machine and that the invasive intervention radiation machine satisfies the requirements of the standards set forth in 21 C.F.R. § 900.12(b) and 21 C.F.R. § 900.12(e) that would apply to the invasive intervention radiation machine if the invasive intervention radiation machine were used to perform mammography as defined in 21 C.F.R. § 900.2(aa):
- (a) Before the invasive intervention radiation machine is placed into service and at least annually thereafter;
- (b) After the invasive intervention radiation machine is disassembled and reassembled at the same or a new location; and
- (c) After a major component of the invasive intervention radiation machine is changed or repaired.
- 2. The medical physicist performing the examination shall make a written record of his or her findings and submit the record to the registrant for an invasive intervention radiation machine within 30 days after the examination.
- 3. If the registrant for an invasive intervention radiation machine does not receive the written record within the period prescribed in subsection 2, the registrant shall remove the machine from service until he or she receives the record.
- 4. If the registrant for an invasive intervention radiation machine receives a written record pursuant to subsection 2 which indicates problems with the invasive intervention radiation machine requiring correction, the registrant shall ensure that the necessary

corrective action is taken before the invasive intervention radiation machine is used to perform any examination on a patient.

- Sec. 11. A copy of the techniques chart described in 21 C.F.R. § 900.12(e)(5) must be posted by the control console or any other assembly approved by the Division of an invasive intervention radiation machine, for each examination performed on a patient.
- Sec. 12. 1. Except as otherwise provided in subsection 2, an invasive intervention radiation machine may not be used to perform screening or diagnostic mammography services.
- 2. A registrant for the invasive intervention radiation machine may use such a machine to perform screening or diagnostic mammography services if:
- (a) The registrant revokes his or her registration certificate issued pursuant to NAC 459.156 for the invasive intervention radiation machine;
- (b) The registrant applies for and receives a valid certificate of authorization issued pursuant to NRS 457.184 for the invasive intervention radiation machine; and
- (c) The invasive intervention radiation machine satisfies the requirements for a radiation machine for mammography set forth in chapters 457 of NRS and NAC.
  - **Sec. 13.** NAC 459.010 is hereby amended to read as follows:
- 459.010 As used in NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation*, unless the context otherwise requires, the words and terms defined in NAC 459.012 to 459.116, inclusive, *and sections 5 and 6 of this regulation* have the meanings ascribed to them in those sections.
  - **Sec. 14.** NAC 459.120 is hereby amended to read as follows:

- 459.120 1. The Division may, upon application or its own initiative, grant exemptions or exceptions from the requirements of NAC 459.010 to 459.950, inclusive, *and sections 5 to 12*, *inclusive, of this regulation* as it determines will not result in undue hazard to public health and safety or property.
- 2. Common and contract carriers, freight forwarders and warehousemen and the United States Postal Service are exempt from *the provisions of* NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation which correspond to the exemptions from federal regulations described in 10 C.F.R. § 30.13* to the extent that they transport or store sources of radiation in the regular course of their carriage for another or store the sources as an incident to such transportation. [Private carriers who are subject to the regulations of the United States

  Department of Transportation are exempt from NAC 459.010 to 459.950, inclusive, to the extent that they transport sources of radiation. Private carriers who are not subject to the regulations of the United States Postal Service are subject to applicable sections of NAC 459.010 to 459.950, inclusive.]
- 3. Any contractor or subcontractor of the United States Department of Energy or the Nuclear Regulatory Commission who is in one of the following categories and operating within this State is exempt from NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation* to the extent that, under his or her contract, he or she receives, possesses, uses, transfers or acquires sources of radiation:
- (a) Any prime contractor performing work for the United States Department of Energy at sites owned or controlled by the United States Government, transporting sources of radiation to or from such sites, or performing contract services during temporary interruptions of such transportation.

- (b) Any prime contractor of the United States Department of Energy performing research in, or development, manufacture, storage, testing or transportation of atomic weapons or components thereof.
- (c) Any prime contractor of the United States Department of Energy using or operating a nuclear reactor or other nuclear device in a vehicle or vessel owned by the United States Government.
- (d) Any other prime contractor or subcontractor of the United States Department of Energy or of the Nuclear Regulatory Commission when the State and the Nuclear Regulatory Commission jointly determine that:
  - (1) The exemption of the prime contractor or subcontractor is authorized by law; and
- (2) Under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to public health or safety.
  - **Sec. 15.** NAC 459.1232 is hereby amended to read as follows:
- 459.1232 1. The provisions of 10 C.F.R. Part 37 are hereby adopted by reference, subject to the following:
  - (a) The exclusion of the following definitions from 10 C.F.R. § 37.5:
    - (1) "Act";
    - (2) "Commission";
    - (3) "Government agency"; and
    - (4) "License."
  - (b) Any reference in 10 C.F.R. Part 37 to:
    - (1) "Byproduct material" shall be deemed a reference to "radioactive material."

- (2) "Commission" or "NRC" shall be deemed a reference to ["Division."] "Division" except for the use of those terms in:
- (I) 10 C.F.R. § 37.25(b), 10 C.F.R. § 37.27(a), 10 C.F.R. § 37.27(c) and 10 C.F.R. § 37.29(a); and
  - (II) The definition of "person" as set forth in 10 C.F.R. § 37.5.
- (3) "Commission or an Agreement State" shall be deemed a reference to "Division, Nuclear Regulatory Commission or an agreement state."
- (4) "Commission's regulations," "federal regulations" or "NRC regulations" shall be deemed a reference to "NAC 459.010 to 459.950, inclusive [."], and sections 5 to 12, inclusive, of this regulation."
- (5) "NRC license" shall be deemed a reference to "license issued by the Division pursuant to NAC 459.010 to 459.950, inclusive [."], and sections 5 to 12, inclusive, of this regulation."
- (6) "NRC Operations Center," "NRC Regional Office listed in § 30.6(a)(2)" or "Director, Division of Security Policy, Office of Nuclear [Material Safety and Safeguards"] Security and Incident Response" shall be deemed a reference to "the [provisions of NAC 459.134] Radiation Control Program and the contact information described in [the State of Nevada Radiological Emergency Response Plan."] NAC 459.134."
- (7) "NRC's license verification system" shall be deemed a reference to "Division, NRC's license verification system or the license issuing authority."
  - (c) The following sections of 10 C.F.R. Part 37 are not adopted by reference:
    - (1) Section 37.1;
    - (2) Section 37.3;
    - (3) Section 37.7;

- (4) Section 37.9;
- (5) Section 37.11(b);
- (6) Section 37.13;
- (7) Section 37.77(f);
- (8) Section 37.107; and
- (9) Section 37.109.
- 2. A copy of the publication that contains 10 C.F.R. Part 37 may be obtained by mail from the Superintendent of Documents, United States Government [Printing] *Publishing* Office, P.O. Box 979050, St. Louis, Missouri 63197-9000, or by toll-free telephone at (866) 512-1800, at the price of \$67, or free of charge at the Internet address [http://www.gpoaccess.gov/efr/index.html.] https://www.ecfr.gov/.
  - **Sec. 16.** NAC 459.134 is hereby amended to read as follows:
- 459.134 All communications and reports concerning the provisions of NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation* and copies of regulatory guides and applications filed under those provisions should be addressed to the Radiation Control Program, Division of Public and Behavioral Health, at the current applicable mailing address provided on the *Internet* website for the Radiation Control Program at <a href="http://health.nv.gov/heqe-Radiological.htm.">http://health.nv.gov/heqe-Radiological.htm.</a>

#### http://dpbh.nv.gov/Reg/Radiation Control Programs/.

- **Sec. 17.** NAC 459.150 is hereby amended to read as follows:
- 459.150 1. NAC 459.150 to 459.166, inclusive, *and sections 7 to 12, inclusive, of this regulation* provide for the registration of radiation machines and registration of persons who install or perform service upon radiation machines.

- 2. Except as otherwise provided in subsection 3, a radiation machine registered in this State must be maintained in the form in which it was manufactured except that modifications may be made to the radiation machine as authorized by the manufacturer of the radiation machine or the United States Food and Drug Administration.
- 3. Except as otherwise provided in paragraph (b) of subsection 5, all parts of an X-ray system must be maintained on a radiation machine registered in this State in the form in which they were manufactured except that modifications may be made to an X-ray system on such a radiation machine if prior written approval is obtained from the Division.
- 4. No person may repair, maintain or install radiation machines unless he or she is registered in conformance with the **[requirement]** requirements of NAC 459.150 to 459.166, inclusive **[.]**, and sections 7 to 12, inclusive, of this regulation.
- 5. A person who is registered with the Division to install, service or repair radiation machines shall not:
  - (a) Install:
- (1) A radiation machine in a facility for human use unless the radiation machine has been certified by the United States Food and Drug Administration for human use; or
- (2) A radiation machine that produces ionizing radiation unless he or she provides written notice to the Division before the installation; or
- (b) Make any modifications to an X-ray system on a radiation machine which affect the field size or output unless prior approval is obtained from the manufacturer, the United States Food and Drug Administration or the Division. Such approval must be in writing and must be maintained on the premises of the registrant of the radiation machine.

- 6. A person may operate a radiation machine only if there is a valid registration or the operator is registered with the Division to install, service or repair the machine.
  - **Sec. 18.** NAC 459.154 is hereby amended to read as follows:
- 459.154 1. Except as otherwise provided in subsection 2, each person who controls an unregistered, operational radiation machine, regardless of whether the radiation machine is in actual service as intended, shall apply to the Division for registration of the machine within 30 days after installing the machine.
- 2. A person who brings a portable machine into this State for a temporary use of 180 days or less in any calendar year:
- (a) Must apply to the Division for registration of the machine for a temporary use at least 3 working days before using it in this State;
- (b) Shall comply with all other applicable provisions of NAC 459.010 to 459.950, inclusive ; , and sections 5 to 12, inclusive, of this regulation;
  - (c) Shall furnish the Division with any other information it may reasonably request; and
  - (d) Shall not use the machine in this State more than 180 days per calendar year.
- 3. The application must be made on the Division's Registration Application for Radiation Machine Installation. A copy of the form may be obtained from the Division. A separate application and registration are required for each control console *or any other assembly approved by the Division* of a radiation machine.
- 4. Each application for registration of a radiation machine must contain a list of the numbers of the X-ray tubes associated with a control panel.
- 5. Each person who controls a radiation machine must designate on the application form a person where the machine is located who is responsible for protection against radiation.

- 6. Each person who seeks to engage in the business of installing radiation machines, furnishing services or repairing radiation machines in this State must apply for registration with the Division and receive a certificate of registration before furnishing any services.
- 7. A radiation machine may only be installed by a person who has obtained a registration certificate pursuant to NAC 459.156 which specifies that the person is authorized to install radiation machines. Within 10 days after installing a radiation machine, the person who installed the machine shall report the fact of the installation to the Division.
- 8. Except as otherwise provided in this subsection, each application for registration by a person to install, service or repair radiation machines must be accompanied by a nonrefundable annual fee of \$140, or the application must not be acted upon by the Division. If a payment was made in error, the Division will refund the fee collected pursuant to this subsection, after deducting an amount calculated to cover the administrative costs directly related to issuing the refund.
  - **Sec. 19.** NAC 459.160 is hereby amended to read as follows:
- 459.160 1. An application for renewal of registration must be filed in accordance with NAC 459.154.
- 2. If a registrant files an application for renewal of his or her registration accompanied by the appropriate fee at least [10] 30 days before its expiration, his or her registration does not expire until the status of his or her registration has been determined by the Division.
  - **Sec. 20.** NAC 459.161 is hereby amended to read as follows:
- 459.161 1. Except as otherwise provided in subsection 6, an application for the registration of a radiation machine submitted pursuant to NAC 459.154 must be accompanied by

a nonrefundable fee for each X-ray tube, electron source or source of ionizing radiation which is installed in the radiation machine, as follows:

- (a) Medical use, other than mammography, \$500.
- (b) Veterinary use, \$150.
- (c) Dental use, \$140.
- (d) Industrial use, \$200.
- (e) Academic use, \$150.
- (f) Accelerator, \$550.
- 2. Except as otherwise provided in subsections 3 and 6, if the Division issues a registration certificate pursuant to NAC 459.156, the registrant must, for each year the certificate is valid, submit to the Division a nonrefundable renewal fee in an amount equal to the appropriate fee set forth in subsection 1.
- 3. The renewal fee must be received by the Division not later than the date on which the registration expires. If the fee is not received by that date, the registrant shall:
- (a) Stop operating the radiation machine which does not have a valid registration on or before the date the registration expires; or
  - (b) Submit to the Division within 5 days after the registration expires:
    - (1) An application for renewal of the registration;
    - (2) A fee in an amount that is equal to the appropriate fee set forth in subsection 1; and
    - (3) A fee for late payment of \$56 per registration.
- 4. Except as otherwise provided in subsection 6, an application for the issuance of a duplicate registration certificate for a radiation machine or for the person installing, servicing or repairing radiation machines must be accompanied by a nonrefundable fee of \$25.

- 5. Any application for registration or renewal of registration which is not accompanied by the appropriate fees will not be acted upon by the Division until such fees are paid.
- [5. Except as otherwise provided in subsection 6, an application for a certificate of authorization for a radiation machine must be accompanied by a nonrefundable fee for each machine as required pursuant to NAC 457.295.]
- 6. If a payment was made in error, the Division will refund the fee collected pursuant to this section, after deducting an amount calculated to cover the administrative costs directly related to issuing the refund.
  - **Sec. 21.** NAC 459.166 is hereby amended to read as follows:
- 459.166 1. Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this State or sells, leases, transfers or disposes of a radiation machine currently registered in this State shall, within 15 days, notify the Division of:
  - (a) The name and address of each person who has received such a machine;
  - (b) The manufacturer, model and serial number of each [control]:
    - (1) Control console or any other assembly approved by the Division; and
    - (2) X-ray tube transferred, installed, disassembled or disposed of;
  - (c) The type of service performed; and
  - (d) The date of transfer, installation, disassembly or disposal of each machine.
- 2. A person shall not make, sell, lease, transfer, lend, assemble or install any radiation machine or the supplies and equipment used in connection with such a machine unless the machine and any supplies and equipment, when properly placed in operation and used, meet the applicable requirements of NAC 459.010 to 459.950, inclusive [.], and sections 5 to 12, inclusive, of this regulation.

- **Sec. 22.** NAC 459.182 is hereby amended to read as follows:
- 459.182 1. Any person is exempt from NAC 459.180 to 459.313, inclusive, to the extent that he or she receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 0.05 percent of the mixture, compound, solution or alloy.
- 2. Any person is exempt from NAC 459.180 to 459.313, inclusive, to the extent that he or she receives, possesses, uses or transfers unrefined and unprocessed ore containing source material. Except as authorized in a specific license, such a person may not refine or process such ore.
- 3. Any person is exempt from the requirements for a license set forth in NAC 459.180 to [459.313,] 459.374, inclusive, and NAC 459.780 to 459.794, inclusive, to the extent that he or she receives, possesses, uses or transfers any of the following:
  - (a) Any quantities of thorium contained in:
    - (1) Incandescent gas mantles;
    - (2) Vacuum tubes;
    - (3) Welding rods;
- (4) Electric lamps for illuminating purposes if each lamp does not contain more than 50 milligrams of thorium;
- (5) Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting if each lamp does not contain more than 2 grams of thorium;
- (6) Rare earth metals and compounds, mixtures and products containing not more than0.25 percent by weight thorium, uranium or any combination of these; or

- (7) Personnel neutron dosimeters if each dosimeter does not contain more than 50 milligrams of thorium.
  - (b) Source material contained in the following products:
- (1) Glazed ceramic tableware manufactured before August 27, 2013, if the glaze contains not more than 20 percent by weight source material;
- (2) Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before August 27, 2013, 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction; or
  - (3) Piezoelectric ceramic containing not more than 2 percent by weight source material.
  - (c) Photographic film, negatives and prints containing uranium or thorium.
- (d) Any finished product or part which is fabricated of or contains tungsten-thorium or magnesium-thorium alloys if the thorium content of the alloy does not exceed 4 percent by weight. This exemption does not authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.
- (e) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of counterweights if:
- (1) Each counterweight has been impressed with the following legend clearly legible through the plating or other covering: "DEPLETED URANIUM"; and
- (2) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED."
- → The exemption contained in this paragraph does not authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration

of any plating or other covering. The requirements specified in subparagraphs (1) and (2) need not be met by counterweights manufactured before December 31, 1969, provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend required by the provisions of [subparagraph (2)] 10 C.F.R. § 40.13(c)(5)(ii) in effect on June 30, 1969.

- (f) Natural or depleted uranium metal used as shielding in any shipping container if:
- (1) The shipping container is conspicuously and legibly impressed with the legend "CAUTION RADIOACTIVE SHIELDING URANIUM"; and
- (2) The uranium metal is encased in mild steel or an equally fire resistant metal with a wall thickness of one-eighth of an inch.
- (g) Thorium or uranium contained in or on finished optical lenses and mirrors, if each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, does not contain more than 30 percent by weight of thorium. The exemption contained in this paragraph does not authorize either:
- (1) The shaping, grinding or polishing of such lenses or mirrors or manufacturing processes other than the assembly of such lenses or mirrors into optical systems and devices without any alteration of the lenses or mirrors; or
- (2) The receipt, possession, use or transfer of uranium or thorium contained in contact lenses, in spectacles, or in eyepieces in binoculars or other optical instruments.
  - (h) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy if:
- (1) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and
  - (2) The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

- 4. The exemptions in subsection 3 do not authorize the manufacture of any of the products described.
- 5. No person may initially transfer for sale or distribution a product containing source material to persons exempt under subsection 3 or the equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a license issued under 10 C.F.R. § 40.52 to initially transfer such products for sale or distribution. Persons:
- (a) Initially distributing source material in products covered by the exemptions in subsection 3 before August 27, 2013, without specific authorization may continue such distribution through August 27, 2014. Initial distribution may also be continued until the Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.
- (b) Authorized to manufacture, process or produce those materials or products containing source material by an agreement state and persons who import finished products or parts for sale or distribution must be authorized by a license issued under 10 C.F.R. § 40.52 for distribution only and are exempt from the requirements of NAC [459.320] 459.316 to 459.374, inclusive, 459.780 to 459.794, inclusive, and paragraphs (a) and (b) of subsection 1 of NAC 459.238.
  - **Sec. 23.** NAC 459.1997 is hereby amended to read as follows:
- 459.1997 1. The provisions of 10 C.F.R. §§ 71.0(c), 71.1(a), 71.3, 71.4, 71.14(a), 71.15, 71.17, 71.21, 71.22, 71.23, 71.47, 71.83 to 71.89, inclusive, 71.91(c), 71.91(d), 71.97, 71.101(a), 71.101(b), 71.101(c), 71.101(g), 71.103(a), 71.103(b), 71.105, 71.106, 71.127 to 71.137, inclusive, and Appendix A to Part 71 are hereby adopted by reference, subject to the following:
  - (a) The exclusion of the following definitions from 10 C.F.R. § 71.4:
    - (1) "Close reflection by water";

- (2) "Licensed material";
- (3) "Optimum interspersed hydrogenous moderation";
- (4) "Spent nuclear fuel or spent fuel"; and
- (5) "State."
- (b) The substitution of the following rule references:
  - (1) "NAC 459.737" for "§ 34.31(b) of this chapter" as found in 10 C.F.R. § 71.101(g);
  - (2) "Subsection 1 of NAC 459.339" for "10 C.F.R § 20.1502";
  - (3) "NAC 459.3062" for "10 C.F.R. Part 35";
  - (4) "Subsection 6 of NAC 459.3585" for "10 C.F.R. § 20.1906(e)";
  - (5) "NAC 459.181" for "10 C.F.R. § 71.5";
- (6) "10 C.F.R. §§ 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105 and 71.127 to 71.137, inclusive," for "subpart H of this part" or "subpart H," except in 10 C.F.R. §§ 71.17(b), 71.21(b), 71.22(b) and 71.23(b);
- (7) "10 C.F.R. §§ 71.0(c), 71.1(a), 71.3, 71.4, 71.17(c)(2), 71.21(d)(2), 71.83 to 71.89, inclusive, 71.97, 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105 and 71.127 to 71.137, inclusive," for "subparts A, G and H of this part";
  - (8) "10 C.F.R. § 71.47" for "subparts E and F of this part"; and
- (9) "10 C.F.R. §§ 71.101(a), 71.101(b), 71.101(c)(1), 71.101(g), 71.105 and 71.127 to 71.137, inclusive," for "§§ 71.101 through 71.137."
  - (c) The substitution of the following terms:
    - (1) "Division" for:
- (I) "Commission" in 10 C.F.R. §§ 71.0(c), 71.17(a), 71.21(a), 71.22(a), 71.23(a) and 71.101(c)(1);

- (II) "Director, Division of [Nuclear] Security [,] *Policy*, Office of Nuclear Security and Incident Response" in 10 C.F.R. §§ 71.97(c)(1) and 71.97(f)(1);
- (III) "Director, Division of [Intergovernmental Liaison and Rulemaking,] Materials

  Safety, Security, State, and Tribal Programs, Office of [Federal and State Materials and

  Environmental Management Programs,] Nuclear Material Safety and Safeguards, U.S. Nuclear

  Regulatory Commission, Washington, D.C. 20555-0001" in 10 C.F.R. § 71.97(c)(3)(iii); and

  (IV) "NRC" in 10 C.F.R. § 71.101(f);
- (2) "The Nuclear Regulatory Commission or an agreement state" for "Commission" in 10 C.F.R. § 71.3;
  - (3) "The Governor of Nevada" for:
    - (I) "The governor of a State" in 10 C.F.R. § 71.97(a);
    - (II) "Each appropriate governor" in 10 C.F.R. § 71.97(c)(1);
    - (III) "The governor" in 10 C.F.R. § 71.97(c)(3);
    - (IV) "The governor of the State" in 10 C.F.R. § 71.97(e);
    - (V) "The governor of each State" in 10 C.F.R. § 71.97(f)(1); and
    - (VI) "A governor" in 10 C.F.R. § 71.97(e);
  - (4) "State of Nevada" for "State" in 10 C.F.R. §§ 71.97(a), 71.97(b)(2) and 71.97(d)(4);
  - (5) "The Governor of Nevada's" for:
    - (I) "The governor's" in 10 C.F.R. §§ 71.97(a), 71.97(c)(3), 71.97(e) and 71.97(f)(1);
    - (II) "Governor's" in 10 C.F.R. §§ 71.97(c)(1) and 71.97(e); and
    - (III) "Governors" in 10 C.F.R. § 71.97(c)(3)(iii);
  - (6) "Specific or general" for "NRC" in 10 C.F.R. § 71.0(c);

- (7) "The Division" for "ATTN: Document Control Desk, Director, Division of Spent Fuel [Storage and Transportation,] *Management*, Office of Nuclear Material Safety and Safeguards" in 10 C.F.R. § 71.101(c)(1);
- (8) "Each" for "Using an appropriate method listed in § 71.1(a), each" in 10 C.F.R. § 71.101(c)(1);
- (9) "The material must be contained in a Type A package meeting the requirements of 49 C.F.R. § 173.417(a)" for "The fissile material need not be contained in a package which meets the standards of subparts E and F of this part; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 C.F.R. 173.417(a)" as found in 10 C.F.R. §§ 71.22(a) and 71.23(a);
  - (10) "Licensee" for "licensee, certificate holder, and applicant for a CoC"; and
  - (11) "Licensee is" for "licensee, certificate holder, and applicant for a CoC are."
- 2. A copy of the publication that contains 10 C.F.R. Part 71 may be obtained by mail from the Superintendent of Documents, United States Government [Printing] *Publishing* Office, P.O. Box 979050, St. Louis, Missouri 63197-9000, or by toll-free telephone at (866) 512-1800, at the price of \$64, or free of charge at the Internet address [http://www.gpoaccess.gov/efr/index.html.] <a href="https://www.ecfr.gov/">https://www.ecfr.gov/</a>.
  - **Sec. 24.** NAC 459.212 is hereby amended to read as follows:
- 459.212 1. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions and federal, state and local governmental agencies to receive, possess, use and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium for research, development, educational, commercial or operational purposes in the following forms and quantities:

- (a) Not more than 1.5 kilograms (3.3 pounds) of uranium and thorium in dispersible forms, including, without limitation, gaseous, liquid and powder forms, at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use and transfer source material under this paragraph may not receive more than a total of 7 kilograms (15.4 pounds) of uranium and thorium in any 1 calendar year. Persons possessing source material in excess of these limits on August 27, 2013, may:
- (1) Continue to possess up to 7 kilograms (15.4 pounds) of uranium and thorium at any one time through August 27, 2014, or until the Division takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and
- (2) Receive up to 70 kilograms (154 pounds) of uranium or thorium in any 1 calendar year until December 31, 2014, or until the Division takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and
  - (b) Not more than one of the following:
- (1) A total of 7 kilograms (15.4 pounds) of uranium and thorium at any one time. A person authorized to possess, use and transfer source material under this subsection may not receive more than a total of 70 kilograms (154 pounds) of uranium and thorium in any 1 calendar year. A person may not alter the chemical or physical form of the source material possessed under this subsection unless it is accounted for under the limits of paragraph (a).
- (2) Seven kilograms (15.4 pounds) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kilograms (154 pounds) of uranium from drinking water during a calendar year under this subsection.

- (3) Seven kilograms (15.4 pounds) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use and transfer source material under this subsection may not receive more than a total of 70 kilograms (154 pounds) of source material in any 1 calendar year.
- 2. Any person who receives, possesses, uses or transfers source material in accordance with the general license issued in subsection 1:
- (a) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Division in a specific license.
  - (b) Shall not abandon such source material. Source material may be disposed of as follows:
- (1) A cumulative total of 0.5 kilogram (1.1 pounds) of source material in a solid, nondispersible form may be transferred each calendar year, by a person authorized to receive, possess, use and transfer source material under the general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this subparagraph is exempt from the requirements to obtain a license under this section to the extent the source material is permanently disposed. This subparagraph does not apply to any person who is in possession of source material under a specific license issued pursuant to NAC 459.180 to 459.3154, inclusive; or
  - (2) In accordance with NAC 459.359.
- (c) Is subject to the provisions of NAC 459.010 to 459.116, inclusive, *and sections 5 and 6 of this regulation*, 459.124, 459.126, 459.128, 459.134, 459.135, 459.180, 459.196, 459.198, 459.208, 459.312, 459.373 and 459.792.

- (d) Shall respond to written requests from the Division to provide information relating to the general license within 30 calendar days after the date of the request, or such other time as specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Division, in accordance with NAC 459.134, a written justification for the request.
  - (e) Shall not export such source material except in accordance with 10 C.F.R. Part 110.
- 3. Any person who receives, possesses, uses or transfers source material in accordance with subsection 1 shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Division, in accordance with NAC 459.134, about such contamination and may consult with the Division as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits set forth in NAC 459.3178.
- 4. A person who receives, possesses, uses or transfers source material pursuant to the general license issued under this section is exempt from the provisions of NAC [459.320] 459.316 to 459.374, inclusive, and 459.780 to 459.794, inclusive, to the extent that the activities are within the terms of the general license except that such person shall comply with the provisions of NAC 459.3178 and 459.359 to the extent necessary to meet the provisions of paragraph (b) of subsection 2 and subsection 3. This exemption does not apply to any person who also possesses a specific license issued pursuant to NAC 459.180 to 459.3154, inclusive.

- 5. Except as otherwise provided in this subsection, no person may initially transfer or distribute source material to persons generally licensed under paragraph (a) of subsection 1, or equivalent regulations of the Nuclear Regulatory Commission or an agreement state, unless authorized by a specific license issued in accordance with NAC [459.180 to 459.3154, inclusive,] 459.241 or equivalent provisions of the Nuclear Regulatory Commission or an agreement state. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph (a) of subsection 1 before August 27, 2013, without specific authorization may continue through August 27, 2014. Distribution may also be continued until the Division takes final action on a pending application for a license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.
- 6. A general license is also issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.
  - **Sec. 25.** NAC 459.337 is hereby amended to read as follows:
- 459.337 1. Each licensee and registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:
- (a) Are necessary for the licensee or registrant to comply with NAC 459.010 to 459.950, inclusive [;], and sections 5 to 12, inclusive, of this regulation; and
  - (b) Are necessary under the circumstances to evaluate:
    - (1) The magnitude and extent of radiation levels;
    - (2) Concentrations or quantities of residual radioactivity; and

- (3) The potential radiological hazards of the radiation levels and residual radioactivity detected.
- 2. The Division [may exempt] shall evaluate surveys of areas made by a licensee or registrant [from the requirements of] pursuant to subsection 1 [if the Division determines that the exemption will not result in] to determine if a significant risk to public health and safety [.] exists. The Division may require the licensee or registrant to make an additional survey of areas if:
  - (a) The conditions under which the previous survey was made have changed; and
- (b) The Division determines that the change in conditions described in paragraph (a) may result in a significant risk to public health and safety.
- 3. Records from surveys describing the location and amount of subsurface residual radioactivity identified at a site must be:
  - (a) Kept with records important to the decommissioning of a facility; and
  - (b) Retained in accordance with the provisions of subsection 13 of NAC 459.1955.
- 4. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated for the radiation measured at intervals not to exceed 12 months.
- 5. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the dose of radiation and that are used by licensees and registrants to comply with NAC 459.325, with other applicable provisions of NAC 459.010 to 459.950, inclusive [-], and sections 5 to 12, inclusive, of this regulation, or with conditions specified in a license or registration, must be processed and evaluated by a dosimetry processor who is

accredited by the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology for the type of radiation or radiations included in the program that most closely approximate the type of radiation for which the person wearing the dosimeter is monitored.

- 6. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of personnel monitoring equipment.
  - **Sec. 26.** NAC 459.570 is hereby amended to read as follows:
- 459.570 1. The exposure measured at the point where the center of the useful beam enters the patient must not exceed 10 roentgens (100 millisieverts) per minute, except during recording of fluoroscopic images or when provided with optional high level control.
- 2. When provided with optional high level control, the equipment must not be operable at any combination of tube potential and current which will result in an exposure rate, measured at the point where the center of the useful beam enters the patient, in excess of:
  - (a) Five roentgens (50 millisieverts) per minute if the high level control is not activated; and
- (b) Twenty roentgens (200 millisieverts) per minute if the high level control is activated and the unit was manufactured on or after May 19, 1995.
- ⇒ Special means of activation of high level controls, such as additional pressure applied continuously by the operator, will be required to avoid accidental use. A continuous signal audible to the fluoroscopist must indicate activation and use of the high level control.
- 3. Any new equipment installed after February 28, 1980, which does not incorporate an automatic exposure control, for example, an automatic brightness control or ionization chamber control, must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (50 millisieverts) per minute at the point where the

center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.

- 4. Compliance with this section is determined as follows:
- (a) If the source is below the table, exposure rate must be measured 1 centimeter above the tabletop or cradle.
- (b) If the source is above the table, the exposure rate must be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- (c) In a C-arm type of fluoroscope, the exposure rate must be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- (d) In a miniature C-arm type of fluoroscope, the exposure rate must be measured with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
- (e) In a lateral type of fluoroscope, the exposure rate must be measured at a point 15 centimeters from the centerline of the tabletop and in the direction of the X-ray source, with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it must be positioned as closely as possible to the lateral X-ray source.
- 5. Periodic measurements of the exposure rate must be made annually [or], at intervals not to exceed 12 months after the date of the last measurement, and after any maintenance of the system which might affect the exposure rate. If the equipment is provided with optional high level control, measurements of the exposure rates must be made both with and without the high level control activated.

- 6. Results of these measurements must be made available at a place where any fluoroscopist will have ready access to them while using that fluoroscope. Results of the measurements must include the maximum possible r/minute, as well as the physical factors used to determine all data, the name of the person performing the measurements and the date the measurements were performed.
- 7. Use of monitoring devices, for example, commercially available film badges, thermoluminescence dosimeters or low energy dosimeters, may be used to perform the test if the measurements are made as in subsection 8.
- 8. The measurement must be made under the conditions that satisfy the requirements of subsection 4.
  - (a) The kVp must be the peak kV that the X-ray system is capable of producing;
- (b) If determining the maximum dose rate below 5 roentgens (50 millisieverts) per minute, the high level control, if present, must not be activated;
- (c) The X-ray system that incorporates automatic exposure control, for example, automatic brightness control, must have sufficient material, for example, lead or lead equivalent, placed in the useful beam to produce the maximum radiation output of the X-ray system; and
- (d) The X-ray system that does not incorporate automatic exposure control must utilize the maximum milliamperage of the X-ray system. The material, for example, an attenuation block, must be placed in the useful beam to protect the imaging system.
- 9. The provisions of this section do not apply to an X-ray system that is used, at any time, for radiation therapy simulation.
  - Sec. 27. NAC 459.5934 is hereby amended to read as follows:

- 459.5934 1. A registrant shall ensure that a program is in place to perform spot checks on each electronic brachytherapy system:
  - (a) At the beginning of each day during which the system will be used;
  - (b) Each time the system is moved to a new room or site; and
  - (c) After the installation of an X-ray tube.
  - 2. The spot check must ensure the following components are operating properly:
- (a) The indicator lights for radiation exposure on the electronic brachytherapy system and on the control console [;] or any other assembly approved by the Division;
  - (b) The viewing and intercom systems in each facility, if applicable;
  - (c) The radiation monitors, if applicable; and
  - (d) The integrity of all cables, catheters or parts of the system that carry high voltages.
- 3. A spot check of the dosimetry of a system must include a check which indicates that the output of the X-ray source is within 3 percent of the expected value, including, as appropriate:
  - (a) Output as a function of time;
  - (b) Output as a function of a setting on a monitor chamber;
- (c) Verification of the consistency of the dose distribution to within 3 percent of that found during calibration;
- (d) Validation of the operation of methods of positioning to ensure that the treatment dose exposes the intended location within 1 millimeter; and
  - (e) Inspection of all treatment components for imperfections on the day of use.
- 4. A registrant shall retain a record of each spot check for at least 3 years. The record must include:
  - (a) The date of the spot check;

- (b) The name of the manufacturer, model number and serial number of the electronic brachytherapy system checked;
- (c) Notations which indicate the operability of radiation monitors, indicator lights for source exposure, viewing and intercom systems, applicators, source transfer tubes, transfer tube-applicator interfaces and the accuracy of source positioning, as applicable; and
  - (d) The name and signature of the person who performed the spot check.
  - **Sec. 28.** NAC 459.622 is hereby amended to read as follows:
- 459.622 1. A means must be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:
- (a) Termination of exposure must cause automatic resetting of the timer to its initial setting or to zero; and
- (b) It must not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.
- 2. A control must be incorporated into each X-ray system so an exposure can be terminated at any time except for:
  - (a) Exposure of one-half second or less; or
- (b) During serial radiography when means must be provided to permit completion of any single exposure of the series in process.
  - 3. Each X-ray control must be located so that it meets the following criteria:
- (a) For stationary X-ray systems, and mobile and portable X-ray systems used as stationary X-ray systems, the control must be permanently mounted in a protected area. The operator shall remain in the protected area during the entire exposure.

- (b) For mobile and portable X-ray systems, the exposure switch cord must be at least 6 feet long.
- (c) The X-ray control must provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.
  - 4. When an automatic exposure control is provided:
  - (a) Indication must be made on the control panel when this mode of operation is selected;
- (b) When the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to two pulses;
- (c) The minimum exposure time for all equipment other than that specified in paragraph (b) must be equal to or less than one-sixtieth of a second or a time interval required to deliver 5 mAs, whichever is greater;
- (d) Either the product of peak X-ray tube potential, current, and exposure time must be limited to not more than 60 kWs per exposure or the product of X-ray tube current and exposure time must be limited to not more than 600 mAs per exposure except when the X-ray tube potential is less than 50 kVp, in which case the product of X-ray tube current and exposure time must be limited to not more than 2000 mAs per exposure; and
- (e) A visible signal must indicate when an exposure has been terminated at the limits described in paragraph (d), and manual resetting must be required before further automatically timed exposures can be made.

- 5. With a timer setting of 0.5 seconds or less, the average exposure period (T) must be greater than or equal to five times the maximum exposure period (T max) minus the minimum exposure period (T min) when four timer tests are performed, for example, T 5 (T max-T min).
- 6. Deviation of measured technique factors from indicated values of kVp and exposure time must not exceed the limits specified for that system by its manufacturer. In the absence of the manufacturer's specifications, the deviation must not exceed 10 percent of the indicated value for kVp and 20 percent for exposure. All timers must be accurate to within  $\pm 20$  percent of the selected value.
- 7. If a fixed X-ray tube potential is within the range of 40 percent to 100 percent of the maximum rated and:
- (a) The equipment has independent selection of X-ray tube current (mA), the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings must not differ by more than 0.10 times their sum. This is  $|X1-X2| \le 0.10(X1+X2)$ , where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by not more than a factor of 2 where the mAs selector provides continuous selection.
- (b) The equipment was manufactured after May 3, 1994, and has selection of X-ray tube current-exposure time product (mAs), the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum. This is  $|X1-X2| \le 0.10(X1+X2)$ , where X1 and X2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by not more than a factor of 2 where the mAs selector provides continuous selection.

- **Sec. 29.** NAC 459.746 is hereby amended to read as follows:
- 459.746 1. A qualified expert, specifically accepted by the Division, must be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.
- 2. Each installation of a particle accelerator must be provided with such primary and secondary barriers as are necessary for compliance with NAC 459.325 and 459.335.
- 3. Instrumentation, readouts and controls on the particle accelerator control console *or any other assembly approved by the Division* must be clearly identified and easily discernible.
- 4. All entrances into a target room or other area of high radiation must be provided with interlocks that shut down the machine when any entrance is penetrated.
- 5. After an interlock system has been tripped, it must be possible to resume operation of the accelerator only by manually resetting controls first at the position where the interlock has been tripped and last at the main control console : or any other assembly approved by the Division.
- 6. Each safety interlock must be on a circuit which allows its operation independently of all other safety interlocks.
- 7. All safety interlocks must be fail safe, that is, designed so that any defect or component failure in the interlock system prevents operation of the accelerator.
- 8. A scram button or other emergency power cutoff switch must be located and easily identifiable in all designated areas of high radiation. Such a cutoff switch must include a manual reset so that the accelerator cannot be restarted from the accelerator control console *or any other assembly approved by the Division* without resetting the cutoff switch.
  - **Sec. 30.** NAC 459.748 is hereby amended to read as follows:

- 459.748 1. All locations designated as areas of high radiation and all entrances to those locations must be equipped with easily observable flashing or rotating warning lights that operate when, but only when, radiation is being produced.
- 2. Except in facilities designed for human exposure, each area of high radiation must have an audible warning device which is activated for 15 seconds before the creation of high radiation within the area. The warning devices must be clearly audible in all high radiation areas and all radiation areas.
- 3. Entrances and pathways leading to high radiation areas must be identified in accordance with NAC 459.355.
  - 4. Particle accelerators, when not in operation, must be secured to prevent unauthorized use.
- 5. The safety interlock system must not be used to turn off the accelerator beam except in an emergency.
- 6. All safety and warning devices, including interlocks, must be checked for proper operability at intervals of not more than 3 months. Results of the checks must be maintained at the accelerator facility for inspection by the Division.
- 7. Diagrams of the electrical circuit of the accelerator and associated interlock systems must be kept current and maintained for inspection by the Division and must be available to the operator at each accelerator facility.
- 8. If it is necessary to bypass a safety interlock or interlocks intentionally, the bypass must be:
  - (a) Authorized by the radiation safety committee or radiation safety officer;
- (b) Recorded in a permanent log and a notice posted at the accelerator control console [;] or any other assembly approved by the Division; and

- (c) Terminated as soon as possible.
- 9. A copy of the current operating and the emergency procedures must be maintained at the accelerator control panel.
  - **Sec. 31.** NAC 459.8231 is hereby amended to read as follows:
- 459.8231 1. A waste generator, waste collector or waste processor who transports or offers for transportation low-level radioactive waste intended for ultimate disposal at a licensed land disposal facility for low-level radioactive waste must, except as otherwise provided in subsection 2, prepare a manifest that includes the information requested on NRC Forms 540, 540A, 541 and 542, as applicable. NRC Forms 540 and 540A must be completed by the waste generator, waste collector or waste processor and must accompany the shipment. Upon agreement between the waste generator, waste collector or waste processor and the consignee, NRC Forms 541, 541A, 542 and 542A may be completed, transmitted and stored in electronic media with the capability of producing legible, accurate and complete records of the forms in the format of a uniform manifest.
  - 2. A licensee is not required to comply with subsection 1 if the licensee ships:
- (a) Low-level waste for processing and expects return of the waste before it is disposed of at a licensed land disposal facility;
  - (b) Low-level waste that is being returned to the licensee who is the generator; or
- (c) Material that is contaminated with radioactivity to a waste processor and the waste becomes the residual waste of the waste processor.
- 3. A licensee who ships the radioactive waste shall provide the following information on the uniform manifest for each disposal container in the shipment:
  - (a) The name, address and telephone number of the licensee shipping the waste;

- (b) A declaration of whether the licensee is acting as a waste generator, waste collector, waste processor or any combination thereof for the shipment;
- (c) The name, address, telephone number and Environmental Protection Agency identification number of the carrier transporting the waste;
  - (d) The date of the shipment;
  - (e) The total number of packages and containers;
  - (f) The total volume and weight of the shipment;
  - (g) The total radionuclide activity in the shipment;
- (h) The identity and activity of each of the radionuclides contained in the shipment, including, without limitation, the activity of any H-3, C-14, Tc-99 and I-129 contained in the shipment;
- (i) The total masses of U-233, U-235 and plutonium in the material shipped, including in any special nuclear material;
- (j) The total mass of uranium and thorium in the material shipped, including in any source material;
- (k) The alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;
- (l) A physical description of the disposal container, including, without limitation, the name of the manufacturer and model of any high integrity container;
  - (m) The volume displaced by the disposal container;
  - (n) The gross weight of the disposal container and the waste contained therein;
- (o) For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

- (p) A physical and chemical description of the waste;
- (q) The total percentage by weight of the chelating agent for any waste containing more than0.1 percent by weight of a chelating agent and the name of the principal chelating agent;
  - (r) The approximate volume of waste within the container;
- (s) The sorbing media or solidification media, if any, and the identity of the vendor and name of the brand of any solidification media;
- (t) For discrete waste types, including, without limitation, activated materials, contaminated equipment, mechanical filters, sealed sources and devices and wastes in solidification media or stabilization media, the identities and activities of individual radionuclides associated with or contained in the waste types;
  - (u) The total radioactivity within each container;
- (v) For waste that is consigned to a disposal facility, the classification of the waste as set forth in NAC 459.8265; and
- (w) The name of any waste that does not meet the structural stability requirements as set forth in NAC 459.8305.
- 4. A licensee who ships radioactive waste that is delivered without a disposal container must provide the following information on the manifest:
  - (a) The approximate volume and weight of the waste;
  - (b) A physical and chemical description of the waste;
- (c) The total percentage by weight of the chelating agent for any waste containing more than 0.1 percent by weight of a chelating agent and the name of the principal chelating agent;
  - (d) For waste that is consigned to a disposal facility:
    - (1) The classification of the waste as set forth in NAC 459.8265; and

- (2) The maximum radiation levels at the surface of the waste;
- (e) The name of any waste that does not meet the structural stability requirements as set forth in NAC 459.8305; and
- (f) The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235 and plutonium in the special nuclear material and the masses of uranium and thorium in the source material.
- 5. A licensee who ships disposal containers of mixtures of waste originating from different waste generators or mixtures of waste shipped without a container for which portions of the mixture within the shipment originate from different waste generators shall provide the following information on the manifest:
- (a) For homogeneous mixtures of waste, including, without limitation, ash from an incinerator, the waste description applicable to the mixture and the volume of the waste attributed to each waste generator.
- (b) For heterogeneous mixtures of waste, including, without limitation, the combined products from a large compactor, the identification of each waste generator contributing waste to the disposal container.
- (c) For discrete waste types, including, without limitation, activated materials, contaminated equipment, mechanical filters, sealed sources and devices, and wastes in solidification media or stabilization media, the identities and activities of individual radionuclides contained in the waste types.
  - (d) For each waste generator:
    - (1) The volume of waste within the disposal container;

- (2) A physical and chemical description of the waste, including, without limitation, the solidification media, if any;
- (3) The total percentage by weight of the chelating agent for any disposal container containing more than 0.1 percent by weight of a chelating agent and the name of the principal chelating agent;
- (4) The sorbing media or solidification media, if any, and the identity of the vendor and name of the brand of any solidification media if the media is claimed to meet stability requirements as set forth in NAC 459.8305; and
- (5) The identities and activities of any radionuclides contained in the waste, the masses of U-233, U-235 and plutonium in special nuclear material and the masses of uranium and thorium in source material in the waste.
- 6. A licensee who ships radioactive waste shall ensure that an authorized representative certifies, by signing and dating the shipment manifest, that the materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the United States Department of Transportation and the Division. By signing the certification, a waste collector certifies that the collected waste has not been tampered with in any manner that would invalidate the certification of the authorized representative of the licensee.
- 7. A licensee who ships radioactive waste shall provide on the required Environmental Protection Agency forms any information regarding hazardous, medical or other waste that is required to comply with Environmental Protection Agency regulations, as codified in 40 C.F.R. Parts 260, 261 and 263, as those provisions existed on January 26, 1999. The required

Environmental Protection Agency forms must accompany the uniform manifest required by this section.

- 8. Copies of the manifests required by this section may be legible carbon copies, photocopies or computer printouts that reproduce the data in the format of the uniform manifest. NRC Forms 540, 540A, 541, 541A, 542 and 542A and their instructions may be obtained at no charge *by mail* from the Information and Records Management Branch, Office of [Information Resources Management,] *the Chief Information Officer*, U.S. Nuclear Regulatory Commission, Washington, D.C. [20555,] 20555-0001, or by toll-free telephone [(301) 415-7232.] at (800) 397-4209, or at the Internet address <a href="https://www.nrc.gov/reading-rm/doc-collections/forms/">https://www.nrc.gov/reading-rm/doc-collections/forms/</a>.
  - 9. As used in this section:
- (a) "EPA identification number" means the number received pursuant to 40 C.F.R. Part 263, as those provisions existed on January 26, 1999.
- (b) "High integrity container" means a container used to meet the structural stability requirements of NAC 459.830 and the United States Department of Transportation requirements for shipping a package that contains a type A quantity of radioactive waste.
- (c) "Waste description" means the physical, chemical and radiological description of the waste that is required on NRC Form 541.
  - **Sec. 32.** NAC 459.910 is hereby amended to read as follows:

459.910 A licensee:

- 1. Shall carry out his or her own written program for ensuring the quality of the packaging of the radioactive waste and radioactive material.
  - 2. Shall package the radioactive waste and radioactive material in accordance with:

- (a) The regulations of the Secretary of Transportation concerning the transportation of hazardous materials in 49 C.F.R. Parts 171 to 177, inclusive. The State Board of Health hereby incorporates those regulations by reference. Those regulations are contained in one volume of the Code of Federal Regulations and may be obtained by mail from the Superintendent of Documents, U.S. Government [Printing] Publishing Office, P.O. Box 979050, St. Louis, Missouri 63197-9000, or by toll-free telephone at (866) 512-1800, at a price of \$75, or free of charge at the Internet address [http://www.gpoaccess.gov/cfr/index.html.] https://www.ecfr.gov/.
- (b) The regulations of the Nuclear Regulatory Commission concerning the packaging and transport of radioactive material *which are set forth* in 10 C.F.R. Part 71 [. The State Board of Health hereby incorporates those regulations by reference. Those regulations may be obtained by mail from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 979050, St. Louis, Missouri 63197-9000, or by toll-free telephone at (866) 512-1800, at a price of \$64, or free of charge at the Internet address http://www.gpoaccess.gov/cfr/index.html.] *and which are adopted by reference pursuant to NAC 459.1997*.
- 3. May ship only solid radioactive waste to the state-owned disposal area. Any liquid radioactive waste must, before shipment, be solidified by a method, other than by using urea formaldehyde, which will ensure that there will not be any liquid in the shipping containers upon their arrival at the disposal area.
  - 4. Shall not ship solid waste contaminated with radium 226 to the state-owned disposal area.
  - **Sec. 33.** NAC 459.949 is hereby amended to read as follows:
- 459.949 1. If an inspection, evaluation or investigation reveals that a person is in violation of NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation*, or any provision of chapter 459 of NRS, the Division may issue a notice of violation.

- 2. Except as otherwise provided in subsection 4, the Division may impose an administrative fine as provided in subsection 3 after sending the notice of violation to the violator by certified mail or personal service. The notice of violation must include a reference to the section of the statute, regulation, order or condition of a license violated, a concise statement of the facts alleged to constitute the violation, a statement of the amount of the administrative fine to be imposed and a statement of the violator's right to a hearing. The violator has [20] 10 business days after receipt of the notice within which to deliver to the Division a written request for a hearing. After the hearing, if requested, and upon a finding that a violation has occurred, the Administrator of the Division may issue a final order and assess the amount of the fine. If no hearing is requested, the notice becomes a final order upon the expiration of the [20-day] 10-day period. Payment of the penalty is due when a final order is issued or when the notice becomes a final order. The authority to levy an administrative fine is in addition to all other provisions for enforcement of NRS 459.010 to 459.290, inclusive, or NAC 459.010 to 459.950, inclusive, and sections 5 to 12, inclusive, of this regulation, and the payment of the administrative fine does not affect the availability of any other provision for enforcement in connection with the violation for which the penalty is levied.
- 3. The Division may, after providing a notice of violation as described in subsection 2, impose an administrative fine:
- (a) Except as otherwise provided in paragraphs (b), (c) and (d), of not more than \$2,000 per day for each violation of NAC 459.010 to 459.950, inclusive, *and sections 5 to 12, inclusive, of this regulation*, or any provision of chapter 459 of NRS, or for a violation of any regulation or order, or any term, condition, or limitation of any license issued pursuant to those provisions.

- (b) Of not more than \$5,000 per day for each violation of a provision described in paragraph(a) that the Division determines is necessary to protect health and minimize danger to life or property.
- (c) In the amount of \$500 for the failure to satisfy the requirement of notifying the Division within the period specified in paragraph (b) of subsection 1 of NAC 459.210.
- (d) In an amount equal to the fee required for the proposed activity if the person fails to receive written permission from the Division, as required pursuant to paragraph (b) of subsection 1 of NAC 459.210, to proceed with the proposed activity before engaging in the proposed activity.
- 4. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the Division may not impose an administrative fine against a licensee or registrant pursuant to this section unless prior to the institution of proceedings pursuant to this section:
- (a) The Division provides written notice to the licensee or registrant of the facts or conduct which may warrant the imposition of the administrative fine;
- (b) The licensee or registrant has been given an opportunity to demonstrate or achieve compliance with all lawful requirements; and
- (c) The licensee or registrant failed to achieve compliance within 30 days after receipt of the written notice or a time period prescribed by the Division as necessary to protect the public health, interest or safety.
- 5. The Division may recover actual damages which result from a violation, in addition to the administrative fine provided in this section. The damages may include, without limitation, expenses incurred by the Division in removing, correcting or terminating any adverse effects

which resulted from the violation and compensation for any damages incurred as a result of the violation.

6. The Division may reduce the administrative fine if there is evidence that the person has initiated, in good faith, comprehensive corrective measures or training relating to radiation safety and preparedness, over and above that required as a response to the violation, valued at least 1.5 times the amount of the administrative fine imposed.

### **NOTICE OF PUBLIC HEARING**

Intent to Adopt Regulations (LCB File No. R021-18RP3)

NOTICE IS HEREBY GIVEN that the State Board of Health will hold a public hearing to consider amendments to Chapter 457 of Nevada Administrative Code (NAC), Cancer and Chapter 459 of Nevada Administrative Code, Hazardous Materials. This public hearing is to be held in conjunction with the State Board of Health meeting on December 6, 2019. The NAC 457 and NAC 459 regulation changes will be heard in the order placed on the State Board of Health agenda.

The State Board of Health will be conducted via videoconference beginning at 9:00 a.m. on Friday, December 6, 2019 at the following locations:

Division of Public and Behavioral Health	Grant Sawyer Building
4150 Technology Way Room 303	555 E. Washington Ave. Room 5100
Carson City, NV 89076	Las Vegas, NV 89101

The proposed addition/change of regulations to NAC 457 and NAC 459 in LCB File No. R021-18RP3 include provisions for:

- The proposed amendment to (NAC 457.295) Section 1 of this regulation increases the fee for the issuance or renewal of a mammographer's certificate from \$88 to \$200.
- Existing regulations require each facility for mammography that has a digital mammography machine to be capable of printing or providing hard copies of images to certain persons. The proposed amendment to (NAC 457.312) Section 2 of this regulation provides the alternative of being capable of providing images in any other manner approved by the Division.
- Existing law requires the owner, lessee or other person responsible for a radiation machine for mammography that was used to perform mammography to provide to a patient who undergoes mammography a certain statement and a notice concerning the patient's breast density. (NRS 457.1857) Existing regulations require such owner, lessee or other person to provide a similar notice concerning the patient's breast density. The proposed amendment to (NAC 457.313) Section 3 of this regulation removes the requirement to provide a notice concerning the patient's breast density from existing regulations because the requirement already exists in existing law.
- Sections 5-12 of this regulation set forth requirements for the operation of invasive intervention radiation machines that are used to perform federally exempt radiography.
- Existing regulations provide various requirements concerning or involving the control console of radiation machines, X-ray machines and particle accelerators. (NAC 459.154, 459.166, 459.5934, 459.746, 459.748) Sections 11, 18, 21, 27, 29 and 30 of this regulation expand the scope of existing regulations to include such control consoles or

- any other assembly approved by the Division of Public and Behavioral Health of the Department of Health and Human Services.
- Section 14 of this regulation revises provisions relating to exemptions from existing regulations governing the control of radiation for certain carriers with regard to transporting and storing sources of radiation in the regular course of carriage for another or storage incident thereto.
- Section 19 of this regulation revises the time limit before which a registrant is required to file his or her application for renewal of a registration certificate for a radiation machine or to install, service or repair radiation machines and pay the appropriate fee to avoid expiration of the registration certificate while the status of the registration certificate is pending with the Division.
- Section 20 of this regulation authorizes the Division to charge \$25 for a duplicate registration certificate for a radiation machine or for the person installing, servicing or repairing radiation machines.
- Section 22 of this regulation revises the requirements for a license for radioactive material from which certain quantities of source material are exempt.
- Sections 15, 23 and 32 of this regulation revise provisions which adopt by reference certain federal regulations.
- Section 24 of this regulation makes certain changes to the provisions relating to certain general licenses.
- Existing regulations require each licensee and registrant to make or cause to be made surveys of areas. Existing regulations authorize the Division of Public and Behavioral Health of the Department of Health and Human Services to exempt a licensee or registrant from making such surveys of areas if the Division determines that the exemption will not result in a significant risk to public health and safety. (NAC 459.337) Section 25 of this regulation requires the Division to evaluate the survey of areas made by a licensee or registrant to determine if a significant risk to public health or safety exists. Section 25 additionally authorizes the Division to require the licensee or registrant to make an additional survey of areas if: (1) the conditions under which the previous survey was made have changed; and (2) the Division determines that such a change may result in significant risk to public health and safety.
- Section 26 of this regulation: (1) revises the requirement relating to the periodic measurements of the exposure rate limits for fluoroscopic X-ray systems; and (2) exempts such an X-ray system from certain requirements if the X-ray system is used, at any time, for radiation therapy simulation.
- Section 31 of this regulation makes a technical change.
- Existing regulations set forth the time limit for a person to file an appeal with a hearing
  officer to contest proposed disciplinary action by the Division. Specifically, existing
  regulations require a request for an appeal to be received by the Administrator within 10
  business days after the date on which the appellant received notice of the proposed
  disciplinary action. (NAC 439.346) Section 33 of this regulation makes conforming
  changes.

- 1. Anticipated effects on the business which NAC 457 and NAC 459 regulates:
  - A. *Adverse effects*: The agency concludes the proposed regulations will produce a negligible impact on small businesses.
  - B. *Beneficial:* Clearly defines what is expected of the regulated community. Protects the public from unnecessary exposure to harmful ionizing radiation. Amends and modifies existing language to make regulations more clear, current and compatible with the intent and scope of the Radiation Control Program.
  - C. *Immediate:* The stated adverse and beneficial effects would be immediate impacts as soon as the proposed regulations become effective.
  - D. *Long-term:* The long-term impacts would be the same as the immediate impacts as it is not be expected that the impacts would go away.
- 2. Anticipated effects on the public:
  - A. Adverse: None anticipated.
  - B. Beneficial: Increased public health and safety.
  - C. *Immediate*: Increased public health and safety.
  - D. Long-term: Increased public health and safety.
- 3. There is no estimated cost to the Division of Public and Behavioral Health for enforcement of the proposed regulations. Enforcement of the proposed regulations will be incorporated into current administrative, registration, licensing and inspection processes.
- 4. The amendment to NAC 457.295 Section 1 of this regulation increases the fee for the issuance or renewal of a mammographer's certificate from \$88 to \$200.
- 5. The proposed regulations do not overlap or duplicate any other Nevada state regulations.
- 6. Per NRS 233B.0608(3), The Division of Public and Behavioral Health prepared and distributed a Small Business Impact Questionnaire (SBIQ) to all licensee's and registrants of the Radiation Control Program. The responses received were analyzed and used to generate the Small Business Impact Statement (SBIS) which was approved by the Administrator on September 9, 2019.
- 7. Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary, Lisa Sherych, to be received no later than Friday, November 15, 2019 at the following address:

Secretary, State Board of Health Division of Public and Behavioral Health 4150 Technology Way, Suite 300 Carson City, NV 89706 Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

A copy of the notice and proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health 675 Fairview Drive, Suite 218

Carson City, NV 89701-5629

Division of Public and Behavioral Health 4220 S. Maryland Parkway, Bldg. D. Suite 810

Las Vegas, NV 89119

Nevada State Library and Archives 100 N. Stewart Street Carson City, NV 89701

Copies may be obtained in person, by mail, or by calling the Radiation Control Program at (775) 687-7550 in Carson City.

A copy of the regulations and this notice can also be found on-line by going to:

http://dpbh.nv.gov/Reg/RPM/Radiation\_Producing\_Machines\_-\_Home/ http://dpbh.nv.gov/Reg/RAM/Radioactive Material Program (RAM) - Home/

https://www.leg.state.nv.us/Register/2018Register/R021-18RP3.pdf (Regulations Only)

https://www.leg.state.nv.us/App/Notice/A/

Copies may also be obtained from any of the public libraries listed below:

**Humboldt County Library** Carson City Library

900 North Roop Street 85 East 5<sup>th</sup> Street

Carson City, NV 89702 Winnemucca, NV 89445-3095

Clark County District Library Lincoln County Library

833 Las Vegas Boulevard 93 Maine Street

North Las Vegas, NV 89101 Pioche, NV 89043-0330

Mineral County Library Elko County Library

110 1st Street 720 Court Street

Elko, NV 89801 Hawthorne, NV 89415-1390

Eureka Branch Library Pershing County Library 1125 Central Avenue 210 South Monroe Street Lovelock, NV 89419-0781 Eureka, NV 89316-0283

Tonopah Public Library 167 Central Street Tonopah, NV 89049-0449

White Pine County Library 950 Campton Street Ely, NV 89301-1965

Churchill County Library 553 South Maine Street Fallon, NV 89406

Douglas County Library 1625 Library Lane Minden, NV 89423

Esmeralda County Library Corner of Crook and 4<sup>th</sup> street Goldfield, NV 89013-0484

Henderson District Public Library 280 S. Green Valley Pkwy Henderson, NV 89102 Lander County Library 625 South Broad Street Battle Mountain, NV 89820-0141

Lyon County Library 20 Nevin Way Yerington, NV 89447-2399

Pahrump Library District 701 East Street Pahrump, NV 89041-0578

Storey County Library 95 South R Street Virginia City, NV 89440-0014

Washoe County Library 301 South Center Street Reno, NV 89505-2151

Per NRS 233B.064(2), upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

# NOTICE OF PUBLIC WORKSHOP

NOTICE IS HEREBY GIVEN; the Nevada Division of Public and Behavioral Health will hold a public workshop to consider amendments to Nevada Administrative Code (NAC) Chapter 457 and (NAC) Chapter 459 in LCB File No. R021-18RP3.

The workshop will be conducted via videoconference beginning at 8:00 AM on October 28, 2019, at the following locations:

Division of Public and Behavioral Health	Division of Public and Behavioral Health
4150 Technology Way Room 303	2080 East Flamingo Road, Suite 319
Carson City, Nevada 89706	Las Vegas, Nevada 89119

Teleconference 1-877-810-9415 Access code: 3054502

The workshop will be conducted in accordance with NRS 241.020, Nevada's Open Meeting Law.

#### **AGENDA**

- 1. Introduction of workshop process
- 2. Public comment on proposed amendments to Nevada Administrative Code Chapter 457 and 459 in LCB File No. R021-18RP3.
- 3. Public Comment.

The proposed changes will revise Chapter 457 of the Nevada Administrative Code and NAC 459 and is being proposed in accordance of regulations in LCB File No. R021-18RP3.

The proposed addition/change of regulations will provide for:

- NAC 457 Operation of Radiation Machine for Mammography. Increasing the fee for a mammographer's certificate and establishing a late payment fee; revising certain requirements for digital mammography machines; removing the requirement to provide a notice concerning a patient's breast density from existing regulations;
- NAC 459 Radiation Control. Prescribing the requirements for the operation of invasive intervention radiation machines that are used to perform radiography which is exempt from the requirements of the federal regulations adopted pursuant to the Mammography Quality Standards Act of 1992, as amended; prescribing the qualifications for persons who operate invasive intervention radiation machines to perform such federally exempt radiography; prescribing the fee for obtaining a duplicate registration certificate for a radiation machine or for a person installing, servicing or repairing radiation machines; revising provisions governing a license or registration authorizing the possession and use of radioactive materials; revising provisions governing surveys of areas; revising requirements concerning X-ray systems; specifying requirements concerning linearity for certain devices; and providing other matters properly relating thereto.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence may submit the material to Adrian Howe, Radiation Control Manager, at the following address:

Division of Public and Behavioral Health Radiation Control Program 675 Fairview Drive, Suite 218 Carson City, NV 89701-5629 FAX (775) 687-7552

Members of the public who require special accommodations or assistance at the workshops are required to notify Adrian Howe, Radiation Control Program Manager, in writing at the Division of Public and Behavioral Health, 675 Fairview Drive, Suite 218, Carson City, NV 89701-5629 or by calling (775) 775-7550 no later than October 22, 2019.

A copy of the notice and the proposed regulations are on file for inspection and/or may be copied at the following locations during normal business hours:

Division of Public and Behavioral Health 675 Fairview Drive, Suite 218 Carson City, NV 89701-5629 Division of Public and Behavioral Health 4220 S. Maryland Parkway, Bldg. D, Ste. 810 Las Vegas, NV 89119

Nevada State Library and Archives 100 Stewart Street Carson City, NV 89701

A copy of the regulations and workshop information can also be found on-line by going to: Nevada State Division of Public and Behavioral Health Radiation Control Program:

http://dpbh.nv.gov/Reg/RPM/Radiation\_Producing\_Machines\_-\_Home/

Nevada Legislature Website: <a href="https://www.leg.state.nv.us/App/Notice/A/">https://www.leg.state.nv.us/App/Notice/A/</a>

A copy of this notice has been posted at the following locations:

- 1. Division of Public and Behavioral Health, 4150 Technology Way, First Floor Lobby, Carson City
- 2. Nevada State Library and Archives, 100 Stewart Street, Carson City
- 3. Legislative Building, 401 S. Carson Street, Carson City
- 4. Grant Sawyer Building, 555 E. Washington Avenue, Las Vegas
- 5. Washoe County District Health Department, 9th and Wells, Reno

Copies may be obtained in person, by mail, or by calling (775) 687-7550.

Copies may also be obtained from any of the public libraries listed below:

Carson City Library 900 Roop Street Carson City, NV 89702 Churchill County Library 553 South Main Street Fallon, NV 89406 Clark County District Library 833 Las Vegas Boulevard North Las Vegas, NV 89101 Douglas County Library 1625 Library Lane Minden, NV 89423

Elko County Library 720 Court Street Elko, NV 89801 Esmeralda County Library Comer of Crook and 4th Street Goldfield, NV 89013-0484

Eureka Branch Library 210 South Monroe Street Eureka, NV 89316-0283 Henderson District Public Library 280 South Water Street Henderson, NV 89105

Humboldt County Library 85 East 5th Street Lander County Library 625 South Broad Street

Winnemucca, NV 89445-3095

Battle Mountain, NV 89820-0141

Lincoln County Library 93 Maine Street

Lyon County Library 20 Nevin Way

Pioche, NV 89043-0330

Yerington, NV 89447-2399

Mineral County Library

Pahrump Library District 701 East Street

110 1st Street Hawthorne, NV 89415-1390

Pahrump, NV 89041-0578

Pershing County Library 1125 Central Avenue Lovelock, NV 89419-0781 Storey County Library 95 South R Street Virginia City, NV 89440-0014

Tonopah Public Library 167 Central Street Tonopah, NV 89049-0449 Washoe County Library

White Pine County Library

301 South Center Street Reno, NV 89505-2151

950 Campton Street Ely, NV 89301-1965

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

#### SMALL BUSINESS IMPACT STATEMENT 2019

# PROPOSED AMENDMENTS TO NAC Chapters 459 and 457, pertaining to LCB File No. R021-18.

The Division of Public and Behavioral Health (DPBH) has determined that the proposed amendments should not have any adverse effect upon a small business or negatively impact the formation, operation or expansion of a small business in Nevada.

A small business is defined in Nevada Revised Statutes NRS 233B as a "business conducted for profit which employs fewer than 150 full-time or part-time employees." This small business impact statement is made pursuant to NRS 233B.0608 (3) and complies with the requirements of NRS 233B.0609. As required by NRS 233B.0608(3), this statement identifies the methods used by the agency in determining the impact of the proposed regulation on a small business in sections 1, 2, 3, and 4 below and provides the reasons for the conclusions of the agency in section 8 below followed by the certification by the person responsible for the agency.

## **Background**

A REGULATION relating to health; increasing the fee for a mammographer's certificate and establishing a late payment fee; revising certain requirements for digital mammography machines; removing the requirement to provide a notice concerning a patient's breast density from existing regulations; prescribing the requirements for the operation of invasive intervention radiation machines that are used to perform radiography which is exempt from the requirements of the federal regulations adopted pursuant to the Mammography Quality Standards Act of 1992, as amended; prescribing the qualifications for persons who operate invasive intervention radiation machines to perform such federally exempt radiography; prescribing the fee for obtaining a duplicate registration certificate for a radiation machine or for a person installing, servicing or repairing radiation machines; revising provisions governing a license or registration authorizing the possession and use of radioactive materials; revising provisions governing surveys of areas; revising requirements concerning X-ray systems; specifying requirements concerning linearity for certain devices; and providing other matters properly relating thereto.

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), the Division of Public and Behavioral Health has requested input from stakeholders, small businesses, registrants and licensees that are likely to be affected by the proposed regulations.

A Small Business Impact Questionnaire was sent to approximately 4810 licensees and registrants of the Radiation Control Program along with a link to the proposed regulation changes, on August 22, 2019. The questions on the questionnaire were:

- 1) How many employees are currently employed by your business?
- 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?

## **Summary of Response**

# Summary of Comments Received (126 responses were received out of 4810 small business impact questionnaires distributed)

Will a specific regulation have an adverse economic effect upon your business?	Will the regulation(s) have any beneficial effect upon your business?	Do you anticipate any indirect adverse effects upon your business?	Do you anticipate any indirect beneficial effects upon your business?
Yes - 6	Yes - 1	Yes-4	Yes – 1
No – 73	No – 78	No – 73	No – 75
Unknown – 47	Unknown – 47	Unknown – 49	Unknown – 50

Number of Respondents out of 4810	Adverse economic effect?	Beneficial effect?	Indirect adverse effects?	Indirect beneficial effects?
126	6	1	4	1

#### 2) Describe the manner in which the analysis was conducted.

The Division of Public and Behavioral Health prepared and distributed a Small Business Impact Questionnaire to all licensees and registrants of the Radiation Control Program. The responses received were analyzed using a spreadsheet formatted to quantify total responses and comments. A Public Workshop will be held on October 28, 2019 allowing for further input by the public and regulated community regarding the proposed regulations and how they will impact Small Businesses. These comments will be taken into consideration for possible revisions to the regulations to reduce the economic impact on facilities. Fees structure was discussed with LCB to be more consistent with future regulations. Modifications to the proposed regulations have been made in consideration of this input. The proposed regulations were reviewed through three revisions with LCB to ensure the terminology and fee structure used is appropriate.

3) 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.

There is no estimated economic effect of the proposed regulations on small business.

4) Provide a description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

A thorough review was conducted regarding increasing the fees which were closely tailored to the program expenses to minimize the impact. DPBH kept the fees at a minimal level by using efficiencies in the administration of the program including program integration with future licensing requirements.

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

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

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

The total annual amount of fees expected is \$17,933.00. This amount reflects an increase of \$10,760.00 annually over the current fees of \$7,173.00 annually. The funds will be used to provide services for the administrative review of mammographer certificate applications and the issuance of mammographer certificates.

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

There are no duplicative or more stringent provisions than federal, state or local standards.

8) Provide a summary of the reasons for the conclusions of the agency regarding the impact of a regulation on small businesses.

The agency concludes the proposed regulations will produce a negligible impact on small businesses. The fee increases will cover law mandated fees as well as material and administrative costs associated with processing mammography certificates, their corrections and other amendments as required. Overall, small businesses in the State of Nevada appear not to be impacted by the proposed regulations.

Any other persons interested in obtaining a copy of the summary may e-mail, call, or mail in a request to Glen Gimenez at the Division of Public and Behavioral Health at:

## DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Bureau of Health Protection and Preparedness Radiation Control Program 675 Fairview Drive, Suite 218 Carson City, Nevada 89701-5629

Attn: Glen Gimenez, Radiation Control Supervisor Phone: (775) 687-7542

Email: glgimenez@health.nv.gov

# **Certification by Person Responsible for the Agency**

I, Lisa Sherych, Administrator of the Division of Public and Behavioral Health certify to the best of my knowledge or belief, a concerted effort was made to determine the impact of the proposed regulation on small businesses and the information contained in this statement was prepared properly and is accurate

Signature Shuph \_Date: \_\_\_\_\_11/4/2019



November 15, 2019

Secretary, State Board of Health Division of Public and Behavioral Health 4150 Technology Way, Suite 300 Carson City, NV 89706

#### Dear Board Member:

I am strongly opposed to the approval of the following proposed 459 NAC regulations as referenced in "LCB Draft of Third Revised Proposed Regulation R021-18". Adopting the following regulations as proposed will result in adverse effects (on patient care) and a decrease in public health and safety, contrary to the declared anticipated effects.

Section 9 (2)(c) states: "If necessary corrective action is taken, the action is taken before the radiation machine is used to perform any examination on a patient."

Section 10 (4) states: If the registrant for an invasive intervention radiation machine receives a written record pursuant to subsection 2 which indicates problems with the invasive intervention radiation machine requiring correction, the registrant shall ensure that the necessary corrective action is taken before the invasive intervention radiation machine is used to perform any examination on a patient."

These sections do not differentiate minor corrective actions, such as those needed to optimize machine performance, from major corrective actions that would have important consequences to patient dose. Requiring corrective action, regardless of ramification to the patient, prior to any further patient examinations will result in adverse effects (on patient care) and a decrease in public health and safety for the following reasons:

- Potential cancer patients will need to be rescheduled days or even a weeks later
- Many facilities only possess one interventional machine rendering accommodation of patients on another unit impossible
- Overall benefit far outweighs the risk, which in most cases is nonexistent in noncompliance issues
  - For example, if the radiation to light alignment exceeds the 2% SID compliance requirement proceeding with the exam carries far greater benefit to the patient than the risk to the patient not being able to have the exam

I would like to propose the regulation state:

Section 9 (2)(c): "If necessary corrective action is taken-corrective action is necessary, the action is taken before the radiation machine is used to perform any examination on a patient." shall be in accordance with the manufacturer's recommendations."

Section 10 (4) states: If the registrant for an invasive intervention radiation machine receives a written record pursuant to subsection 2 which indicates problems with the invasive intervention radiation machine requiring correction, the registrant shall ensure that the necessary corrective action is taken before the

(734) 662-3197

(801) 272-2952



invasive intervention radiation machine is used to perform any examination on a patient." in accordance with the manufacturer's recommendations."

Adoption of the alternative language I have proposed would allow for continued patient imaging when non-compliance issues of minimal concern are identified and discontinuing use when non-compliance issues of grave concern are identified.

Thank you for your consideration of my comments.

Sincerely,

Lisa M. Bosworth, M.S.

Lyw4Benworth

**Medical Physicist**