REVISED PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

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

AUTHORITY: §§ 1, 2, 4-57, 59 and 61-67, NRS 459.201; §§ 3, 58 and 60, NRS 439.150 and 459.201.

A REGULATION relating to radiation; establishing procedures for the registration of persons who install, perform services upon or repair radiation machines; requiring certain persons to obtain such registration; prescribing requirements governing the use of computed tomography X-ray systems and X-ray security systems; establishing certain requirements governing the registration and use of a stereotactic radiosurgery device; requiring the registration of a radiation machine that is disassembled or in storage; authorizing the termination of the registration of a radiation machine under certain circumstances; prescribing requirements governing the determination of the amount of radiation in certain materials; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the State Board of Health to adopt regulations for the licensing by the Division of Public and Behavioral Health of the Department of Human Services of persons to receive, possess or transfer radioactive materials, or devices or equipment utilizing such materials. Existing law authorizes the Division to require compliance with specific standards to be promulgated by the Board. (NRS 459.201) Existing regulations provide for the registration of radiation machines and persons who install or perform services upon radiation machines. (NAC 459.150) Existing regulations define "qualified expert" to mean a person who has demonstrated to the satisfaction of the Division that he or she possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs. (NAC 459.488) **Section 3** of this regulation: (1) establishes specific procedures to apply for registration as a person who installs, performs services upon or repairs radiation machines; and (2) prohibits such a registrant from providing services that have not been approved by the Division as part of that application process. **Sections 3 and 64** of this regulation require a qualified expert, including an authorized medical physicist for electronic brachytherapy, to obtain such registration. **Sections 2, 53 and 67** of this regulation make conforming changes so that "qualified expert" is defined for the purposes of **section 3**.

Existing regulations prescribe requirements governing the use of X-rays in the healing arts. (NAC 459.400-459.624) **Section 4** of this regulation defines "computed tomography" or "CT" to mean the use of computer-processed X-rays to produce virtual slices of the body of a

patient. **Sections 5-23 and 25-28** of this regulation define other terms relating to CT, and **section 63** of this regulation establishes the applicability of those definitions. **Sections 29-43** of this regulation enact specific requirements governing CT. Specifically, **section 29** establishes requirements concerning the equipment and capabilities of a CT X-ray system. **Section 30** requires a registrant for a CT X-ray system to ensure that the CT X-ray system is evaluated by a qualified expert: (1) upon installation and every 12 months thereafter; and (2) after the replacement of certain components. **Section 31** requires a registrant for a CT X-ray system to establish and implement a routine quality control program for the CT X-ray system. **Section 32** establishes requirements for shielding from the radiation emitted by a CT X-ray system that differ based on whether the CT X-ray system is stationary, transportable or mobile. **Section 33** prescribes the required qualifications of an operator of a CT X-ray system and certain other requirements governing the operation of a CT X-ray system. **Section 34** requires the registrant for a CT X-ray system, in consultation with a qualified expert and a qualified provider of health care, to establish certain policies and protocols for the operation of the CT X-ray system. **Section 34** also requires the annual review of certain protocols for the operation of a CT X-ray system. **Section 35**: (1) prescribes limitations regarding the dose of radiation provided by a CT X-ray system; and (2) requires the reporting to the Division of a medical misadministration of radiation in certain circumstances.

Section 36 provides that **sections 29-35** do not apply to a cone-beam CT X-ray system, and **sections 36-39** establish separate requirements governing cone-beam CT X-ray systems. **Section 36** establishes requirements concerning: (1) the equipment and capabilities of a cone-beam CT X-ray system; and (2) the development and documentation of protocols for the operation of a cone-beam CT X-ray system. **Section 37** prescribes the required qualifications and training for an operator of a cone-beam CT X-ray system. **Section 38** requires a registrant for a cone-beam CT X-ray system to provide for the periodic evaluation by a qualified expert of the performance of the cone-beam CT X-ray system. **Section 39** requires the registrant for a cone-beam CT X-ray system to establish and implement a routine quality control program for the cone-beam CT X-ray system.

Sections 40 and 41 establish requirements governing remote computed tomography, where the patient and the operator of the CT X-ray system are at different locations. **Section 42** exempts a CT X-ray system that is used solely for veterinary medicine from the requirements of **sections 29-41**, except for certain requirements governing evaluations for system performance and shielding from radiation. **Section 65** of this regulation exempts a CT X-ray system from certain requirements relating to total filtration permanently in the useful beam of an X-ray system that is used for veterinary medicine. (NAC 459.614) **Section 43**: (1) exempts a CT simulator that is used solely for the planning of treatment in radiation oncology from the requirements of **sections 29-41**; and (2) requires the registrant for such a CT simulator, a conventional simulator that is used for the planning of treatment in radiation oncology or an X-ray system that is used for guidance during therapeutic radiation to perform certain quality control procedures.

Section 24 of this regulation defines “stereotactic radiosurgery device” to mean a robotic stereotactic radiosurgery system that uses a linear accelerator mounted on a robotic arm to deliver non-isocentric, image-guided radiation. **Section 63** establishes the applicability of that definition. **Section 44** of this regulation establishes certain required contents of an application for the registration of a stereotactic radiosurgery device. **Section 45** of this regulation establishes

certain requirements governing: (1) protection from the radiation generated by a stereotactic radiosurgery device; and (2) quality control for a stereotactic radiosurgery device.

Section 46 of this regulation defines "X-ray security system" to mean a radiation machine that is used to screen natural persons to identify contraband items that would present a threat to security within the perimeter of a secured facility. **Section 47** of this regulation adopts by reference a publication prescribing standards governing radiation safety for X-ray security systems. **Section 48** of this regulation: (1) prohibits the use of an X-ray security system on humans without the approval of the Division; and (2) prescribes the procedure for obtaining such approval. **Section 48** also prohibits the use on humans of a handheld X-ray security system. **Section 49** of this regulation prescribes certain requirements and prohibitions governing the use of an X-ray security system. **Section 50** of this regulation prescribes certain additional requirements governing the use of an X-ray security system to screen persons who are known to be pregnant and minors. **Section 51** of this regulation requires an X-ray security system to be operated and maintained in accordance with the standards prescribed in the publication adopted by reference in **section 47**.

Existing regulations require each registrant for a radiation machine to develop, document, carry out and annually review the content and implementation of a program for protection against radiation. (NAC 459.321) **Section 52** of this regulation: (1) prescribes certain required contents of such an annual review conducted by the registrant for an X-ray security system; and (2) requires such a registrant to develop and carry out certain policies and procedures to ensure the proper operation, use and maintenance of the X-ray security system. **Sections 53-55** of this regulation make various conforming changes to establish the applicability of **sections 2-52**. **Sections 62 and 66** of this regulation authorize the Division to impose certain sanctions for a violation of the provisions of **sections 2-52**.

Existing regulations exempt a radiation machine that has been previously registered and is disassembled or in storage from the requirement to be registered with the Division. (NAC 459.152) **Sections 56-58** of this regulation remove that exemption and require a radiation machine that is disassembled or in storage to be so registered. However, **section 59** of this regulation authorizes the termination of registration of a radiation machine if the radiation machine or the radiation-generating portion of the radiation machine is disposed of. **Section 60** of this regulation establishes the fee for registering a radiation machine that is disassembled or in storage.

Existing regulations exempt from registration a person who receives, possesses, uses, transfers, owns or acquires naturally occurring radioactive material that contains less than 5 picocuries of radium-226 per gram of material. (NAC 459.184) **Section 61** of this regulation: (1) specifies that this measurement is calculated in reference to background radiation; and (2) prescribes the manner in which background radiation must be determined for that purpose.

Section 1. Chapter 459 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 52, inclusive, of this regulation.

Sec. 2. *"Qualified expert" means a person who is registered with the Division pursuant to NAC 459.150 to 459.166, inclusive, and section 3 of this regulation, to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.*

Sec. 3. *1. A person who wishes to install, perform services upon or repair radiation machines must apply to the Division for registration. The application must be made on the Division's Radiation Producing Machine Registration for Service Providers, which may be obtained from the Division on the Internet website of the Division.*

2. An application made pursuant to this section must:

(a) Specify the services that the applicant intends to provide, which may include, without limitation:

(1) Installation and servicing of radiation machines and components thereof.

(2) Services relating to the provision of equipment.

(3) Provider of equipment.

(4) Calibration of radiation machines or instruments or devices for measurements associated with radiation machines.

(5) Consultation or surveys relating to health physics or protection from radiation.

(6) Services relating to dosimetry for personnel.

(7) Design and evaluation of shielding from radiation.

(8) Qualified expert services for electronic brachytherapy.

(9) Qualified expert services for therapeutic X-ray machines.

(10) Qualified expert services for computed tomography.

(b) For an applicant who intends to provide the services listed in subparagraph (1), (2) or (3) of paragraph (a), proof that the applicant has sufficient training and experience to perform the relevant services.

(c) For an applicant who intends to provide any service listed in subparagraphs (4) to (10), inclusive, of paragraph (a), proof that the applicant has received:

(1) A bachelor's degree or more advanced degree in health physics, medical physics, another physical science or engineering from an accredited college or university;

(2) At least 40 hours of practical training or supervised experience in X-ray physics;

(3) Training specific to the type of equipment for which the applicant intends to provide services;

(4) Certification as a health physicist, medical physicist, physicist or dosimetrist, as appropriate for the services that the applicant intends to provide from a nationally recognized certifying agency; or

(5) Other relevant education, training and experience approved by the Division.

3. A holder of registration to install, perform services upon or repair radiation machines:

(a) Shall not provide any services that:

(1) Were not listed pursuant to paragraph (a) of subsection 2 on the holder's application for registration; or

(2) Have not been approved by the Division; and

(b) Shall maintain a copy of any proof described in paragraph (b) or (c) of subsection 2 for the term of his or her registration and any renewal thereof and make such proof available for inspection upon the request of the Division.

4. For the purposes of this chapter, a person who performs the services of a qualified expert shall be deemed to be a person who installs, performs services upon or repairs radiation machines.

Sec. 4. *"Computed tomography" or "CT" means the use of computer-processed X-rays to produce virtual slices of the body of a patient.*

Sec. 5. *"Cone-beam CT X-ray system" means a CT X-ray system that rotates around the patient to capture data using a cone-shaped X-ray beam for the purpose of reconstructing a three-dimensional image of the patient or a part of the patient.*

Sec. 6. *"CTDI100" means the accumulated dose of radiation over multiple CT scans at the center of a 100-millimeter scan, as acquired using a standard acrylic CT phantom and a commercially available pencil ionization chamber that is 100 millimeters long and has an active volume of 3 cubic centimeters. CTDI100 is calculated using the following equation:*

$$\boldsymbol{CTDI100} = (1/\mathrm{NT}) \int_{-50\ \mathrm{mm}}^{50\ \mathrm{mm}} D(\mathrm{z})\mathrm{dz}$$

where

z= Position along a line perpendicular to the tomographic plane.

D(z)= Dose at position z.

N= Number of tomograms produced in a single scan.

T= Nominal tomographic section thickness of a tomographic section.

Sec. 7. *"CTDIvol" means a standardized, scanner-reported metric measured in milligrays indicating the radiation output of a CT procedure which accounts for the pitch of the beam. CTDIvol is calculated using the following equation:*

CTDIvol=(N)(T)(CTDIw)/I

where:

N= Number of simultaneous axial CT scans per rotation of the source of X-rays.

T= Thickness of one axial CT scan in millimeters.

I= Table increment for an axial CT scan.

Sec. 8. *"CTDIw" means the estimated average CTDI100 across the field of view. CTDIw is calculated using the following equation:*

CTDIw=1/3CTDI100(center)+2/3CTDI100(edge)

where:

CTDI100(center)= CTDI100 at the center of the CT phantom.

CTDI100(edge)= CTDI100 at the edge of the CT phantom.

Sec. 9. *"CTN" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image. CTN is calculated using the following equation:*

$CTN= (k(\mu_x-\mu_w))/\mu_w$

where:

k= A constant equal to the normal value of 1,000 when the Hounsfield scale of CTN is used.

μ_x*= Linear attenuation coefficient of the material of interest.*

μ_w*= Linear attenuation coefficient of water.*

Sec. 10. *"CT parameter" means settings for a CT X-ray system that are capable of being modified, including, without limitation, peak tube potential, filtration thickness, tube current and exposure time.*

Sec. 11. *"CT phantom" means an object used to determine the dose delivered by a CT X-ray system.*

Sec. 12. *"CT procedure" means an activity directed at or performed on a patient using a CT X-ray system for the purpose of making a diagnosis. The term includes, without limitation, setting, modifying or applying CT parameters or CT protocols.*

Sec. 13. *"CT protocol" means a collection of CT parameters and other settings for operating a CT X-ray system that:*

1. Affect dose or image quality; or

2. Specify matters related to the collection of data, the positioning of the patient or contrast administration.

Sec. 14. *"CT scan" means the complete process of collecting data from the transmission of X-rays for the purpose of producing a tomogram.*

Sec. 15. *"CT X-ray system" means a gantry-style X-ray system that generates a tomographic image by acquiring cross-sectional image slices that are perpendicular to the plane of travel of the gantry.*

Sec. 16. *"Mobile CT X-ray system" means a CT X-ray system that is mobile equipment.*

Sec. 17. *"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Noise is calculated using the following equation:*

$Noise = (100*CS*s)/\mu_w$

where:

CS= Linear attenuation coefficient of the material of interest.

μ_w*= Linear attenuation coefficient of water.*

s= Standard deviation of the CTN of picture elements in a specified area of the CT image.

Sec. 18. *"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.*

Sec. 19. *"PET CT system" means a CT X-ray system that uses positron emission tomography and computed tomography and combines structural anatomic information with functional data that is collected during a CT procedure.*

Sec. 20. *"Remote CT operating location" means the location from which a CT X-ray system is operated remotely.*

Sec. 21. *"Remote CT service location" means the location where a patient receives computed tomography services through a CT X-ray system that is operated remotely.*

Sec. 22. *"SPECT CT system" means a CT X-ray system that uses single-photon emission computed tomography and computed tomography and combines structural anatomic information with functional data that is collected during a CT procedure.*

Sec. 23. *"Stationary CT X-ray system" means a CT X-ray system that is stationary equipment.*

Sec. 24. *"Stereotactic radiosurgery device" means a robotic stereotactic radiosurgery system that uses a linear accelerator mounted on a robotic arm to deliver non-isocentric, image-guided radiation.*

Sec. 25. *"Table increment" means the distance that the patient is moved per full rotation of the gantry during a CT procedure.*

Sec. 26. *"Tomogram" means a two-dimensional image that:*

1. Is created using a CT X-ray system; and

2. Represents a slice or section of a three-dimensional object.

Sec. 27. ***"Tomographic plane" means the geometric plane which is identified as corresponding to a specific tomogram.***

Sec. 28. ***"Transportable CT X-ray system" means a CT X-ray system that is transportable equipment.***

Sec. 29. ***1. A CT X-ray system must:***

(a) Meet the requirements of 21 C.F.R. § 1020.33 at the time of installation and throughout the period during which the CT X-ray system is registered;

(b) Be equipped with:

(1) A visible signal that indicates when X-ray exposure is occurring; and

(2) An X-ray production indicator that:

(I) Is located near the gantry and visible from any point outside the opening of the gantry; and

(II) Remains visible for at least one-half second;

(c) Allow the operator at any time to immediately terminate any X-ray exposure longer than one-half second;

(d) Display the CT parameters used during a CT procedure before the beginning of a CT scan in a manner that is visible from any location at which scanning may be initiated; and

(e) Require resetting the CT parameters of an X-ray exposure immediately following the premature termination of an X-ray exposure by the operator and before another CT scan may be initiated.

2. The maximum deviation of the laser or optical positioning system of a CT X-ray system must not exceed 5 millimeters on the axial position.

3. A transportable CT X-ray system or stationary CT X-ray system must:

(a) Allow for two-way verbal communication between the patient and the operator who is at the control panel;

(b) Allow the operator to continuously observe the patient from the control panel during radiation exposure using windows, mirrors, closed-circuit television or an equivalent method; and

(c) Have an alternate, analog method for an operator to observe a patient pursuant to paragraph (b) if the primary method is electronic.

Sec. 30. *1. A registrant for a CT X-ray system shall ensure that the CT X-ray system is evaluated by a qualified expert for system performance:*

(a) Upon installation before the CT X-ray system is used and at least once every 12 months thereafter; and

(b) Unless the CT X-ray system is a PET CT system used solely to calculate attenuation coefficients in nuclear medicine or a SPECT CT system used solely for that purpose, not later than 30 days after the replacement of a component of the CT X-ray system if a qualified expert determines that such replacement changes:

(1) The radiation output of the CT X-ray system; or

(2) The quality of the images produced by the CT X-ray system.

2. An evaluation pursuant to subsection 1 must include, without limitation:

(a) Determinations of the accuracy of the alignment light and the table increment;

(b) An assessment of the functioning of image localization from scanned projection radiographs;

(c) A determination of the width of the radiation beam;

(d) Assessments of image quality, including, without limitation:

(1) High-contrast resolution;

(2) Low-contrast resolution;

(3) Image uniformity;

(4) Noise; and

(5) Artifacts;

(e) A test of CT number accuracy;

(f) An assessment of image quality for display devices of acquisition workstations;

(g) A review of the results of the reports from the routine quality control performed pursuant to section 31 of this regulation;

(h) An evaluation for safety of audible and visual signals and the posting of safety information;

(i) A dosimetry determination; and

(j) Any quality control tests recommended by the manufacturer of the CT X-ray system.

Sec. 31. *A registrant for a CT X-ray system shall:*

1. Establish and implement a routine quality control program for the CT X-ray system. Such a program must:

(a) Be developed by a qualified expert;

(b) Include tolerances for each test performed that are acceptable based on the recommendations of the manufacturer or nationally recognized standards for CT X-ray systems;

(c) Incorporate the use of a CT phantom;

(d) Evaluate noise, CT number and artifacts; and

(e) Be completed at time intervals and under system conditions specified by the recommendations of the manufacturer or nationally recognized standards for CT X-ray systems.

2. Document each activity performed under the routine quality control program established pursuant to subsection 1, maintain such documentation for at least 3 years after the date on which the activity is performed and make such documentation available to the Division upon request.

Sec. 32. *1. For a stationary or transportable CT X-ray system:*

(a) The operator's booth and surrounding occupied areas must be designed in accordance with nationally recognized standards for the design of CT X-ray systems.

(b) The ceiling, floor and walls of the enclosure for the CT X-ray system must be equipped with protective barriers to ensure that exposure to radiation from the CT X-ray system does not exceed the limits established by NAC 459.325, 459.331, 459.333 or 459.335, as applicable.

(c) The control panel must be shielded by a protective barrier that cannot be removed and remains between the operator and the source of radiation at all times while the CT X-ray system is in operation.

2. The registrant for a stationary CT X-ray system or transportable CT X-ray system:

(a) Shall develop a radiation shielding plan for the CT X-ray system and submit the radiation shielding plan to the Division for review and approval;

(b) Shall revise and resubmit the radiation shielding plan after:

(1) Replacing a CT X-ray system; or

(2) Making any change to the construction of the room in which a CT X-ray system is located or any surrounding room; and

(c) Shall not operate a CT X-ray system without a radiation shielding plan approved by the Division pursuant to paragraph (a) or (b).

3. Not later than 30 days after a stationary CT X-ray system or transportable CT X-ray system is first used, the registrant shall complete a survey of the shielding for protection from radiation. The registrant shall retain the survey and any records relating to the design of shielding for protection from radiation until the CT X-ray system is no longer registered or in use.

4. A registrant for a mobile CT X-ray system shall ensure that:

(a) Exposure to radiation from the mobile CT X-ray system does not exceed the limits established by NAC 459.325, 459.331, 459.333 or 459.335, as applicable; and

(b) During radiation exposure, the operator of the mobile CT X-ray system is:

(1) Provided with a protective barrier that is at least 2 meters high; or

(2) Located at least 2.7 meters from the tube housing assembly of the mobile CT X-ray system.

Sec. 33. *1. A registrant for a CT X-ray system shall ensure that the operator of the CT X-ray system:*

(a) Is authorized to administer computed tomography pursuant to NRS 653.620 or 653.630 or exempt from the provisions of chapter 653 of NRS pursuant to NRS 653.430; and

(b) Operates the CT X-ray system only within the scope of his or her license or exemption from licensure, as applicable.

2. A registrant for a CT X-ray system shall ensure that the operator of the CT X-ray system does not adjust the CT parameters for a CT procedure outside the limits established in the CT protocols established pursuant to section 34 of this regulation.

Sec. 34. *1. Before operating a CT X-ray system, the registrant for the CT X-ray system shall, in consultation with a qualified expert and a qualified provider of health care, establish:*

(a) Policies to ensure the correct dose of radiation and the quality of images produced during CT procedures; and

(b) CT protocols.

2. The policies established pursuant to paragraph (a) of subsection 1 must include, without limitation:

(a) A method to monitor radiation output;

(b) Procedures for recording and retrieving applicable records concerning dosage of radiation, including, without limitation, CTDIvol and DLP;

(c) Procedures for developing and naming CT protocols;

(d) Policies for designating only appropriate persons to make changes to the CT protocols;

(e) Procedures and measures relating to software and engineering to prevent anyone from changing CT protocols, including, without limitation, CT parameters, without the approval of a qualified provider of health care and the radiation safety officer, which may include, without limitation, password protection;

(f) If the CT X-ray system is used for CT fluoroscopy, policies and training to minimize the exposure of patients and occupational exposure to radiation during CT fluoroscopy;

(g) Policies for retaking CT scans, including, without limitation:

(1) The number of CT scans authorized for a patient; and

(2) The persons who can authorize additional CT scans; and

(h) A standardized process for modifying the CT protocols as necessary.

3. The registrant for the CT X-ray system must obtain the approval of the radiation safety officer for the policies described in paragraph (g) of subsection 2 before implementing the policies or any changes thereto.

4. CT protocols must be established in consultation with a qualified expert and a qualified provider of health care. In consultation with such persons, a registrant for a CT X-ray system, other than a PET CT system used solely to calculate attenuation coefficients in nuclear medicine or a SPECT CT system used solely for that purpose, shall annually review:

(a) Any CT protocols that have changed within the immediately preceding year; and

(b) At least six CT protocols that are frequently performed or involve the highest dosages of radiation.

5. During a review pursuant to subsection 4, a registrant for a CT X-ray system shall:

(a) Determine whether the CT protocols being reviewed are appropriate, including, without limitation, by comparing determinations of the doses of radiation delivered by the CT X-ray system to previous determinations of such doses and, based on such comparisons, determining whether those CT protocols:

(1) Could be modified to lower the CTDIvol without an unacceptable sacrifice in image quality; or

(2) Could be eliminated; and

(b) Establish guidelines of variability for the CT protocols and CT parameters for each CT procedure.

6. A registrant for a CT X-ray system shall ensure that the operators of the system:

(a) Do not adjust the CT protocols or CT parameters outside any applicable limits contained in the guidelines of variability established pursuant to paragraph (b) of subsection 5;

(b) Check the display panel to review dose indicators or indices before or after performing a CT scan to ensure that the amount of radiation delivered is appropriate for the CT procedure being performed and the patient; and

(c) Document any doses that are outside the expected values and submit such documentation to the radiation safety officer for review.

7. A registrant for a CT X-ray system shall maintain documentation of each CT protocol or CT parameter for at least 3 years after the date on which the CT protocol or CT parameter ceases to be in use.

8. A registrant for a CT X-ray system must approve in writing any change made by representatives of the manufacturer of the CT X-ray system or a qualified expert that could impact radiation exposure or image quality before performing CT procedures using the CT X-ray system. Such changes may include, without limitation, changes to CT protocols or software.

9. As used in this section:

(a) "DLP" means the product of CTDIvol and the scan length for a single CT scan or a group of CT scans performed on the same body part, calculated over the length of a CT procedure to provide an estimate of the total dose for that CT procedure.

(b) "Guidelines of variability" means guidelines to minimize inconsistencies in the acquisition of images by a CT X-ray system and the interpretation of such images to ensure accurate diagnosis and treatment.

(c) "Qualified provider of health care" means a provider of health care, as defined in NRS 629.031, who has sufficient knowledge, training and experience relating to the operation of CT X-ray systems to competently perform the duties prescribed by this section.

Sec. 35. *1. The CTDIvol for CT procedures, as measured on a CT phantom, must:*

(a) Indicate a dose of radiation that is as low as reasonably achievable; and

(b) Meet nationally recognized standards for:

(1) The adult head and abdomen;

(2) The head of a minor who is 1 year of age; and

(3) The abdomen of a minor who weighs 40 pounds.

2. A registrant for a CT X-ray system shall submit a report of medical misadministration pursuant to NAC 459.551 and take the other actions required by that section for a medical misadministration if:

(a) The cumulative CTDIvol calculated over the course of a CT procedure at a particular anatomical location exceeds:

(1) One hundred fifty rem for an adult; or

(2) Sixty rem for a minor; or

(b) Exposure to radiation from any CT procedure results in unanticipated hair loss, erythema or functional damage to an organ or physiological system.

3. Not later than 10 business days after receiving a request from a patient, a registrant for a CT X-ray system shall provide the patient with an estimate of the dose of radiation received by the patient during a CT procedure.

Sec. 36. *1. A cone-beam CT X-ray system is not subject to the requirements of sections 29 to 35, inclusive, of this regulation.*

2. A cone-beam CT X-ray system must:

(a) Meet the requirements of 21 C.F.R. § 1020.33 at the time of installation and throughout the period during which the cone-beam CT X-ray system is registered;

(b) Be equipped with:

(1) A visible signal that indicates when X-ray exposure is occurring; and

(2) An X-ray production indicator that:

(I) Is located near the gantry and visible from any point outside the opening of the gantry; and

(II) Remains visible for at least one-half second;

(c) Allow the operator at any time to immediately terminate any X-ray exposure longer than one-half second;

(d) Display the CT parameters used during a CT procedure before the beginning of a CT scan in a manner that is visible from any location at which scanning may be initiated; and

(e) Require resetting the CT parameters of an X-ray exposure immediately following the premature termination of an X-ray exposure by the operator and before another CT scan may be initiated.

3. The maximum deviation of the laser or optical positioning system of a cone-beam CT X-ray system must not exceed 5 millimeters on the axial position.

4. The X-ray field in the plane of the image receptor for a cone-beam CT X-ray system must not exceed the edge of the image receptor by more than 2 percent of the source-to-image distance when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

5. The center of the X-ray field of a cone-beam CT X-ray system must be aligned with the center of the image receptor to within 2 percent of the source-to-image distance.

6. The registrant for a cone-beam CT X-ray system shall:

(a) Develop CT protocols for imaging using the cone-beam CT X-ray system. The CT protocols must include, without limitation, allowable variations to those CT protocols applicable to specific CT parameters.

(b) Document each CT protocol developed pursuant to paragraph (a), maintain such documentation for at least 3 years after the date on which the relevant CT protocol is last used and make such documentation available to the Division upon request.

Sec. 37. *1. A registrant for a cone-beam CT X-ray system shall ensure that the operator of the cone-beam CT X-ray system is:*

(a) Authorized to administer computed tomography pursuant to NRS 653.620 or 653.630 or exempt from the provisions of chapter 653 of NRS pursuant to NRS 653.430; and

(b) Operates the cone-beam CT X-ray system only within the scope of his or her license or exemption from licensure, as applicable.

2. A registrant for a cone-beam CT X-ray system shall provide each operator of the cone-beam CT X-ray system with:

(a) Training in routine procedures for quality control in accordance with the program established and implemented pursuant to section 39 of this regulation, including, without limitation, using a CT phantom;

(b) A schedule of routine procedures for quality control in accordance with the program established and implemented pursuant to section 39 of this regulation;

(c) Allowable variations to the CT protocols developed pursuant to section 36 of this regulation; and

(d) The results of the most recent quality control performed in accordance with the program established and implemented pursuant to section 39 of this regulation.

Sec. 38. *1. The registrant for a cone-beam CT X-ray system shall ensure that the cone-beam CT X-ray system is evaluated by a qualified expert for system performance:*

(a) Upon installation before the cone-beam CT X-ray system is used and at least:

(1) Once every 24 months thereafter, for a cone-beam CT X-ray system that is capable of operating at not greater than 100 kilovolts or 20 milliamps; or

(2) Once every 12 months thereafter, for all other cone-beam CT X-ray systems; and

(b) Not later than 30 days after the replacement of a component of the cone-beam CT X-ray system if a qualified expert determines that such replacement changes:

(1) The radiation output of the cone-beam CT X-ray system; or

(2) The quality of the images produced by the cone-beam CT X-ray system.

2. An evaluation conducted pursuant to subsection 1 must include, without limitation:

(a) An evaluation of the alignment of the beam;

(b) Confirmation that the system meets the requirements of subsections 4 and 5 of section 36 of this regulation;

(c) Assessments of image quality, including, without limitation:

(1) High-contrast resolution;

(2) Low-contrast resolution;

(3) Image uniformity;

(4) Noise; and

(5) Artifacts;

(d) An assessment of image quality for display devices of acquisition workstations;

(e) A review of the results of the reports from the routine quality control performed pursuant to section 39 of this regulation;

(f) An evaluation for safety of audible and visual signals and the posting of safety information;

(g) A dosimetry determination; and

(h) Any quality control tests recommended by the manufacturer of the cone-beam CT X-ray system.

Sec. 39. *A registrant for a cone-beam CT X-ray system shall:*

1. Establish and implement a routine quality control program for the cone-beam CT X-ray system. Such a program must:

(a) Be developed by a qualified expert;

(b) Be completed at time intervals and under system conditions that are appropriate for the cone-beam CT X-ray system, as determined based on the recommendations of the manufacturer or nationally recognized standards for cone-beam CT X-ray systems; and

(c) Incorporate the use of a CT phantom.

2. Document each activity performed under the routine quality control program established pursuant to subsection 1, maintain such documentation for at least 3 years after the date on which the activity is performed and make such documentation available to the Division upon request.

Sec. 40. *1. To engage in remote computed tomography from a remote CT operating location in this State, the remote CT operating location and the CT X-ray system must be registered with the Division.*

2. To engage in remote computed tomography from a remote CT operating location outside this State with remote CT service locations in this State:

(a) The CT X-ray system must be registered with the Division;

(b) The registrant must provide proof to the Division that the remote CT operating location is operating in accordance with the laws of the state in which it is located, including, without limitation, holding any license, certificate, registration or other credential required by the laws of that state; and

(c) The registrant must designate a location in this State where the Division may inspect documents to ensure compliance with the provisions of this chapter, chapter 653 of NAC and chapters 459 and 653 of NRS.

3. All components of a CT X-ray system used for remote computed tomography for which federal law requires approval of the United States Food and Drug Administration must be so approved.

4. Throughout a CT procedure performed using remote computed tomography:

(a) An operator who meets the requirements of subsection 1 of section 33 of this regulation must be physically present at the remote CT operating location; and

(b) An assisting radiologic imaging technologist who meets the requirements of subsection 5 must be physically present at the remote CT service location.

5. An assisting radiologic imaging technologist must:

(a) Be authorized to administer computed tomography pursuant to NRS 653.620 or 653.630 or exempt from the provisions of chapter 653 of NRS pursuant to NRS 653.430;

(b) Engage in computed tomography only within the scope of his or her license or exemption from licensure, as applicable; and

(c) Be trained for the computed tomography that he or she performs in accordance with:

(1) The training requirements established by the American Registry of Radiologic Technologists, or its successor organization, for computed tomography technologists; and

(2) The appropriate sections of the Computed Tomography Curriculum established by the American Society of Radiologic Technologists, or its successor organization.

Sec. 41. *A registrant for a CT X-ray system used for remote computed tomography or a remote CT operating location shall establish and implement a radiation safety program that includes, without limitation:*

1. Measures to ensure that CT X-ray systems, components thereof, remote CT service locations and any other locations at which information concerning patients is viewed adequately protect such information;

2. A list of each remote CT operating location and each associated remote CT service location, including, without limitation:

(a) The name and address of each remote CT operating location or remote CT service location; and

(b) The contact information for a member of the staff of each remote CT operating location or remote CT service location;

3. The roles and responsibilities of each operator and each assisting radiologic technologist, including, without limitation, procedures for each task performed by those persons;

4. A requirement that each assisting radiologic technologist completes annual training in radiation safety that is relevant to his or her duties;

5. Requirements that an assisting radiologic technologist:

(a) Maintains constant surveillance of the patient during a CT procedure; and

(b) Performs only one CT procedure at any time;

6. Requirements that an operator:

(a) Maintains constant surveillance of the patient during a CT procedure through vocal communication and visual means; and

(b) Performs only one CT procedure at any time;

7. A prohibition on the performance of computed tomography if communication or connectivity between the remote CT operating location and the remote CT service location is not functioning or is otherwise not reliable;

8. Procedures for checks to ensure functioning communication and connectivity between the remote CT operating location and the remote CT service location before beginning a CT procedure;

9. Procedures for a loss in communication or connectivity between the remote CT operating location and the remote CT service location and other emergencies; and

10. Policies and procedures to ensure adequate oversight of remote computed tomography operations, which must include, without limitation:

(a) Regular audits to evaluate the effectiveness and safety of remote computed tomography operations;

(b) The reporting of misadministrations in accordance with NAC 459.551;

(c) Observation of work at the remote CT operating location and the remote CT service location; and

(d) Processes to:

(1) Identify, track and investigate incidents that cause the incompletion or repetition of CT procedures; and

(2) Develop and implement corrective action in response to an incident described in subparagraph (1).

Sec. 42. *1. Except as otherwise provided in this section, the provisions of sections 29 to 41, inclusive, of this regulation do not apply to a CT X-ray system that is used solely for veterinary medicine and is not used for any human use.*

2. A registrant for a CT X-ray system, other than a cone-beam CT X-ray system, that is used solely for veterinary medicine shall:

(a) Ensure that the CT X-ray system is evaluated for system performance in accordance with section 30 of this regulation at least once every 4 years; and

(b) Comply with the requirements of paragraph (b) of subsection 1 or subsection 4, as applicable, of section 32 of this regulation.

3. A registrant for a cone-beam CT X-ray system that is used solely for veterinary medicine shall ensure that the CT X-ray system is evaluated for system performance in accordance with section 38 of this regulation at least once every 4 years.

Sec. 43. *1. The provisions of sections 29 to 41, inclusive, of this regulation do not apply to a CT simulator that is used solely for the planning of treatment in radiation oncology and is not used for diagnostic imaging.*

2. A registrant for a CT simulator or a conventional simulator that is used solely for the planning of treatment in radiation oncology or an X-ray system that is used for guidance during therapeutic radiation shall ensure that regular procedures for quality control are

performed on the CT simulator, conventional simulator or X-ray system, as applicable, in accordance with:

(a) Current published recommendations from a nationally recognized professional organization with expertise in technologies used for therapeutic radiation; or

(b) If no suitable recommendations described in paragraph (a) exist, the procedures for quality control established by the manufacturer of the CT simulator, conventional simulator or X-ray system, as applicable, or equivalent procedures.

3. Procedures for quality control performed pursuant to subsection 2 must include, without limitation:

(a) Acceptance testing upon installation; and

(b) Periodic verification that the CT simulator, conventional simulator or X-ray system, as applicable, is performing adequately.

4. As used in this section:

(a) "Acceptance testing" means to ensure that a CT simulator, a conventional simulator or an X-ray system used for guidance during therapeutic radiation:

(1) Meets the specifications of the manufacturer and the requirements of applicable laws and regulations; and

(2) Is sufficiently accurate for all purposes for which the CT simulator, a conventional simulator or an X-ray system will be used.

(b) "Conventional simulator" means an X-ray system, other than a CT simulator, that is used to plan treatment in radiation oncology by demonstrating the relationship between the tumor that is the target of the treatment and healthy tissues while the patient is positioned for treatment.

(c) "CT simulator" means a CT X-ray system that is used to plan treatment in radiation oncology by demonstrating the relationship between the tumor that is the target of the treatment and healthy tissues while the patient is positioned for treatment.

Sec. 44. *In addition to the requirements of NAC 459.154, an application to register a stereotactic radiosurgery device must include, without limitation:*

1. Proof acceptable to the Division that the design of the treatment room and shielding meet the requirements of section 45 of this regulation;

2. Specifications for the stereotactic radiosurgery device and other associated equipment;

3. Procedures for conducting surveys to ensure adequate protection against radiation;

4. Protocols for quality assurance that meet the requirements of subsection 3 of section 45 of this regulation; and

5. Procedures for operating the stereotactic radiosurgery device, including, without limitation, procedures for motion tracking systems.

Sec. 45. *1. In addition to meeting the requirements of NAC 459.590, a treatment room for a stereotactic radiosurgery device must:*

(a) Provide sufficient clearance for the motion of the robotic arm of the stereotactic radiosurgery device;

(b) Comply with the specifications or recommendations of the manufacturer of the stereotactic radiosurgery device concerning dimensions and structural support;

(c) Include such shielding as necessary to comply with NAC 459.320 to 459.374, inclusive, and 459.400 to 459.624, inclusive;

(d) Allow for clear placement of X-ray imagers and detectors; and

(e) Be equipped with the following patient support:

(1) An immobilization device appropriate for the duration of the treatment;

(2) A system for continuous audiovisual monitoring; and

(3) Climate control and lighting sufficient to ensure the comfort of the patient.

2. Before using a stereotactic radiosurgery device for a clinical purpose, the registrant for the device shall ensure that a survey is conducted to ensure adequate protection against radiation in accordance with the procedures included in the application for registration pursuant to section 44 of this regulation.

3. A registrant for a stereotactic radiosurgery device shall establish and implement a quality control program for the stereotactic radiosurgery device that is consistent with:

(a) The recommendations of the manufacturer; and

(b) At least one set of nationally recognized standards for quality control in stereotactic radiosurgery devices.

Sec. 46. *As used in sections 46 to 52, inclusive, of this regulation, unless the context otherwise requires, "X-ray security system" means a radiation machine that is used to screen natural persons to identify contraband items that would present a threat to security within the perimeter of a secured facility. The term does not include a radiation machine that is used to screen nonhuman animals or inanimate objects.*

Sec. 47. *1. Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation," published by the American National Standards Institute and the Health Physics Society is hereby adopted by reference. The publication is available from the Health Physics Society on the Internet website https://hps.org/hpssc/index/ at no charge for members and a cost of $50 for nonmembers.*

2. The Division shall review each revision of the publication adopted by reference in subsection 1 to ensure its suitability for this State. If the Division determines that a revision is not suitable for this State, the Division shall hold a public hearing to review its determination within 90 days after the date of the publication of the revision and give notice of that hearing. If, after the hearing, the Division does not revise its determination, the Division shall give notice within 30 days after the hearing that the revision is not suitable for this State. If the Division does not give such notice, the revision becomes part of the publication adopted by reference.

Sec. 48. *1. A person shall not engage in the human use of an X-ray security system without the approval of the Division.*

2. To obtain the approval of the Division to engage in the human use of an X-ray security system, a person must:

(a) Register the X-ray security system pursuant to NAC 459.150 to 459.166, inclusive, and section 3 of this regulation;

(b) Submit a completed Security Screening on Humans Application form made available on the Internet website of the Division;

(c) Demonstrate to the Division:

(1) The need for enhanced security for the relevant facility; and

(2) That the applicant will comply with sections 46 to 52, inclusive, of this regulation; and

(d) Submit any additional information required by the Division.

3. A registrant for an X-ray security system shall not engage in the human use of the X-ray security system in a manner that has not been approved by the Division. To revise the scope of his or her approval, such a registrant must submit a written request to the Division.

4. A person shall not engage in the human use of a handheld X-ray security system.

Sec. 49. *1. A registrant for an X-ray security system shall:*

(a) Designate a person to be responsible for protection against radiation with regard to the X-ray security system. That designated person must have:

(1) Sufficient experience and training to make proper decisions concerning the risk created by radiation and the safe operation of the X-ray security system; and

(2) The authority to make such decisions.

(b) Ensure that the X-ray security system:

(1) Is not used for theft detection or any human use other than screening a natural person to identify contraband items that would present a threat to security within the perimeter of a secured facility;

(2) Is not used for any purpose for which the X-ray security system was not designed, as specified by the manufacturer; and

(3) Except as otherwise provided in subsection 2, is maintained and serviced in accordance with the recommendations of the manufacturer.

(c) Ensure that a person is not exposed to the useful beam unless authorized by the registrant and in a manner that demonstrably benefits the security of the relevant facility. A person must not be deliberately exposed to the useful beam for training, demonstration or other purposes unless the exposure also meets the requirements of this paragraph.

(d) Ensure that no person receives a dose of radiation that exceeds the maximum dose specified in Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation," as adopted by reference in section 47 of this regulation.

2. The requirements of subparagraph (3) of paragraph (b) of subsection 1 do not apply to an X-ray security system:

(a) For which the manufacturer has made a documented change to its recommendations concerning maintenance and service; or

(b) That is certified and labeled in accordance with applicable requirements of the United States Food and Drug Administration.

3. Any maintenance and service of an X-ray security system pursuant to this section must be performed by a person who is registered to perform service on radiation machines pursuant to NAC 459.150 to 459.166, inclusive, and section 3 of this regulation.

4. As used in this section:

(a) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the X-ray field.

(b) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Sec. 50. *If it is necessary to use the X-ray security system to screen a person who is known to be pregnant or a minor, the registrant for an X-ray security system shall ensure that:*

1. The pregnant person or the parent or guardian of the minor, as applicable, is informed of the exposure to radiation from the X-ray security system and the risks associated with such exposure;

2. If the pregnant person or the parent or guardian of the minor, as applicable, declines screening using the X-ray security system, alternative screening procedures are offered; and

3. If the pregnant person or the parent or guardian of the minor, as applicable, authorizes screening using the X-ray security system, the dose of radiation received by the pregnant person or minor, as applicable, does not exceed the applicable maximum dose for special populations specified in Annex A of Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation," as adopted by reference in section 47 of this regulation.

Sec. 51. *1. An X-ray security system must be operated and maintained in accordance with Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation," as adopted by reference in section 47 of this regulation, including, without limitation, with regard to operational protocols, safety features and signage.*

2. A registrant for an X-ray security system shall:

(a) Ensure that all operators are trained in the safe operation of the X-ray security system in accordance with the recommendations of the manufacturer and Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation"; and

(b) Maintain documentation of all initial and refresher training provided pursuant to paragraph (a) for at least 3 years after the date of the training.

Sec. 52. *1. A review of a program for protection against radiation conducted pursuant to paragraph (c) of subsection 1 of NAC 459.321 by the registrant for an X-ray security system must include, without limitation:*

(a) Any procedures stated in the application for registration of the X-ray security system submitted pursuant to section 48 of this regulation;

(b) Any procedures required by Standard N43.17-2009, "Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation," as adopted by reference in section 47 of this regulation; and

(c) Any measures necessary to correct a violation of the program for protection against radiation or sections 46 to 52, inclusive, of this regulation.

2. A registrant for an X-ray security system shall develop and carry out policies and procedures to ensure that:

(a) Tests are performed to ensure the proper operation of the X-ray security system in accordance with the recommendations of the manufacturer; and

(b) The X-ray security system is operated, used and maintained in accordance with the recommendations of the manufacturer, except where otherwise provided in section 49 of this regulation, and the provisions of sections 46 to 52, inclusive, of this regulation.

Sec. 53. NAC 459.010 is hereby amended to read as follows:

459.010 As used in NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 459.012 to 459.116, inclusive, ***and section 2 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 54. NAC 459.021 is hereby amended to read as follows:

459.021 1. "Background radiation" means:

(a) Radiation from cosmic sources;

(b) Naturally occurring radioactive materials, including radon, except as a product of decay from source or special nuclear materials; and

(c) Global fallout as it exists in the environment from the testing of nuclear explosive devices, or past nuclear accidents, that contributes to background radiation and is not under the control of the licensee ~~.~~ ***or registrant.***

2. The term does not include sources of radiation from any radioactive material regulated by the Division pursuant to NAC 459.010 to 459.950, inclusive ~~.~~ ***, and sections 2 to 52, inclusive, of this regulation.***

Sec. 55. NAC 459.118 is hereby amended to read as follows:

459.118 The provisions of NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation,*** including the provisions of the federal regulations adopted by reference in NAC 459.1232, 459.1997, 459.3062, 459.3205 and 459.737 apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation except as otherwise specifically provided in NAC 459.010 to 459.950, inclusive ~~.~~ ***, and sections 2 to 52, inclusive, of this regulation.*** Nothing in NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation,*** applies to any person to the extent he or she is subject to regulation by the Nuclear Regulatory Commission.

Sec. 56. NAC 459.150 is hereby amended to read as follows:

459.150 1. NAC 459.150 to 459.179, inclusive, ***and section 3 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 ***that has not been disassembled*** 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 requirements of NAC 459.150 to 459.179, inclusive ~~.~~ ***, and section 3 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. 57. NAC 459.152 is hereby amended to read as follows:

459.152 1. ~~[Except as otherwise provided in subsection 5, electronic]~~ ***Electronic*** equipment that produces radiation incidental to its operation for other purposes is exempt from the requirements of registration and notification in NAC 459.150 to 459.166, inclusive, ***and section 3 of this regulation*** if the dose equivalent rate, averaged over an area of 10 square centimeters, does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of the equipment. The production, testing or factory servicing of the equipment is not exempt.

2. Radiation machines which ~~[:~~

~~(a) Are]~~ ***are*** in transit or in storage incident to transportation ~~[; or~~

~~(b) Have been previously registered and are disassembled or in storage,~~

~~➥]~~ are exempt from the requirements of NAC 459.150 to 459.166, inclusive ~~[.]~~ ***, and section 3 of this regulation.***

3. Domestic television receivers are exempt from the requirements of NAC 459.150 to 459.166, inclusive ~~[.~~

~~4. For the purposes of subsection 2, a radiation machine is considered to be:~~

~~(a) In storage if it is safely stored in an inoperable status, with no supplied power.~~

~~(b) Disassembled if it is rendered inoperable by means of physical disassembly of the machine components and structure.~~

~~5. An operational radiation machine which is not in service for the purpose for which the radiation machine was registered is exempt from the requirements of NAC 459.150 to 459.166, inclusive, which are applicable to electronic equipment.~~

~~6.]~~ ***, and section 3 of this regulation.***

4. Nothing in this section exempts a person from the licensing requirements of NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation*** and chapter 459 of NRS applicable to the possession and use of radioactive materials.

Sec. 58. 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 ~~[,]~~ ***that is operational, stored or disassembled,*** 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]~~ ***receiving*** the machine ~~[.]~~ ***at the location where the machine will be operated or stored. Each person who controls a radiation machine that was previously registered as operational and is now stored or disassembled shall apply to the Division for registration of the machine as stored or disassembled.***

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 2 to 52, 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 ***Producing*** 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. 59. NAC 459.158 is hereby amended to read as follows:

459.158 ***1.*** Except as provided by NAC 459.160, each registration certificate expires on the last day of the month and year indicated on the certificate or 30 days after notification of expiration by the Division.

2. The Division may terminate a registration certificate for a radiation machine upon the request of the registrant if:

(a) The machine has been disposed of; or

(b) The portion of the machine that generates radiation has been removed and disposed of.

Sec. 60. NAC 459.161 is hereby amended to read as follows:

459.161 1. Except as otherwise provided in subsection 7, 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.

(g) In storage or disassembled, $50.

2. Except as otherwise provided in subsections 4 and 7, 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. Upon the issuance or renewal of a registration for a radiation machine, the registrant shall pay to the Division a nonrefundable fee equal to 6 percent of the registration fee or renewal fee, as applicable, set forth in subsection 1. The Division shall use the fees collected pursuant to this

subsection during the immediately following fiscal year to support the system for the reporting of information on cancer and other neoplasms established pursuant to NRS 457.230.

4. The renewal fee must be electronically received by the Division not later than the date on which the registration expires unless, before that date, the registrant electronically submits to the Division pursuant to NAC 459.162 a notice that the registrant has transferred ownership of the radiation machine, placed the radiation machine in storage or disposed of the radiation machine. If the fee or notice is not electronically received by that date, the registrant must electronically submit to the Division in the form prescribed by the Division:

(a) An application for renewal of the registration;

(b) A fee in an amount that is equal to the appropriate fee set forth in subsection 1; and

(c) A fee for late payment of $56 per registration.

5. Except as otherwise provided in subsection 7, 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.

6. 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.

7. 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. 61. NAC 459.184 is hereby amended to read as follows:

459.184 1. Except as otherwise provided in subsection 3, any person is exempt from NAC 459.180 to 459.3154, inclusive, to the extent that he or she receives, possesses, uses, transfers, owns or acquires products or materials containing:

(a) Radioactive material in concentrations not in excess of those listed in NAC 459.186; or

(b) Naturally occurring radioactive material that contains less than 5 picocuries (0.185 becquerels) of radium-226 per gram of material ~~.~~ ***above background radiation, where background radiation is determined:***

(1) Through an evaluation conducted by the National Voluntary Laboratory Accreditation Program, or its successor program, of the National Institute of Standards and Technology of the United States Department of Commerce; or

(2) By sampling surrounding materials that are not from the same geologic body as the naturally occurring radioactive material but are from locations adjacent to that geologic body.

2. Any person who possesses by-product material received or acquired before September 25, 1971, under the general license then provided pursuant to 10 C.F.R. § 31.4, or a similar general license of a state, is exempt from the requirements of NAC 459.180 to 459.3184, inclusive, 459.737 and 459.738 to the extent that the person possesses, uses, transfers or owns such by-product material.

3. A person shall not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection 1 or the equivalent regulations of the Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 C.F.R. § 32.11 or the general licenses provided in NAC 459.210.

4. A manufacturer, processor or producer of a product or material is exempt from the requirements for a license set forth in 10 C.F.R. Part 81 and from NAC 459.180 to 459.3154, inclusive, to the extent that the person transfers by-product material contained in a product or material:

(a) In concentrations not in excess of those specified in NAC 459.186; and

(b) Introduced into the product or material by a licensee holding a specific license issued by the Division expressly authorizing such introduction.

➥ This exemption does not apply to the transfer of by-product material contained in any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

5. Except as otherwise provided in subsections 6 and 7, any person is exempt from the provisions of NAC 459.010 to 459.950, inclusive, to the extent that he or she receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in NAC 459.188.

6. The provisions of NAC 459.180 to 459.3154, inclusive, do not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

7. A person shall not, for purposes of commercial distribution, transfer radioactive material in the individual quantities in NAC 459.188, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under subsections 5 and 6 or the equivalent regulations of the Nuclear Regulatory Commission or any agreement state, except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to 10 C.F.R. § 32.18. The license must state that the radioactive material may be transferred by the licensee to persons exempt under subsections 5 and 6 or the equivalent regulations of the Nuclear Regulatory Commission or any agreement state.

8. Except for by-product material combined within a device placed in use before May 3, 1999, or as otherwise authorized by this chapter, no person may combine quantities of by-

product material covered by this exemption in such a manner that the aggregate quantity exceeds the limits set forth in NAC 459.188 for purposes of producing an increased radiation level.

Sec. 62. NAC 459.209 is hereby amended to read as follows:

459.209 In addition to the grounds for disciplinary action set forth in NAC 459.208, the Division may deny, refuse to renew, suspend or revoke the license, certificate or registration of an applicant for or a holder of a license, certificate or registration issued pursuant to NAC 459.118 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation*** if the applicant, licensee or holder of the certificate or registrant:

1. Receives, possesses, uses, transfers, owns or acquires any source of radiation or operates a radiation machine in violation of a provision of NRS 459.010 to 459.290, inclusive, and NAC 459.010 to 459.950, inclusive, or any other applicable state or federal laws or regulations;

2. Fails to comply with any applicable order issued pursuant to a provision of NRS 459.010 to 459.290, inclusive, and NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation*** or any other applicable state or federal laws or regulations;

3. Violates any term, condition or limitation of a license, certificate or registration issued pursuant to a provision of NRS 459.010 to 459.290, inclusive, and NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation*** or any other applicable state or federal laws or regulations;

4. Allows a person, including, without limitation, an employee, contractor or subcontractor who is under the supervision of the applicant, licensee, holder of the certificate or registrant or an employee of such a person, including, without limitation, a contractor or subcontractor to violate a provision of NRS 459.010 to 459.290, inclusive, and NAC 459.010 to 459.950, inclusive, ***and***

sections 2 to 52, inclusive, of this regulation or any other applicable state or federal laws or regulations, including, without limitation, violating subsection 1 of NAC 459.135;

5. Fails or refuses to cooperate with the Division during an investigation, evaluation or inspection;

6. Fails or refuses to comply with a written request from the Division, the Nuclear Regulatory Commission or any applicable local or national accreditation body for records, reports or other materials;

7. Provides false or misleading or otherwise inaccurate information on an application for a license, certificate or registration or for renewal of a license, certificate or registration;

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

9. Held a license issued by the Division or by the appropriate agency in another jurisdiction and the license was withdrawn, revoked, terminated or suspended; or

10. Fails to obtain a license, certificate or registration required pursuant to a provision of NRS 459.010 to 459.290, inclusive, and NAC 459.010 to 459.950, inclusive, ***and sections 2 to 52, inclusive, of this regulation*** or any other applicable state or federal laws or regulations.

Sec. 63. NAC 459.400 is hereby amended to read as follows:

459.400 As used in NAC 459.400 to 459.624, inclusive, ***and sections 4 to 45, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 459.402 to 459.546, inclusive, ***and sections 4 to 28, inclusive, of this regulation*** have the meanings ascribed to them in those sections.

Sec. 64. NAC 459.5923 is hereby amended to read as follows:

459.5923 1. A registrant for any therapeutic X-ray device shall require an authorized medical physicist for electronic brachytherapy to:

(a) Be currently licensed as a therapeutic radiological physicist by a professional organization specified by the Division or in another state;

(b) ***Be currently registered with the Division as a qualified expert for electronic brachytherapy pursuant to NAC 459.150 to 459.166, inclusive, and section 3 of this regulation;***

(c) Have completed specific training on the device provided by the manufacturer and approved by the Division; and

~~[(c)]~~ ***(d)*** Have had his or her training reviewed and approved by the Division.

2. An authorized medical physicist for electronic brachytherapy shall:

(a) Evaluate the output from the electronic brachytherapy device;

(b) Prepare the necessary dosimetric information;

(c) Supervise and review the treatment calculations before the initial treatment of any treatment site;

(d) Establish written procedures for performing a spot check pursuant to NAC 459.5934;

(e) Supervise the conducting of a spot check required by NAC 459.5934;

(f) Review a spot check conducted pursuant to NAC 459.5934 within 2 days after completion of the spot check;

(g) Notify the registrant, in writing, of any failures detected during a spot check within 24 hours after the failure is detected;

(h) Consult with the authorized user in treatment planning, as needed; and

(i) Perform any calculations and assessments of patient treatments which may constitute medical events.

3. The training and experience required by subsection 1 must be obtained within the 7 years immediately preceding the date of the application, or the person must have related continuing education experience in the same type of radiation therapy on an annual basis.

4. The registrant shall retain all records of:

(a) Annual training for at least 3 years; and

(b) Initial training until the Division authorizes the disposal of the records.

Sec. 65. NAC 459.614 is hereby amended to read as follows:

459.614 1. The protective tube housing must be of the diagnostic type.

2. Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the housing.

3. ~~[The]~~ ***Except as otherwise provided in this subsection, the*** total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp. ***The requirements of this subsection do not apply to a CT X-ray system.***

4. A device must be provided to terminate the exposure after a preset time or exposure.

5. A dead-man type of exposure switch must be provided together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 6 feet from the animal during all X-ray exposures.

6. All wall, ceiling and floor areas must be equivalent to or provided with applicable protective barriers as required in NAC 459.325, 459.331 and 459.335.

7. The operator shall stand well away from the useful beam and the animal during radiographic exposures.

8. No person other than the operator may be in the X-ray room while exposures are being made unless the person's assistance is required.

9. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by a person, the person must be protected with appropriate shielding devices, such as protective gloves and apron, and he or she must be positioned so that no part of his or her body will be struck by the useful beam. The exposure of any person used for this purpose must be monitored and permanently recorded.

10. For an X-ray system that has not been previously approved for human use, the degree of accuracy of:

(a) The indicated value of kVp of an X-ray system used for veterinary medicine must be within 10 percent when measured or the limits set by the manufacturer for that X-ray system if those limits specify otherwise;

(b) The timer of an X-ray system used for veterinary medicine must be within 20 percent when measured or the limits set by the manufacturer for that X-ray system if those limits specify otherwise; and

(c) An indicator of the field size which measures in inches or centimeters on a variable aperture beam-limiting device of an X-ray system used for veterinary medicine equipped with such an indicator must be within 2 percent of the source-image receptor distance when measured or, if a variable aperture beam-limiting device of an X-ray system used for veterinary medicine is not equipped with such an indicator, the X-ray field must be aligned with the center of the beam axis and the adjustable field size must be operable.

11. An X-ray system that was previously approved and used for human use may be used for veterinary medicine if the X-ray system continues to comply with the criteria of the United States Food and Drug Administration for systems approved for human use.

Sec. 66. 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 2 to 52, 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 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 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 2 to 52, 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 2 to 52, 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.

Sec. 67. NAC 459.488 is hereby repealed.

TEXT OF REPEALED SECTION

459.488 "Qualified expert" defined. (NRS 459.201) "Qualified expert" means a person who has demonstrated to the satisfaction of the Division that he or she possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.