PROPOSED REGULATION OF THE

STATE BOARD OF HEALTH

LCB FILE NO. R025-26I

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STATE BOARD OF HEALTH

LCB File No. XXXXXX

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

AUTHORITY: NRS 459.030 and 459.201

A REGULATION relating to radiation machines; adopting new regulations to clarify requirements for service providers and qualified experts who service or provide services for radiation machines; adopting new regulations for computed tomography and cone beam computed tomography; adopting new regulations for the use of radiation machines for security screening in correctional or other facilities; adopting new regulations for stereotactic radiosurgery devices for radiation therapy; revising certain provisions for registration of radiation machines to include those in storage or disassembled; revising certain provisions for alignment with new proposed regulations and revising certain provisions related to exempt concentrations of natural occurring Radium-226.

Legislative Counsel's Digest:

Existing law requires the State Board of Health to adopt certain regulations for the administration of chapter 459 of NRS which relates to Hazardous Materials.

New regulation **Section 1** proposed to clarify regulatory requirements for individuals and companies that service radiation machines or provide qualified expert services for certain radiation machines.

New regulation **Section 2** proposed to provide regulations for computed tomography and cone beam computed tomography x-ray machines, to include new technologies and remote operation settings.

New regulation **Section 3** proposed to provide regulations for stereotactic radiosurgery devices used for radiation therapy.

New regulation **Section 4** proposed to provide requirements for the use of radiation machines on humans for security screening purposes in correctional facilities or other institutions with security screening needs.

New regulation **Section 5** adds a definition of stereotactic radiosurgery device to align with new Sec. 3.

Existing regulation (NAC 459.150 to NAC 459.154) **Section 6** revised to incorporate language from proposed new regulation sections and expand registration requirements to radiation machines that are in storage and disassembled, with termination of the registration only after documented disposal or removal of the radiation machine from the facility.

Existing regulation (NAC 459.470) **Section 7** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.488) **Section 8** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.554, 2) **Section 9** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.581) **Section 10** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.5923) **Section 11** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.614) **Section 12** revised to incorporate language from proposed new regulation or revisions noted in Sec. 1 – Sec. 6.

Existing regulation (NAC 459.184) **Section 13** revised to provide clarification for determination of Ra-226 concentrations to include consideration of background.

Existing regulation **(**NAC 459.021) **Section 14** revised to provide clarification on the definition of background for Ra-226 and other NORM concentrations.

Section 1. Proposed New Regulation

Registration Requirements of Service Providers and Qualified Experts for of Servicing and Services

1. In addition to the requirements of NAC 459.150 to 459.179, each person applying for registration as a service provider shall:

(a) Submit a completed Service Provider Application Form provided by the Division and made available on its website.

(b) Specify the services for which he/she is applying for registration;

(c) Provide documentation of the training and experience that demonstrate the person is qualified to perform the services they provide.

2. For the purpose of "b" above, services may include but shall not be limited to:

(a) Installation and/or servicing of radiation machines and associated radiation machine components;

(b) Calibration of radiation machines or radiation measurement instruments or devices;

(c) Radiation protection or health physics consultations or surveys;

(d) Personnel dosimetry services;

(e) Provider of equipment;

(f) Shielding design and evaluation;

(g) Qualified Expert services for e-brachytherapy;

(h) Qualified Expert services for therapeutic machines.

(i) Qualified Expert services for CT equipment.

3. No individual shall perform services that are not specifically stated in their registration application.

4. Documentation of the education, training and experience must be maintained and be available upon request for inspection for persons providing services outlined in 459.151,2,(b), (c), (d), (f), (g), (h), and (i). The documentation education, training, and education must include:

(a) Proof of a bachelor's degree or higher in health physics, medical physics, other physical science or engineering from an accredited college or university;

(b) Documentation of forty (40) hours practical training and/or supervised experience in x-ray physics;

(c) Proof of training specific to the type of equipment for which the individual will be providing qualified expert services; or

(d) Certification as a Health Physicist, Medical Physicist, Physicist or Dosimetrist by a nationally recognized certifying agency, (or)

(e) A combination of other education, training, and experience as approved by the Division.

Sec. 2. Proposed New Regulation

Computed Tomography X-Ray systems: Authority, purpose, and scope.

1. The requirements of this chapter are adopted pursuant to the provisions of NRS 459.201.

2. This section establishes CT X-ray system requirements for the intentional exposure of humans to ionizing radiation for diagnostic imaging.

3. Exemptions. Registrants using CT for simulation exclusively for treatment planning purposes in conjunction with a megavoltage radiation therapy or brachytherapy are exempt from the requirements of this chapter, except that the registrant shall comply with the requirements of the subsection Quality Assurance For Radiation Therapy Simulation Systems and Imaging Systems Used for Guidance During Therapeutic Radiation' of section 2'.

4. In addition to the requirements established in this chapter, registrants shall also comply with applicable requirements in NAC 459.010 to 459.950, inclusive.

Computed Tomography X-Ray systems: Definitions, abbreviations, and acronyms.

1. The definitions, abbreviations, and acronyms in this section, apply specifically to this section unless the context clearly indicates otherwise.

"Assisting Radiologic Imaging Technologist" means a person licensed pursuant to NRS 653 to perform radiologic imaging and who has been trained in the operation of the CT X-ray system for the CT tasks they perform, according to the ARRT educational and clinical training requirements for CT technologist. The assisting technologist is the person who is present at the imaging facility where the patient is located during remote CT operations.

"Cone Beam Computed Tomography" or "(CBCT)" means a variation of gantry-style CT X-ray system that rotates around the patient, capturing data using a cone-shaped X-ray beam. This data is used to reconstruct a three-dimensional image.

"CT" or "computed tomography" means technology that uses computer-processed X-rays to produce tomographic images (virtual slices) of specific areas of the patient's body or scanned object.

"CT technologist" means a person licensed pursuant to NRS 653 to perform CT radiologic imaging.

"CTDI" or "computed tomography dose index" means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan that is:

Where:,

, Z = Position along a line perpendicular to the tomographic plane;

, D(z) = Dose at position z;

, T = Nominal tomographic section thickness;

, N = Number of tomograms produced in a single scan.

, and:

the dose profile is centered around z and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"CTDI100" means the accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The CTDI100, requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of CTDI100, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available "pencil" ionization chamber. CTDI100 is acquired using a 100-mm long, 3-cc active volume CT "pencil" ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table. The equation is:

$$CTDI_{100} = \frac{1}{NT} \int_{-50mm}^{50mm} D(z)dz$$

"CTDIvol" means the product of the CTDIw and NT, divided by the table increment I and expressed as milliGray.

CTDIvol = (N)(T)(CTDIw)/I, where:

N = number of simultaneous axial scans per x-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

CTDIvol = CTDIw / pitch

"CDTIw" means the estimated average CTDI100 across the field of view (FOV). The equation is:

$$CTDI_w = 1/3\, CTDI_{100,center} + 2/3\, CDTI_{100,edge}.$$

"CT dosimetry phantom" means an object used to determine the dose delivered by a CT or CBCT X-ray system.

"CTN" or "computed tomography number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image:

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:,

, k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

, μx = Linear attenuation coefficient of the material of interest;

, μw = Linear attenuation coefficient of water.

"CT procedure" means an activity directed at or performed on a patient necessary to make a diagnosis using a CT X-ray system including, but not limited to, setting, modifying, or applying parameters or protocols.

"CT simulator" means a CT unit that allows for precise cancer treatment planning by demonstrating the relationship between the target tumor and healthy tissues while the patient is in a treatment position.

"CT X-ray system" means a gantry-style X-ray system that generates a tomographic image through acquisition of cross-sectional image slices perpendicular to the plane of travel of the gantry.

"Dose profile" means the dose as a function of position along a line.

"DLP" or "dose length product" means the product of the CTDIvol and the scan length of a single or group of scans performed on the same body part. This number can be calculated over the entire CT procedure to give an estimate of the total dose. The formula results in a value expressed in milliGray centimeters.

DLP (mGy-cm) = CTDIvol (mGy) x scan length (cm)

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (Sn) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

Where:,

, CS = Linear attenuation coefficient of the material of interest;

, μw = Linear attenuation coefficient of water;

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

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

"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.

"O-Arm" means a multidimensional surgical imaging system that provides real-time 2D and 3D images during operations.

"Operator" means a person licensed to perform CT pursuant to NRS 653 within the scope of practice in NAC 653.400 or a person exempted from the requirements of NRS 653 working within the scope of practice for their license type..

"PACS" or "picture archiving and communication system" means a medical imaging technology that provides economical storage of and convenient access to images from CT.

"Parameter" means settings on the CT X-ray system that can be modified including, but not limited to, peak tube potential in kV, filtration thickness, the tube current in mA and the exposure time in milliseconds, and the product of tube current and exposure time in mAs.

"Protocol" means the collection of settings and parameters affecting CT dose and image quality that specify how data collection and reconstruction, patient positioning, and contrast administration are performed.

"PET CT" means an imaging modality that uses positron emission tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

"Radiologic technologist" means an individual licensed pursuant to NRS 653.

"Remote CT location" means operation of a CT X-ray system by licensed and qualified operators who are not physically present with the CT X-ray system or the patient.

"Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

"Sensitivity profile" means the relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

"SPECT CT" means an imaging modality that uses single-photon emission computed tomography and computed tomography in one device to combine the structural anatomic information with functional data collected during the examination.

"Tomogram" means a two-dimensional image representing a slice or section through a three-dimensional object using a CT X-ray system.

"Tomographic plane" means the geometric plane which is identified as corresponding to the tomogram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

Computed Tomography X-Ray systems: Equipment Requirements.

1. The CT X-ray system must:

(a) Meet the requirements of 21 C.F.R. Sec. 1020.33 at the time of installation and while the CT X-ray system is registered with the Division under chapter NAC 459.150 through 459.166 inclusive

(b) Be equipped:

(1) With a visible signal that indicates when the X-ray exposure is occurring;

(2) So that the operator can immediately terminate an X-ray exposure of greater than one-half second duration at any time during the X-ray exposure;

(3) So that the parameters used during a CT procedure are:

(i) Displayed prior to beginning a scan; and

(ii) Visible by the operator from any location scanning can be initiated.

(4) So that radiation leakage from the tube port does not exceed limits established in NAC 459.564 when data are not being collected for image production;

(5) So that the accuracy of the laser or optical positioning system is within five millimeters maximum deviation on the axial position (z-axis);

(6) With an X-ray production indicator of at least one-half second at or near the gantry that is visible from any point outside the gantry opening;

(7) So that premature termination of the X-ray exposure by the operator requires resetting of the parameters prior to initiating another scan.

(c) Be evaluated for system performance by a qualified expert upon initial installation and before use on human patients, at intervals not to exceed 12 months thereafter, and within 30 days of any change or component replacement determined by a qualified expert to change the radiation output or image quality. The evaluation shall include, but not be limited to:

(1) Geometric factors and alignment including:

(i) Alignment light accuracy;

(ii) Table increment accuracy.

(2) Image localization from scanned projection radiograph (localization image);

(3) Radiation beam width;

(4) Image quality including:

(i) High-contrast (spatial) resolution;

(ii) Low-contrast resolution;

(iii) Image uniformity;

(iv) Noise;

(v) Artifact evaluation.

(5) CT number accuracy;

(6) Image quality for acquisition workstation display devices;

(7) A review of the results of the routine QC required by subsection Computed Tomography X-Ray systems: Equipment Requirements, 1(d) of Section2;

(8) A safety evaluation of audible and visual signals, posting requirements;

(9) Dosimetry.

(10) Any applicable manufacturer quality control tests

(d) Be evaluated with a routine QC program that meets the following requirements:

(1) Be developed by a qualified expert and include acceptable tolerances for tests evaluated based on manufacturer recommendations or nationally recognized industry standards;

(2) Incorporate the use of a CT phantom. At a minimum, noise, CT number, and artifacts shall be evaluated.

(3) Be completed at time intervals and under system conditions specified by the manufacturer's recommendations or based on nationally recognized industry standards

(4) Be documented and maintained for a minimum of three years for inspection by the Division

Computed Tomography X-Ray systems: Design requirements.

1. The location of a transportable and fixed CT X-ray system must be designed and constructed:

(a) To provide for two-way verbal communication between the patient and the operator at the control panel;

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

(c) With an alternate viewing system when the primary viewing system is electronic.

2. Within thirty days of first use of a transportable or stationary CT X-ray system, the registrant shall complete and keep on file a radiation protection shielding survey of the room and surrounding areas consistent with nationally accepted industry standards.

3. Records of shielding design and survey must be retained for the duration of the use and registration of the CT X-ray system.

Computed Tomography X-Ray systems: Shielding design requirements for transportable, mobile, and stationary CT X-ray systems.

(1) The operator's booth and surrounding occupied areas must be designed and constructed in accordance with nationally accepted industry standards;

(2) Protective barriers must be provided in the ceiling, floor, and walls of the CT X-ray system enclosure to ensure exposure does not exceed dose limits established in NAC 459.325, NAC 459.331, and NAC 459.333 for occupational exposure and NAC 459.335 for individual members of the public.

(3) The control panel must be shielded by a protective barrier that cannot be removed from a protective position between the operator and the radiation source during CT X-ray system operation.

(4) The registrant shall submit a revised radiation shielding plan for department review in accordance with this section after replacement of a transportable or stationary CT X-ray system, or any change in the CT X-ray system room's construction or surrounding rooms' construction.

(5) Rooms in which a mobile CT X-ray system is used are exempt from the requirements of subsections (1), (2), (3), and (4) of this section while ensuring that:

a. Exposure does not exceed dose limits established in NAC 459.325, NAC 459.331, and NAC 459.333 for occupational exposure and NAC 459.335 for individual members of the public, and

b. A protective barrier at least 2 meters (6.5 feet) high is provided for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during the exposure.

Computed Tomography X-Ray systems: Operating procedures.

1. The registrant shall:

(a) Ensure that the operator of the CT X-ray system is licensed to engage in CT pursuant to NRS 653 or is exempt from the requirements of NRS 653 and complies with the scope of their practice for their license type.

(b) Establish a procedure to record and retrieve CTDIvol, DLP, and other applicable dose records from the CT X-ray system.

2. The registrant shall provide estimated patient dose for an individual study within ten business days of a patient request.

3. The registrant shall establish CT procedures for each CT X-ray system in consultation with a qualified expert and licensed practitioner of the healing arts to ensure they are correct for the intended dose and image quality. The CT procedures must include:

(a) A method to be used to monitor the CT radiation output.

(b) A standardized protocol development and naming policy.

(c) A process determining who has access and authority to make changes to the protocol management systems, including a method to prevent inadvertent or unauthorized modifications to a CT protocol.

(d) Procedural, software, and engineering measures that prohibit anyone from changing protocols or parameters without approval from a licensed practitioner of the healing arts and the radiation safety officer such as password protection.

(e) Documentation of protocols and any associated parameter changes must be maintained for three (3) years.

(f) If CT fluoroscopy is performed, the registrant shall establish and implement operating procedures and training designed to minimize patient and occupational radiation exposure.

4. The registrant must approve in writing all changes made by a CT manufacturer's representatives or a qualified expert including protocol and software changes or upgrades that would impact radiation dose or image quality before imaging patients.

5. The registrant shall establish and review CT protocols in consultation with a qualified expert and licensed practitioner of the healing arts, to ensure they are correct for the intended dose and image quality as follows:

(a) Establish all CT protocols upon installation of a CT X-ray system;

(b) Annually review any new or changed protocols since the last review.

(c) Annually review the most frequently performed or highest dose protocols so that a total of at least six existing protocols are reviewed annually.

(d) As part of the review, the registrant shall:

(i) Compare current protocols to the dose assessments that were made during the last annual performance evaluation required in subsection Equipment requirements, 1(d) of Section 2.

(ii) Determine whether the protocols from each CT procedure are appropriate, can be modified to lower the CTDIvol without an unacceptable sacrifice in image quality, or can be eliminated;

(iii) Establish guidelines of variability that establish parameter and protocol limits.

6. The registrant shall ensure the operators do not adjust parameters or protocols for a CT procedure outside the approved limits established in the guidelines of variability.

7. The registrant shall ensure that all operators check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the CT procedure and individual patient. This may be accomplished by reviewing dose indicator devices if available or dose indices. The

registrant shall ensure the operators document dose indicators or indices which are outside the expected values and submit the documentation to the radiation safety officer for review.

8. Each registrant shall create a written policy establishing procedures for retaking CT scans including, but not limited to, how many scans are authorized for a patient and who can authorize additional retakes. The policy must be approved by the radiation safety officer.

Computed Tomography X-Ray systems: Dose limits; event investigation and reporting.

1. The CTDIvol for the following CT procedure on phantoms must be consistent with ALARA practices and meet recognized national industry standards for the following procedures;

(a) adult head,

(b) adult abdomen,

(c) pediatric head (one year old),

(d) pediatric abdomen (40 pounds).

2. Registrants shall report the following the following events as a medical misadministration in accordance with NAC 459.551:

(a) The cumulative CTDIvol over the course of an individual study at a particular anatomical location exceeds 60 rem (600 mGy) for a pediatric CT procedure or 150 rem (1500 mGy) for an adult CT procedure; or

(b) Any ionizing radiation exposure from a CT procedure results in unanticipated hair loss, erythema, or functional damage to an organ or physiological system.

Computed Tomography X-Ray systems: Cone-Beam CT (CBCT) X-ray systems.

1. The CBCT X-ray system, excluding those used with therapy X-ray equipment must:

(a) Meet the requirements of 21 C.F.R. Sec. 1020.33 at the time of installation and while the CT X-ray system is registered with the department under chapter NAC 459.150 through 459.166, inclusive; and

(b) Be equipped:

(1) With a visible signal that indicates when the X-ray exposure is occurring;

(2) So that the operator can immediately terminate an X-ray exposure of greater than one-half second duration at any time during the X-ray exposure;

(3) So that the parameters used during a CT procedure are:

(i) Displayed prior to beginning a scan; and

(ii) Visible by the operator from any location scanning can be initiated.

(4) So that radiation leakage from the tube port does not exceed limits established in NAC 459.564;

(5) So that the accuracy of the laser or optical positioning system is within five millimeters maximum deviation on the axial position (z-axis);

(6) With an X-ray production indicator of at least one-half second at or near the gantry that is visible from any point outside the gantry opening;

(7) So that premature termination of the X-ray exposure by the operator requires resetting of the parameters prior to initiating another scan.

(c) Be evaluated for system performance by a qualified expert upon initial installation and before use on human patients, at intervals not to exceed 12 months thereafter, and within 30 days of any change or component replacement determined by a qualified expert to change the radiation output or image quality. The evaluation shall include, but not be limited to:

(1) Beam alignment.

(i). The X-ray field in the plane of the image receptor may not exceed beyond the edge of the image receptor by more than 2% of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

(ii). The center of the X-ray field must be aligned with the center of the image receptor to within 2% of the SID.

(2) Image quality including:

(i) High-contrast (spatial) resolution;

(ii) Low-contrast resolution;

(iii) Image uniformity;

(iv) Noise;

(v) Artifact evaluation.

(3) Image quality for acquisition workstation display devices;

(4) A review of the results of the routine QC required under subsection Cone-Beam (CBCT) X-ray Systems, 1(c) of Section 2.

(5) A safety evaluation of audible and visual signals, posting requirements;

(6) Dosimetry.

(7) Any applicable manufacturer quality control tests

2. The registrant shall document and follow QC recommendations in accordance with manufacturer recommendations or as established by a qualified expert in accordance with nationally recognized guidelines.

3. The registrant shall document and implement imaging protocols and a policy addressing deviations from established protocols.

4. The CBCT X-ray system shall only be operated by a person licensed to perform CT pursuant to NRS 653 within the scope of practice in NAC 653.400 or a person exempted from the requirements of NRS 653 working within the scope of practice for their license type.

(a) The CBCT operator shall have instructions on all of the following:

(1) Performing routine QC, including the use of the CBCT phantom.

(2) A schedule of routine QC appropriate for the system.

(3) Allowable variations to protocols set by the qualified expert and approved by the radiation safety officer, if required, for the indicated parameters.

(4) The results of at least the most recent routine QC completed on the system

5. The registrant shall maintain documentation of the established protocols, policies, and QC testing for three (3) years for inspection by the Department.

6. CBCT systems are exempt from the requirements in subsection Computed Tomography X-Ray systems: Equipment Requirements of Section 2.

7. Exemption. A QMP [QE] performance evaluation on CBCT systems capable of operating at no greater than 100 kV or 20 mA shall be performed at intervals not to exceed 24 months, or an interval approved by the Agency.).

Computed Tomography X-Ray systems: Quality Assurance For Radiation Therapy Simulation Systems and Imaging Systems Used for Guidance During Therapeutic Radiation.

1. Simulation and imaging systems solely used for treatment planning in radiation oncology shall meet the applicable requirements in NAC 459.582 to 459.5927, inclusive, and NAC 459.594 to 459.612, inclusive, and

2. Quality assurance for a conventional or virtual simulator and for imaging systems used for guidance during therapeutic radiation shall include acceptance testing and periodic verification of system performance; and

3. Be performed in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols,

shall be followed.

4. If the CT simulator will be used for diagnostic imaging purposes, the machine must meet the requirements of the following subsections Computed Tomography X-Ray systems: Equipment Requirements, Computed Tomography X-Ray systems: Design requirements, Computed Tomography X-Ray systems: Shielding design requirements for transportable, mobile, and stationary CT X-ray systems Computed Tomography X-Ray systems: Operating procedures, Computed Tomography X-Ray systems: Dose limits; event investigation and reporting of Section2.

Computed Tomography X-Ray systems: PET CT and SPECT CT Systems.

1. PET CT and SPECT CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in the following subsections Computed Tomography X-Ray systems: Equipment Requirements, Computed Tomography X-Ray systems: Design requirements, Computed Tomography X-Ray systems: Shielding design requirements for transportable, mobile, and stationary CT X-ray systems Computed Tomography X-Ray systems: Operating procedures except sub section 5, Computed Tomography X-Ray systems: Dose limits; event investigation and reporting of Section 2, unless otherwise designated below:

(a) In lieu of the requirement in subsection Computed Tomography X-Ray systems: Equipment Requirements (1)(c) of Section 2, a qualified expert shall complete a performance evaluation on the CT system following nationally recognized guidelines at intervals not to exceed 12 months.

(b) Each person who operates PET CT and SPECT CT must be licensed to perform nuclear medicine pursuant to NRS 653 and comply with the scope of practice in NAC 653.400 or be exempted from the requirements of NRS 653 and comply with the scope of practice for their license type.

(c) If the CT component of the PET/CT will be used for diagnostic imaging purposes, the machine must meet all requirements of a diagnostic CT X-ray system.

Computed Tomography X-Ray systems: Remote CT or CBCT X-ray system operations.

1. Each person who seeks to operate CT X-ray systems from a remote CT location in this State must apply for registration with the Division pursuant to NAC 459-150 through 459.166. inclusive, and receive a certificate of registration before engaging in remote CT procedures.

2. A person may engage in remote CT operations only if the remote CT location and each CT X-ray system at the imaging site is registered with the Division.

(a) Remote CT locations or CT X-ray systems at imaging sites located outside the state must be registered with the state where they are located and proof of such registration shall be provided to the Division with the registration for this in-state remote location or CT X-ray system.

3. Each person who engages in remote CT procedures must comply with the requirements of NAC 459.788 and be located within the State or have a physical location within the state that provides the Division with the opportunity to conduct inspections.

4. The Remote CT X-Ray system must meet all applicable requirements in section 2.

(a) All components of the Remote CT systems or components must be approved by the Food and Drug Administration (FDA) prior to use, when approval is required by the FDA.

(b) Each remote CT-Xray system including all components shall be maintained, serviced, and tested in accordance with the manufacturer's specifications and recommendations, regardless of physical location.

5. Appropriately licensed persons must be physically located at all locations where the Remote CT X-ray system is being controlled or performed, as follows:

(a) The operator at the remote CT location must:

(1) Be licensed to perform CT pursuant to NRS 653 and comply with the scope of practice in NAC 653.400 or be exempted from the requirements of NRS 653 and comply with the scope of practice for their license type.

(2) Be physically present at the remote CT location throughout the entire CT exam,

(b) The Assisting Radiologic Imaging Technologist at the facility where the patient and imaging CT X-ray system is located must:

(1) Be licensed to perform radiological imaging as Radiologic Technologists (RT), Radiation Therapist, or Nuclear Medicine Technologists (NMT) pursuant to NAC 653 and comply with the scope of practice in NAC 653.400 or be exempted from the requirements of NRS 653 and comply within the scope of practice for their license type.

(2) Be trained for the CT tasks they perform according to the ARRT educational and clinical training requirements for CT technologists. The training must incorporate appropriate sections of the CT Curriculum established by the American Society of Radiologic Technologists (ASRT)., and

(3) Be physically present with the patient throughout the entire CT exam.

6. Radiation Safety Program Elements for Remote Computed Tomography

(a) The Applicant will develop, document, and maintain a radiation safety program with the following provisions:

(1) Use only remote CT systems and components that can adequately protect patient information and to establish policies and procedures for ensuring patient information is protected at the imaging facility, remote imaging locations, and locations where other members of the medical team will view or access patient information.

(2) Maintain a list of the remote operating locations and associated imaging sites. The list must contain the name of the facility, location, and a contact person.

(3) Define the roles and responsibilities for the remote CT technologist and the assisting technologist.

(4) Identify the tasks performed by the assisting and remote technologists and develop procedures for these tasks.

(5) Ensure the assisting technologist completes annual radiation safety training related to their CT responsibilities.

(6) Ensure the assisting technologist maintains constant surveillance of the patient throughout the CT imaging procedure and performs only one CT imaging procedure at a time.

(7) Ensure remote CT will not be performed if communications (verbal and virtual) or connectivity between the remote site and the imaging facility is not functioning properly or is otherwise unreliable.

(8) Perform checks of the communication system (verbal and visual) and the functionality and connectivity between the remote location and the imaging facility prior to initiating each CT imaging procedure.

(9) Develop procedures for responding to emergencies and situations where there may be a loss of connectivity between the remote site and the imaging facility.

(10) Ensure the remote CT technologist maintains constant surveillance via vocal and visual communications throughout a CT imaging procedure and performs only one CT imaging procedure at a time.

(11) Develop policies and procedures to ensure adequate management oversight of remote operations, including audits to evaluate the effectiveness and safety of the remote CT operations, reporting misadministrations, observations of work being performed at both the imaging facility and the remote location, and processes to identify, track, investigate, and implement corrective actions for incidents where CT exams are incomplete or repeated.

Sec. 3. Proposed New Regulation

STEREOTACTIC RADIOSURGERY DEVICES

All stereotactic radiosurgery devices must meet the applicable therapy system requirements NAC 459.400 - 459.624, inclusive, and the specific requirements listed in this section.

Stereotactic Radiosurgery Devices: Registration.

The registration application provided to comply with NAC 459.150 to 459.166, inclusive, must include, without limitation:

1. Room design and shielding calculations,

2. Equipment specifications,

3. Radiation protection survey procedures,

4. Quality assurance protocols,

5. Operational procedures, including procedures for motion tracking systems.

Stereotactic Radiosurgery Devices: Radiation Safety Requirements.

1. Shielding and Treatment Room Design Requirements:

(a) In addition to complying with the room design requirements of NAC 459.590, the design of the treatment room must meet the following requirements:

(1) Provide sufficient clearance for robotic arm motion,

(2) Comply with the manufacturer's specified or recommended minimum dimensions and structural support requirements,

(3) Include shielding for all wall, floor, and ceiling surfaces as necessary, to comply with NAC 459.320 to NAC 459.374, inclusive, and NAC 459.400 to 459.624, inclusive.

(4) Allow for clear placement of X-ray imagers and detectors.

(5) Provide for the following patient support:

(i) Immobilization devices appropriate for treatment duration shall be provided,

(ii) Continuous audio-visual monitoring systems shall be in place,

(iii) Climate control and lighting suitable for patient comfort shall be maintained.

(b) A radiation protection survey shall be conducted prior to clinical use.

Stereotactic Radiosurgery Devices: Quality Assurance.

1. The registrant shall implement a QA program consistent with manufacturer recommendations and nationally accepted quality control standards.

2. Comply with applicable sections of 459.582 through 459.5927.

Sec. 4. Proposed New Regulation

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Applicability.

These rules apply to the registration and operation of radiation emitting body scanners used for nonmedical, security-related purposes. Use of such scanners are prohibited unless specifically approved by the department.

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Definitions.

Definitions. As used in this section, unless the context otherwise requires, the words and terms defined in this section, have the meanings ascribed to them in this section.

"General-use system" (GU) means a scanner delivering ≤10 µrem (0.1 µSv) per scan and used without limitations on individuals scanned.

"Limited-use system" (LU) means a scanner delivering >(10 µrem (0.1 µSv) and ≤ 1mrem (10 µSv) per scan, subject to administrative controls.

"Responsible person" means an individual designated to oversee scanner operation, training, maintenance, and safety compliance.

"Security screening system (human)" means radiation-generating equipment used for the sole purpose of screening an individual to identify contraband items that would present a security threat within a secured facility perimeter. This does not include security screening devices used for objects.

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Registration Requirements.

Persons who seek to perform security screening on humans must:

1. Register the X-ray system pursuant to NAC 459.150 to 459.166, inclusive unless otherwise required in this section;

2. Demonstrate to the Division the need for enhanced security measures to secure their facility and operations;

3. Submit a completed Security Screening on Humans Application Form provided by the Division and made available on its website; and

4. Submit any additional information requested by the Division.

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Equipment Requirements

1. All security screening systems must:

(a) Only be used for its designed purpose, as specified by the manufacturer; and

(b) Be maintained and serviced in accordance with the manufacturer's recommendations unless there is a documented change to the maintenance and service requirements by the manufacturer or the security screening system is certified and labeled in accordance with applicable FDA requirements.

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Operational Requirements.

1. Equipment must be used only as approved, and any deviation from the approved application shall require written department approval.

2. All equipment must be operated and maintained in accordance with the American National Standards Institute (ANSI)/Health Physics Society (HPS) N43.17-2009 standard, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation." This includes compliance with dose limits for security scans, operational protocols, safety features, and signage requirements outlined in the standard.

3. Registrants of security screening systems must comply with the following administrative and radiation safety requirements:

(a) A person shall be designated as responsible for radiation protection who has experience, training and authority to make decisions related to radiation risk and safe operation of the security screening device.

(b) No person will be exposed to the useful beam unless authorized by the registrant for a demonstrated security benefit. This provision specifically prohibits deliberate exposure of a person for training, demonstration or other purposes unless there are also security requirements and proper authorizations have been provided.

(c) Human security screening devices shall not be used for theft detection purposes.

(d) Screening must be performed to identify any minors under the age of 18 years of age or pregnant persons. For these persons the registrant shall:

(1) Inform the person, or for minors their parent/guardian, of the radiation exposure from the security screening and the risks associated with exposures.

(2) Offer alternative screening procedures if the individual declines security screening using the radiation machine.

(3) Ensure minors or pregnant persons do not exceed doses for special populations as specified in Annex A of ANSI/HPS 43.17.

(e) The registrant shall ensure that no person exceeds the dose limitations specified in ANSI/HPS 43.17 - 2009.

(f) The registrant shall ensure that all operators are trained in the safe operation of the security screening systems in accordance with manufacturer instructions and ANSI/HPS N43.17-2009. Documentation of initial and refresher training must be maintained for three (3) years;

(g) The registrant shall follow the manufacturer's recommended maintenance schedule unless otherwise approved by the Division. Maintenance shall be performed by a registered service provider.

(h) Handheld X-ray systems shall not be used for human security screening purposes.

Radiation Emitting Body Scanners for Security-Related Purposes (non-healing arts exposure to humans): Radiation Safety Program and Audits

1. The registrant shall review, at intervals not to exceed 12 months, the content and implementation of the program for protection against radiation. The audit must include the requirements in the registration application and ANSI/HPS N43.17-2009, and any applicable corrective actions.

2. 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.

(a) Require proper operation of the unit, consistent with the manufacturer's manual;

(b) Must only be used for its designed purpose, as specified by the manufacturer;

(c) Must be maintained and serviced in accordance with the manufacturer's recommendations.

Adoption of publications by reference.

1. The ANSI/HPS N43.17-2009, approved in August 2009 and reaffirmed on 24 July 2018, by the American National Standards Institute, Inc., is hereby adopted by reference. The publication is available for purchase at https://hps.org/hpssc/index/. The cost is $50.00.

2. If the website ceases to exist, the Division will provide a new access option. If the publication adopted by reference in subsection 1 is revised, the Division must review the revision to determine its suitability for this State. If the Division determines that the revision is not suitable for the State, the Division must hold a public hearing to review its determination and give notice of that hearing within 90 days after the date of publication of the revision. If, after the hearing, the Division does not revise its determination, the Division must give notice that the revision is not suitable for this State within 90 days after the hearing. If the Division does not give such notice, the revision becomes part of the publication adopted by reference pursuant to subsection 1, as applicable.

Sec. 5. Proposed New Definition *"Stereotactic Radiosurgery Device" (NRS 459.201) means a robotic stereotactic radiosurgery system using a linear accelerator mounted on a robotic arm, capable of delivering non-isocentric, image-guided radiation with sub-millimeter precision.*

Sec. 6. NAC 459.150 to NAC 459.154 proposed amendment to read as follows:

NAC 459.150 Scope of provisions; registration of radiation machines and persons who install or perform service upon such machines required; modifications of radiation machines; prohibitions. (NRS 459.201)

1. NAC 459.150 to 459.179, inclusive, provide for the registration of radiation machines and registration of persons who install or perform service *including services defined in Sec. 1* 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*, unless disassembled,* 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 *or provide qualified expert services* unless he or she is registered in conformance with the requirements of NAC 459.150 to 459.179, inclusive.

5. A person who is registered with the Division to install, service or repair radiation machines *or provide qualified expert services* 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.

NAC 459.152 Exemptions from requirements. (NRS 459.201)

1. Except as otherwise provided in subsection 5, 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, 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) A]~~*a*re 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.

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

~~[4. For the purposes of subsection 5 [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.]~~ *4.* A~~[n 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.]~~ *must be registered as stored or disassembled.*

~~[6.]~~ *5.* Nothing in this section exempts a person from the licensing requirements of NAC 459.010 to 459.950, inclusive, and chapter 459 of NRS applicable to the possession and use of radioactive materials.

NAC 459.154 Applications for registration; temporary use of portable machine; installation by authorized holder of registration certificate required; fee for registration; refund of fee if paid in error. (NRS 439.150, 459.201)

1. Except as otherwise provided in subsection 2, each person who controls an unregistered, operational, *stored, or disassembled* 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]~~ *receipt* of the machine *at the facility location*. *Each person who controls a radiation machine that was previously registered and is disassembled or in storage 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;

(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 *or provide qualified expert services* in this State must apply for

registration with the Division, meet the requirements of *Sec. 1* 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 *or provide qualified expert services* 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.

9. A radiation machine registration may be terminated after the radiation machine has been disposed of or the radiation generating portion of the machine, such as the X-ray tube or target, if an accelerator, has been removed and disposed.

Sec. 7. NAC 459.488 proposed amendment to read as follows:

NAC 459.488 "Qualified expert" defined. (NRS 459.201) "Qualified expert" means a person who has *registered as a service provider and* meets the education, training, and experience requirements in section 1.

Sec. 8. NAC 459.554, 2 proposed amendment to read as follows:

NAC 459.554 Administrative controls: Radiographic exposure. (NRS 439.200, 459.201)

2. Persons must not be exposed to the useful beam except for the purposes of the healing arts where each exposure has been authorized by a licensed practitioner of the healing arts *or for security screening authorized pursuant to Sec. 4.* This provision specifically prohibits deliberate exposure for the following purposes:

(a) Exposure of a person for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided.

(b) Exposure of a person for the purpose of healing arts screening without prior written approval of the Division. Screening means an exposure of a person without a prior examination by a licensed practitioner.

Sec. 9. NAC 459.581 proposed amendment to read as follows:

NAC 459.581 Registration of electronic brachytherapy systems, *stereotactic radiosurgery device,* or additional therapeutic X-ray systems. (NRS 459.201)

1. Except as otherwise provided in subsection 4, each person who acquires an electronic brachytherapy system, *stereotactic radiosurgery device,* or an additional therapeutic X-ray system shall apply to the Division for registration of the machine within 30 days after installing the machine. The application must include, without limitation:

(a) A list of all authorized users, radiation therapy physicists and operators;

(b) The name of the radiation safety officer and radiation safety committee members;

Sec. 10. NAC 459.5923 proposed amendment to read as follows:

NAC 459.5923 Therapeutic X-ray systems: Requirements for authorized medical physicist for electronic brachytherapy. (NRS 459.201)

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

(c) Have had his or her training reviewed and approved by the Division.

(d) Be registered as a service provider pursuant to Sec. 1.

Sec. 11. NAC 459.614 proposed amendment to read as follows:

NAC 459.614 Veterinary medicine radiographic installations. (NRS 459.201)

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 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.

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.

12. CT systems, including CBCT systems, solely used in non-human imaging are exempt from the standards of Sec. 3 but shall meet the requirements of:

(a) Sec. 3 sub section Computed Tomography X-Ray systems: Equipment Requirements, 1. c and Computed Tomography X-Ray systems: Cone-Beam CT (CBCT) X-ray systems, 1. c, at a frequency of every 4 years.

(b) Section 3, sub section Computed Tomography X-Ray systems: Shielding design requirements for transportable, mobile, and stationary CT X-ray systems, 2 and 5, to ensure occupational and public exposure limits.

(c) All other applicable provisions of NAC 459.150-166, inclusive.

Sec. 12. NAC 459.184 proposed amendment to read as follows:

NAC 459.184 Exemption for certain concentrations and quantities of radioactive material other than source material. (NRS 459.030, 459.201)

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 the natural background as provided by a National Laboratory evaluation or as determined by sampling of surrounding materials not of the same geologic body of materials but in adjacent locations.*

Sec. 13. NAC 459.021 proposed amendment to read as follows:

NAC 459.021 "Background radiation*/activity*" defined. (NRS 459.030, 459.201)

1. "Background radiation" means:

a. Radiation from cosmic sources;

b. ~~[N]~~*Radiation and/or activity of n*aturally 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.