HEARING SUMMARY

REGULATION: 180 NAC 6, Diagnostic X-Rays in the Healing Arts and 180 NAC 21, Dental Radiographic Equipment

DATE OF HEARING: November 1, 2019

Name/Affiliation of Person Commenting	Comments	Department Response
1. Ahaileas Harisis/Atomos Physics LLC	Supports all changes made to 180 NAC 6 and full repeal of 180 NAC 21. Changes made to 180 NAC 6 will add more flexibility to client's needs for hand-held dental equipment and better outlines requirements for cone beam CT systems.	No changes will be made at this time based on comments received.

180 NAC 6

TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS IN THE HEALING ARTS

<u>001.</u> <u>SCOPE AND AUTHORITY.</u> This chapter establishes requirements for the use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed according to State statutes to engage in the healing arts, dental healing arts, or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 18, and 20.

<u>001.01</u> PART 21 CODE OF FEDERAL REGULATIONS. Part 21 Code of Federal Regulations (CFR) as published on April 1, 2017 and referred throughout this Chapter are incorporated by reference and available for viewing at the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

002. DEFINITIONS. The following definitions apply:

<u>002.01</u> <u>AIR KERMA RATE (AKR).</u> Air kerma rate (AKR) has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.02</u> <u>ALUMINUM EQUIVALENT.</u> Aluminum equivalent has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.03</u> <u>AUTOMATIC EXPOSURE CONTROL (AEC).</u> Automatic exposure control (AEC) has the same meaning as set out in 21 CFR §1020.30(b).

002.04 BARRIER. See "Protective barrier".

<u>002.05</u> <u>BEAM-LIMITING DEVICE</u>. Beam-limiting device has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.06</u> <u>BONE DENSITOMETRY SYSTEMS.</u> A bone densitometry system is a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

<u>002.07</u> <u>C-ARM FLUOROSCOPIC SYSTEM.</u> C-arm fluoroscopic system has the same meaning as set out in 21 CFR §1020.30(b).

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<u>002.08</u> CASSETTE HOLDER. Cassette holder has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.09</u> <u>COEFFICIENT OF VARIATION OR "C"</u>. Coefficient of variation or "C" has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.10</u> <u>COMPUTED TOMOGRAPHY.</u> Computed tomography has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.11</u> <u>CONE BEAM COMPUTED TOMOGRAPHY (CBCT).</u> Cone beam computed tomography (CBCT) is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a cone-shaped x-ray beam that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

<u>002.12</u> <u>CONTINUOUS PRESSURE SWITCH.</u> A continuous pressure switch is a switch constructed so that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

<u>002.13</u> <u>CONTROL PANEL</u>. Control panel has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.14</u> <u>COOLING CURVE.</u> Cooling curve has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.15</u> <u>DENTAL RADIATION GENERATING EQUIPMENT</u>. Dental radiation generating equipment is equipment specifically used for making dental radiographs of the human teeth or tissues or the oral cavity. Dental radiographic equipment does not include dental tomography, dental computed tomography, cone beam dental computed tomography, dental fluoroscopic equipment, or rotating anode tube radiation generating equipment.

<u>002.16</u> <u>DIAGNOSTIC X-RAY SYSTEM.</u> Diagnostic x-ray system has the same meaning as set out in 21 CFR §1020.30(b).

002.17 EQUIPMENT. See "X-ray equipment".

<u>002.18</u> EXPOSURE (X). Exposure or "X" has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.19</u> <u>FACILITY</u>. A facility is the location at which one or more radiation generating devices or sources of radiation are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

<u>002.20</u> <u>FILTER.</u> A filter is material placed in the useful beam to preferentially absorb selected radiations.

<u>002.21</u> <u>FLUOROSCOPY.</u> Fluoroscopy has the same meaning as set out in 21 CFR §1020.30(b).

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<u>002.22</u> <u>GENERAL PURPOSE RADIOGRAPHIC X-RAY SYSTEM.</u> General purpose x-ray system has the same meaning as set out in 21 CFR §1020.30(b).

002.23 GONAD SHIELD. A gonad shield is a protective barrier for the testes or ovaries.

<u>002.24</u> <u>HAND HELD X-RAY EQUIPMENT.</u> Hand held x-ray equipment is equipment that is designed to be hand-held during operation.

<u>002.25</u> <u>HEALING ARTS SCREENING.</u> A healing arts screening is the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe x-ray tests for the purpose of diagnosis or treatment.

<u>002.26</u> <u>IMAGE INTENSIFIER.</u> Image intensifier has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.27</u> <u>IMAGE RECEPTOR.</u> Image receptor has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.28</u> INTERIM INSPECTION. An interim inspection is an examination by the Department of information submitted by the registrant on a form provided by the Department.

002.29 INTERPRETATIVE FLUOROSCOPIC PROCEDURES. See Neb. Rev. Stat. §38-1904.

002.30 IRRADIATION. Irradiation is the exposure of matter to ionizing radiation.

002.31 KERMA. Kerma has the same meaning as set out in 21 CFR §1020.30(b).

002.32 KILOVOLTS PEAK (KVP). See "Peak tube potential".

<u>002.33</u> <u>LEAD EQUIVALENT.</u> Lead equivalent is the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

002.34 MOBILE X-RAY EQUIPMENT. See "X-ray equipment".

<u>002.35</u> <u>NON-IMAGE-INTENSIFIED FLUOROSCOPY.</u> Non-image-intensified fluoroscopy has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.36</u> <u>PATIENT.</u> A patient is an individual subjected to healing arts examination, diagnosis, or treatment.

<u>002.37</u> <u>PEAK TUBE POTENTIAL.</u> Peak tube potential has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.38</u> <u>PHANTOM.</u> A phantom is a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number, Z, and the density of the material be similar to that of tissue.

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002.39 PORTABLE X-RAY EQUIPMENT. See "X-ray equipment".

<u>002.40</u> <u>POSITION INDICATING DEVICE (PID).</u> A position indicating device (PID) is a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface of the skin distance. It may or may not incorporate, or serve as, a beam-limiting device.

<u>002.41</u> <u>PRIMARY PROTECTIVE BARRIER.</u> Primary protective barrier has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.42</u> <u>PROTECTIVE APRON.</u> A protective apron is an apron made of radiation absorbing materials used to reduce radiation exposure.

<u>002.43</u> <u>PROTECTIVE GLOVE.</u> A protective glove is a glove made of radiation absorbing materials used to reduce radiation exposure.

<u>002.44</u> <u>QUALIFIED EXPERT.</u> A qualified expert is an individual who meets the requirements of 180 NAC 15-004.03.

<u>002.45</u> <u>RADIATION THERAPY SIMULATION SYSTEM.</u> Radiation therapy simulation system has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.46</u> <u>RADIOGRAPH.</u> A radiograph is an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

002.47 RADIOGRAPHY. Radiography has the same meaning as 21 CFR §1020.30(b).

<u>002.48</u> <u>RADIOLOGICAL MEDICAL PHYSICIST.</u> A radiological medical physicist is an individual who meets the requirements of 180 NAC 15-004.01.

002.49 RADIOLOGICAL HEALTH PHYSICIST. A radiological health physicist is an individual who meets the requirements of 180 NAC 15-004.02.

002.50 RATING. Rating has the same meaning as set out in 21 CFR §1020.30(b).

002.51 <u>RECORDING.</u> Recording has the same meaning as set out in 21 CFR §1020.30(b).

002.52 SCAN. Scan has the same meaning as set out in 21 CFR §1020.30(b).

002.53 SCAN TIME. Scan time has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.54</u> <u>SCATTERED RADIATION.</u> Scattered radiation is radiation that during passage through matter has been deviated in direction.

<u>002.55</u> <u>SHUTTER.</u> A shutter is a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and has a lead equivalency not less than that of the tube housing assembly.

002.56 SOURCE. Source has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.57</u> <u>SOURCE-IMAGE RECEPTOR DISTANCE (SID)</u>. Source-image receptor distance (SID) has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.58</u> <u>SOURCE-SKIN DISTANCE (SSD).</u> Source-skin distance has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.59</u> <u>SPOT CHECK.</u> A spot check procedure is a procedure which is performed to assure that a previous calibration continues to be valid.

002.60 STATIONARY X-RAY EQUIPMENT. See "X-ray equipment".

002.61 STRAY RADIATION. Stray radiation is the sum of leakage and scattered radiation.

<u>002.62</u> <u>TECHNIQUE FACTORS.</u> Technique factors has the same meaning as set out in 21 CFR §1020.30(b).

002.63 TOMOGRAM. Tomogram has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.64</u> <u>TOMOGRAPHIC PLANE</u>. Tomographic plane has the same meaning as set out in 21 CFR §1020.33(b)(18).

<u>002.65</u> TRACEABLE TO A NATIONAL STANDARD. Traceable to a national standard means a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

002.66 TUBE. Tube has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.67</u> <u>TUBE HOUSING ASSEMBLY.</u> Tube housing assembly has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.68</u> <u>TUBE RATING CHART.</u> Tube rating chart has the same meaning as set out in 21 CFR §1020.30(b).

002.69 USEFUL BEAM. Useful beam has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.70</u> <u>X-RAY CONTROL.</u> X-ray control has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.71</u> X-RAY EXPOSURE CONTROL. X-ray exposure control is a device, switch, button or other similar means that an operator initiates or terminates the radiation exposure. The x-ray exposure control may include other associated equipment.

<u>002.72</u> X-RAY EQUIPMENT. X-ray equipment has the same meaning as set out in 21 CFR §1020.30(b).

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002.73 X-RAY FIELD. X-ray field has the same meaning as set out in 21 CFR §1020.30(b).

<u>002.74</u> <u>X-RAY SYSTEM.</u> X-ray system has the same meaning as set out in 21 CFR §1020.30(b).

002.75 X-RAY TUBE. X-ray tube has the same meaning as set out in 21 CFR §1020.30(b).

<u>003.</u> <u>ADMINISTRATIVE CONTROLS.</u> The registrant is responsible for directing the operation of the x-ray system or systems under the registrant's administrative control. The registrant or registrant's agent must assure that requirements of 180 NAC 6-003 are met in the operation of the x-ray system or systems.

<u>003.01</u> <u>HEALING ARTS USES OF X-RAY EQUIPMENT.</u> The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment must be by or under the supervision of one licensed to practice the healing arts in Nebraska.

<u>003.02</u> <u>VETERINARY USES OF X-RAY EQUIPMENT</u>. The use of x-ray equipment in the practice of veterinary medicine must be by or under the supervision of an individual licensed to practice veterinary medicine in the State of Nebraska.

<u>003.03</u> <u>DENTAL USES OF X-RAY EQUIPMENT.</u> The use of x-ray equipment for the exposure of individuals for dental diagnosis or treatment must be by or under the supervision of one licensed to practice dentistry in Nebraska.

<u>003.04</u> <u>X-RAY SYSTEM REQUIREMENTS.</u> An x-ray system which does not meet the requirements of Title 180 must not be operated for diagnostic purposes.

- 003.05 OPERATOR REQUIREMENTS. Registrants must only allow individuals to operate:
 - (A) X-ray systems under the direction of healing arts practitioners who meet the requirements as specified in Neb. Stat. Rev. §§ 38-1901 to 1920, Medical Radiography Practice Act; and
 - (B) Dental x-ray systems who meet the requirements as specified in Neb. Rev. Stat. § 38-1131 to practice as dental hygienists, or Neb. Rev. Stat. § 38-1135 to practice as dental assistants.

<u>003.06</u> <u>TECHNIQUE CHART.</u> A technique chart must be provided in the vicinity of the diagnostic x-ray system's control panel.

<u>003.06(A)</u> <u>DIAGNOSTIC X-RAY EQUIPMENT.</u> Except for dental radiation generating systems, a technique chart must include the following information for all examinations performed with that system:

- (i) Patient's body part and anatomical size, or body part thickness, or age, for pediatrics;
- (ii) Technique factors;
- (iii) Type and focal distance of the grid to be used, if any;
- (iv) Source to image receptor distance (SID) to be used;
- (v) Type and location of placement of gonad shielding to be used; and
- (vi) Type and size of the film or film-screen combination to be used.

<u>003.06(B)</u> <u>DENTAL RADIATION GENERATING EQUIPMENT</u>. Registrants using dental radiation generating equipment must have a technique chart displayed in the vicinity of the x-ray machine's control panel.

<u>003.07</u> WRITTEN SAFETY PROCEDURES. The registrant must create and make available to x-ray operators written safety procedures, to include patient holding and any restriction of the operating technique required for the safe operation of the particular x-ray system. The operator must be able to demonstrate familiarity with these procedures.

<u>003.08</u> <u>INDIVIDUALS PRESENT DURING A RADIOGRAPHIC EXPOSURE.</u> Except for patients who cannot be moved out of the room only the staff, ancillary personnel, or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient being examined:

- (A) Each individual must be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent;
- (B) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and
- (C) Human patients who cannot be removed from the room must be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or must be positioned so the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

<u>003.09</u> <u>GONAD SHIELDING</u>. Except for cases where gonad shielding would interfere with the diagnostic procedure, gonad shielding of not less than 0.5 millimeter lead equivalent must be used for human patients that have not passed the reproductive age during radiographic procedures where the gonads are in the useful beam.

<u>003.10</u> EXPOSURE TO THE USEFUL BEAM. Individuals must not be exposed to the useful beam except for healing arts purposes unless the exposure has been specifically and individually ordered by a licensed practitioner of the healing arts. This provision prohibits deliberate exposure for the following purposes:

- (A) Exposure to an individual for training, demonstration, or other non-healing-arts purposes; and
- (B) Exposure to an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.14.

<u>003.11</u> EXPOSURE FOR RESEARCH PURPOSES. Radiation exposure to an individual for research is prohibited, except when the research has been approved by an institutional review board and is conducted under federal regulations for the protection of human subjects in research under 45 CFR §46 (October 1, 2016 edition).

<u>003.12</u> <u>AUXILIARY SUPPORT.</u> Auxiliary support must be used when a patient or film must be provided with supplemental support during a radiation exposure. The following requirements apply:

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices must be used except in individual cases

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where the registrant has determined the devices used for holding are contraindicated. The written safety procedures, required by 180 NAC 6-003.07, must list projections where holding devices cannot be utilized;

- (B) The human holder must be instructed in personal radiation safety and protected as required by 180 NAC 6-003.08;
- (C) An individual must not be used routinely to hold film or patients;
- (D) Written safety procedures, as required by 180 NAC 6-003.07, must indicate the requirements for selecting a holder and the procedure the holder must follow;
- (E) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam must be protected by not less than 0.5 millimeter lead equivalent material; and
- (F) Each registrant must have leaded protective aprons and protective gloves available in sufficient numbers to provide protection to all personnel who are involved with xray operations and who are not shielded.

<u>003.13</u> <u>PROCEDURES AND EQUIPMENT</u>. Procedures and equipment designed to minimize patient and personnel exposure while providing the needed diagnostic information must be utilized. The following requirements apply:

- (A) The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens must not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography;
- (B) The radiation exposure to the patient must be the minimum exposure required to produce images of good diagnostic quality;
- (C) Portable or mobile x-ray equipment must be used only for examinations where it is not feasible to transfer the patient or patients to a stationary x-ray installation;
- (D) X-ray systems subject to this chapter must not be used in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems; and
- (E) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid must be positioned properly and, if the grid is of the focused type, be the proper focal distance for the source to image distance (SID) being used.

<u>003.14</u> <u>HEALING ARTS SCREENING.</u> An individual requesting to conduct a healing arts screening must submit information about the healing arts screening on a form provided by the Department. If any information submitted to the Department becomes invalid or outdated, the Department must be notified immediately.

<u>003.15</u> <u>X-RAY ROOM DOORS.</u> Doors that are an integral part of room shielding must be closed during x-ray procedures and must be posted "Close door during x-ray procedures" or words having a similar intent.

<u>003.16</u> INFORMATION AND MAINTENANCE RECORDS FOR X-RAY SYSTEMS. The registrant must maintain the following records on each x-ray system for inspection by the Department:

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- (A) The model and serial numbers of all certifiable components, and user's manuals for those components;
- (B) The records of surveys, calibrations, maintenance, and modifications performed;
- (C) The tube rating charts and cooling curves; and
- (D) A copy of all correspondence with the Department regarding each x-ray system.

<u>003.17</u> <u>X-RAY UTILIZATION LOG.</u> Except for registrants using only dental radiation generating equipment, registrants must maintain an x-ray log or chart containing the patient's identification, the type of examinations, the dates the examinations were performed, and the x-ray equipment operator's name.

<u>003.18</u> <u>SCALE DRAWING.</u> Except for registrants using only dental radiation generating equipment or bone densitometers, a scale drawing must be available of the room where a stationary x-ray system is located. The drawing must indicate the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in those areas. The drawing must include:

- (A) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
- (B) The type and thickness of materials, or lead equivalency, of each protective barrier.

<u>003.19</u> <u>PLAN REVIEW.</u> Except for registrants using only dental radiation generating equipment or bone densitometers, the following requirements apply:

- (A) The floor plans and equipment arrangement of all new installations, modifications of existing installations, or any analysis of operating conditions that indicates an individual may receive a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 or 4-013, must be submitted within 30 days to an individual meeting the requirements of 180 NAC 2-005.04(C) for review and comment; and
- (B) All permanent protective barriers must be constructed so the requirements of 180 NAC 4-005, 4-011, and 4-013 will be met.

<u>003.20</u> <u>X-RAY FILM PROCESSING.</u> A registrant using radiographic film must have equipment for handling and processing radiographic film.

<u>003.20(A)</u> <u>MANUALLY DEVELOPED FILM.</u> The following requirements apply to film that is developed manually:

- (i) Processing tanks must be constructed of mechanically rigid, corrosion resistant material; and
- (ii) The temperature of solutions in the tanks must be maintained within the range of 60° Fahrenheit to 80° Fahrenheit (16° Celsius to 27° Celsius). Film must be developed according to the time-temperature relationships recommended by the film manufacturer, or, in the absence of those recommendations, with the following time chart:

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Time-Temperature Chart			
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)	
°Celsius	°Fahrenheit		
26.7	80	2	
26.1	79	2	
25.6	78	2.5	
25.0	77	2.5	
24.4	76	3	
23.9	75	3	
23.3	74	3.5	
22.8	73	3.5	
22.2	72	4	
21.7	71	4	
21.1	70	4.5	
20.6	69	4.5	
20.0	68	5	
19.4	67	5.5	
18.9	66	5.5	
18.3	65	6	
17.8	64	6.5	
17.2	63	7	
16.7	62	8	
16.1	61	8.5	
15.6	60	9.5	

- (iii) Devices must be used that indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.
- (iv) The specified developer temperature and development time must be posted in the darkroom.

003.20(B) AUTOMATIC FILM PROCESSING. Films must be developed according to the time-temperature relationships recommended by the film manufacturer; in the absence of those recommendations, the film must be developed using the following chart:

Developer		Minimum
Temperature		Immersion Time
(Degrees)		(Seconds)
^o Celsius	°Fahrenheit	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23

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33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
39.5	85	30
Immersion time only, no crossover time included.		

<u>003.20(C)</u> <u>FILM PROCESSING REQUIREMENTS.</u> Processing deviations and the reason for the deviation from the requirements of 180 NAC 6-003.20 must be documented by the registrant.

<u>003.20(D)</u> <u>DARKROOM REQUIREMENTS.</u> Registrants must maintain a light-tight darkroom, as applicable, use proper safelights and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

(i) Each darkroom, other than those used for dental, podiatric and veterinary purposes, must use proper safelights so that any film type exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must prevent fogging of the film.

<u>003.20(E)</u> <u>FILM.</u> Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light tight container.

<u>003.20(F)</u> <u>FILM CASSETTES.</u> Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

<u>O03.20(G)</u> <u>OUTDATED FILM.</u> Outdated x-ray film must not be used for diagnostic radiographs, except when the film has been stored according to the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

<u>003.20(H)</u> <u>FILM DEVELOPING SOLUTIONS.</u> Film developing solutions must be prepared according to the directions given by the manufacturer and must be maintained in strength by replenishment or renewal, so full development is accomplished within the time specified by the manufacturer.

<u>003.20(I)</u> <u>PASS BOXES.</u> Pass boxes must be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes. Pass Boxes must have adequate shielding from stray radiation to prevent exposure of undeveloped film.

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<u>003.20(J)</u> <u>ALTERNATIVE PROCESSING SYSTEMS.</u> The use of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems will follow manufacturer's recommendations for image processing.

<u>004.</u> <u>GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC AND INTERVENTIONAL X-RAY</u> <u>SYSTEMS.</u> In addition to other requirements of 180 NAC 6-004, all diagnostic and interventional x-ray systems must meet the specifications of 21 CFR §1020.30.

<u>004.01</u> <u>FILTRATION CONTROL.</u> X-ray systems that have variable kilovolt peak (kVp) and variable filtration for the useful beam must have a device to link the kilovolt peak (kVp) selector with the filter or filters and must prevent an exposure unless the minimum amount of filtration required in 21 CFR §1020.30(m) is in the useful beam for the kVp that has been selected.

004.02 BEAM LIMITATION. The useful beam must be limited to the area of clinical interest.

<u>004.03</u> <u>MULTIPLE TUBES.</u> When two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication must be on the x-ray control panel and at or near the tube housing assembly that has been selected.

<u>004.04</u> <u>MECHANICAL SUPPORT OF TUBE HEAD.</u> The tube housing assembly supports must be adjusted so that the tube housing assembly will remain stable during the exposure except when the tube housing movement is a designed function of the x-ray system.

<u>MAINTAINING COMPLIANCE.</u> Diagnostic x-ray systems and their associated components used on humans and certified under the Federal X-ray Equipment Performance Standard, 21 CFR Part 1020, must be maintained in compliance with applicable requirements of that standard.

<u>004.06</u> <u>LOCKS.</u> All position locking, holding, and centering devices on x-ray systems components and systems must function as intended.

<u>004.07</u> <u>EQUIPMENT PERFORMANCE EVALUATION.</u> For all radiation generating equipment, except bone densitometry, veterinary, computed tomography (CT), and cone beam computed tomography (CBCT) the registrant must perform, or cause to be performed, tests necessary to insure the proper function of equipment. These tests must be performed every three years. For dental radiation generating equipment, these tests must be performed every five years. The evaluation must include the following measures.

<u>004.07(A)</u> <u>TIMER.</u> The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy must be within plus or minus 10% of the indicated time with testing performed at 0.5 second.

<u>004.07(B)</u> EXPOSURE REPRODUCIBILITY. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05. This requirement applies to clinically used techniques.

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<u>004.07(C)</u> <u>KILOVOLT PEAK (kVp).</u> The kilovolt peak (kVp) must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the indicated kilovolt peak must be accurate to within plus or minus 10% of the indicated setting or settings. For dental radiation generating equipment, with fewer than three fixed kilovolt peak (kVp) settings, the machine must be checked at those settings.

<u>004.07(D)</u> <u>TUBE STABILITY.</u> The x-ray tube must remain physically stable during exposures. When tubes are designed to move during exposure, the registrant will assure proper and free movement of the radiation generating equipment.

<u>004.07(E)</u> <u>COLLIMATION.</u> Field limitation must meet the requirements of 21 CFR §1020.32(b) for fluoroscopic systems, 21 CFR §1020.31(d) for radiographic systems, 21 CFR §1020.31(f)(1), for dental intraoral equipment, or 21 CFR §1020.31(f)(4) for dental extraoral equipment.

<u>004.07(F)</u> <u>CORRECTION OR REPAIR.</u> Any items not meeting the specifications of the tests must be corrected or repaired. Correction or repair must begin within 30 days following the check and must be performed according to a plan developed by the registrant. Correction or repair must be completed 90 days from discovery unless authorized by the Department.

<u>004.07(G)</u> <u>IN-AIR EXPOSURE.</u> A measurement of the in-air exposure or exposures at a technique factor or factors for an average adult thickness for the most common procedure or procedures performed.

<u>004.07(H)</u> <u>DOSIMETRY SYSTEM.</u> The measurement of the radiation output of an x-ray system must be performed with a calibrated dosimetry system. The calibration of that system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years. During the calendar year the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months must be performed.

<u>005.</u> <u>FLUOROSCOPIC X-RAY SYSTEMS.</u> Fluoroscopic x-ray systems must meet the machine performance standards of 21 CFR §1020.32. Use of non-image intensified fluoroscopic equipment is prohibited. The provisions of this chapter apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography (CT) x-ray systems manufactured on or after November 29, 1984.

<u>005.01</u> <u>PERIODIC MEASUREMENT OF AIR KERMA RATE (AKR).</u> A periodic measurement of air kerma rate (AKR) must be performed as follows.

<u>005.01(A)</u> <u>MEASUREMENTS OF AIR KERMA RATE (AKR)</u>. Measurements must be made for both typical and maximum values of the air kerma rate (AKR), materials may be placed in the useful beam to protect the imaging system when performing the periodic measurements.

<u>005.01(A)(i)</u> Measurements must be made annually or after any maintenance of the system which might affect the air kerma rate (AKR).

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<u>005.01(A)(ii)</u> For units manufactured before June 10, 2006, results of the measurements must be posted where a fluoroscopist may have access to those results while using the fluoroscope.

<u>005.01(B)</u> <u>RECORDS OF MEASUREMENTS OF AIR KERMA RATE (AKR).</u>The measurement results may be stated in roentgens per minute (R/min) or milliGray per minute (mGy/min). The results must include the technique factors used to determining the results, the name of the individual that performed the measurements, and the date the measurements were performed.

<u>005.01(C)</u> <u>CONDITIONS OF PERIODIC MEASUREMENT OF TYPICAL AIR KERMA</u> <u>RATE (AKR).</u> The following conditions apply to the periodic measurement of the typical Air Kerma Rate (AKR):

- (i) The measurement must be made under the conditions that satisfy the requirements of 21 CFR §1020.32(d)(3);
- (ii) Fluoroscopic systems that do not incorporate automatic exposure rate control (AERC) must use a milliamperage (mA) and kilovolt peak (kVp) typical of clinical use of the fluoroscopic system; and
- (iii) Fluoroscopic systems that incorporate automatic exposure rate control (AERC) must have sufficient material placed in the useful beam to produce a milliamperage (mA) and kilovolt peak (kVp) typical of the clinical use of the fluoroscopic system.

<u>005.01(D)</u> <u>CONDITIONS OF PERIODIC MEASUREMENT OF MAXIMUM AIR KERMA</u> <u>RATE (AKR).</u> The following conditions apply to the periodic measurement of the maximum air kerma rate (AKR):

- (i) The measurement must be made under the conditions that satisfy the requirements of 21 CFR §1020.32(d)(3);
- (ii) Fluoroscopic systems that do not incorporate automatic exposure rate control (AERC) must be adjusted to those settings which give the maximum air kerma rate (AKR); and
- (iii) Fluoroscopic systems that incorporate automatic exposure rate control (AERC) must have sufficient material placed in the useful beam to produce the maximum air kerma rate (AKR) of the system.

<u>005.02</u> <u>CONTROL OF SCATTERED RADIATION.</u> The following requirements apply to controlling the scatter of radiation.

<u>005.02(A)</u> <u>FLUOROSCOPIC TABLE DESIGNS.</u> Fluoroscopic table designs, when combined with the procedures performed at the registrant's facility, must ensure that no unprotected part of any staff or ancillary individual's body is exposed to unattenuated scattered radiation that originates from under the table. The attenuation provided must be not less than 0.25 millimeter lead equivalent.

<u>005.02(B)</u> <u>EQUIPMENT CONFIGURATION.</u> Equipment configuration, when combined with procedures performed at the registrant's facility, must ensure that no portion of any staff or ancillary individual's body, except the extremities, is exposed to the unattenuated scattered radiation that originates from above the tabletop unless:

(i) That individual is 120 centimeters from the center of the useful beam; or

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(ii) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or selfsupporting curtains. This requirement is in addition to any lead equivalency provided by the protective apron specified in 180 NAC 003.08.

<u>005.02(C)</u> EXEMPTIONS TO THE USE OF PROTECTIVE BARRIERS. When a sterile field will not permit the use of the normal protective barriers or drapes, the shielding required by 180 NAC 6-005.02(B) must be maintained to the degree possible under the clinical conditions.

<u>005.03</u> <u>FLUOROSCOPIC RADIATION THERAPY SIMULATION SYSTEMS.</u> Fluoroscopic radiation therapy simulation systems are exempt from the requirements of 180 NAC 6-005.01. In addition, these systems are exempt from the requirements of 21 CFR §1020.32(a) provided these systems are designed and used in a manner that no individual other than the patient is in the x-ray room during the time the system is producing x-rays.

<u>005.04</u> <u>EQUIPMENT OPERATION.</u> The following requirements apply to the operation of fluoroscopic equipment.

<u>005.04(A)</u> Images formed by the use of fluoroscopic x-ray systems must be under the direction of and interpreted by a licensed practitioner of the healing arts.

<u>005.04(B)</u> Only a licensed practitioner may perform interpretative fluoroscopic procedures.

<u>005.04(C)</u> Fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.

<u>005.04(D)</u> Operators must be competent in the standard operating procedures of the unit in use.

<u>005.04(E)</u> Registrants must maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record must include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

<u>006.</u> <u>REQUIREMENTS FOR RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC,</u> <u>BONE DENSITOMETRY, VETERINARIAN, OR COMPUTED TOMOGRAPHY (CT) X-RAY</u> <u>SYSTEMS.</u> In addition to the requirements of 180 NAC 6-006, radiographic systems other than fluoroscopic, bone densitometry, veterinarian, or computed tomography (CT), must meet the specifications of 21 CFR §1020.31.

<u>006.01</u> INITIATION AND INDICATION OF RADIATION EXPOSURE. The following apply to the initiation and indication of radiation exposure.

<u>006.01(A)</u> <u>EXPOSURE INITIATION.</u> Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator. In addition, it must not be

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possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

<u>006.01(B)</u> <u>EXPOSURE INDICATION.</u> Means must be provided for visual indication, observable at or from the operator's protected position, whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.

<u>006.01(C)</u> <u>OPERATOR PROTECTION.</u> Initiation of the production of x-rays must occur in an area that protects the operator from radiation exposure.

<u>006.01(C)(i)</u> <u>STATIONARY X-RAY SYSTEMS.</u> Stationary x-ray systems must have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

<u>006.01(C)(ii)</u> <u>DENTAL X-RAY SYSTEMS.</u> The x-ray control for dental x-ray systems must be positioned so the operator must stand at least six feet from the useful beam or behind a protective barrier, except when using units designed to be hand-held.

<u>006.01(D)</u> <u>EXPOSURE CONTROL LOCATION.</u> The x-ray exposure control must be placed so the operator can maintain verbal, aural, and visual contact with the patient while making any exposure.

<u>006.02</u> <u>TUBE STANDS FOR PORTABLE X-RAY SYSTEMS.</u> A tube stand or other mechanical support must be used for portable x-ray systems so the x-ray tube housing assembly is not hand-held during exposures.

<u>007.</u> <u>VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS.</u> This section applies to registrants using x-ray generating equipment in veterinary medicine.

<u>007.01</u> <u>VETERINARY MEDICINE EQUIPMENT REQUIREMENTS.</u> Radiation generating equipment used in veterinary medicine must meet the following requirements:

- (A) The protective tube housing must be constructed to meet the specifications of 21 CFR §1020.30(k);
- (B) 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 tube housing;
- (C) The total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kilovolt peak (kVp), 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kilovolt (kVp), and 2.5 millimeters aluminum equivalent for machines operating above 70 kilovolt peak (kVp);
- (D) A device must be provided to terminate the exposure after a preset time or exposure; and
- (E) A continuous pressure type of exposure switch must be provided, with an electrical cord of adequate length, so the operator can stand out of the useful beam and at least 6 feet (1.83 meters) from the animal during all x-ray exposures.

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<u>007.02</u> <u>OPERATING PROCEDURES.</u> The following requirements apply to the operation of x-ray generating equipment used in veterinary medicine.

 $\underline{007.02(A)}$ The operator must be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or must be positioned so the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.

<u>007.02(B)</u> 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 an individual, the individual must be protected with appropriate shielding devices, and be positioned so no part of the body will be struck by the useful beam.

007.03 <u>VETERINARY ASSISTANT OR VETERINARY TECHNICIAN TRAINING</u> <u>REQUIREMENTS.</u> Veterinary assistants and veterinary technicians must meet the following requirements prior to operating x-ray generating equipment:

- (A) Eight hours of classroom instruction in the fundamentals of radiation safety, radiographic equipment, state regulations, and operating and emergency procedures; or
- (B) Be a graduate of an accredited veterinarian technician's program.

<u>008.</u> <u>COMPUTED TOMOGRAPHY (CT) AND CONE BEAM COMPUTED TOMOGRAPHY</u> (<u>CBCT</u>) <u>SYSTEMS.</u> This section applies to registrants using computed tomography (CT) systems and cone beam computed tomography (CBCT) systems.

<u>008.01</u> <u>DEFINITIONS.</u> In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions apply to 180 NAC 6-008.

<u>008.01(A)</u> <u>CONTRAST SCALE</u>. Contrast scale has the same meaning as 21 CFR §1020.33(b).

<u>008.01(B)</u> <u>COMPUTED TOMOGRAPHY (CT) CONDITIONS OF OPERATION.</u> Computed tomography (CT) conditions of operation are all selectable parameters governing the operation of a computed tomography (CT) system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in this chapter.

<u>008.01(C)</u> <u>COMPUTED TOMOGRAPHY (CT) NUMBER.</u> Computed tomography (CT) number has the same meaning as set out in 21 CFR §1020.33(b).

008.01(D) NOISE. Noise has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.01(E)</u> <u>NOMINAL TOMOGRAPHIC SECTION THICKNESS.</u> Nominal tomographic section thickness has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.01(F)</u> <u>REFERENCE PLANE</u>. Reference plane is a plane which is displaced from and parallel to the tomographic plane.

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<u>008.01(G)</u> <u>SCAN.</u> Scan is the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

<u>008.01(H)</u> <u>SCAN INCREMENT.</u> Scan increment has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.01(I)</u> <u>SCAN SEQUENCE.</u> Scan sequence has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.01(J)</u> <u>TOMOGRAPHIC PLANE</u>. Tomographic plane has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.01(K)</u> <u>TOMOGRAPHIC SECTION.</u> Tomographic section has the same meaning as set out in 21 CFR §1020.33(b).

<u>008.02</u> <u>COMPUTED TOMOGRAPHY (CT) AND CONE BEAM COMPUTED TOMOGRAPHY</u> (<u>CBCT</u>) <u>EQUIPMENT REQUIREMENTS</u>. Computed tomography (CT) and cone beam computed tomography (CBCT) equipment must meet the following requirements, except for fluoroscopic systems capable of performing cone beam computed tomography (CBCT).

<u>008.02(A)</u> <u>TERMINATION OF EXPOSURE</u>. The timer must meet the specifications of 21 CFR §1020.33(f)(2).

<u>008.02(B)</u> <u>TOMOGRAPHIC PLANE INDICATION AND ALIGNMENT</u>. Tomographic plane indication and alignment must meet the specifications of 21 CFR §1020.33(g).

<u>008.02(C)</u> <u>BEAM-ON AND SHUTTER STATUS INDICATORS AND CONTROL</u> <u>SWITCHES.</u> Visual indication of x-ray production and shutter status must meet the specifications of 21 CFR §1020.33(h). Each emergency button or switch must be clearly labeled as to its function.

<u>008.02(D)</u> INDICATION OF CONDITIONS OF OPERATION. Visual indication of the conditions of operation to be used during a scan or scan sequence must meet the specifications of 21 CFR §1020.33(f).

<u>008.02(E)</u> <u>SCAN INCREMENT ACCURACY.</u> The accuracy of scanning increments must meet the specifications of 21 CFR §1020.33(i).

<u>008.02(F)</u> <u>MEAN AND STANDARD DEVIATION.</u> The method used to calculate the mean and standard deviation must meet the specifications of 21 CFR §1020.33(j).

<u>008.03</u> <u>FACILITY DESIGN REQUIREMENTS.</u> Registrants using computed tomography (CT) equipment must meet facility design specifications.

<u>008.03(A)</u> <u>AURAL COMMUNICATION.</u> There must be two-way aural communication between the patient and the operator at the control panel.

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008.03(B) VIEWING SYSTEMS. Viewing systems must include the following:

- (i) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and must be located so the operator can observe the patient from the control panel; and
- (ii) When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, must be available for use in the event of failure of the primary viewing system.

<u>008.04</u> <u>PLAN REVIEWS, CALIBRATIONS, SPOT CHECKS, AND OPERATING</u> <u>PROCEDURES.</u> Plan reviews, calibration, spot checks and operating procedures for computed tomography (CT) and cone beam computed tomography (CBCT) systems must meet the following requirements.

<u>008.04(A)</u> <u>PLAN REVIEWS.</u> For computed tomography (CT) and cone beam computed tomography (CBCT) x-ray systems, the plan review required by 180 NAC 6-003.19 must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist meeting the requirements of 180 NAC 2-005.04(C)(ii). In addition, radiation surveys must be performed after any change in the registrant's facility or equipment that might cause an individual to receive a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 or 4-013.

<u>008.04(B)</u> <u>PLAN REVIEW RESULTS.</u> The registrant must obtain a written report of the results of the plan review from the radiological medical physicist or radiological health physicist. A copy of the report must be maintained for inspection by the Department.

<u>008.04(C)</u> <u>RADIATION CALIBRATIONS OF COMPUTED TOMOGRAPHY (CT) AND</u> <u>CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEMS.</u> The calibration of radiation output of computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist meeting the requirements of 180 NAC 2-005.04(C)(ii) who is physically present at the registrant's facility during the calibration. Calibration procedures must be in writing.

<u>008.04(C)(i)</u> <u>FREQUENCY OF CALIBRATION.</u> The calibration of a computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed after initial installation, prior to the first use on a patient, and at intervals specified by a radiological medical physicist or radiological health physicist, not to exceed two years. Additionally, a calibration must be performed by a radiological medical physicist within 30 days after any change or replacement of components that, in the opinion of the radiological medical physicist or radiological medical physicist, could cause a change in the radiation output. Calibration of a computed tomography (CT) system must include the spot-checks specified in 180 NAC 6-008.05(A)(ii). Calibration of a cone beam computed tomography (CBCT) system must include the quality control checks specified in 180 NAC 6-008.07(C).

<u>008.04(C)(ii)</u> <u>DOSIMETRY SYSTEM.</u> The measurement of the radiation output of a computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed with a calibrated dosimetry system. The calibration of that system

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must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

<u>008.04(C)(iii)</u> <u>DOSIMETRY PHANTOMS.</u> Computed tomography (CT) dosimetry phantom or phantoms must be used to ensure the computed tomography (CT) system meets the specifications of 21 CFR §1020.33(b)(6).

<u>008.04(C)(iv)</u> <u>HEAD, BODY, OR WHOLE-BODY SCANS.</u> A computed tomography (CT) system must be calibrated for each type of head, body, or whole-body scan or scans performed at the registrant's facility to ensure that the system meets the specifications of 21 CFR §1020.33(c)(2).

<u>008.04(C)(v)</u> <u>RECORDS OF COMPUTED TOMOGRAPHY (CT) CALIBRATIONS</u> <u>AND CONE BEAM COMPUTED TOMOGRAPHY (CBCT).</u> Records of calibrations performed must be maintained for inspection by the Department.

<u>008.05</u> <u>SPOT CHECKS OF COMPUTED TOMOGRAPHY (CT) EQUIPMENT.</u> Spot-check procedures must be in writing and must be developed by a radiological medical physicist or radiological health physicist.

<u>008.05(A)</u> <u>SPOT-CHECK PROCEDURES.</u> Spot-check procedures must include the following:

- (i) Use of a computed tomography (CT) phantom or phantoms that meets the requirements of 21 CFR §1020.33(d)(1);
- (ii) A check of the contrast scale, noise, nominal tomographic section thickness, spatial resolution of the system for low and high contrast objects, and a measurement of the mean computed tomography (CT) number of water or a reference material; and
- (iii) Acquisition of images must be obtained with the computed tomography (CT) phantom or phantoms using the same processing mode and computed tomography (CT) conditions of operation used to perform calibrations required by this chapter.

<u>008.05(B)</u> FREQUENCY OF SPOT-CHECKS. All spot checks must be performed at the frequency and under system conditions specified by a radiological medical physicist or radiological health physicist.

<u>008.05(C)</u> <u>SPOT-CHECK RECORDS.</u> Records of the spot-checks performed must be maintained for inspection by the Department.

<u>008.06</u> <u>OPERATING PROCEDURES FOR COMPUTED TOMOGRAPHY (CT) SYSTEMS.</u> Registrants must develop written operating procedures for computed tomography (CT) systems as follows.

<u>008.06(A)</u> <u>OPERATION OF THE COMPUTED TOMOGRAPHY (CT) SYSTEM.</u> The system must only be operated by an individual who has been specifically trained in its operation and meets the requirements of 180 NAC 6-003.05.

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<u>008.06(B)</u> INFORMATION ON OPERATION AND CALIBRATION. Information must be available in the operator control area regarding the operation and calibration of the system. The information must include:

- (i) Dates of the latest calibration and spot-checks and the location where the results of those tests may be found;
- (ii) Instructions on the use of the computed tomography (CT) phantom or phantoms including a schedule of spot-checks appropriate for the system, allowable variations for the indicated parameters, and the results of the most recent spotchecks performed on the system;
- (iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
- (iv) A current technique chart available at the control panel which specifies, for each routine examination, the computed tomography (CT) conditions of operation and the number of scans for each examination.

<u>008.06(C)</u> <u>OPERATING PARAMETERS.</u> If the calibration or spot-check of the computed tomography (CT) system identifies that a system operating parameter has exceeded a tolerance established by the radiological medical physicist or radiological health physicist, use of the system on patients must be limited to those permitted by written instructions of the radiological medical physicist or radiological health physicist.

<u>008.07</u> <u>CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEMS.</u> In addition to other requirements of this chapter, this section applies to registrants using with cone beam computed tomography (CBCT) systems.

<u>008.07(A)</u> <u>OPERATION OF THE CONE BEAM COMPUTED TOMOGRAPHY (CBCT)</u> <u>SYSTEM.</u> The cone beam computed tomography (CBCT) system must only be operated by an individual who has been specifically trained in its operation and meets the requirements of 180 NAC 6-003.05.

<u>008.07(B)</u> <u>BEAM ALIGNMENT.</u> The x-ray field in the plane of the image receptor must not exceed beyond the edge of the image receptor by more than two percent of the source-to-image distance (SID) when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field must be aligned with the center of the image receptor to within 2 percent of the source-to-image distance (SID).

<u>008.07(C)</u> <u>QUALITY CONTROL.</u> The registrant must follow the quality control recommendations of the manufacturer. If manufacturer recommendations are not obtainable, the registrant must perform quality control on the cone beam computed tomography (CBCT) system that has been developed by a radiological medical physicist or radiological health physicist.

<u>008.07(D)</u> <u>INFORMATION FOR THE CONE BEAM COMPUTED TOMOGRAPHY</u> (<u>CBCT</u>) <u>OPERATOR</u>. The following information must be readily available to the operator of the cone beam computed tomography (CBCT) system:

(i) Instructions on performing quality control on the cone beam computed tomography (CBCT) system;

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- (ii) The time interval for performing quality control on the cone beam computed tomography (CBCT) system;
- (iii) The allowable uses of the cone beam computed tomography (CBCT) system if a quality control check identifies a system operating parameter has exceeded a tolerance established by the manufacturer. If tolerances from the manufacturer are not obtainable, a radiological medical physicist or radiological health physicist must establish the tolerances and the cone beam computed tomography (CBCT) system must be limited to those uses allowed by the radiological medical physicist or radiological health physicist; and
- (iv) The results of the most recent quality control completed on the cone beam computed tomography (CBCT) system.

<u>009.</u> <u>DENTAL REGISTRANTS.</u> In addition to other requirements of this chapter, this section applies to registrants using dental radiation generating equipment.

<u>009.01</u> EXEMPTION FROM INDIVIDUAL MONITORING. Individual monitoring is not required for personnel operating only dental radiation generating equipment for dental diagnostic purposes.

<u>009.02</u> <u>TUBE HOUSING.</u> The tube housing and position indicating device (PID) must not be hand-held during an exposure, except for units designed to be hand-held.

<u>009.03</u> <u>TUBE HOUSING SUPPORT.</u> The tube housing support must be constructed and adjusted so that the tube housing will not drift from its set position during an exposure.

<u>009.04</u> <u>X-RAY CONTROL.</u> Each x-ray system must have a control that allows the operator to terminate the exposure at any time, except for exposures of 0.5 second or less. The exposure switch will be of the continuous pressure type.

<u>009.05</u> <u>SOURCE-TO-SKIN DISTANCE (SSD).</u> X-ray systems designed for use with an intraoral image receptor must be provided with means to limit the source-to-skin distance (SSD) to meet the requirements of 21 CFR §1020.31(i).

<u>009.06</u> <u>KVP LIMITATIONS</u>. Dental x-ray radiation generating equipment with a fixed kilovolt peak (kVp) of less than 50 kilovolt peak (kVp) must not be used to make diagnostic dental radiographs of humans.

<u>009.07</u> <u>DENTAL INTERIM INSPECTIONS.</u> This subsection addresses interim inspections of dental registrants.

<u>009.07(A)</u> <u>INTERIM INSPECTIONS.</u> For interim inspections of dental radiation generating equipment, each registrant must:

- (i) Respond to a request from the Department for an interim inspection;
- (ii) Complete the Interim Inspection Form NRH-6. Form NRH-6 is set out as Attachment 1 to this chapter; and
- (iii) Return the completed interim inspection form with documentation of the most recent equipment performance evaluation or evaluations performed according to 180 NAC 6-004.07 by the deadline indicated in the inspection notice.

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<u>010.</u> <u>HAND-HELD DENTAL AND VETERINARY EQUIPMENT</u>. In addition to the requirements of this chapter, hand-held dental and veterinary equipment must meet these requirements.

<u>010.01</u> <u>BACKSCATTER SHIELD.</u> Hand-held dental and veterinary equipment must be equipped with a backscatter shield of at least 0.25 millimeter (mm) lead equivalent and be at least 15.2 centimeters (cm) in diameter. The shield must be positioned as close as practical to the distal end of the position indicating device (PID).

<u>010.02</u> <u>MANUFACTURER TRAINING.</u> Individuals operating hand-held dental and veterinary equipment must complete training as specified by the manufacturer.

<u>010.03</u> <u>MANUFACTURER PROTOCOLS.</u> Registrants with hand-held dental and veterinary equipment must follow manufacturer protocols for the safe operation of the equipment.

<u>010.04</u> <u>UNAUTHORIZED REMOVAL OR USE.</u> The registrant must secure hand-held dental and veterinary equipment from unauthorized removal or use.

<u>010.05</u> EXPOSURE PREVENTION. Hand-held dental or veterinary equipment must be kept in a mode that prevents an exposure when the device is not being used.

Attachment 1



Form NRH-6 Effective Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF PUBLIC HEALTH X-RAY PROGRAM

DENTAL INTERIM INSPECTION FORM

Registration Number:		Date:
Name:		
Address:	City, State, Zip:	
Phone Number:		
Email:	Fax Number:	

- Complete this form and return it to this Department by the date specified in the enclosed letter.
- Submit copies of the most recent equipment performance evaluation results for each dental radiation generating equipment.

1.	Yes	No	Has your registration of radiation generating equipment expired? (180 NAC 2)
2.	Yes	No	Is all operable dental radiation generating equipment at this facility properly registered? (180 NAC 2)
3.	Yes	No	Has your service provider performed equipment performance evaluations on all dental radiation equipment at the facility at the required five year interval? (180 NAC 6-004.07)

Comments:

Form Completed by	Date	

• Please retain a copy of this completed inspection form for your records

TITLE 180 - CONTROL OF RADIATION

CHAPTER 21 - (Repealed)