

TITLE 180 CONTROL OF RADIATION

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FORM(S)

- Form NRH-3 Notice to Employees
- Form NRH-4 Application for Registration of Radiation Generating Equipment
- Form NRH-21 Dental Interim Inspection Form
- Form NRH 21A Equipment List
- Form NRH-21B – Equipment Performance Evaluation

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
<http://www.gpoaccess.gov/cfr/index.html>

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TITLE 180 CONTROL OF RADIATION

CHAPTER 21 DENTAL RADIOGRAPHIC EQUIPMENT

21-001 SCOPE AND AUTHORITY:

21-001.01 180 NAC 21 applies to all persons who receive, possess, use, transfer, own, or acquire any dental radiographic equipment. Persons that receive, possess, use, transfer, own or acquire dental computed tomography, dental fluoroscopic equipment, rotating anode tube radiation generating equipment or other radiation generating equipment will need to refer to 180 NAC 1, 2, 4, 6, 9, 10, 15, 17, 18, and 20.

21-001.02 180 NAC 21 establishes the following:

1. The registration of dental radiation generating equipment.
2. The standards for protection against ionizing radiation resulting from activities conducted pursuant to registrations issued by the Department.
3. The requirements to control the receipt, possession, use, transfer, and disposal of dental radiation generating equipment by any person so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in 180 NAC 21. However, nothing in 180 NAC 21 will be construed as limiting actions that may be necessary to protect health and safety.
4. Requirements for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the practice of dentistry.
5. The requirements for notices, instructions and reports by dental registrants to individuals engaged in activities under a registration and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations, orders issued there under regarding radiological working conditions.
6. Specific record keeping requirements and general provisions for records and reports.

7. The training and experience requirements of dental personnel.
8. The conduct of proceedings under the Radiation Control Act, the administrative procedures of the Department and the Formal Hearing Procedures of the Department of Health and Human Services, for the issuing, denying, renewing, transferring, amending, suspending, revoking of any registration and for determining compliance with or granting of exemptions from Department rule, order, or condition of registration; for assessing administrative penalties; and for determining content of other Department orders. Proceedings held under the Radiation Control Act will be governed by the Rules of Practice and Procedure of the Department of Health and Human Services, 184 NAC 1.
9. Establishes the fees for registration, other regulatory services and provide for their payment.

21-001.03 The use of x-ray equipment for the intentional exposure of individuals for dental diagnosis or treatment will be by or under the supervision of one licensed to practice dental healing arts in Nebraska. The registrant will assure that the requirements of 180 NAC 21 are met in the operation of such dental radiation generating equipment.

21-001.04 The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 71-3520.

21-001.05 Part 21 Code of Federal Regulations (CFR) as published on April 1, 2014 and referred throughout this Chapter are herein 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.

21-002 DEFINITIONS: As used in 180 NAC 21, these terms have the definitions set forth below:

Absorbed dose means the energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE and dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI Unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Act means Radiation Control Act Neb. Rev. Stat. §§ 71-3501 to 71-3520.

Adult means an individual 18 or more years of age.

Air Kerma see [Kerma]

Applicant means a person seeking a certificate of registration or a person's certification to use radiation sources issued under the provisions of the Act and these rules.

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As low as is reasonably achievable (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and registered sources of radiation in the public interest.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Background radiation means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the registrant. Background radiation does not include sources of radiation from radioactive materials regulated by the Department.

Barrier [See "Protective barrier"].

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Beam quality (diagnostic x-ray) is a term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kVp and filtration.

Certificate of Registration means a document issued pursuant to the Act and rules promulgated thereunder.

Certified equipment means equipment that has been certified in accordance with Title 21, Code of Federal Regulations.

CFR means Code of Federal Regulations.

Civil penalty means any monetary penalty levied on a licensee or registrant because of violations of statutes, rules, regulations, licenses or registration certificates, but does not include criminal penalties.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where

\underline{s} = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample.

Continuous pressure switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

Declared pregnant woman means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Deep dose equivalent (DDE) (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm²).

Deliberate misconduct means an intentional act or omission by a person that (a) would intentionally cause a licensee, registrant, or applicant for a license or registration to be in violation of any rule, regulation, or order of or any term, condition or limitation of any license or registration issued by the Department under the Radiation Control Act or (b) constitutes an intentional violation of a requirement, procedure, instruction, contract, purchase order, or policy under the Radiation Control Act of a licensee, a registrant, an applicant for a license or registration, or contractor or subcontractor of a licensee, registrant, or applicant for a license or registration.

Dental healing arts means diagnosis, treatment, prescribing, or operation for any disease, pain, deformity, deficiency, injury, or physical condition of the teeth or jaws or adjacent structures.

Dental radiographic equipment is radiation generating equipment that is 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, rotating anode tube radiation generating equipment or other radiation generating equipment.

Dentist means an individual who holds a current Nebraska license to practice dentistry.

Department means the Department of Health and Human Services.

Diagnostic source assembly means the tube housing assembly with a beam limiting device attached.

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Director means Director of the Division of Public Health.

Discipline means the imposition by the Department of a sanction, including revocation, suspension, limitation, condition, or civil penalty.

Dose is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of 180 NAC 21, radiation dose is an equivalent term.

Dose equivalent (H_i) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose limits means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, limits is an equivalent term.

Embryo/fetus means the developing human organism from conception until the time of birth.

Enforcement Conference is a meeting held by the Department with registrant management to discuss safety, safeguards, or environmental problems; the registrant's compliance with regulatory, or registration condition requirements; a registrant's proposed corrective measures (including, but not limited to, schedules for implementation); and enforcement options available to the Department.

Entrance exposure means the exposure expressed in roentgens (R), measured in air with the specified technique, calculated or adjusted to represent the exposure at the point where the center of the useful beam enters the patient.

Exposure means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg).

Exposure rate means the exposure per unit of time, such as roentgen per minute (R/min) or milliroentgen per hour (mR/h).

Extremity means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to preferentially absorb selected radiations.

Gray (Gy) means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray [1 Gy=1 rad].. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

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Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Hearing is a proceeding to examine an application or other matter before the Department in order to receive information or to adjudicate rights, duties, or privileges.

Hearing Examiner means a person selected by the Director of the Division of Public Health to conduct hearings.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" must mean the preselected portion of the device.

Individual means any human being.

Individual monitoring means the assessment of dose equivalent by the use of individual monitoring devices or by the use of survey data.

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLD's), and pocket ionization chambers. For the purposes of these regulations, personnel dosimeter and dosimeter are equivalent terms.

Inspection means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department. The registrant is notified of any items of noncompliance and/or recommendation of the Department.

Interim inspection means an examination by the Department of information submitted by the registrant on a form provided by the Department.

Kerma means the quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K , is the quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

kV means kilovolts.

kVp [See Peak tube potential]

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

1. The useful beam; and
2. Radiation produced when the exposure switch or timer is not activated.

Lens dose equivalent(LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).

Limits [See Dose limits]

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Mobile services means the utilization of radiation generating equipment in temporary locations for limited time periods. The radiation generating equipment may be fixed inside a mobile van or transported to temporary locations.

Mobile x-ray equipment [See X-ray equipment].

Monitoring means the measurement of radiation to evaluate potential exposures and doses. For the purposes of 180 NAC 21 radiation monitoring and radiation protection monitoring are equivalent terms.

Notice of Violation is a written statement of one or more infringements of a legally binding requirement. The notice normally requires the registrant to provide a written statement describing:

1. Corrective steps taken by the registrant, and the results achieved;
2. Corrective steps to be taken to prevent recurrence; and
3. The projected date for achieving full compliance.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from sources of radiation, whether in the possession of the registrant, or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Title 180, from voluntary participation in medical research programs, or as a member of the public.

Order means a specific directive contained in a legal document issued by the Department.

Party is a person designated as such by the Hearing Examiner. A party may consist of the following:

1. The Department;
2. An applicant/registrant; and
3. Any person affected.

Patient means an individual subjected to dental healing arts examination, diagnosis, or treatment.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Person means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

Personnel dosimeter [See Individual monitoring devices].

Personnel monitoring equipment [See Individual monitoring devices]

PID [See Position indicating device]

Position indicating device (PID) means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Portable x-ray equipment [See X-ray equipment].

Preliminary Report is a document prepared by the Department containing:

1. A statement of facts on which the Department bases the conclusion that a violation has occurred;
2. Recommendations that an administrative penalty be imposed on the person charged; and
3. Recommendations for the amount of that proposed penalty.

Primary protective barrier [See Protective barrier].

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

Primary protective barrier means the material, excluding filters, placed in the useful beam;

Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Public dose means the dose received by a member of the public from exposure to sources of radiation released by a registrant, or to any other source of radiation under the control of a registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Title 180, or from voluntary participation in medical research programs.

Public Hearing means a proceeding which will be open to the public, for the purpose of hearing testimony or receiving written statements from any person who chooses to offer information on the subject matter set for hearing, conducted after notice to the public of the time, date, and place of the hearing.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means ionizing and nonionizing radiation as follows:

- (a) Ionizing radiation means gamma rays, x-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other atomic or nuclear particles or rays, but does not include sound or radiowaves or visible, infrared, or ultraviolet light; and
- (b) Nonionizing radiation means (i) any electromagnetic radiation which can be generated during the operations of electronic products to such energy density levels as to present a biological hazard to occupational and public health and safety and the environment, other than ionizing electromagnetic radiation, and (ii) any sonic, ultrasonic, or infrasonic waves which are emitted from an electronic product as a result of the operation of an electronic circuit in such product and to such energy density levels as to present a biological hazard to occupational and public health and safety, and the environment.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose [See Dose]

Radiation generating equipment means any manufactured product or device, component part of such a product or device, or machine or system which during operation can generate or emit radiation except devices which emit radiation only from radioactive material. Radiation generating equipment in 180 NAC 21 refers to only dental radiographic equipment.

Radiation Safety Officer (RSO) means an individual who has the knowledge of and the authority and responsibility to apply appropriate radiation protection regulations, and practices, who is specifically named on a certificate of registration, and who is the primary contact with the Department.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Registrant means any person who is registered with the Department and is legally obligated to register with the Department pursuant to Title 180 or the Act.

Registration means registration with the department pursuant to the Radiation Control Act and in accordance with the regulations adopted by the Department.

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Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

Restricted area means an area, access to which is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction.

Secondary protective barrier [See "Protective barrier"].

Severity level means a classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

Shallow dose equivalent (SDE) (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeters (7 mg/cm^2).

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Sources of radiation means any radioactive material, any radiation-generating equipment or any device or equipment emitting or capable of emitting radiation or radioactive material.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Source-to-skin distance means the distance from the source to the skin of the patient.

Special Units means the conventional units historically used by registrants, i.e. rad (absorbed dose), and rem (dose equivalent).

Stationary x-ray equipment [See X-ray equipment].

Stray radiation means the sum of leakage and scattered radiation.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or disposal or radiation generating equipment.

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When appropriate, such evaluation includes, but is not limited to, tests, physical examinations of location of equipment or radiation generating equipment, and measurements of levels of radiation present, and evaluation of administrative and/or engineered controls.

Technique Chart means the chart that provides all necessary generator control settings and geometry needed to make clinical radiographs.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and
3. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Total effective dose equivalent (TEDE) means the sum of the dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Traceable to a national standard indicates that a quantity or a measurement has been compared to a national standard, for example, the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Unrestricted area means an area, access to which is neither limited nor controlled by the registrant. For purposes of these regulations, uncontrolled area is an equivalent term.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Violation means an infringement of any rule, registration condition, order of the Department, or any provision of the Act.

Whole body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a registration issued by the Department and controlled by a registrant, but does not include the registrant.

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X-ray exposure control means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timer and back-up timers.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the focus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including but not limited to an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system must be considered integral parts of the system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

Year means the period of time beginning in January used to determine compliance with the provisions of Title 180. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

21-003 EXEMPTIONS

21-003.01 General Provision: The Department may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of 180 NAC 21 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

21-003.02 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5 μ Sv) per hour at 5 cm from any accessible surface of such equipment. The production, testing or factory servicing of such equipment will not be exempt.

21-003.03 Dental radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 21. This exemption does not apply to the providers of dental radiation generating equipment for mobile services. Facilities that have placed all dental radiation generating equipment in storage, including storage in place, and have notified the Department in writing, are exempt from the requirements of 180 NAC 21. This exemption is void if any radiation machine is energized resulting in the production of radiation.

21-003.04 Inoperable dental radiation generating equipment is exempt from the requirements of 180 NAC 21. For the purpose of 180 NAC 21, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

21-003.05 Financial institutions that take possession of dental radiation generating equipment as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in 180 NAC 21 to the extent that they demonstrate that the radiation machine is operable for the sole purpose of selling, leasing or transferring.

21-003.06 No individual monitoring will be required for personnel operating only dental radiation generating equipment for dental diagnostic purposes.

21-003.07 Individuals who are sole practitioners and sole operators and the only occupationally exposed individual are exempt from the requirements of 180 NAC 21-007.03, 21-007.04C and 21-007.05B and C.

21-004 GENERAL PROVISIONS

21-004.01 Communications

1. All communications and reports concerning 180 NAC 21, and applications filed thereunder, should be addressed to the Department at its office:

Department of Health and Human Services
Division of Public Health
Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, Nebraska 68509-5026

2. Documents received by the Department will be deemed to have been received on the date of the postmark, telegram, FAX, or electronic media transmission.

21-004.02 Discrimination Prohibited: The Department must not exclude any person on the ground of sex from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity registered by this Department. This provision will be enforced through provisions established, with respect to racial and other discrimination, under the Nebraska Fair Employment Act. This remedy is not exclusive,

however, and will not prejudice or cut off any other legal remedies available to a discriminate.

21-004.03 Citizenship Attestation: All applicants and renewals for registration or licensure must: Attest that the applicant is a citizen of the United States or a qualified alien under the Federal Immigration and Nationality Act, for the purpose of complying with Neb. Rev. Stat. §§Stat. 4-108 through 4-114. The applicant must provide his/her immigration status and alien number, and agree to provide a copy of his/her United States Citizenship and Immigration Services (USCIS) documentation upon request. If a corporation or other separate legal entity, this section does not apply.

21-005 FEES

21-005.01 Initial Application Fee: Each application for a Certificate of Registration will be accompanied by a non-refundable fee as specified in 180 NAC 21-005.05. No application will be accepted for filing or processing prior to full fee payment or the application will be returned to the applicant.

21-005.02 Annual Fee for Certification of Registration: A non-refundable fee as specified in 180 NAC 21-005.05 must be paid in full each year on or before the last day of the expiration anniversary month of the certificate of registration.¹

21-005.03 An Application for Amendment: If a new piece of equipment is purchased during the year an additional fee will be prorated as follows:

1. The prorated costs will be based on monthly intervals and will be charged from the first day of the month the amendment is effective until the end of the current billing period.
2. The Department will bill the registrant the additional fee.

The replacement of part(s) for an existing radiation machine or replacement of an existing machine will not result in an additional fee.

21-005.04 Reciprocity Fees: Each application for reciprocal recognition of an out-of-state registration must be accompanied by the applicable annual fee, provided that no such fee has been submitted within 12 months of the date of commencement of the proposed activity.

21-005.05 Initial Application and Annual Fees

	<u>Dental Radiation Generating Equipment</u>	<u>Fee Per Unit</u>
1.	Dental Diagnostic	\$70.00
2.	Reciprocity (Registration of out-of-state radiation	

¹Example: If the certificate of registration expires on June 30, 2007, annual fees are due on or before June 30, of each year.

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Generating equipment brought into Nebraska for
Temporary use). \$70.00

21-005.06 Method of Payment: Fee payments will be made payable to: Nebraska
Department of Health and Human Services

Send to: Department of Health and Human Services
Radiological Health
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026.

21-005.07 Failure to Pay Prescribed Fees

21-005.07A In any case where the Department finds that an applicant for a
certificate of registration has failed to pay the fee, the Department will not process
that application until the fee is paid.

21-005.07B In any case where the Department finds that a registrant has failed
to pay a fee by the due date, the Department may implement the appropriate
compliance procedures.

21-006 REGISTRATION OF DENTAL RADIATION GENERATING EQUIPMENT:

21-006.01 Application for Registration: Each person having dental radiation generating
equipment must:

1. Apply for registration of such facility with the Department within 30 days
following the commencement of the operation of a dental radiation generating
equipment facility. Application for registration must be completed on form NRH-
4 furnished by the Department and must contain all the information required by
the form NRH-4 and accompanying instructions.
2. Designate on the application form an individual to be responsible for radiation
protection. A radiation safety officer will be designated on the application form.
The radiation safety officer will carry out the responsibilities of 180 NAC 21-
007.01B.
3. An application for use of a dental radiation generating equipment must be
signed by the applicant and the radiation safety officer if the radiation safety
officer is someone other than the applicant.
4. The Department may at any time after the filing of the original application require
further statements in order to enable the Department to determine whether the
certification of registration should be issued or denied.
5. An application for a certificate of registration may include a request for a
certificate of registration authorizing one or more activities. If an application
includes a request for an additional authorization other than use of a dental
radiation machine, compliance with other applicable chapters of Title 180 NAC
will be required.

6. Each application for a certificate of registration will be accompanied by the fee prescribed in 180 NAC 21-005.
7. The applicant's proposed dental radiation generating equipment, facilities, and operating and safety procedures must be adequate to minimize danger to occupational and public health and safety.
8. Each registrant must prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his/her radiation generating equipment facility until such person provides evidence that s/he has been registered with the Department as a provider of services in accordance with 180 NAC 2-005.

21-006.02 Issuance of Certificate of Registration

21-006.02A Upon a determination that an applicant meets the requirements of the regulations, the Department will issue a Certificate of Registration.

21-006.02B The Department may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of dental radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary in order to:

1. Minimize danger to occupational and public health and safety;
2. Require additional records and the keeping of additional records as may be appropriate or necessary; and
3. Prevent loss or theft of dental radiation generating equipment subject to 180 NAC 21.

21-006.03 Specific Terms and Conditions of Certificates of Registration

21-006.03A Each certificate of registration issued in accordance to 180 NAC 21 will be subject to the applicable provisions of the Nebraska Radiation Control Act, Neb. Rev. Stat. §§ 71-3501 to 17-3520 now or hereafter in effect, and to the applicable rules and order of the Department.

21-006.03B No certificate of registration issued or granted under 180 NAC 21 will be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the Department authorizes the transfer in writing.

21-006.03C Each person registered by the Department for dental radiation generating equipment use in accordance with 180 NAC 21 will confine use and possession of the dental radiation generating equipment registered to the locations and purposes authorized in the certificate of registration.

21-006.03D The registrant is responsible for complying with 180 NAC 21 and the conditions of the Certificate of Registration.

21-006.04 Responsibilities of the Registrant

21-006.04A The registrant will notify the Department in writing within 30 days of any change which would render the information contained in the application for registration no longer accurate.

21-006.04B The following criteria applies to the loaner dental radiation generating equipment and dental radiation generating equipment used for clinical trial evaluations:

1. Dental radiation generating equipment used for clinical trial evaluations and loaner or demonstration dental radiation generating equipment may be used for up to 60 days without adding the dental radiation generating equipment to an existing certificate of registration. If the use period will exceed 60 days, the facility will be required to add the dental radiation generating equipment to their certificate of registration and a fee will be assessed. Dental radiation generating equipment must be registered in accordance with 180 NAC 21-006.
2. No fees will be assessed for the operation of dental radiation generating equipment for clinical trial evaluations or loaner or demonstration dental radiation generating equipment used for a period of 60 days or less at a facility with a current certificate of registration.

21-006.04C The following applies to voluntary or involuntary petitions for bankruptcy:

1. Each registrant will notify the Department, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy.
2. The notification specified in 180 NAC 21-006.04C, item 1. will include the bankruptcy court in which the petition for bankruptcy was filed; and the date of the filing of the petition.
3. A copy of the "petition for bankruptcy" must be submitted to the Department along with the written notification.

21-006.04D Receipt, transfer, and disposal of dental radiation generating equipment. The registrant will ensure that records of receipt, transfer, and disposal of dental radiation generating equipment are made and/or maintained for each unit of dental radiation generating equipment. Records of receipt, transfer, and disposal of dental radiation generating equipment will include the following:

1. Manufacturer's name and model and serial number from the control panel; and
2. Date of the receipt, transfer, and disposal.

21-006.04E Approval not implied: No person, in any advertisement, will refer to the fact that s/he or his/her facility is registered with the Department pursuant to the

provision of 180 NAC 21-006, and no person will state or imply that any activity under such registration has been approved by the Department.

21-006.04F Inventory

21-006.04F1 Each registrant will annually inventory all dental radiation generating equipment possessed. The inventory will include the manufacturer's name, model, and serial number of the control panel and will be made and maintained for inspection by the Department in accordance with 180 NAC 21-009.01.

21-006.04F2 Notification is required within 30 days of any change of dental radiation generating equipment inventory. This includes installation or removal and the disposition of any equipment disposed of or transferred. The assembler's notification of installation may be accepted in lieu of notification by the registrant. This does not relieve the registrant of the responsibility to assure that proper notification has been made.

21-006.05 Expiration of Certificates of Registration

21-006.05A Except as provided by 180 NAC 21-006.07B, each certificate of registration will expire annually on the anniversary of the date issued. Expiration does not relieve the registrant of the requirements of 180 NAC 21.

21-006.05B If a registrant does not renew the certificate of registration per 180 NAC 21-006.01, the registrant will on or before the expiration date on the certificate of registration:

1. Terminate use of all dental radiation generating equipment;
2. Submit a record of disposition of the dental radiation generating equipment; and
3. Pay any outstanding fees per 180 NAC 21-005.

21-006.06 Termination of Certificates of Registration: When a registrant decides to terminate all activities involving dental radiation generating equipment authorized under the certification of registration, the registrant must notify the Department immediately and:

1. Request termination of the certificate of registration in writing;
2. Submit a record of disposition of the dental radiation generating equipment; and
3. Pay any outstanding fee per 180 NAC 21-005.

21-006.07 Renewal of Certificate of Registration

21-006.07A Application for renewal of registration will be filed in accordance with 180 NAC 21-006.01.

21-006.07B In any case in which a registrant has filed an application in proper form for renewal, the existing certificate of registration will not expire until the application has been finally determined by the Department.

21-006.08 Reciprocal Recognition of Out-of State Certificate of Registration: Whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, it must be registered by this Department.

21-006.09 Application for Registration of Mobile Services Used in Dentistry: In addition to the requirements of 180 NAC 21-006.01, each applicant will apply for and receive authorization for mobile services before beginning mobile service operation. The following will be submitted:

1. An established main location where the equipment, records, etc. will be maintained for inspection. This will be a street address, not a post office box number.
2. A sketch or description of the normal configuration of each dental radiation generating equipment unit's use, including the operator's position and any ancillary personnel's location during exposure. If a mobile van is used with a fixed dental radiation generating equipment unit inside, furnish the floor plan indicating protective shielding and the operator's location.
3. A current copy of the applicant's operating and safety procedures regarding radiological practices for protection of patients, operators, employees, and the general public.

21-007 REQUIREMENTS

21-007.01 Administrative Controls

21-007.01A Registrant: The registrant must be responsible for directing the operation of the x-ray system(s) under his/her administrative control. The registrant or the registrant's agent must assure that the requirements listed as follows are met in the operation of the x-ray system(s):

1. An x-ray system which does not meet the provisions of Title 180 must not be operated for diagnostic purposes.
2. Registrants must assure that individuals who will operate dental x-ray systems are authorized under Neb. Rev. Stat. §38-1115 to practice dentistry, or 38-1131 to practice as dental hygienists or § 38-1135 to practice as a dental assistant.
3. A technique chart relevant to the particular x-ray machine must be provided or electronically displayed in the vicinity of the control panel and used by all operators.
4. Individuals must not be exposed to the useful beam except for dental healing arts purposes and unless the exposure has been ordered by a dentist. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing arts purpose.

21-007.01B Radiation safety officers responsibilities are:

1. Preparing operating and safety procedures and keeping them updated;
2. Informing this Department of lost or stolen dental radiation generating equipment or overexposures;
3. Knowing policies and procedures;
4. Stopping unsafe practices;
5. Keeping records;
6. Training employees; and
7. Ensuring that 180 NAC 21 is followed.

21-007.01C Information and Maintenance Record and Associated Information: The registrant must maintain the following information for each x-ray system for inspection by the Department:

1. Model and serial numbers of all certifiable components, and user's manuals for those components;
2. Tube rating charts and cooling curves;
3. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and
4. A copy of all correspondence with this Department regarding that x-ray system.

21-007.01D The registrant must maintain control of registered dental radiation generating equipment that are in an unrestricted area and that are not in storage.

21-007.02 ALARA: The registrant must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

21-007.03 Operating and Safety Procedures:

21-007.03A Each registrant must have and implement written operating and safety procedures. These procedures must be made available to each individual operating a dental radiation generating machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. These procedures must include, but are not limited to, the following procedures as applicable:

1. Use of a technique chart in accordance with 180 NAC 21-007.01A, item 3
2. Radiation dose requirements in accordance with 180 NAC 21-007.04A and B
3. Holding of patients or film in accordance with 180 NAC 21-007.09B and E
4. Film processing program in accordance with 180 NAC 21-007.12 and/or 180 NAC 21-007.13
5. Posting notices to worker in accordance with 180 NAC 21-007.05B
6. Instructions to workers in accordance with 180 NAC 21-007.04C

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7. Notification and reports to individuals in accordance with 180 NAC 21-008.02D
8. Ordering x-ray exams in accordance with 180 NAC 21-007.01A, item 4

21-007.03B The registrant must at intervals not to exceed 12 months, review the operating and safety procedures.

21-007.04 Personnel Requirements

21-007.04A Occupational limits

21-007.04A1 The registrant must control the occupational dose to individual adults to the following dose limits:

1. An annual limit, total effective dose equivalent being equal to 0.05 Sv (5 rem).
2. The annual limits to the lens of the eye, to the skin of the whole body, and to skin of the extremities which are:
 - a. An lens dose equivalent of 0.15 Sv (15 rem), and
 - b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

21-007.04A2 The registrant must ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem).

1. The registrant must make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 180 NAC 21-007.04A2.²
2. If by the time the woman declares pregnancy to the registrant, the dose equivalent to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the registrant must be deemed to be in compliance with 180 NAC 21-007.04A2 if the additional dose to the embryo/fetus does not exceed 0.50 mSv (0.05 rem) during the remainder of the pregnancy.

21-007.04A3 Occupational Dose Limits for Minors: The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in 180 NAC 21-007.04A1.

²The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 116 "Limitation of Exposure to Ionizing Radiation" (March 31, 1993) that no more than 0.5 mSv (0.05 rem) to the embryo/fetus be received in any one month.

21-007.04A4 The assigned deep dose equivalent and shallow dose equivalent must be for the portion of the body receiving the highest exposure.

21-007.04A5 The deep dose equivalent, lens-dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

21-007.04A6 The registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

21-007.04B Dose limits for individual members of the public

21-007.04B1 Each registrant must conduct operations so that:

1. The total effective dose equivalent to individual members of the public from exposure to radiation from radiation generating machines does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in authorized medical research programs; and
2. The dose in any unrestricted area from external exposure to radiation from radiation generating equipment does not exceed 0.02 mSv (0.002 rem) in any one hour.

21-007.04B2 If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

21-007.04B3 The Department may impose additional restrictions on radiation levels in unrestricted areas.

21-007.04C Instruction to workers: The registrant must provide instructions to radiation workers prior to beginning initial work in restricted areas. These instructions will include the following:

1. Precautions or procedures to minimize exposure;
2. The applicable provisions of Department requirements and certificates of registration for the protection of personnel from exposures to radiation occurring in such areas; and
3. The radiation worker's responsibility to report promptly to the registrant any condition that may constitute, lead to, or cause a violation of Department requirements or certificate of registration conditions, or unnecessary exposure to radiation.

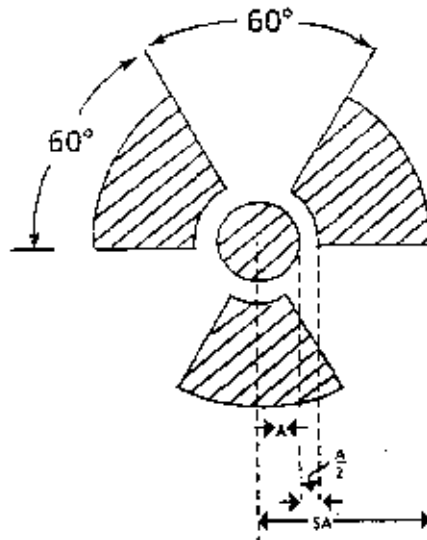
21-007.05 Facility Requirements

21-007.05A Caution Signs

21-007.05A1 Standard Radiation Symbol: Unless otherwise authorized by the Department, the symbol prescribed by 180 NAC 21-007.05 must use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



21-007.05A2 Exception to Color Requirements for Standard Radiation Symbol: Notwithstanding the requirements of 180 NAC 21-007.05A1, registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

21-007.05A3 Additional Information on Signs and Labels: In addition to the contents of signs and labels prescribed in 180 NAC 21, the registrant must provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

21-007.05B Posting of notices to workers

21-007.05B1 Each registrant must post current copies of the following documents:

1. The regulations - 180 NAC 21;
2. The certificate of registration;
3. The operating procedures applicable to activities under the registration; and
4. Any notice of violation involving radiological working conditions, proposed, imposition of civil penalty, or order issued pursuant to 180 NAC 21-010 and any response from the registrant.

21-007.05B2 If posting of a document specified in 180 NAC 21-007.05B1, item 1, 2., or 3. is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

21-007.05B3 Department documents posted pursuant to 180 NAC 21-007.05B1, item 4., must be posted within two working days after receipt of the documents from the Department; the registrant's response, if any, must be posted within two working days after dispatch from the registrant. The documents must remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

21-007.05B4 Documents, notices or forms posted pursuant to 180 NAC 21-007.05B must appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies, must be conspicuous, and must be replaced if defaced or altered.

21-007.05C Notice to employees: Department Form NRH-3, "Notice to Employees" must be posted by each registrant wherever individuals work in or frequent any portion of a restricted area.

21-007.05D Registrants required to have tests performed per 180 NAC 21-007.10 must select any qualified person authorized by registration through the Department.

21-007.06 Dental Radiation Machine Requirements

21-007.06A Technique Indicators

21-007.06A1 The technique factors to be used during an exposure must be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure must be indicated.

21-007.06A2 The requirement of 180 NAC 21-007.06A may be met by permanent markings on equipment having fixed technique factors.

21-007.06A3 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.

21-007.06A4 The indicated technique factors must be accurate to within manufacturer's specification. If these specifications are not available from the manufacturer, the factors must be accurate to within $\pm 10\%$ of the indicated setting.

21-007.06B Warning Label: The control panel containing the main power switch will bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

21-007.06C Mechanical Support of Tube Head: The tube housing assembly support must be adjusted such that the tube housing assembly will remain stable during the exposure, unless the tube housing movement is a designed function of the x-ray system or its supports. The position indicating device must not be hand held.

21-007.06D Battery Charge Indicator: On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

21-007.06E Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (100 milliroentgens (mR) exposure)) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

21-007.06F Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly will not exceed an air kerma of 18 microgray (2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance will be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

21-007.06G Timer

21-007.06G1 The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer

accuracy must be $\pm 10\%$ of the indicated time with testing performed at 0.5 second.

21-007.06G2 Means must be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

21-007.06H 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.

21-007.06I Kilovolt Peak: If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within $\pm 10\%$ of the indicated setting(s). For dental radiation generating equipment with fewer than three fixed kilovolt peak settings, the radiation machine will be checked at those settings.

21-007.06J Tube Stability: The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant will assure proper and free movement of the dental radiation generating equipment.

21-007.06K Collimation: Field limitation must meet the requirements of 180 NAC 21-007.07 or 180 NAC 21-007.08.

21-007.06L kVp Limitations: Dental x-ray radiation generating equipment with a nominal fixed kVp of less than 50 kVp must not be used to make diagnostic dental radiographs of humans.

21-007.06M Beam Quality

21-007.06M1 Half-value Layer

1. The half-value layer of the useful beam for a given x-ray tube potential must not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means must be provided to ensure that at least minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter

interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE I		
Design Operating Range	Measured Potential (kVp)	Half-value Layer in mm Aluminum
Below 51	30	N/A
	40	N/A
	50	1.5
51 to 70	51	1.5 (1.2)*
	60	1.5 (1.3)*
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

\1\ Dental intra-oral x-ray systems manufactured on or before December 1, 2006.

- For capacitor energy storage equipment, compliance with the requirements of 180 NAC 21-007.06F must be determined with the system fully charged.

21-007.06M2 Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device will link the kVp selector with the filter(s) and will prevent an exposure unless the minimum amount of filtration required by 180 NAC 21-007.06M, item 1 is in the useful beam for the given kVp which has been selected.

21-007.06M3 Any other system having removable filters will be required to have the minimum amount of filtration as required by 180 NAC 21-007.06M1, item 1 permanently located in the useful beam during each exposure.

21-007.06N Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected will be clearly

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indicated prior to initiation of the exposure. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

21-007.06O Maintaining Compliance: Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020.30 and 1020.31) must be maintained in compliance with applicable requirements of that standard.

21-007.06P X-ray Control: An x-ray control will be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less. Each x-ray control will be located in such a way as to permit the operator to remain in an area of less than 2 millirem in any one hour during the entire exposure. The exposure switch will be of the continuous pressure type.

21-007.06Q Security and Control of Dental Radiation Generating Equipment

21-007.06Q1 The registrant must secure dental radiation generating equipment from unauthorized removal.

21-007.06Q2 The registrant must use devices and/or administrative procedures to prevent unauthorized use of dental radiation generating equipment.

21-007.06R Certified Dental Radiation Generating Equipment for Dental Facilities: In addition to the requirements of 180 NAC 21, the registrant must not make, nor cause to be made, any modification of components or installations of components certified in accordance with the United States Food and Drug Administration Title 21, CFR, Part 1020.30 & 1020.31, "Performance Standards for Ionizing Radiation Emitting Products," as amended, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in Title 21, CFR, Part 1020.30 and 1020.31, except where a variance has been granted by the Director, Center for Devices and Radiological Health, United States Food and Drug Administration. A copy of the variance must be maintained by the registrant in accordance with 180 NAC 21-009.21 for inspection by the Department.

21-007.07 Additional requirements for dental intraoral systems: In addition to the provisions of 180 NAC 21, the requirements of 180 NAC 21-007.07 apply to x-ray equipment used for dental intraoral radiography.

21-007.07A Source-to-Skin Distance (SSD): X-ray systems designed for use with an intraoral image receptor must be provided with means to limit the SSD.

21-007.07B Beam Limitation:

21-007.07B1 Radiographic systems designed for use with an intraoral image receptor must be provided with means to limit the x-ray beam such that the

beam at the minimum SSD must be containable in a circle having a diameter of no more than 7 centimeters.

21-007.07B2 If the minimum source-to-skin distance is less than 18 centimeters, the x-ray field at the minimum source-to-skin distance will be restricted to a dimension of no more than 6 centimeters.

21-007.08 Additional Requirements for Dental Extraoral System

21-007.08A Field limitation: Dental rotational panoramic systems must be provided with means to restrict the x-ray beam to the following:

1. The imaging slit in the transverse axis;
2. No more than a total of 0.5 inches larger than the imaging slit in the vertical axis;

21-007.08B All other dental extraoral radiographic systems (e.g., cephalometric) will be provided with means to restrict the x-ray field to the image receptor. The x-ray field must not exceed the image receptor by more than:

1. 2.0% of the source-to-image receptor distance for the length or width of the image receptor for rectangular collimation; or
2. 2.0% of the source-to-image receptor distance for the diagonal of the image receptor for circular or polygon collimations.

21-007.09 Additional Operational Controls

21-007.09A 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 in which the registrant has determined that the hold devices are contraindicated.

21-007.09B The registrant's written operating and safety procedures required by 180 NAC 21-007.03 will include the following:

1. A list of circumstances in which exceptions to using mechanical holding devices may apply;
2. A procedure used for selecting an individual to hold or support the patient or image receptor; and
3. A procedure the individual must follow when holding or supporting the patient or image receptor.

21-007.09C The operator must stand at least six feet from the useful beam or behind a protective barrier. The operator must maintain verbal, aural, and visual contact with the patient.

21-007.09D The tube housing support must be constructed and adjusted so that the tube housing will not drift from its set position during an exposure. Neither the tube housing nor support housing will be hand-held during an exposure.

21-007.09E Patient and film holding devices must be used when the techniques permit.

21-007.09F The tube housing and the PID (position indicating device) will not be hand-held during an exposure.

21-007.10 Equipment Performance Evaluation

21-007.10A For all dental radiation generating equipment, the registrant must perform, or cause to be performed, tests necessary to assure proper function of equipment with the indicated standard for each item specified in 180 NAC 21-007.06G through K and for dental intraoral systems a measurement of the in-air exposure at the technique factors used for an average adult patient thickness in routine intraoral (bitewing) radiography. After installation, the tests listed must be performed every five years.

21-007.10B Records of the test results, including any numerical readings must be maintained by the registrant in accordance with 180 NAC 21-009.21.

21-007.10C 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 designated by the registrant. Correction or repair must be completed no longer than 90 days from discovery unless authorized by the Department. Records of corrections or repairs will be maintained by the registrant in accordance with 180 NAC 21-009.21.

21-007.10D Measurements of the radiation output of a x-ray system must be performed with a calibrated dosimetry system. The dosimetry system must have been calibrated within the preceding 24 months and the calibration must be traceable to a national standard. During the calendar year in which the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months must be performed.

21-007.11 Dental Research: Any research using dental radiation generating equipment on humans must be approved by an Institutional Review Boards required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The Institutional Review Board must include at least one dentist to direct any use of radiation in accordance with 180 NAC 21.

21-007.12 Automatic and Manual Film Processing for Dental Facilities and Mobile Dental Services

21-007.12A Films will be developed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual

processing will be posted in the darkroom. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, that time-temperature relationship must be documented and posted.

21-007.12B Devices must be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

21-007.12C Chemicals must be replaced according to the chemical manufacturer's or supplier's recommendations or at an interval not to exceed three months.

21-007.12D The darkroom must be light tight and use a proper safelight in accordance with 21-007.12E.

21-007.12E Lighting in the film processing/loading area will be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products that provide an equivalent level of protection against fogging.

21-007.13 Alternative Processing Systems: Users of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems will follow manufacturer's recommendations for image processing. Documentation that the registrant is following manufacturer's recommendations will include the date and initials of the individual completing the document and will be made and maintained at the site where performed in accordance with 180 NAC 21-009.21 for inspection by the Department.

21-007.14 The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examination.

21-008 RECORDS AND REPORTS

21-008.01 General Provisions

21-008.01A Each registrant must use the SI units gray, sievert and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and must clearly indicate the units of all quantities on records required by 180 NAC 21.

21-008.01B The registrant must make a clear distinction among the quantities entered on the records required by 180 NAC 21, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent.

21-008.01C All records required by 180 NAC 21 must be accurate and factual.

21-008.01D Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Records, such as letters, drawings, and specifications, will include all pertinent information, such as stamps, initials, and signatures.

21-008.01E Form of Records: Each record required by 180 NAC 21 must be legible throughout the specified retention period. The record must be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The registrant must maintain adequate safeguards against tampering with and loss of records.

21-008.02 Reports

21-008.02A Reports of Stolen Lost, or Missing or Registered Sources of Radiation

21-008.02A1 Telephone Reports: Each registrant must report to the Department by telephone a stolen, lost or missing radiation machine immediately after its occurrence becomes know to the registrant.

21-008.02A2 Written Reports: Each registrant required to make a report pursuant to 180 NAC 21-008.02B1, item 1 must, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

1. A description of the registered dental radiation generating equipment involved, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
2. A description of the circumstances under which the loss or theft occurred;
3. A statement of disposition, or probable disposition, of the registered dental radiation generating equipment involved;
4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
5. Actions that have been taken, or will be taken, to recover the source of radiation; and
6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

21-008.02A3 Subsequent to filing the written report, the registrant must also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

21-008.02A4 The registrant must prepare any report filed with the Department pursuant to 180 NAC 21-008.02B1 so that names of individuals who may have

received exposure to radiation are stated in a separate and detachable portion of the report.

21-008.02B Notification of Incidents

21-008.02B1 Immediate Notification: Notwithstanding other requirements for notification, each registrant must immediately report each event involving dental radiation generating equipment possessed by the registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:
 - a. A total effective dose equivalent of 0.25 Sv (25 rem) or more; or
 - b. A lens dose equivalent of 0.75 Sv (75 rem) or more; or
 - c. A shallow dose equivalent to the skin or extremities of 2.5 Gy (250 rad) or more; or

21-008.02B2 Twenty-Four Hour Notification: Each registrant must, within 24 hours of discovery of the event, report to the Department each event involving loss of control of dental radiation generating equipment possessed by the registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:
 - a. A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
 - b. A lens dose equivalent exceeding 0.15 Sv (15 rem); or
 - c. A shallow dose equivalent to the skin or extremities exceeding 0.5 Sv (50 rem); or

21-008.02B3 The registrant must prepare each report filed with the Department pursuant to 180 NAC 21-008.02B2 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

21-008.02B4 Registrants must make the reports required by 180 NAC 21-008.02B1 and 2 by initial contact by telephone to the Department and must confirm the initial contact by telegram, FAX, or electronic media to the Department.

21-008.02C Reports of Exposure and Radiation Levels Exceeding the Limits

21-008.02C1 Reportable Events: In addition to the notification required by 180 NAC 21-008.02B, each registrant must submit a written report within 30 days after learning of any of the following occurrences:

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1. Any incident for which notification is required by 180 NAC 21-008.02B; or
2. Doses in excess of any of the following:
 - a. The occupational dose limits for adults in 180 NAC 21-007.04A1.; or
 - b. The occupational dose limits for a minor in 180 NAC 21-007.04A3; or
 - c. The limits for an embryo/fetus of a declared pregnant woman in 180 NAC 21-007.04A2 or
 - d. The limits for an individual member of the public in 180 NAC 21-007.04B; or
 - e. Any applicable limit in the registration; or
3. Levels of radiation in:
 - a. A restricted area in excess of applicable limits in the registration; or
 - b. An unrestricted area in excess of 10 times the applicable limit set forth in 180 NAC 21.007.04B, whether or not involving exposure of any individual in excess of the limits in 180 NAC 21-007.04B.

21-008.02C2 Contents of Report

21-008.02C2a Each report required by 180 NAC 21-008.02C1 must describe the extent of exposure of individuals to radiation:

1. Estimates of each individual's dose; and
2. The levels of radiation; and
3. The cause of the elevated exposures, or dose rates; and
4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated registration conditions.

21-008.02C2b Each report filed pursuant to 180 NAC 21-008.02C1 must include for each individual exposed: the name, the individual's identification number, and date of birth. With respect to the limit for the embryo fetus in 180 NAC 21-007.04A2, the identifiers should be those of the declared pregnant woman. The report must be prepared so that this information is stated in a separate and detachable portion of the report.

21-008.02C3 All registrants who make reports pursuant to 180 NAC 21-008.02C1 must submit the report in writing to the Department.

21-008.02D Notification and Reports to Individuals

21-008.02D1 If applicable, radiation exposure data for an individual must be reported to the individual as specified in 180 NAC 21-008.02D. The information reported must include data and results obtained pursuant to Title 180, orders or certificate of registration conditions, as shown in records maintained by the registrant pursuant to 180 NAC 21-008. Each notification and report must:

1. Be in writing;
2. Include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's identification number.
3. Include the individual's exposure information; and
4. Contain the following statement:

"This report is furnished to you under the provisions of 180 NAC 21. You should preserve this report for further reference."

21-008.02D2 If applicable, each registrant must furnish each worker annually a written report of the worker's dose as shown in records maintained by the registrant pursuant to 180 NAC 21-008.02C.

21-008.02D3 When a registrant is required pursuant to 180 NAC 21-008.02B and C, to report to the Department any exposure of an individual to sources of radiation, the registrant must also provide the individual a written report on the exposure data included therein. The reports must be transmitted at a time not later than the transmittal to the Department.

21-009 COMPLIANCE PROCEDURES

PRESENCE OF REPRESENTATIVE OF REGISTRANT AND WORKERS DURING INSPECTION

21-009.01 Each registrant must afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 180 NAC 21. The registrant must make available to the Department for inspection records maintained pursuant to 180 NAC 21.

21-009.02 During an inspection, Department inspectors may consult privately with workers as specified in 180 NAC 21-009.08 through 21-009.10. The registrant may accompany Department inspectors during other phases of an inspection.

21-009.03 If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant must notify the inspectors of the authorization and must give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

21-009.04 Each workers' representative must be routinely engaged in work under control of the registrant and must have received instructions as specified in 180 NAC 21-007.04C.

21-009.05 Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

21-009.06 With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, must be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

21-009.07 Notwithstanding the other provisions of 180 NAC 21-009.01 through 21.009.07, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area must be an individual previously authorized by the registrant to enter that area.

CONSULTATION WITH WORKERS DURING INSPECTIONS

21-009.08 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the regulations and certificates of registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

21-009.09 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, 180 NAC 21, or registration condition, or any unnecessary exposure of an individual to sources of radiation under the registrant's control. Any such notice in writing must comply with the requirements of 180 NAC 21-009.11.

21-009.10 The provisions of 180 NAC 21-009.09. must not be interpreted as authorization to disregard instructions pursuant to 180 NAC 21-007.04C.

REQUESTS BY WORKER FOR INSPECTIONS

21-009.11 Any worker or representative of workers who believes that a violation of the Act, 180 NAC 21 or registration conditions exists or has occurred in work under a registration to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy will be provided to the registrant by the Department no later than at the time of inspection except that, upon the request of the worker giving the notice, his/her name and the name of individuals referred to therein must not appear in the copy or on any record published, released, or made available by the Department, except for good cause shown.

21-009.12 If, upon receipt of the notice, the Department determines that the complaint meets the requirements set forth in 180 NAC 21-009.11, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, s/he must cause an inspection to be made as soon as practicable, to determine if the alleged violation exists or has occurred. Inspections pursuant to 180 NAC 21-009.11, 21-009.12 and 21-009.13 need not be limited to matters referred to in the complaint.

21-009.13 A registrant, or contractor or subcontractor of a registrant must not discharge or in any manner discriminate against any worker because the worker has filed any complaint or instituted or caused to be instituted any proceeding under 180 NAC 21 or has testified or is about to testify in any such proceeding or because of the exercise by the worker on behalf of himself/herself or others of any option afforded by 180 NAC 21.

INSPECTIONS NOT WARRANTED: INFORMAL REVIEW

21-009.14 If the Department determines, with respect to a complaint under 180 NAC 21-009.11 through 21-009.13 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department will notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position to the Director of the Division of Public Health, who will provide the registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position to the Director of the Division of Public Health, who will provide the complainant with a copy of the statement by certified mail.

21-009.15 Upon the request of the complainant, the Director of the Division of Public Health, may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Director of the Division of Public Health, will affirm, modify, or reverse the determination of the Department and furnish the complainant and the registrant a written notification of the decision and the reason therefor.

21-009.16 If the Department determines that an inspection is not warranted because the requirements of 180 NAC 21-009.11 have not been met, the Director of the Division of Public Health will notify the complainant in writing of such determination. The determination must be without prejudice to the filing of a new complaint meeting the requirements of 180 NAC 21-009.11.

21-009.17 The routine inspection interval for dental facilities is five years. On-site inspection and interim inspections may be alternated. Registrant's having certificates of registration authorizing multiple uses will be inspected on-site at the most frequent interval specified for the uses authorized.

21-009.18 Notwithstanding the inspection interval of 180 NAC 21-009.17, the Department may inspect registrants more frequently due to:

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1. The persistence or severity of violations found during an inspection;
2. Investigation of an incident or complaint concerning the facility;
3. A request for an inspection by a worker(s) in accordance with 180 NAC 21-009.11 through 21-009.13;
4. Any changes in a facility or dental radiation generating equipment that might cause a significant increase in radiation output or hazard; or

21-009.19 For interim inspection of dental radiation generating equipment, each registrant must:

1. Respond to a request from the Department for a interim inspection;
2. Complete the interim inspection forms (NRH-21) in accordance with the instructions included with the forms; and
3. Return to the Department the completed interim inspection forms with documentation of the most recent equipment performance evaluation performed in accordance with 180 NAC 21-007.10D by the deadline indicated in the notice.

21-009.20 Each registrant must perform, upon instruction from the Department, or must permit the Department to perform such reasonable surveys as the Department deems appropriate or necessary including but not limited to, surveys of:

1. Dental radiation generating equipment;
2. Facilities where dental radiation generating equipment are used; and
3. Other equipment and devices used in connection with utilization or storage of dental radiation generating equipment.

21-009.21 Record/document requirements: Each registrant must maintain the following records/documents at each location and make available to the Department for inspection.

	Name of Records/Document	Regulation Cross-Reference	Time Interval for Keeping Record/Document
I	Inventory of all Dental Radiation Generating Equipment Possessed	180 NAC 21-006.04F	5 Years after records is made
II	Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	180 NAC 21-006.04D	Until termination of registration
III	Current Operating and Safety Procedures	180 NAC 21-007.03	Until termination of registration
IV	Current 180 NAC 21	180 NAC 21-007.05B	Until termination of registration
V	Current Certificate of Registration (NRH-4)	180 NAC 21-007.05B	Until termination of registration
VI	Notice of Violation From Last Inspection	180 NAC 21-007.05B	Until next on-site inspection
VII	Documentation of Corrections of any Violations	180 NAC 21-007.05B	Until next on-site inspection
VIII	Equipment Performance Evaluation Tests	180 NAC 21-009.19	Until next on-site inspection
IX	Automatic and Manual Film Processing Records	180 NAC 21-007.12	1 Year
X	Alternative Film Processing Records	180 NAC 21-007.13	1 Year
XI	United States Food and Drug Administration Variance	180 NAC 21-007.06R	Until transfer of machine or termination of registration

21-010 HEARING AND ENFORCEMENT PROCEDURES - ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING PROCEDURES FOR REGISTRANTS; PENALTIES.

21-010.01 Public Hearings: The Department will hold public hearings in any proceeding for the issuance or modification of rules or regulations relating to control of sources of radiation, the Department will provide an opportunity for public participation through written comments and a public hearing.

21-010.02 Right to a Public Hearing: When the Department:

1. Denies:
 - a. An application for a license or registration,
 - b. An amendment to a license or registration, or
 - c. An application for an exemption from license or registration requirements;
2. Revokes, suspends, modifies, conditions, or limits a license or registration; or

3. Imposes a civil penalty or appropriate order.

The Department will provide the applicant or licensee an opportunity for a hearing in accordance with the Department's Rules of Practice and Procedures for Administrative Hearings, adopted pursuant to the Administrative Procedures Act, currently at 184 NAC 1.

21-010.03 Discipline

21-010.03A Any person who violates any provision of the Radiation Control Act, or any rule, regulation, or order issued pursuant to such Act, or any term, condition, or limitation of any registration issued pursuant to such Act or has engaged in deliberate misconduct is subject to:

1. Revocation, denial, suspension, modification, condition or limitation;
2. The imposition of a civil penalty; or
3. The terms of an appropriate order issued by the Department.

21-010.03B Compliance

21-010.03B1 In all instances other than the issuance of emergency sanctions pursuant to 180 NAC 21-010.06, the Department may afford the registrant the opportunity to:

1. Correct violations and show compliance with applicable provisions of the Act, or the rules and regulations, or registration requirements, and any orders of the Department issued thereunder, or
2. Attend an enforcement conference to discuss with the Department methods and schedules for correcting the violation(s) or to show compliance with the Act, rules and regulations and registration conditions. Notice of any enforcement conference will be sent by personal service or certified mail, return receipt requested. An enforcement conference is not a prerequisite for any action.

21-010.03B2 The Department may permit the registrant to respond in writing to the alleged violation of the Act, rule, regulation, order, or any term, conditions of limitation of registration.

21-010.03B3 Failure of a registrant to respond is cause for the Department to proceed with disciplinary action.

21-010.04 Hearings: Whenever the Department proposes to subject a registrant to the provisions of 180 NAC 21-010.03A, the Department will notify the person in writing, (a) setting forth the date, facts, and nature of each act or omission with which the person is charged, (b) specifically identifying the chapter, rule, regulation, order, registration certificate involved in the violation and (c) of the sanction or order to be imposed. If a civil penalty is imposed, the notice will include a statement that it can be collected by civil action. The notice will be delivered to each alleged violator by personal service, by

certified or registered mail to his/her last known address, or by publication. Notice by publication will only be made if personal service or service by mail cannot be effectuated. The sanction or order in the notice will become final 30 days after the mailing of the notice unless the applicant or registrant, within the 30-day period, requests, in writing, a hearing before the department. If the notice is served by personal service or publication, the sanction order will become final 30 days after completion of the service unless the applicant, or registrant, within the 30-day period, requests, in writing, a hearing before the department.

21-010.05 Sanctions

21-010.05A The Department may consider the following:

1. Criteria in determining what sanctions are appropriate:
 - a. Previous history of noncompliance;
 - b. Action necessary to deter future violations;
 - c. Lack of reasonable efforts to correct the violation(s);
 - d. Willfulness; and
 - e. Any other aggravating factors.

2. The severity levels: The seriousness of violations will be categorized by one of the following severity levels:
 - a. Severity Level I - Violations that are most significant and have a direct negative impact on occupational and/or public health and safety or on the environment.
 - b. Severity Level II - Violations that are very significant and have an impact on occupational and/or public health and safety or on the environment.
 - c. Severity Level III - Violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.
 - d. Severity Level IV - Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances affecting public health and safety.
 - e. Severity Level V - Violations that are of minor public health and safety or environmental significance.

21-010.05B Civil Penalties: May impose a civil penalty in an amount not to exceed \$10,000 for each violation. If any violation is a continuing one, each day a violation continues may be considered a separate violation for purposes of penalty assessment. Table II provides examples for civil penalties.

TABLE II
Examples of
Civil Penalty Base

Amounts Based on Severity Level of Violations

Severity Level	Amount
I	\$5,000
II	\$3,000
III	\$1,500
IV	\$ 500
V	\$ 100

Adjustments to the amounts in Table II may be made for the presence of the criteria set out in 180 NAC 21-010.05A, item 1.

21-010.05C Suspension and Revocation of a Registration: In addition to the other factors set out in 180 NAC 21-010, used by the Department to determine appropriateness of registration revocation or suspension, the Department may act to suspend or revoke a registration if a person:

1. Knowingly causes a material misstatement or misrepresentation to be made in the application for registration if such misstatement would impair the Department's ability to evaluate the applicant's qualifications, or
2. Willfully aids another person in violating the Act or these regulations.

21-010.06 Emergency Sanctions: In the event of an emergency requiring immediate action to protect the occupational or public health and safety, or the environment, the Department may immediately, without prior notice or hearing:

1. Issue a regulation or order citing the existence of such emergency and require that certain actions be taken to meet the emergency:
 - a. An emergency regulation or order takes effect immediately upon service on the person to whom the order is directed.
 - b. Any person receiving such emergency regulation or order must comply immediately.
2. If the Department determines that a person possessing sources of radiation is not equipped to observe or fails to observe the provisions of the Act or these rules and regulations, then the Department may impound or order the impounding of the sources of radiation. Any person receiving an order of impoundment will comply immediately.

3. Service of any regulation order, or other notice or pleading under 180 NAC 21-010 will be made by personal service or by certified mail, return receipt requested. Affidavit of service, proof of mailing to the proper address, or the return receipt is evidence of service.
4. Hearings on Emergency Sanctions
 - a. A hearing will be held on an emergency regulation or order pursuant to 180 NAC 21-010.06 item 1 or upon an impoundment or order of impoundment pursuant to 180 NAC 21-010.06 item 2 if the person to whom the regulation or order of impoundment is directed makes a written application to the Department for a hearing; said application must be filed within 15 days of receipt of the emergency regulation or order of impoundment or notice of impoundment.
 - b. The hearing must be held not less than 15 days nor more than 30 days after filing the written application for hearing unless waived by the person requesting the hearing.
 - c. On the basis of the evidence presented at the hearing, the Department will, within 30 days after such hearing, continue, modify or revoke the emergency regulation or order of impoundment or order of impoundment that was the subject of the hearing, and the Department will send the applicant a copy of its findings of fact and determination.
5. Any final department action on emergency regulations or orders of impoundment of sources of radiation is subject to judicial review pursuant to the Administrative Procedure Act.

21-011 DISPOSITION OF AN IMPOUNDED SOURCE OF RADIATION: Any source of radiation impounded by the Department is declared to be a common nuisance and cannot be subject to a replevin action. Disposal of an impounded source of radiation will be determined by 180 NAC 21-010.07 and Neb. Rev. Stat. §71-3516.01.

21-011.01 The Department will keep any source of radiation impounded under Neb.Rev.Stat. §71-3516 for as long as it is needed as evidence for any hearing.

21-011.02 Prior to the issuance of an order of disposition for an impounded source of radiation, the Department will notify in writing any person, known by the Department to claim an interest in the source of radiation that the Department intends to dispose of the source of radiation. Notice will be served by personal service, by certified or registered mail to the last-known address of the person, or by publication. Notice by publication will only be made if personal service or service by mail cannot be effectuated.

21-011.03 Within 15 days after service of the notice under 180 NAC 21-011.02, any person claiming an interest in the impounded source of radiation may request, in writing, a hearing before the Department to determine possession of the source of radiation. The hearing will be held in accordance with rules and regulations adopted and promulgated by the Department. If the Department determines that the person claiming an interest in the source of radiation has proven by a preponderance of the evidence that such person:

1. Had not used or intended to use the source of radiation in violation of the Radiation Control Act,
2. Has an interest in the source of radiation acquired in good faith as an owner, a lien holder, or otherwise, and
3. Has the authority under the Radiation Control Act to possess such source of radiation, the Department will order that possession of the source of radiation be given to such person. If possession of the impounded source of radiation is not given to the person requesting the hearing, such person may appeal the decision of the Department, and the appeal will be in accordance with the Administrative Procedure Act. If possession of the impounded source of radiation is not given to the person so appealing, the Department will order such person to pay for the costs of the hearing, storage fees, and any other reasonable and necessary expenses related to the impounded source of radiation.

21-011.04 If possession of the impounded source of radiation is not given to the person requesting the hearing under 180 NAC 21-011.03, the Department will issue an order of disposition for the source of radiation and will dispose of the source of radiation as directed in the order. Disposition methods are at the discretion of the Department and may include, but are not limited to:

1. Sale of the source of radiation to a person authorized to possess the source of radiation under the act,
2. Transfer to the manufacturer of the source of radiation, or
3. Destruction of the source of radiation.

The order of disposition will be considered a transfer of title of the source of radiation.

21-011.05 If expenses related to the impounded source of radiation are not paid under 180 NAC 21-011.03, the Department will pay such expenses from:

1. Proceeds from the sale of the source of radiation, if sold; or
2. Available funds in the Department of Health and Human Services Cash Fund.

21-012 DELIBERATE MISCONDUCT

21-012.01 Any registrant, applicant for a registration, employee of a registrant, contractor or subcontractor to a registrant, or applicant for a registration, or employee of any contractor or subcontractor to a registrant, or applicant for a registration, who knowingly provides to any registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a registrant's or applicant's activities covered by the Radiation Control Act, must not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any registration issued by the Department; or

EFFECTIVE DATE
NOVEMBER 28, 2016

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

180 NAC 21

2. Intentionally submit to the Department, a registrant, an applicant, or a registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

21-012.02 Any person who violates 180 NAC 21-012, is subject to the provisions of 180 NAC 21-010.03.



Nebraska Department of Health and Human Services
Division of Public Health - Radiological Health, P.O. Box 95026
301 Centennial Mall South
Lincoln, Nebraska 68509-5026

NOTICE TO EMPLOYEES

Standards for Protection Against Radiation; Notices,
Instructions and Reports to Workers; Inspections

In Title 180, Regulations for Control of Radiation, the Nebraska Department of Health and Human Services has established standards for your protection against radiation hazards and has established certain provisions for the options of workers engaged in work under an Department license or registration.

YOUR EMPLOYER'S RESPONSIBILITY:

Your Employer is Required to:

1. Apply these regulations to work involving sources of radiation.
2. Post or otherwise make available to you a copy of Title 180, Regulations for Control of Radiation, Chapter 21 (180 NAC 21) and the operating procedures which apply to work you are engaged in, and explain their provisions to you.
3. Post any Notice of Violation involving radiological working conditions, proposed imposition of civil penalties or orders.

YOUR RESPONSIBILITY AS A WORKER:

You should familiarize yourself with those provisions of 180 NAC 21 and operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co-worker.

WHAT IS COVERED BY THESE REGULATIONS:

1. Limits on exposure to radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports; and
6. Options for workers regarding Department Inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY:

1. The 180 NAC 21 require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in any license. The basic limits for exposure to employees are set forth in 180 NAC 21-007.04. These sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air.
2. If you work where personnel monitoring is required:
 - (a) Upon your request, your employer must give you a written report of your radiation exposures upon termination of your employment; and
 - (b) Your employer must advise you annually of your exposure to radiation.

INSPECTIONS:

All licensed or registered activities are subject to inspection by representatives of the Department of Health and Human Service, Division of Public Health, Radiological Health. In addition, any worker or representative of workers who believes that there is a violation of the Nebraska Radiation Control Act, the regulations issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, Nebraska 68509-5026. The request must set forth the specific grounds for the notice, and must be signed by the worker as representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which s/he believes contributed to or caused any violation as described above.

POSTING REQUIREMENTS

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities licensed or registered, pursuant to 180 NAC 21 by the Department of Health and Human Services, to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

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Department of Health & Human Services



APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Type or print except where indicated.
 Retain one copy for your records.
 Refer to NRH-4 Instructions as needed.

Submit original application to:

**Nebraska Dept. of Health and Human Services
 Office of Radiological Health
 301 Centennial Mall South
 P.O. Box 95026
 Lincoln, NE 68509-5026**

Department Use Only	
County	Reg. Number
State	Region
Priority	Label
Renewal Date	Fee

1.a LEGAL NAME AND STREET ADDRESS (INSTITUTION, FIRM, PERSON, ETC.)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone :		FAX:	
E-Mail:			
1.b RADIATION GENERATING EQUIPMENT LOCATION (IF DIFFERENT THAN 1.a)			
Applicant/ Facility Name:			
Address:			
City, State, Zip:			
Telephone:		FAX:	
Temporary job sites throughout Nebraska? <input type="checkbox"/> Yes <input type="checkbox"/> No			
2. BILLING INFORMATION			
Address (if different than 1.a):			
City, State, Zip:			
Telephone:		FAX:	
Contact Person:			
3. PRACTICE TYPE (SEE NRH-4 INST)			

4. RADIATION GENERATING EQUIPMENT (use additional sheets if necessary – NRH-4a)

List each machine on a separate line.

Machine Type (See NRH-4 Inst)	Number Tubes	Control Manufacturer	Control Model No.	Control Serial No.	Manufacture Date	Install Date	Master Control Location

5. RADIATION SAFETY OFFICER (RSO) (see 180 NAC 2-004.02 or 21-007.01B)

Radiation Safety Officer (Print or Type)	Signature	Date

6. ATTESTATION AND CERTIFICATION

For the purpose of complying with Neb. Rev Stat. §§. 4-108 through 4-114, I attest as follows:

Check only ONE box below:

- I am a citizen of the United States
- I am a qualified alien under the Federal Immigration and Nationality Act.
Immigration status and alien number: _____
USCIS documentation enclosed.
- Application is for a separate legal entity (Ex: corporation, partnership, etc.) **Explain:** _____

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

The applicant and any official executing this document on behalf of the applicant named in Item 1.a. certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Title 180 Regulations for Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of their knowledge.

Certifying Official (Print or Type)	Applicant/Facility Name (see item 1.a)
Signature	Date

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

DENTAL INTERIM INSPECTION FORM

Registration No.: _____

Date: _____

Name: _____

Address: _____

City – State – Zip _____

Phone Number _____

Fax Number _____

E-Mail _____

- Complete this form and return it to this Department by the date specified in the enclosed letter.
- Include all corrective actions taken for any violation.
- Submit copies of the Equipment Performance Evaluation results for each radiation machine.
- Include a current inventory list of all radiation machines.

1.	Yes	No	Do you have a copy of a current Certificate of Registration?
2.	Yes	No	Are all operable dental radiation generating machines properly registered?
3.	Yes	No	Do you have a record of receipt for all radiation machines?*
4.	Yes	No	Have you transferred any radiation machines to another location or disposed of any units? (Must notify the Department within 30 days of any radiation inventory change)
5.	Yes	No	Is a copy of the current regulations 180 NAC 21 available in your facility? (Regulations available at http://www.dhhs.ne.gov/rad)
6.	Yes	No	Is a "Notice to Employees" (NRH-3) posted? (It is available at http://www.dhhs.ne.gov/rad)
7.	Yes	No	Have *Equipment Performance Evaluations been performed on all radiation machines at the required five year interval?
8.	Yes	No	Do you have written Operating and Safety Procedures available for all operators of the dental radiation generating machines?
9.	Yes	No	Do operators maintain a six foot distance while continuously viewing the patient during exposures?
10.	Yes	No	(If all radiographs are obtained digitally, STOP HERE) Are all films developed using the time/temperature method recommended by the film manufacturer?
11.	Yes	No	Is the specified developer time/temperature for auto/manual processing posted in the film processing area?
12.	Yes	No	Have all film processing chemicals been replaced according to the chemical manufacturer/supplier recommendations or at an interval which does not exceed three months?
13.	Yes	No	Is a log maintained that includes the date the processing chemicals were replaced and initials of individual performing the change?
14.	Yes	No	If a daylight processor is used, STOP:HERE Is the lighting in the film processing/loading area maintained using the manufacturer's recommendation for the filter, bulb wattage and working distance?
15.	Yes	No	Have darkroom light leak tests been performed at an interval not exceeding six months?

*Equipment Performance Evaluations (machine calibrations) are performed by your service company.

**If records of receipt are not available (Question 3), document the following information:

- Name of manufacturer
- Model number from control panel
- Serial number from control panel
- Approximate date of manufacture
- Name of company from which equipment was purchased

Comments:

Form Completed by: _____ Date _____

Signature of Radiation Safety Officer _____ Date _____

- Please retain a copy of the completed inspection form for your records

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

DENTAL EQUIPMENT PERFORMANCE EVALUATION

Evaluation Date: _____

Registrant: _____

Registration Number: _____

Service Company: _____

Registration Number: **RS** _____

Survey Instrument: _____

Calibration Date: _____

Ion Chamber: Within A Housing

External Probe

Control Panel Information

Manufacturer: _____

Model Number: _____

Serial Number: _____

Location: _____

TIMER

PASS **FAIL**

The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy must be ±10% of the indicated time with the testing performed at 0.5 second.

Manufacturer's Specifications: _____ OR ±10%

Time Used for Testing: _____ seconds milliseconds pulses

Measured				
Deviation	%	%	%	%

EXPOSURE REPRODUCIBILITY

PASS **FAIL**

When all technique factors are held constant, the coefficient of variation of exposures for both manual and automatic exposure control systems must not exceed 0.05. This requirement applies to clinically used techniques.

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

s = estimated standard deviation of the population
 X = mean value of observations in sample
 Xi = ith observation in sample
 n = number of observations in sample.

Technical Factors Selected: _____ kVp _____ mA / mAs _____ seconds / milliseconds / pulses

Measured	mR	mR	mR	mR
----------	----	----	----	----

Coefficient of Variation: _____

Manufacturer: _____

Serial Number: _____

Kilovolt Peak

PASS **FAIL**

If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within $\pm 10\%$ of the indicated setting(s). For dental radiation generating equipment with fewer than three fixed kilovolt peak settings, the radiation machine will be checked at those settings.

Manufacturer's Specifications: _____ OR $\pm 10\%$

Kilovolt Peak Used for Testing: _____

Measured:				
Deviation:	%	%	%	%

Tube Stability

PASS **FAIL**

The tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant must assure proper and free movement of the unit.

Collimation

PASS **FAIL**

Field limitation must meet the requirements of 180 NAC 21-007.07 or 21-007.08

Intraoral:

Source-to-Skin Distance (SSD): _____ cm Greater than 18 cm: Yes No

AND

Beam limited to a diameter of 7 cm at minimum SSD: Yes No

Panoramic:

Transverse axis: x-ray beam restricted to 0.0 inches of the imaging slit: Yes No

AND

Vertical axis: x-ray beam restricted to no more than 0.5 inches larger than the imaging slit: Yes No

Cephalometric:

Rectangular collimation: x-ray field does not exceed 2.0% of the source-to-image receptor distance for the length or the width of the image receptor Yes No

OR

Circular or polygon collimation: x-ray field does not exceed 2.0% of the source-to-image distance for the diagonal of the image receptor Yes No

IN-AIR EXPOSURE MEASUREMENT

For dental intraoral systems, use techniques factors used for the average adult patient thickness in routine bitewing radiography.

Technique Factors: _____ kVp _____ mA / mAs _____ seconds / milliseconds / pulses

For Calculated Measurement only

Source to Skin Distance (SSD): _____ cm Source to Detector Distance (SDD): _____ cm

Measured: _____ mR Calculated Measurement Direct Measurement

Surveyor Name: _____ Surveyor Signature: _____

DETERMINING IN-AIR EXPOSURE MEASUREMENT FOR INTRAORAL DENTAL EXAMINATIONS

A. CALCULATION

Note: Ion chambers may be located within the instrument housing rather than within an external probe. In this situation, the distance from the top surface of the housing to the ion chamber below must be known. If this type of instrument is used for the measurements, the inverse square law must be utilized for accurate results.

$$\text{IAE} = \text{Measured} \times (\text{SDD} \div \text{SSD})^2$$

Where: IAE = in-air exposure
Measured = indicated exposure on measuring instrument
SDD = source (target) to detector (ion chamber) distance in centimeters
SSD = source (target) to skin distance in centimeters

1. Place the tip of the cone within ½ inch from the housing of the measuring instrument.
2. Measure the distance from the source to the entrance/tube side surface of the housing. This is the SSD.
3. Determine the distance from the source to the ion chamber within the housing. This is the SDD.
4. Select the kVp, mA(s), and time normally used for an average adult patient thickness in routine bitewing radiography at that facility.
5. Make an exposure and document the radiation output in millirem.
6. Using the above formula, calculate the in-air exposure.

B. DIRECT MEASUREMENT

Note: Use this procedure only if an external probe (ion chamber) is available for the measurements.

1. Position the tube so the end of the cone is not greater than ½ inch from the probe. Do not put the probe inside the cone or allow the cone to have direct contact with the probe.
2. Select the kVp, mA(s), and time normally used for an average adult patient thickness in routine bitewing radiography at that facility.
3. Make an exposure and document the radiation output in millirem. This direct measurement is the in-air exposure.

EXPOSURE REPRODUCIBILITY

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

Where:

s = Estimated standard deviation of the population

\bar{x} = Mean value of observations in sample

X_i = i^{th} observation in sample

n = Number of observations in sample

Example:

The four (n) exposures (X_i) measured 409 mR, 387 mR, 391 mR, and 410 mR

STEP 1 Determine the mean value (\bar{x}) of the four exposures taken

$$(409 \text{ mR} + 387 \text{ mR} + 391 \text{ mR} + 410 \text{ mR}) \div 4 = 399.25 \text{ mR}$$

STEP 2 Find the difference between each exposure and the mean value (\bar{x}) (disregard sign)

409.00 mR	387.00 mR	391.00 mR	410.00 mR
-399.25 mR	-399.25 mR	-399.25 mR	-399.25 mR
9.75 mR	12.25 mR	8.25 mR	10.75 mR

STEP 3 Square each of the differences

$$(9.75)^2 = 95.06 \quad (12.25)^2 = 150.06$$

$$(10.75)^2 = 115.56 \quad (8.25)^2 = 68.06$$

STEP 4 Divide each number by 3 ($n-1$) and add the results

$$95.06 \div 3 = 31.69$$

$$150.06 \div 3 = 50.02$$

$$68.06 \div 3 = 22.69$$

$$115.56 \div 3 = 38.52$$

$$142.92$$

STEP 5 For s, determine the square root of the above number

$$\sqrt{142.92} = 11.95$$

STEP 6 Divide s by the mean value (\bar{x})

$$11.95 \div 399.25 = .0299 = \text{the coefficient of variation (C)}$$

STEP 7 If $C \leq 0.05$, the exposures are considered to be reproducible