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

ATTTACHMENTS

Attachment Number 21-1 21 CFR 56
Attachment Number 21-2 21 CFR 1020.30 and 1020.31
Attachment Number 21-3 45 CFR 46

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, 2004; 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.

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.

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:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
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/cm^2).

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 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.

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_t) 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).

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.

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, termoluminescence 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.

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/cm^2).

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).

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.

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 2.58E-4 coulombs per kilogram of air.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

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 (7mg/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. 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 ~~deep~~ 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.

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 μSv) 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

Dental Radiation Generating Equipment	Fee Per Unit
1. Dental Diagnostic	$70.00
2. Reciprocity (Registration of out-of-state radiation Generating equipment brought into Nebraska for Temporary use).	$70.00

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

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. The dental radiation generating equipment of the applicant must be operated by personnel per Nebraska Practice of Dentistry Neb. Rev. Stat. §§ 71-183.01 (9) and 71-193.17 and in such a manner as to minimize danger to public health and safety.
4. 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.
5. 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.
6. 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.
7. Each application for a certificate of registration will be accompanied by the fee prescribed in 180 NAC 21-005.

8. 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.
9. 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. A list of these registrants will be available for distribution by the Department.

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 or 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 21-009.02.

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. § 38-1130 and 38-1131 to practice as dental hygienists and dental assistants who meet the requirements of Neb. Rev. Stat. § 38-1135.
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. Making sure 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: 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.;
2. Radiation dose requirements in accordance with 180 NAC 21-007.04A
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
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
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

21-007.04 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.

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.

[2]The 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.

21-007.04B2 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.

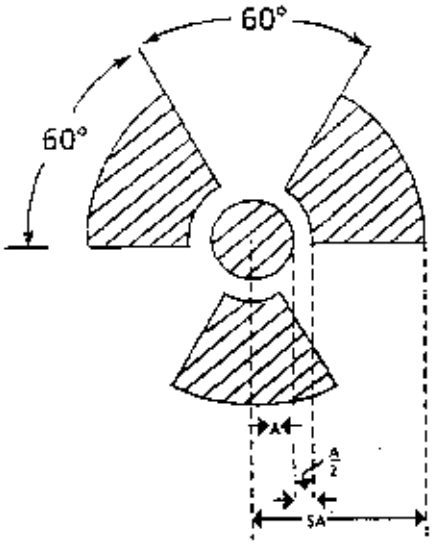
21-007.05 Facility Requirements

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 ~~The x-ray control must provide visual indication of the production of x-rays.~~

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 ±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 it's supports and 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 25.8 uC/kg(100 milliroetgens) in 1 hour when the x-ray tube is operated at its leakage technique factors. 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 2 milliroentgens (0.516 uC/kg) 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 ±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 an 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 ± 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.

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.

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
	60	1.5
	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

2. 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 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 SSD, to not less than:

1. 18 centimeters if operable above 50 kVp, or
2. 10 centimeters if not operable above 50 kVp.

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

21-007.12C Darkroom light leak tests must be performed and any light leaks corrected at intervals not to exceed six months.

21-007.12D 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.

21-007.12E Corrections or repairs of the light leaks or other deficiencies in 180 NAC 21-007.12B, C and D will be maintained at the site where performed and will include the date and initials of the individual completing these items. These records will be maintained in accordance with 180 NAC 21-009.21.

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.

21-008 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:

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 Social Security account 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 Social Security account 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 inspection registrants more frequently due to:

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 on the forms.

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	Unit 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 or 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 that 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 or 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 or 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. §71-2516 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
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.

Form NRH-3D
Effective Date

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 maters.

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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NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
RADIOLOGICAL HEALTH
X-RAY PROGRAM

For Department Use Only
Regist. No. _____
State _____ **Co.** _ _____
~~**Priority** _____ **Fee Det. No.** ____~~
Region

APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, P O Box 95026, Lincoln, NE 68509-5026.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip: _____

Telephone #: _____

FAX #: _____

E-Mail Address:

1.b Street address(es) at which Radiation Generating Equipment will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip: _____

(2) Temporary Job Sites Throughout Nebraska? ❒ Yes ❒ No

2. Billing Information

Address(if different than 1.a):

_____

_____

Person to Contact: _____

Telephone #: _____

3. Radiation Safety Officer (RS0) (See 180 NAC 2-004.02 or 21-007.01B)

_____

Title: _____

Telephone #: _____

4. Type of Practice (see Instruction Sheet) _____

5. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY)

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control. Serial No.	Date Installed	Date Manufactured	Control Room #

6. I do hereby accept the responsibility of radiation safety officer.

Type or Print Name of Radiation Safety Officer from item 3. | Signature of Radiation Safety Officer | Date

7. CITIZENSHIP ATTESTATION

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

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

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows: _____ and I am providing a copy of my USCIS documentation.

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.

Name (type or print first, middle, last) | Signature | Date

8. CERTIFICATION
(This Item must be completed by applicant.)

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 our knowledge.

_____
Applicant Name from Item 1.a.

By: _____ *Date:* _____
Signature of certifying official authorized to act on behalf of applicant

_____
Print Name and Title of certifying official

Your Application will not be processed without items 6., 7., and 8. being completed.

FORM NRH-4a (Additional Machines) **Registration No.** _____

Effective Date

5a. LIST ADDITIONAL MACHINES ON THIS SHEET

List each machine on a separate line.

Type	# Tubes	Control Manufacturer	Control. Model No.	Control Serial No.	Date Installed	Date Manufactured	Control Room #

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Form NRH -21
Effective Date

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 all corrective actions taken for any violation.
●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**) 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**: 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?
16.	Yes	No	Is a log maintained that includes date and initials of individual performing darkroom light leak tests or dates of any corrective repairs?

*Equipment Performance Evaluations (machine calibrations) are performed by your service company.
**If records of receipt are not available (Question ~~1~~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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Form NRH -21A

Effective Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH

X-RAY PROGRAM

EQUIPMENT LIST

Registration Number _____ Name of Registrant _____ Date_____

Machine Number on NRH 4	Machine Type	Manufacturer	Date Installed	Model No. from Control Panel	Serial No. from Control Panel	Location	Date of Manufacture	Calibration Dates

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FORM NRH 21B
Effective Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC HEALTH

X-RAY PROGRAM

EQUIPMENT PERFORMANCE EVALUATION
DENTAL UNIT

Registration Number _____ Date_____
Name of Registrant _____

Registration Number of Service Company _____
Service Company _____

Survey instrument used _____ Calibration date _____

Type of measuring device: External Probe (ion chamber) _____
Ion Chamber within a housing _____
X-ray unit identification (control panel):_____
Manufacturer Model No._____
Serial No. _____ Location _____

TIMER ACCURACY

The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer specifications are not obtainable, the timer accuracy must be within10% of the indicated time with the testing performed at 0.5 second.

Timer accuracy determined by (select which one used):

Manufacturer's timer deviation tolerance _____ **OR**
10% tolerance with testing performed at 0.5 second (.500 milliseconds)

Time used for testing _____ ____mS _____Pulses
Perform four measurements at the above time setting:
_____milliseconds/pulses
_____milliseconds/pulses
_____milliseconds/pulses
_____milliseconds/pulses

EXPOSURE REPRODUCIBILITY

When all technique factors are held constant, the coefficient of exposures for both manual and AEC systems must not exceed 0.05.

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

Technical Factors Selected: _____ma _____kVp _____time
Output Measurements:
_____mR
_____mR
_____mR
_____mR

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.

KVP TEST

The indicated kVp must be accurate to within 10% of the indicated setting at no less than three points over the usual operating range of the machine. For units with fewer than three fixed kVp settings, the units shall be checked at those settings.

Indicated kVp _____Measured kVp _____Deviation _____%
Indicated kVp _____Measured kVp _____Deviation _____%
Indicated kVp _____Measured kVp _____Deviation _____%
Indicated kVp _____Measured kVp _____Deviation _____%

((Measured kVp - Indicated kVp) ÷ Indicated kVp) H 100 = % Deviation

Measured kVp within " 10% of the indicated setting: Yes ( ) No ( )

TUBE STABILITY

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.

Tube stable in all orientations: Yes ( ) No ( ) Free movement where designed: Yes ( ) No ( )

COLLIMATION

Field limitation must meet the requirements of 180 NAC 21

Intraoral:
Minimum source to skin distance (SSD) _____cm.
Field size at tip of cone cm.
Field size to 7 cm.: If the minimum SSD is 18 cm or more Yes ( ) No ( ) N/A ( )
Field size to 6 cm.: If the minimum SSD is less than 18 cm Yes ( ) No ( ) N/A ( )

Panoramic:
X-ray field misalignment at image receptor slit: _____in. X _____in.
(transverse) (vertical)

Misalignment cannot exceed 0.0 inches in the transverse axis: In compliance Yes ( ) No ( )
Misalignment cannot exceed 0.5 inches in the vertical axis: In compliance Yes ( ) No ( )

Cephalometric:
Source to image distance (SID) _____in./cm.
Indicated field size in./cm. X _____in./cm.
Measured field size in./cm. X _____ in./cm.
Misalignment _____ in./cm. X _____ in./cm.
Does misalignment exceed 2% of the SID: Yes ( ) No ( )

ENTRANCE EXPOSURE (EE) (See Form NRH 21B for instructions)

EE levels-
Technique Factors selected: kVp _____mA(s) _____time _____(for intraoral bite wing only)
Source to Skin Distance (SSD):_____ in/cm Source to Detector Distance (SDD):_____ in/cm
Is tip of cone positioned ½ inch or less from surface of instrument housing or probe? Yes __No__
EE _____mR Calculated Measurement _____ Direct Measurement _____

Signature of surveyor:_____ Date:_____

DETERMINING THE ENTRANCE EXPOSURE (EE) FOR INTRAORAL DENTAL EXAMINATIONS

A. DETERMINING ENTRANCE EXPOSURE BY 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 EE measurements, the inverse square law must be utilized for accurate results.

EE=mR(measured) X (SDD ÷ SSD) ^{2}

Where: EE = entrance exposure
mR (measured) = indicated exposure on measuring instrument
SDD = source (target) to detector (ion chamber) distance
SSD = source (target) to skin distance

(a) Place the tip of the cone within ½ inch from the housing of the measuring instrument.
(b) Measure the distance form the source to the entrance/tube side surface of the housing.
(c) Determine the distance from the source to the ion chamber within the housing.
(d) Convert all measurements to the same unit. (i.e., Do not use the SDD in inches and the SSD in centimeters.)
(e) Select the kVp, mA, and time normally used for an intraoral bite wing x-ray at that facility. Document the selected technique factors.
(f) Make an exposure and document the measurement in millirem.
(g) Using the above formula, calculate the EE.

B. DETERMINING ENTRANCE EXPOSURE BY DIRECT MEASUREMENT:

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

(a) Position the tube so the end of the cone is not greater the ½ inch from the probe. Do not put the probe inside the cone or allow the cone to have direct contact with the probe.
(b) Select the kVp, mA, and time normally used for an intraoral bite wing x-ray at the facility. Document the selected technique factors.
(c) Measure the distance from the target (source) to the end of the cone. Document this distance.
(d) Make and exposure and document the radiation output in millirem. This direct measurement is the entrance exposure.

EXPOSURE REPRODUCIBILITY CALCULATIONS

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

EQUATION

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.

In this example, the exposures are considered to be reproducible.
Example:

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

STEP 1 Determine the mean value (X) of the four exposures taken.

(409 MR + 387 mR + 391 mR +410 mR) ÷ 4 – 399.25 mR

STEP 2 Find the difference between each exposure and the mean value (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

$9.75^2 = 95.06$ $12.25^2 = 150.06$
$10.75^2 = 115.56$ $8.23^2 = 68.06$

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

95.06 • • 3 = 31.88
150.06 • • 3 = 50.02

68.06 • • 3 = 22.69
115.56 • • 3 = 38.85
143.11

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

$\sqrt{143.11} = 11.96$

STEP 6 Divide s by the mean value (0)

11.9629 • • 399.25 = .0299 = c = the coefficient of variation

STEP 7 If c=0.05 or less, the exposures are considered to be reproducible

ATTACHMENT 21-1

21 CFR 56

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pertaining to the financial interests of clinical investigators who conducted studies on which the application relies and who are not full or part-time employees of the applicant, as follows:

(i) Complete records showing any financial interest or arrangement as described in §54.4(a)(3)(i) paid to such clinical investigators by the sponsor of the covered study.

(2) Complete records showing significant payments of other sorts, as described in §54.4(a)(3)(ii), made by the sponsor of the covered clinical study to the clinical investigator.

(3) Complete records showing any financial interests held by clinical investigators as set forth in §54.4(a)(3)(iii) and (a)(3)(iv).

(b) *Requirements for maintenance of clinical investigators' financial records.* (1) For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for 2 years after the date of approval of the application.

(2) The person maintaining these records shall, upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to and copy and verify these records.

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

Sec.
56.101 Scope.
56.102 Definitions.
56.103 Circumstances in which IRB review is required.
56.104 Exemptions from IRB requirement.
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56.124 Actions alternative or additional to disqualification.

AUTHORITY: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

SOURCE: 46 FR 8975, Jan. 27, 1981, unless otherwise noted.

Subpart A—General Provisions

§56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[46 FR 8975, Jan. 27, 1981, as amended at 64 FR 399, Jan. 5, 1999; 66 FR 20599, Apr. 24, 2001]

§56.102 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended

(secs. 201–902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–392)).

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §170.35.

(3) A food additive petition, described in part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in §180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in part 312 of this chapter.

(7) A new drug application, described in part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(10) An application for a biologics license, described in part 601 of this chapter.

(11) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in part 601 of this chapter.

(12) An Application for an Investigational Device Exemption, described in part 812.

(13) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in part 860.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in part 861.

(15) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(16) A product development protocol for a medical device for human use, described in section 515 of the act.

(17) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(18) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in §1010.4.

(19) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in §1010.5.

(20) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003.

(21) Data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the Federal Food, Drug, and Cosmetic Act.

(22) Data and information submitted in a petition for a nutrient content claim, described in §101.69 of this chapter, and for a health claim, described in §101.70 of this chapter.

(23) Data and information from investigations involving children submitted in a new dietary ingredient notification, described in §190.6 of this chapter.

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part.

(d) *Emergency use* means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) *Institution* means any public or private entity or agency (including Federal, State, and other agencies). The term *facility* as used in section 520(g) of the act is deemed to be synonymous with the term *institution* for purposes of this part.

(g) *Institutional Review Board (IRB)* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase *institutional review committee* as used in section 520(g) of the act.

(h) *Investigator* means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Sponsor* means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354–360F of the Public Health Service Act.

(m) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the

IRB and by other institutional and Federal requirements.

[46 FR 8975, Jan. 27, 1981, as amended at 54 FR 9038, Mar. 3, 1989; 56 FR 28028, June 18, 1991; 64 FR 399, Jan. 5, 1999; 64 FR 56448, Oct. 20, 1999; 65 FR 52302, Aug. 29, 2000; 66 FR 20599, Apr. 24, 2001; 74 FR 2368, Jan. 15, 2009]

§56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

[46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

§56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991]

§56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

Subpart B—Organization and Personnel

§56.106 Registration.

(a) *Who must register?* Each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site maintained by the Department of Health and Human Services (HHS). (A research permit under section 505(i) of

the act is usually known as an investigational new drug application (IND), while a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE).) An individual authorized to act on the IRB's behalf must submit the registration information. All other IRBs may register voluntarily.

(b) *What information must an IRB register?* Each IRB must provide the following information:

(1) The name, mailing address, and street address (if different from the mailing address) of the institution operating the IRB and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer of that institution who is responsible for overseeing activities performed by the IRB;

(2) The IRB's name, mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address; each IRB chairperson's name, phone number, and electronic mail address; and the name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(3) The approximate number of active protocols involving FDA-regulated products reviewed. For purposes of this rule, an "active protocol" is any protocol for which an IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months; and

(4) A description of the types of FDA-regulated products (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols that the IRB reviews.

(c) *When must an IRB register?* Each IRB must submit an initial registration. The initial registration must occur before the IRB begins to review a clinical investigation described in paragraph (a) of this section. Each IRB must renew its registration every 3 years. IRB registration becomes effective after review and acceptance by HHS.

(d) *Where can an IRB register?* Each IRB may register electronically through *http://ohrp.cit.nih.gov/efile.* If an IRB lacks the ability to register electronically, it must send its registration information, in writing, to the Good Clinical Practice Program (HF–34), Office of Science and Health Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(e) *How does an IRB revise its registration information?* If an IRB's contact or chair person information changes, the IRB must revise its registration information by submitting any changes in that information within 90 days of the change. An IRB's decision to review new types of FDA-regulated products (such as a decision to review studies pertaining to food additives whereas the IRB previously reviewed studies pertaining to drug products), or to discontinue reviewing clinical investigations regulated by FDA is a change that must be reported within 30 days of the change. An IRB's decision to disband is a change that must be reported within 30 days of permanent cessation of the IRB's review of research. All other information changes may be reported when the IRB renews its registration. The revised information must be sent to FDA either electronically or in writing in accordance with paragraph (d) of this section.

[74 FR 2368, Jan. 15, 2009]

§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards or professional conduct and

practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the instituton's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[46 FR 8975, Jan 27, 1981, as amended at 56 FR 28028, June 18, 1991; 56 FR 29756, June 28, 1991]

Subpart C—IRB Functions and Operations

§56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (4) for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used (see §56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28028, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

§56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 50.27 of this chapter, except as follows:

(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or

(2) The IRB may, for some or all subjects, find that the requirements in § 50.24 of this chapter for an exception from informed consent for emergency research are met.

(d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under § 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under § 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.

(f) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(g) An IRB shall provide in writing to the sponsor of research involving an exception to informed consent under § 50.24 of this chapter a copy of information that has been publicly disclosed under § 50.24(a)(7)(ii) and (a)(7)(iii) of this chapter. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred. Upon receipt, the sponsor shall provide copies of the information disclosed to FDA.

(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with part 50, subpart D of this chapter, at the time of its initial review of the research. When some or all of the subjects in a study that is ongoing on April 30, 2001 are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date.

[46 FR 8975, Jan. 27, 1981, as amended at 61 FR 51529, Oct. 2, 1996; 66 FR 20599, Apr. 24, 2001]

§ 56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may use the expedited review procedure to review either or both of the following: (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, (2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the IRB chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all

of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited review procedure set forth in §56.108(c).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991]

§56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by §50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 66 FR 20599, Apr. 24, 2001]

§56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any

suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

Subpart D—Records and Reports

§ 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by § 56.108 (a) and (b).

(7) Statements of significant new findings provided to subjects, as required by § 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

[46 FR 8975, Jan. 27, 1981, as amended at 56 FR 28029, June 18, 1991; 67 FR 9585, Mar. 4, 2002]

Subpart E—Administrative Actions for Noncompliance

§ 56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under §56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in §56.123.

§56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under part 20.

§56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under §56.121(c).

§56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to

or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

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AUTHORITY: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999]

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ATTACHMENT 21-2

Title 21, CFR §1020.30 & 1020.31

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the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x radiation, with the beam blocking device in the open position, shall not exceed (Pi) steradians.

(2) *Measurements.* (i) Compliance with the exposure rate limit defined in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(*a*) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(*b*) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.* (i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(*a*) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (*b*) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability.* (1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977, or after June 10, 2006.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006.

(G) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32, which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and § 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) "Technique factors";

(iii) Section 1020.30(b) "CT," "Dose," "Scan," "Scan time," and "Tomogram";

(iv) Section 1020.30(h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33(a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions.* As used in this section and §§ 1020.31, 1020.32, and 1020.33, the following definitions apply:

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

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air (see definition of *Kerma*).

Air kerma rate (AKR) means the air kerma per unit time.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

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.

Automatic exposure rate control (AERC) 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 per unit time.

Beam axis means a line from the source through the centers of the x-ray fields.

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

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and the x-ray tube

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from The Aluminum Association, New York, NY.

housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

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

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

where:

s = Estimated standard deviation of the population.

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

X_i = ith observation sampled.

n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

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

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

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

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

Exposure (X) 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 and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

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

Fluoroscopic air kerma display device means a device, subsystem, or component that provides the display of AKR and cumulative air kerma required by §1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. 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.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, 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" shall mean the preselected portion of the device.

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity as 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."

Last-image-hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

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.

Leakage technique factors means the technique factors associated with the

diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100(V_n - V_l)/V_l$$

where:

V_n = No-load line potential and
V_l = Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

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

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or §1020.31 or 1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube

housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§ 1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

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

Source-skin distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) 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.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

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 they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

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

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

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

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *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 locus of points at which the AKR 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 subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally 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 are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Communication, Education, and Radiation Programs of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by § 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters (mm) of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts. If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-

pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information.* For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) *Displays of values of AKR and cumulative air kerma.* For fluoroscopic x-ray systems manufactured on or after

June 10, 2006, the following shall be provided:

(i) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by § 1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(ii) Identification of the distances along the beam axis:

(A) From the focal spot to the isocenter, and

(B) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to § 1020.32(k)(4);

(iii) A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to § 1020.32(k)(4)(ii).

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall 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, operating instructions and maintenance schedules are observed."

(k) *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 shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at the 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 shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microGy (vice 2 mR exposure) in 1 hour at 5 cm 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 shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Beam quality*—(1) *Half-value layer (HVL).* The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table 1 in paragraph (m)(1) of this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I—Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II—Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 in paragraph (m)(1) of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

[2] 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 1

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems [1]	I—Other X-Ray Systems [2]	II—Other X-Ray Systems [3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.
[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(2) *Optional filtration.* Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of §1020.30(m)(1). The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

(3) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table 2 in paragraph (n) of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in table 1 in paragraph (m)(1) of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Front panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems.* (1) Diagnostic x-ray components and systems certified in accordance with §1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with §1010.4 of this chapter or an exemption under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §1020.31, 1020.32, or 1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with §1020.31, 1020.32, or 1020.33.

[71 FR 34028, June 10, 2006, as amended at 72 FR 17401, Apr. 9, 2007]

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the

fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field

emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA).* The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs).* For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10\ (X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters (cm) shall be equal to or less than 5 cm.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm; and

(ii) If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 cm.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography*—(i) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this

section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(iii) Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size.* When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL.* When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 cm;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance.* Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing.* The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the

image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure
The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices.* The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen cm if operable above 50 kVp; or

(ii) Ten cm if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided

with means to limit the source-skin distance to not less than 30 cm.

(j) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube shall not exceed:

(1) An air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimension greater than 20 cm; and

(2) An air kerma of 0.88 mGy (vice 100 mR exposure) in 1 hour at 100 cm from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Primary protective barrier for mammography x-ray systems*—(1) For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(2) For mammographic x-ray systems manufactured on or after September 30, 1999:

(i) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(ii) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(2)(i) of this section.

(iii) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(3) Compliance with the requirements of paragraphs (m)(1) and (m)(2)(iii) of this section for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

[70 FR 34036, June 10, 2005]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is

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learned that the United States or an employee, agent or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

PART 36—INDEMNIFICATION OF HHS EMPLOYEES

§ 36.1 Policy.

(a) The Department of Health and Human Services may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with the Department and that such indemnification is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(b) The Department of Health and Human Services may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Secretary or his or her designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of the Department of Health and Human Services becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify the Department that such an action is pending.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

(Authority: 5 U.S.C. 301)

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a).

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost—sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject

to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether

the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be

submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

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[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§ 46.104–46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § 46.103(b)(4) and, to the extent required by, § 46.103(b)(5).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be

expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the

basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described is §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo

or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the

representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragarph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

SOURCE: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of § 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in § 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point

of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.205 Research involving neonates.

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate

may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.204 or 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

SOURCE: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research

SOURCE: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§46.402 Definitions.

The definitions in §46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) That the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent

may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E—Registration of Institutional Review Boards

SOURCE: 74 FR 2405, Jan. 15, 2009, unless otherwise noted.

§46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and

the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

Each IRB must be registered electronically through *http://ohrp.cit.nih.gov/efile* unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

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AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 et seq.); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the Department of State to recommend to the Attorney General waiver of the two-year foreign residence requirement for Exchange Visitors under the Mutual