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Chapter 1**

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006 X-RAYS IN THE HEALING ARTS

006.01 Purpose and Scope.

006.01A This subsection establishes requirements, for which a registrant is responsible, 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 healing arts or veterinary medicine.

006.01B The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment shall be by or under the supervision of one licensed to practice the healing arts in Nebraska.

006.01C The use of x-ray equipment in the practice of veterinary medicine shall be by or under the supervision of an individual authorized to practice veterinary medicine in the State of Nebraska.

006.01D The provisions of this subsection are in addition to, and not in substitution for, other applicable provisions of Sections 001, 002, 004, 009, 010, 015, 016, 017 and 018 of these regulations.

006.02 Definitions. As used in this subsection, the following definitions apply:

006.02A "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

006.02B "Added filtration" means any filtration which is in addition to the inherent filtration.

006.02C "Aluminum equivalent" means the thickness of type 1100 aluminum alloy¹ affording the same attenuation, under specified conditions, as the material in question.

006.02D "Assembler" means any person assembling, replacing, or installing one or more components into an x-ray system or subsystem. It includes adjustment of components which affect output of radiation generating equipment. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

006.02E "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy² or other materials having equivalent attenuation.

006.02F "Automatic exposure control" 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 (See also "Phototimer").

006.02G "Barrier" (See "Protective barrier").

006.02H "Beam axis" means a line from the source through the centers of the x-ray fields.

¹The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.

²ibid.

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006.02I "Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.

006.02J "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

006.02K "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

006.02L "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 8 and incorporated herein by this reference.

006.02M "Certified system" means any x-ray system which has one or more certified component(s).

006.02N "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

006.02O "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where

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

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

x_i = i^{th} observation in sample.

n = Number of observations in sample.

006.02P "Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

006.02Q "Contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

006.02R "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.

006.02S "Cooling curve" means the graphical relationship between heat units stored and cooling time.

006.02T "CT" (See "Computed tomography").

006.02U "Deadman switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

006.02V "Detector" (See "Radiation detector").

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006.02W "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

006.02X "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.

006.02Y "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

006.02Z "Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

006.02AA "Equipment" (See "X-ray equipment").

006.02BB "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.

006.02CC "Filter" means material placed in the useful beam to absorb preferentially selected radiations.

006.02DD "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

006.02EE "Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

006.02FF "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.

006.02GG "Gonad shield" means a protective barrier for the testes or ovaries.

006.02HH "Half-value layer" 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 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.

006.02II "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

006.02JJ "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

006.02KK "HVL" (See "Half-value layer").

006.02LL "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.

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006.02MM "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.

006.02NN "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

006.02OO "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

006.02PP "Irradiation" means the exposure of matter to ionizing radiation.

006.02QQ "Kilovolts peak" (See "Peak tube potential").

006.02RR "kV" means kilovolts.

006.02SS "kVp" (See "Peak tube potential").

006.02TT "kWs" means kilowatt second. It is equivalent to $E + 3$ kV mA s, i.e.,

$$(A)kWs = (X)kV \times (Y)mA \times (Z)s \times \frac{kWs}{E + 3 \text{ kV} \times mA \times s} = \frac{XYZ \text{ kWs}}{E + 3}$$

006.02UU "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

006.02VV "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

006.02WW "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

006.02WW1 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, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

006.02WW2 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.

006.02WW3 For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

006.02XX "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 illumination is one-fourth of the maximum in the intersection.

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006.02YY "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

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

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

006.02ZZ "Linear attenuation coefficient" or "u" means the quotient of dN/N divided by $d1$ when dN/N is the fraction of unchanged ionizing radiation that experience interactions in traversing a distance $d1$ in a specified material.

006.02AAA "uC/kg" means microcoulomb/kilogram.

006.02BBB "mA" means milliampere.

006.02CCC "mAs" means milliampere second.

006.02DDD "mC/kg" means millicoulomb/kilogram.

006.02EEE "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

006.02FFF "Mobile x-ray equipment" (See "X-ray equipment").

006.02GGG "nC/kg" means nanocoulomb/kilogram.

006.02HHH "Patient" means an individual subjected to healing arts examination, diagnosis, or treatment.

006.02III "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

006.02JJJ "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

006.02KKK "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

006.02LLL "PID" (See "Position indicating device").

006.02MMM "Portable x-ray equipment" (See "X-ray equipment").

006.02NNN "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

006.02OOO "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.

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006.02PPP "Primary protective barrier" (See "Protective barrier").

006.02QQQ "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

006.02RRR "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

006.02RRR1 "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

006.02RRR2 "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

006.02SSS "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

006.02TTT "Qualified expert" with reference to radiation protection, a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs (for example, persons certified in this field by the American Board of Radiology, or the American Board of Health Physics, or those having equivalent qualifications). With reference to the calibration of radiation therapy equipment, a person having in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications) or meets the minimum qualifications specified in Section 015.13C of these regulations.

006.02UUU "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

006.02VVV "Radiation therapy simulation system" means a fluoroscopic or radiographic 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.

006.02WWW "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.

006.02XXX "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

006.02YYY "Radiological physicist" means an individual who meets the requirements of Part 015.13A Radiological Medical Physicist or Part 015.13B Radiological Health Physicist of these regulations.

006.02ZZZ "Rating" means the operating limits as specified by the component manufacturer.

006.02AAA "Recording" means producing a permanent form of an image resulting from x-ray photons.

006.02BBB "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

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006.02CCCC "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

006.02DDDD "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

006.02EEEE "Secondary protective barrier" (See "Protective barrier").

006.02FFFF "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

006.02GGGG "SID" (See "Source-image receptor distance").

006.02HHHH "Source" means the focal spot of the x-ray tube.

006.02IIII "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

006.02JJJJ "Special Purpose X-Ray System" means any radiographic x-ray system which, by design, is limited to radiographic examination of a specific anatomical region.

006.02KKKK "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.

006.02LLLL "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

006.02MMMM "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 an image intensifier for the purpose of making a radiograph.

006.02NNNN "SSD" means the distance between the source and the skin of the patient.

006.02OOOO "Stationary x-ray equipment" (See "X-ray equipment").

006.02PPPP "Stray radiation" means the sum of leakage and scattered radiation.

006.02QQQQ "Technique factors" means the conditions of operation. They are specified as follows:

006.02QQQQ1 For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

006.02QQQQ2 For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

006.02QQQQ3 For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

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006.02QQQQ4 For CT x-ray systems 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

006.02QQQQ5 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.

006.02RRRR "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

006.02SSSS "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

006.02TTTT "Traceable to a national standard" means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

006.02UUUU "Tube" means an x-ray tube, unless otherwise specified.

006.02VVVV "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.

006.02WWWW "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

006.02XXXX "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.

006.02YYYY "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

006.02ZZZZ "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

006.02AAAAA "Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

006.02BBBBB "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.

006.02CCCCC "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

006.02CCCCC1 "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

006.02CCCCC2 "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

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006.02CCCCC3 "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

006.02DDDDD "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 exposure rate is one-fourth of the maximum in the intersection.

006.02EEEEEE "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.

006.02FFFFFF "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 shall be considered integral parts of the system.

006.02GGGGG "X-ray subsystem" means any combination of two or more components of an x-ray system.

006.02HHHHH "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

006.03 General Requirements

006.03A Administrative Controls.

006.03A1 Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of 006.03A1 are met in the operation of the x-ray system(s).

006.03A1a An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes, unless the Agency makes a finding that its continued use will not constitute a risk to the health and safety of the public.

006.03A1b Registrants shall assure that individuals who will operate x-ray systems under the direction of healing arts practitioners shall meet the requirements as specified in Section 016 of these regulations. The Limited X-Ray System Operator shall be instructed in the radiation safety and use of the x-ray equipment as specified in Subsection 016.05 of these regulations.

006.03A1c A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information.

006.03A1c(1) Patient's anatomical size versus technique factors to be utilized;

006.03A1c(2) Type and focal distance of the grid to be used, if any;

006.03A1c(3) Source to image receptor distance to be used;

006.03A1c(4) Type and location of placement of gonad shielding to be used; and

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006.03A1c(5) Type and size of the film or film-screen combination to be used.

006.03A1d Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

006.03A1d(1) Doors that are an integral part of room shielding shall be closed during x-ray procedures; and

006.03A1d(2) The door in 006.03A1d(1) shall be posted "Close door during x-ray procedures".

006.03A1e Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

006.03A1e(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

006.03A1e(2) Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

006.03A1e(3) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

006.03A1f Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

006.03A1g Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

006.03A1g(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and

006.03A1g(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 006.03A1k.

006.03A1h When a patient or film must be provided with auxiliary support during a radiation exposure:

006.03A1h(1) Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 006.03A1d, shall list projections where holding devices cannot be utilized;

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006.03A1h(2) The human holder shall be protected as required by paragraph 006.03A1e;

006.03A1h(3) No individual shall be used routinely to hold film or patients;

006.03A1h(4) Written safety procedures, as required by 006.03A1d, shall indicate the requirements for selecting a holder and the procedure the holder shall follow; and

006.03A1h(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

006.03A1i Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

006.03A1i(1) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

006.03A1i(2) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

006.03A1i(3) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

006.03A1i(4) X-ray systems subject to 006.06 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

006.03A1j All individuals who are associated with the operation of an x-ray system are subject to the requirements of 004.06, 004.49 and 004.23 of these regulations. In addition:

006.03A1j(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

006.03A1j(1)(a) When an apron is worn, the monitoring device shall be worn at the collar outside the apron.

006.03A1j(1)(b) The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 004.51 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

006.03A1j(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

006.03A1k Healing Arts Screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix 1 of this section. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

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006.03A2 Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

006.03A2a Model and serial numbers of all certifiable components;

006.03A2b Aluminum equivalent filtration of the useful beam, including any routine variation;

006.03A2c Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s) after June 27, 1983 with the names of persons who performed such services.

006.03A2d A scale drawing shall be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

006.03A2d(1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

006.03A2d(2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

006.03A2e A copy of all correspondence with this Agency regarding that x-ray system.

006.03B X-Ray Log. Each facility shall maintain an x-ray log or chart containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

006.03C Plan Review.

006.03C1 Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to a qualified expert or the Agency for review and comment. The required information is denoted in Appendices 2 and 3 of this section.

006.03C2 The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and comment. For particle accelerator facilities the qualified expert shall be a radiological physicist.

006.03C3 The review of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 004.06, 004.12, and 004.14 of these regulations.

006.04 General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this subsection, all diagnostic x-ray systems shall meet the following requirements:

006.04A 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 and operating instructions are observed."

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006.04B Battery Charge Indicator. On battery-powered x-ray 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.

006.04C 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 100 milliroentgens (25.8 uC/kg) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

006.04D Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall 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 shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

006.04E Beam Quality.

006.04E1 Half-value Layer.

006.04E1a The half-value layer of the useful beam for a given x-ray tube potential shall 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 (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
150	4.1	

006.04E1b The requirements of 006.04E1a will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

<u>Operating Voltage (kVp)</u>	<u>Total Filtration (inherent plus added) (millimeters aluminum equivalent)</u>
Below 50	0.5 millimeters
50 - 70	1.5 millimeters
Above 70	2.5 millimeters

006.04E1c In addition to the requirements of 006.04E1a, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

006.04E1d Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

006.04E1e For capacitor energy storage equipment, compliance with the requirements of 006.04E shall be determined with the maximum quantity of charge per exposure.

006.04E1f The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

006.04E2 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 006.04E1a is in the useful beam for the given kVp which has been selected.

006.04F 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 prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

006.04G Mechanical Support of Tube Head. The tube housing assembly supports shall 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.

006.04H Technique Indicators.

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006.06B4 Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed.

$$T \geq 5(T_{max} - T_{min})$$

006.06C Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeters.

006.06D Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min})$$

006.06E Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 uC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

006.06F Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

006.06F1 Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

006.06F2 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10 (\bar{X}_1 + \bar{X}_2)$$

where \bar{X}_1 and \bar{X}_2 are the average mR/mAs (uC/kg per mAs) values obtained at each of 2 consecutive tube current settings.

006.06F3 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

006.06F4 Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

006.06F4a There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

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006.06F4b When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

006.06F4c The edge of the light field at 100 centimeters 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 equipment. The contrast ratio is defined as $1_1/1_2$ where 1_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and 1_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

006.06F5 Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 006.06A1 and 006.06F4.

006.06F6 Field Limitation and Alignment on Stationary General Purpose X-Ray Systems. The requirements of this subpart shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c).

006.06F6a Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:

006.06F6a(1) The image receptor is inserted into a permanently mounted cassette holder;

006.06F6a(2) The image receptor length and width are each less than 50 centimeters;

006.06F6a(3) The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

006.06F6a(4) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;

006.06F6a(5) Neither tomographic nor stereographic radiography is being performed, and

006.06F6a(6) The PBL system has not been intentionally overridden. This override provision is subject to 006.06F6c.

006.06F6b Positive beam limitation (PBL) shall prevent the production of x-rays when:

006.06F6b(1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 006.06F6e, from the corresponding image receptor dimensions by more than 3 percent of the SID; or

006.06F6b(2) The sum of the length and width differences as stated in 006.06F6b(1) without regard to sign exceeds 4 percent of the SID.

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006.06B2a(2) During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

006.06B2b Each x-ray control shall be located in such a way as to meet the following requirements:

006.06B2b(1) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

006.06B2b(2) Mobile and portable x-ray systems which are:

006.06B2b(2)(a) Used in one location, i.e., a room or suite, shall meet the requirements of subdivision 006.06B2b(1).

006.06B2b(2)(b) Used in different locations shall provide operator protection at the controls by adequate shielding or operator positioning at a distance from the tube head of 12 feet (3.66m).

006.06B2b(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

006.06B3 Automatic Exposure Controls. When an automatic exposure control is provided:

006.06B3a Indication shall be made on the control panel when this mode of operation is selected;

006.06B3b If the x-ray tube potential is equal to or greater than 50 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 2 pulses;

006.06B3c The minimum exposure time for all equipment other than that specified in 006.06B3b shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

006.06B3d Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW 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 that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

006.06B3e A visible signal shall indicate when an exposure has been terminated at the limits required by 006.06B3d, and manual resetting shall be required before further automatically timed exposures can be made.

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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 which performs as prescribed in 006.06A5c. 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 006.06A5c(1) and (2) shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

006.06A5 Special Purpose X-Ray Systems.

006.06A5a Means shall be provided 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.

006.06A5b 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.

006.06A5c 006.06A5a and b may be met with a system that meets the requirements for a general purpose x-ray system as specified in 006.06A1 or, when alignment means are also provided, may be met with either:

006.06A5c(1) 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 with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

006.06A5c(2) 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.

006.06B Radiation Exposure Control Devices.

006.06B1 Timers. Means shall 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 shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

006.06B2 X-Ray Control.

006.06B2a An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

006.06B2a(1) Exposures of one-half (1/2) second or less, or

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006.04H1 The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

006.04H2 The requirement of 006.04H1 may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

006.04I Structural Shielding. Structural shielding shall be provided as necessary to meet the requirements of 004.06, 004.23 and 004.14.

006.05 Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

006.05A Limitation of Useful Beam.

006.05A1 Primary Barrier.

006.05A1a 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.

006.05A1b The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

006.05A2 X-Ray Field.

006.05A2a Use of nonimage-intensified fluoroscopic equipment shall not be used.

006.05A2b For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

006.05A2b(1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

006.05A2b(2) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less;

006.05A2b(3) For equipment manufactured after February 25, 1978, when the angle between 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

006.05A2b(4) Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with

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circular image receptor, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

006.05A2c Spot-film devices which are certified components shall meet the following additional requirements, except when the spot-film device is provided for use with a radiation therapy simulation system:

006.05A2c(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished when the x-ray field size in the plane of the film is greater than that of the selected portion of the film. If the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

006.05A2c(2) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

006.05A2c(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

006.05A2c(4) 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.

006.05B Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist 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.

006.05C Exposure Rate Limits.

006.05C1 Entrance Exposure Rate Allowable Limits.

006.05C1a The exposure rate measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens (2.58 mC/kg) per minute, except during recording of fluoroscopic images or when provided with optional high level control.

006.05C1b When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

006.05C1b(1) Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.

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006.05C1b(2) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

006.05C1c In addition to the other requirements of 006.05, certified systems which do not incorporate an automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.

006.05C1d Compliance with the requirements of 006.05C shall be determined as follows:

006.05C1d(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.

006.05C1d(2) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.

006.05C1d(3) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

006.05C1d(4) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

006.05C1e Periodic measurement of entrance exposure rate shall be performed as follows:

006.05C1e(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

006.05C1e(2) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 006.03A2c. The measurement results shall be stated in roentgens (C/kg) per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

006.05C1e(3) Personnel monitoring devices may be used to perform the measurements required by 006.05C1e(1), provided the measurements are made as described in 006.05C1e(4).

006.05C1e(4) Conditions of periodic measurement of entrance exposure rate are as follows:

006.05C1e(4)(a) The measurement shall be made under the conditions that satisfy the requirements of 006.05C1d;

006.05C1e(4)(b) The kVp shall be the kVp typical of clinical use of the x-ray system;

006.05C1e(4)(c) The x-ray system(s) that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and

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006.05C1e(4)(d) X-ray system(s) that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.³

006.05D Barrier Transmitted Radiation Rate Limits.

006.05D1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

006.05D2 Measuring Compliance of Barrier Transmission.

006.05D2a The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

006.05D2b If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

006.05D2c If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

006.05D2d Movable grids and compression devices shall be removed from the useful beam during the measurement.

006.05D2e The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly. Closer distances may be used if corrections are applied for poor geometry.

006.05E Indication of Potential and Current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

006.05F Source-to-Skin Distance. The SSD shall not be less than:

006.05F1 38 centimeters on stationary fluoroscopes installed after June 27, 1983,

006.05F2 35.5 centimeters on stationary fluoroscopes which were in operation prior to the effective date of these regulations.

006.05F3 30 centimeters on all mobile fluoroscopes, and

³Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system.

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006.05F4 20 centimeters for image intensified fluoroscopes used for specific surgical application. The written safety procedures must provide precautionary measures to be adhered to during the use of this device.

006.05G Fluoroscopic Timer.

006.05G1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

006.05G2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this subpart, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between examinations.

006.05G3 The total time of exposure shall be recorded.

006.05H Mobile Fluoroscopes. In addition to the other requirements of 006.05, mobile fluoroscopes shall provide intensified imaging.

006.05I Control of Scattered Radiation.

006.05I1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

006.05I2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

006.05I2a Is at least 120 centimeters from the center of the useful beam, or

006.05I2b The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, (drapes, Bucky-slot cover panel, or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in 006.03A1e.

006.05I3 The Agency may grant exceptions to 006.05I2 where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exception.

006.05J Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 006.05A, 006.05C, 006.05D, and 006.05G provided that:

006.05J1 Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

006.05J2 Systems which do not meet the requirements of 006.05G are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

006.06 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography X-Ray Systems.

006.06A Beam Limitation. The useful beam shall be limited to the area of clinical interest.

006.06A1 General Purpose Stationary and Mobile X-Ray Systems.

006.06A1a There shall be provided a means for stepless adjustment of the size of the x-ray field.

006.06A1b A method shall be provided for visually defining the perimeter of the x-ray field. 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.

006.06A1c The Agency may grant an exemption on non-certified x-ray systems to 006.06A1a and b provided the registrant makes a written application for such exemption and in that application:

006.06A1c(1) Demonstrates it is impractical to comply with 006.06A1a and b; and

006.06A1c(2) The purpose of 006.06A1a and b will be met by other methods.

006.06A2 Additional Requirements for Stationary General Purpose X-Ray Systems. In addition to the requirements of 006.06A1, all stationary general purpose x-ray systems shall meet the following requirements:

006.06A2a A method 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;

006.06A2b The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

006.06A2c Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, 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.

006.06A3 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.

006.06A4 Systems Designed for or Provided with Special Attachments for Mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with

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006.06F6c If a means of overriding the positive beam limitation (PBL) system exists, that means:

006.06F6c(1) Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and

006.06F6c(2) If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator;

006.06F6c(2)(a) Shall require that a key be utilized to defeat the PBL;

006.06F6c(2)(b) Shall require that the key remain in place during the entire time the PBL system is overridden; and

006.06F6c(2)(c) Shall require that the key or key switch be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

006.06F6d Compliance with 006.06F6b shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 006.06F6a are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

006.06F6e The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

006.06F6f The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 006.06F6b, then any change of image receptor size or SID must cause the automatic return.

006.06F7 Timers. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

006.06F7a Except during serial radiography, the operator shall be able to terminate the exposure at anytime during an exposure of greater than one-half second. 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.

006.06F7b 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.

006.06F8 Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 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 exposure 5 centimeters from any accessible

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surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen (25.8 nC/kg) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

006.07 Intraoral Dental Radiographic Systems. In addition to the provisions of 006.03 and 006.04, the requirements of 006.07 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 006.06.

006.07A Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

006.07A1 18 centimeters if operable above 50 kVp, or

006.07A2 10 centimeters if not operable above 50 kVp.

006.07B Field Limitation.

006.07B1 Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

006.07B1a If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

006.07B1b If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

006.07B2 An open ended position indicating device shall meet the requirements of 006.04C.

006.07C Timers. Means shall be provided to terminate the exposure at the 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:

006.07C1 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.

006.07C2 Reproducibility. With a timer setting of 0.5 seconds or, not less than 0.1 second, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed;

$$\bar{T} \geq 5 (T_{max} - T_{min})$$

006.07D X-Ray Control.

006.07D1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

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006.07D2 Each x-ray control shall be located in such a way as to meet the following requirements:

006.07D2a Stationary x-ray systems installed after June 27, 1983 shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in the protected area during the entire exposure; and

006.07D2b Stationary x-ray systems installed prior to June 27, 1983, the operator shall remain in a protected area which permits compliance with subsections 004.06, 004.23, and 004.14; and

006.07D2c Mobile and portable x-ray systems which are:

006.07D2c(1) Used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of 006.07D2a and 006.07D2b; or

006.07D2c(2) Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of 006.07D2c(1) or be provided with a 6.5 feet (1.98m) high protective barrier which is placed at least 6 feet (1.83m) from the tube housing assembly and at least 6 feet (1.83m) from the patient; or

006.07D2c(3) Used to make an exposure(s) of a patient at the use location shall meet the requirement of 006.07D2c(1) or (2) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66m) from the tube housing assembly during an exposure.

006.07D2c(4) For those x-ray systems used infrequently to make an exposure(s) of a patient at the use location, it shall be provided with a method of x-ray control which will permit the operator to be at least 6 feet (1.83m) from the tube housing assembly or the patient and be out of the primary beam during the exposure.

006.07D3 The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

006.07E Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, that the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5 (E_{max} - E_{min})$$

006.07F Administrative Controls.

006.07F1 Patient and film holding devices shall be used when the techniques permit.

006.07F2 The tube housing and the position indicating device shall not be hand-held during an exposure.

006.07F3 For intraoral radiography, the x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 006.07B1.

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006.07F4 Dental fluoroscopy without image intensification shall not be used.

006.07G Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

006.07G1 Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

006.07G2 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperereconds product, obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10 (\bar{X}_1 + \bar{X}_2)$$

where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

006.07G3 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

006.07G4 Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

006.07G5 Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of 006.04E1.

006.08 Therapeutic X-Ray Systems of Less Than One MeV.

006.08A Equipment Requirements.

006.08A1 Leakage Radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that x-ray system.

006.08A1a Contact Therapy Systems. Leakage radiation shall not exceed 100 milliroentgens (25.8 $\mu\text{C/kg}$) per hour at 5 centimeters from the surface of the tube housing assembly.

006.08A1b 0-150 kVp Systems. Systems which were manufactured prior to June 27, 1983 shall have a leakage radiation which does not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source.

006.08A1c 0-150 kVp Systems. Systems which are manufactured on or after June 27, 1983 shall have a leakage radiation which does not exceed 100 milliroentgens (25.8 $\mu\text{C/kg}$) in 1 hour at 1 meter from the source.

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006.08A1d 151 to 999 kVp Systems. The leakage radiation shall not exceed 1 roentgen (0.258 mC/kg) in 1 hour at 1 meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

006.08A2 Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.

006.08A3 Removable and Adjustable Beam Limiting Devices.

006.08A3a Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

006.08A3b Adjustable beam limiting devices installed after the effective date of these regulations shall meet the requirements of 006.08A3a.

006.08A3c Adjustable beam limiting devices manufactured prior to August 1, 1974 and installed before the effective date of these regulations shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

006.08A4 Filter System. The filter system shall be so designed that:

006.08A4a Filters cannot be accidentally displaced at any possible tube orientation;

006.08A4b Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray; and

006.08A4c The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions.

006.08A5 Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

006.08A6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

006.08A7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

006.08A8 Reserved.

006.08A9 Timer.

006.08A9a A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

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006.08A9b The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

006.08A9c The timer shall terminate irradiation when a pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.

006.08A9d The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

006.08A9e The timer shall not permit an exposure if set at zero.

006.08A9f The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

006.08A10 Control Panel Functions. The control panel, in addition to the displays required in other provisions of 006.08, shall have:

006.08A10a An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

006.08A10b An indication of whether x-rays are being produced;

006.08A10c Means for indicating x-ray tube potential and current;

006.08A10d The means for terminating an exposure at any time;

006.08A10e A locking device which will prevent unauthorized use of the x-ray system; and

006.08A10f For x-ray equipment manufactured after June 27, 1983, shall have a positive display of specific filter(s) in the beam.

006.08A11 Multiple Tubes. When a control panel may energize more than one x-ray tube:

006.08A11a It shall be possible to activate only one x-ray tube during any time interval;

006.08A11b There shall be an indication at the control panel identifying which x-ray tube is energized; and

006.08A11c There shall be an indication at the tube housing assembly when that tube is energized.

006.08A12 Source-to-Skin Distance. There shall be means of determining the source-to-skin distance to within 1 centimeter.

006.08A13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,

006.08A13a After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

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006.08A13b An indication of shutter position shall appear at the control panel.

006.08A14 Low-Filtration X-Ray Tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

006.08B Facility Design Requirements for X-Ray Systems Capable of Operating Above 50 kVp. In addition to shielding adequate to meet requirements of Section 004 and Section 006 of these regulations, the treatment room shall meet the following design requirements:

006.08B1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

006.08B2 Viewing Systems.

006.08B2a Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

006.08B2b When the primary viewing system is by electronic means an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

006.08B3 Additional Requirements for X-Ray Systems Capable of Operation Above 150 kVp.

006.08B3a All protective barriers shall be fixed except for entrance doors or beam interceptors.

006.08B3b The control panel shall be located outside the treatment room.

006.08B3c Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

006.08B3d When any door referred to in 006.08B3c is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgens (25.8 uC/kg) per hour.

006.08C Surveys, Calibrations, Spot Checks, and Operating Procedures.

006.08C1 Surveys.

006.08C1a All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

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006.08C1b The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

006.08C1c The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

006.08C2 Calibrations.

006.08C2a The calibration of an x-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.

006.08C2b The calibration of the x-ray system shall be performed by a radiological physicist.

006.08C2c The calibration of radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding 2 years.

006.08C2d The calibrations shall be such that the dose at a reference point in soft tissue can be calculated to an accuracy within ± 5 percent.

006.08C2e The calibration of the x-ray system shall include, but not be limited to, the following determinations:

006.08C2e(1) Verification that the x-ray system is operating in compliance with the design specifications;

006.08C2e(2) The exposure rates as a function of field size, technique factors, filter, and treatment distance used;

006.08C2e(3) The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

006.08C2e(4) An evaluation of the uniformity of the largest radiation field used.

006.08C2f Records of calibration shall be maintained by the registrant for 5 years after completion of the calibration.

006.08C2g A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

006.08C3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

006.08C3a The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be available to the Agency.

006.08C3b If a radiological physicist does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

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006.08C3c The spot-check procedures shall specify the frequency at which tests or measurements are to be performed. The spot-check procedures shall specify that the spot check shall be performed during the calibration specified in 006.08C2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 006.08C2 shall be stated.

006.08C3d The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

006.08C3e Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist spot-check procedures, the system shall be recalibrated as required in 006.08C2.

006.08C3f Records of spot-check measurements shall be maintained by the registrant for 5 years after completion of the spot-check measurements and any necessary corrective actions.

006.08C3g Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 006.08C2 or which has been intercompared with a system meeting those requirements within the previous year.

006.08C4 Operating Procedures.

006.08C4a X-ray systems shall not be left unattended unless the system is secured against unauthorized use.

006.08C4b When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

006.08C4c The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5mm lead equivalency at 100 kVp.

006.08C4d No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of 004.06 of these regulations. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp.

006.08C4e No person shall operate an accelerator until they meet the training requirements of Subsection 015.24.

006.08C4f The x-ray system shall not be used in the administration of radiation therapy unless the requirements of 006.08C2 and 006.08C3e have been met.

006.09 X-Ray and Electron Therapy Systems with Energies of One MeV and Above. Section 009 except 009.11C and 009.11D shall apply to medical facilities using therapy systems with energies 1 MeV and above.

006.09A Definitions. In addition to the definitions provided in 006.02, the following definitions shall be applicable to 006.09:

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006.09A1 "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

006.09A2 "Beam scattering filter" means a filter used in order to scatter a beam of electrons.

006.09A3 "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

006.09A4 "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

006.09A5 "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

006.09A6 "Existing equipment" means therapy systems subject to 006.09 which were manufactured on or before January 1, 1985.

006.09A7 "Field flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

006.09A8 "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

006.09A9 "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

006.09A10 "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

006.09A11 "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

006.09A12 "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.

006.09A13 "New equipment" means systems subject to 006.09 which were manufactured after January 1, 1985.

006.09A14 "Normal treatment distance" means:

006.09A14(a) For electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

006.09A14(b) For x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

006.09A15 "Radiation head" means the structure from which the useful beam emerges.

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006.09A16 "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

006.09A17 "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

006.09A18 "Target" means that part of a radiation head source which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

006.09A19 "Virtual source" means a point from which radiation appears to originate.

006.09B Requirements for Equipment.

006.09B1 Leakage Radiation to the Patient Area.

006.09B1a New equipment shall meet the following requirements:

006.09B1a(1) For operating conditions, producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

006.09B1a(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 006.09B1a(1) for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

006.09B1b Existing equipment shall meet the following requirements:

006.09B1b(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meter radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

006.09B1b(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 006.09B1b(1) for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

006.09B2 Leakage Radiation Outside the Patient Area for New Equipment.

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006.09B2a The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 006.09B1a(1) when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in 006.09B1a(1).

006.09B2b The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 006.09B2a for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

006.09B3 Beam Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

006.09B4 Filters.

006.09B4a Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

006.09B4b If the absorbed dose rate data required by 006.09B16 relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.

006.09B4c For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

006.09B4c(1) Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

006.09B4c(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position; and

006.09B4c(3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

006.09B5 Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

006.09B5a The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

<u>Maximum Energy of Electron Beam in MeV</u>	<u>X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose</u>
1	0.03
15	0.05
35	0.10
50	0.20

006.09B5b Compliance with 006.09B5a shall be determine using:

006.09B5b(1) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

006.09B5b(2) The largest field size available which does not exceed 15 by 15 centimeters; and

006.09B5b(3) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

006.09B5c The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

<u>Maximum Photon Energy in MeV</u>	<u>Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose</u>
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

006.09B5d Compliance with 006.09B5c shall be determined by measurements made:

006.09B5d(1) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

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006.09B5d(2) Using a phantom whose size and placement meet the requirements of 006.09B5b;

006.09B5d(3) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

006.09B5d(4) Using the largest field size available which does not exceed 15 by 15 centimeters.

006.09B5e The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

006.09B6 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

006.09B6a New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

006.09B6b Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

006.09B6c The detectors and the system into which that detector is incorporated shall meet the following requirements:

006.09B6c(1) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

006.09B6c(2) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

006.09B6c(3) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

006.09B6c(4) For new equipment, the design of the dose monitoring systems shall assure that:

006.09B6c(4)(a) The malfunctioning of one system shall not affect the correct functioning of the second system; and

006.09B6c(4)(b) The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

006.09B6c(5) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

006.09B6c(5)(a) Maintain a reading until intentionally reset to zero;

006.09B6c(5)(b) Have only one scale and no scale multiplying factors;

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006.09B6c(5)(c) Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdose of radiation, the absorbed dose may be accurately determined; and

006.09B6c(5)(d) In the event of power failure, the dose monitoring information required in 006.09b6c(5) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

006.09B7 **Beam Symmetry.** In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

006.09B8 **Selection and Display of Dose Monitor Units.**

006.09B8a Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

006.09B8b The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

006.09B8c After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

006.09B8d For new equipment after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

006.09B9 **Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.**

006.09B9a Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

006.09B9b If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

006.09B9c For new equipment, a second dose monitoring system shall be present. The system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

006.09B9d For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

006.09B10 **Interruption Switches.** It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of

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operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

006.09B11 Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

006.09B12 Timer.

006.09B12a A timer which has a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator.

006.09B12b The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

006.09B12c The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

006.09B12d For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

006.09B13 Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

006.09B13a Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

006.09B13b An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

006.09B13c An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

006.09B13d An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

006.09B13e An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

006.09B13f The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

006.09B14 Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

006.09B14a Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

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006.09B14b An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

006.09B14c The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

006.09B14d For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

006.09B15 Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

006.09B15a Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

006.09B15b An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

006.09B15c An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

006.09B15d For new equipment, an interlock system shall be provided to terminate irradiation if:

006.09B15d(1) Movement of the gantry occurs during stationary beam therapy, or

006.09B15d(2) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

006.09B15e Moving beam therapy shall be so controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

006.09B15e(1) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

006.09B15e(2) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

006.09B15f The mode of operation shall be displayed at the treatment control panel.

006.09B15g Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 006.09B9.

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006.09B16 Absorbed Dose Rate Monitor. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.⁴ In addition:

006.09B16a The dose monitor unit rate shall be displayed at the treatment control panel.

006.09B16b If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

006.09B17 Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

006.09B17a The x-ray target or the virtual source of x-rays; and

006.09B17b The electron window or the virtual source of electrons if the system has electron beam capabilities.

006.09C Facility and Shielding Requirements. In addition to Section 004 of these regulations, the following design requirements shall apply:

006.09C1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

006.09C2 Control Panel. The control panel shall be located outside the treatment room.

006.09C3 Viewing Systems.

006.09C3a Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.

006.09C3b When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

006.09C4 Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

006.09C5 Room Entrances. Treatment room entrances shall be provided with warning lights, in readily observable positions near the outside of all access doors to indicate when the useful beam is "on".

⁴The radiation detectors specified in 006.09B6 may form part of this system.

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006.09C6 Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

006.09D Surveys, Calibrations, Spot Checks, and Operating Procedures.

006.09D1 Surveys.

006.09D1a All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

006.09D1b The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be transmitted by the registrant to the Agency within 30 days of receipt of the report.

006.09D1c The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist is in violation of applicable regulations.

006.09D2 Calibrations.

006.09D2a The calibration of systems subject to 006.09 shall be performed in accordance with an established calibration protocol acceptable to the Agency⁵ before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

006.09D2b The calibration shall be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration.

006.09D2c Calibration radiation measurements required by 006.09D2a shall be performed using a dosimetry system:

006.09D2c(1) Having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

006.09D2c(2) Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;

006.09D2c(3) Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

006.09D2c(4) Which has had constancy checks performed on the system as specified by a radiological physicist.

⁵The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user shall submit that protocol to the Agency for concurrence that the protocol is acceptable.

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006.09D2d Calibrations shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an accuracy of ± 5 percent.

006.09D2e The calibration of the therapy beam shall include but not be limited to the following determinations:

006.09D2e(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth.

006.09D2e(2) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

006.09D2e(3) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

006.09D2e(4) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

006.09D2e(5) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

006.09D2f Records of calibration measurements under 006.09D2a and dosimetry system calibrations under 006.09D2c shall be maintained for 5 years after completion of the full calibration.

006.09D2g A copy of the latest calibration performed pursuant to 006.09D2a shall be available in the area of the control panel.

006.09D3 Spot checks. Spot checks shall be performed on systems subject to 006.09 during calibrations and thereafter at intervals not to exceed one month. Such spot checks shall meet the following requirements.

006.09D3a The spot-check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedure shall be submitted to the Agency prior to its implementation.

006.09D3b If a radiological physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a radiological physicist within 15 days.

006.09D3c The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

006.09D3d At intervals not to exceed one week, spot checks shall be made of absorbed dose measurements at a minimum of 2 depths in a phantom for photon beams.

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006.09D3e Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check measurement.

006.09D3f The cause for a parameter exceeding a tolerance set by the radiological physicist shall be investigated and corrected before the system is used for patient irradiation.

006.09D3g Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system shall be recalibrated as required in 006.09D2.

006.09D3h Records of spot-check measurements shall be maintained by the registrant for a period of 5 years after completion of the spot-check measurements and any necessary corrective actions.

006.09D3i Where a spot-check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 006.09D2c or which has been intercompared with a system meeting those requirements within the previous year.

006.09D4 Operating Procedures.

006.09D4a No individual other than the patient shall be in the treatment room during treatment of a patient.

006.09D4b If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

006.09D4c No person shall operate an accelerator until they meet the training and experience requirements of Subsection 015.21.

006.09D4d The system shall not be used in the administration of radiation therapy unless the requirements of 006.09D1, 2 and 3 have been met.

006.10 Veterinary Medicine Radiographic Installations.

006.10A Equipment.

006.10A1 The protective tube housing shall be equivalent to the requirements of 006.04C.

006.10A2 Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

006.10A3 The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

006.10A4 A device shall be provided to terminate the exposure after a preset time or exposure.

006.10A5 A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures.

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006.10B Structural Shielding. All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 004.06, 004.12, and 004.14 of these regulations.

006.10C Operating Procedures.

006.10C1 The operator shall be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.

006.10C2 No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.

006.10C3 When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

006.10D Veterinary Assistant's Training Requirements. On the effective date of these regulations, veterinary assistant's shall have eight (8) hours of classroom instruction in the fundamentals of radiation safety, radiation detection instrumentation, radiographic equipment, state and federal regulations, operating and emergency procedures and case histories of radiography accidents as outlined in Subsection 015.24, "Minimum Training Requirements for Operators of Non-Human X-Ray" of these regulations.

006.11 Computed Tomography Systems.

006.11A Definitions. In addition to the definitions provided in 001.02 and 006.02 of these regulations, the following definitions shall be applicable to 006.11:

006.11A1 "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

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

D(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

006.11A2 "CTDI" (See "Computed tomography dose index").

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006.11A3 "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{u_x - u_w}{(CTN)_x - (CTN)_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.

u_w = Linear attenuation coefficient of water. $(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

006.11A4 "CS" (See "Contrast scale").

006.11A5 "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 006.02.

006.11A6 "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

006.11A7 "CTN" (See "CT number").

006.11A8 "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant⁶

u_x = Linear attenuation coefficient of the material of interest.

u_w = Linear attenuation coefficient of water.

006.11A9 "Dose profile" means the dose as a function of position along a line.

006.11A10 "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

006.11A11 "Multiple tomogram system" means a system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

⁶The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.

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006.11A12 "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Contrast scale

u_w = Linear attenuation coefficient of water.

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

006.11A13 "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

006.11A14 "Picture element" means an elemental area of a tomogram.

006.11A15 "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

006.11A16 "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

006.11A17 "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.

006.11A18 "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

006.11A19 "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

006.11A20 "Single tomogram system" means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.

006.11A21 "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

006.11A22 "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

006.11B Requirements for Equipment.

006.11B1 Termination of Exposure.

006.11B1a Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total

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scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

006.11B1b A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 006.11B1a.

006.11B1c The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration.

006.11B2 Tomographic Plane Indication and Alignment.

006.11B2a For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

006.11B2b For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

006.11B2c If a device using a light source is used to satisfy 006.11B2a or b, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

006.11B3 Beam-on and Shutter Status Indicators and Control Switches.

006.11B3a The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

006.11B3b Each emergency button or switch shall be clearly labeled as to its function.

006.11B4 Indication of CT Conditions of Operation. The CT System shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

006.11B5 Entraneous Radiation. When data are being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 006.04C.

006.11B6 Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

006.11B7 Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

006.11B7a The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

006.11B7b If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall

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be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

006.11B7c The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass of 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

006.11B7d Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

006.11C Facility Design Requirements.

006.11C1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

006.11C2 Viewing Systems.

006.11C2a Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

006.11C2b When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

006.11D Surveys, Calibrations, Spot Checks, and Operating Procedures.

006.11D1 Surveys.

006.11D1a All CT x-ray systems installed after the effective date of these regulations and those systems not previously surveyed shall have a survey made by, or under the direction of, a radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

006.11D1b The registrant shall obtain a written report of the survey from the radiological physicist, and a copy of the report shall be made available to the Agency upon request.

006.11D2 Radiation Calibrations.

006.11D2a The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a radiological physicist.

006.11D2b The calibration of a CT x-ray system shall be performed at intervals specified by a radiological physicist and after any change or replacement of components which, in the opinion of the radiological physicist could cause a change in the radiation output.

006.11D2c The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a

national standard. The dosimetry system shall have been calibrated within the preceding two years.

006.11D2d CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

006.11D2d(1) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

006.11D2d(2) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

006.11D2d(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

006.11D2d(4) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

006.11D2e The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

006.11D2f Calibration shall meet the following requirements:

006.11D2f(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

006.11D2f(2) The CTDI⁷ along the two axes specified in 006.11D2d(2) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant.

006.11D2f(3) The spot checks specified in 006.11D3 shall be made.

⁷For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

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006.11D2g Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Agency.

006.11D3 Spot Checks.

006.11D3a The spot-check procedures shall be in writing and shall have been developed by a radiological physicist.

006.11D3b The spot-check procedures shall incorporate the use of a CT phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

006.11D3c All spot checks shall be included in the calibration required by 006.11D2 and at time intervals and under system conditions specified by a radiological physicist.

006.11D3d Spot checks shall include acquisition of images obtained with the CT phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 006.11D2. The images shall be retained, until a new calibration is performed, in two forms as follows:

006.11D3d(1) Photographic copies of the images obtained from the image display device; and

006.11D3d(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system.

006.11D3e Written records of the spot checks performed shall be maintained for inspection by the Agency.

006.11D4 Operating Procedures.

006.11D4a The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

006.11D4b Information shall be available in the control area regarding the operation and calibration of the system. Such information shall include the following:

006.11D4b(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

006.11D4b(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.

006.11D4b(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

006.11D4b(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

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006.11D4c If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the radiological physicist, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the radiological physicist.

APPENDIX 1

**INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO
CONDUCT HEALING ARTS SCREENING**

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
3. Description in detail of the x-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.
6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the x-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the x-ray system(s).
10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

APPENDIX 2

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

1. The plans should show, as a minimum, the following:
 - (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
 - (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
 - (c) The dimensions of the room(s) concerned.
 - (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
 - (e) The make and model of the x-ray equipment and the maximum technique factors.
 - (f) The type of examination(s) or treatment(s) which will be performed with the equipment.
2. Information on the anticipated workload of the x-ray system(s).
3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

APPENDIX 3

DESIGN RECOMMENDATIONS FOR AN OPERATOR'S BOOTH

1. Space Requirements:

- (a) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth.
- (b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).
- (c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- (d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette not reach the operator's station in the booth.

2. Structural Requirements:

- (a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.
- (b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- (c) Shielding shall be provided to meet the requirements of Section 004 of these regulations.

3. X-Ray Control Placement:

The x-ray control for the system shall be fixed within the booth and:

- (a) Shall be at least 40 inches (1.02 m) from any open edge of the booth wall which is nearest to the examining table.
- (b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

- (a) Each booth shall have at least one viewing device which will:
 - (1) Be so placed that the operator can view the patient during any exposure, and
 - (2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room can not be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.
- (b) When the viewing system is a window, the following requirements also apply:
 - (1) It shall have a viewing area of at least 1 square foot (0.0929m²) with the lower edge of the window at least 4.5 feet (1.37m) above the floor.

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- (2) The distance between the nearest edge of the window and the open edge of the booth shall not be less than 18 inches (0.457m).
- (3) The glass shall have the same lead equivalence as that required in the booth's wall in which it is mounted.
- (c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix 3, 4.(a).
- (d) When the viewing system is by electronic means:
 - (1) The camera shall be so located as to accomplish the general requirements of Appendix 3, 4.(a), and
 - (2) There shall be an alternate viewing system as a backup for the primary system.

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Section 007 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

007.01 Purpose and Scope. This section establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this Section are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of Sections 001, 003, 004, 010, 013, 015, 017, and 018 of these regulations apply to applicants and licensees subject to this section unless specifically exempted.

007.02 Definitions As used in Section 007, the following definitions apply:

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be received, used, or stored.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Authorized nuclear pharmacist" means a pharmacist who is:

- (1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
- (2) Identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or
- (3) Identified as an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

"Authorized user" means a physician who meets the training and experience requirements in Part 007.66B, 007.66C, 007.66D, 007.66F, 007.66H, or 007.66I and who is identified as an authorized user on an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

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"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

"Misadministration" means the administration of:

- (1) A radiopharmaceutical dosage greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131:
 - (a) Involving the wrong individual or wrong radiopharmaceutical, or
 - (b) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 MBq (30 microcuries).
- (2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
 - (a) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - (b) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.
- (3) A gamma stereotactic radiosurgery radiation dose:
 - (a) Involving the wrong individual or wrong treatment site; or
 - (b) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.
- (4) A teletherapy radiation dose:
 - (a) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
 - (b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
 - (c) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
 - (d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
- (5) A brachytherapy radiation dose:
 - (a) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
 - (b) Involving a sealed source that is leaking;

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- (c) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - (d) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.
- (6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131, both:
- (a) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
 - (b) When the dose to the individual exceeds 50 mSv (5 rem) effective dose equivalent or 500 mSv (50 rem) dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means someone licensed or otherwise authorized to perform medicine and surgery pursuant to Neb Rev. Stat. Sections 71-1, 102. to 71-1, 107.14 Neb. Rev. Stat. and Sections 71-1, 137 through 71-1, 141 of the Act.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

- (1) In a written directive; or
- (2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

- (1) For gamma stereotactic radiosurgery, the total dose;
- (2) For teletherapy, the total dose and dose per fraction;
- (3) For brachytherapy, either the total source strength and exposure time or the total dose.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on an Agency license.

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

- (1) For any administration of a quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
- (2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

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- (3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
- (4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
- (5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
- (6) For all other brachytherapy:
 - (i) Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

007.03 Provisions for Research Involving Human Subjects.

A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

007.04 FDA, Federal and State Requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs or devices.

GENERAL REGULATORY REQUIREMENTS

007.05 License Required.

007.05A No person shall manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these regulations.

007.05B Unless prohibited by license condition, an individual may manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material in accordance with the regulations in this section under the supervision of an authorized user as provided in 007.13.

007.05C Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with these regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in 007.13

007.06 Application for License, Amendment, or Renewal.

007.06A If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

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007.06B An application for a license for medical use of radioactive material as described in 007.34, 007.36, 007.40, 007.44, and 007.46 of this Section must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy". For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

007.06C An application for a license for medical use of radioactive material as described in 007.52 of this Section must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy" and Form NRH-5A Supplement C, "Application for Radioactive Material License - Medical or Teletherapy Requirements Specific to Teletherapy". For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

007.06D For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to Subsection 001.12.

007.06E An applicant that satisfies the requirements specified in Part 003.13B of these regulations may apply for a Type A specific license of broad scope.

007.07 License Amendments. A licensee shall apply for and receive a license amendment:

007.07A Before using radioactive material for a method or type of medical use not permitted by the license issued under this section;

007.07B Before permitting anyone, to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

007.07B1 An authorized user certified by the organizations specified in 007.66B1, 007.66C1, 007.66D1, 007.66F1, 007.66H1, or 007.66I2;

007.07B2 An authorized nuclear pharmacist certified by the organization specified in 007.01;

007.07B3 Identified as an authorized user or an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

007.07B4 Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

007.07C Before changing a Radiation Safety Officer or Teletherapy Physicist;

007.07D Before receiving radioactive material in excess of the amount authorized, or radionuclide or form different than authorized on the license;

007.07E Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

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007.07E Before changing statements, representations, and procedures which are incorporated into the license.

007.08 Notifications.

007.08A A licensee shall provide to the Agency a copy of the board certification, the Agency, U.S. Nuclear Regulatory Commission, or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 007.07B1 through 007.07B4.

007.08B A licensee shall notify the Agency by letter no later than 30 days after:

007.08B1 An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

007.08B2 The licensee's mailing address changes.

007.08C The licensee shall mail documents required in this Subsection to the appropriate address identified in Subsection 001.02.

ADDITIONAL REQUIREMENTS

007.09 ALARA Program.

007.09A Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in Subsection 001.02 of these regulations.

007.09B To satisfy the requirement of 007.09A:

007.09B1 At a medical institution, the management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

007.09B2 For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

007.09C The program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents ALARA, a review of the summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety measures, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make every reasonable effort to maintain individual and collective occupational doses ALARA.

007.09D The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

007.09D1 A commitment by management to keep occupational doses as low as reasonably achievable;

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007.09D2 A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

007.09D3 Personnel exposure investigational levels as established in accordance with 007.11B8 that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

007.09D4 Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

007.10 Radiation Safety Officer.

007.10A A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

007.10B The Radiation Safety Officer shall:

007.10B1 Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations and other deviations from approved radiation safety practice and implement corrective actions as necessary;

007.10B2 Establish, collect in one binder or file and implement written policy and procedures for:

007.10B2a Authorizing the purchase of radioactive material;

007.10B2b Receiving and opening packages of radioactive material;

007.10B2c Storing radioactive material;

007.10B2d Keeping an inventory record of radioactive material;

007.10B2e Using radioactive material safely;

007.10B2f Taking emergency action if control of radioactive material is lost;

007.10B2g Performing periodic radiation surveys;

007.10B2h Performing checks and calibrations of survey instruments and other safety equipment;

007.10B2i Disposing of radioactive material;

007.10B2j Training personnel who work in or frequent areas where radioactive material is used or stored; and

007.10B2k Keeping a copy of all records and reports required by the Agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

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007.10B3 Brief management once each year on the radioactive material program;

007.10B4 Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

007.10B5 For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; and

007.10B6 For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

007.11 Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

007.11A The Committee shall meet the following administrative requirements:

007.11A1 Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

007.11A2 The committee shall meet at least once each calendar quarter.

007.11A3 To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative.

007.11A4 The minutes of each Radiation Safety Committee meeting shall include:

007.11A4a The date of the meeting;

007.11A4b Members present;

007.11A4c Members absent;

007.11A4d Summary of deliberations and discussions;

007.11A4e Recommended actions and the numerical results of all ballots; and

007.11A4f Documentation of any reviews required in 007.09C and 007.11B

007.11A5 The Committee shall provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

007.11B To oversee the use of licensed material, the Committee shall:

007.11B1 Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

007.11B2 Review:

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007.11B2a Review, on the basis of safety and with regard to the training and experience standards of this Section, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;

007.11B2b Review, pursuant to 007.07B1 through 007.07B4, on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

007.11B3 Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

007.11B4 Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

007.11B5 Review quarterly with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

007.11B6 Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken; and

007.11B7 Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

007.12 Statement of Authorities and Responsibilities.

007.12A A licensee shall provide sufficient authority and organizational freedom and management prerogative to the Radiation Safety Officer and at a medical institution the Radiation Safety Committee to:

007.12A1 Identify radiation safety problems;

007.12A2 Initiate, recommend, or provide corrective actions; and

007.12A3 Verify implementation of corrective actions.

007.12B A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

007.13 Supervision.

007.13A A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 007.05B shall:

007.13A1 Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;

007.13A2 Review the supervised individual's use of radioactive material, provide re-instruction as needed and review records kept to reflect this use;

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007.13A3 Require the authorized user to be immediately available to communicate with the supervised individual;

007.13A4 Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects.

007.13B A licensee shall require the supervised individual receiving, possessing, using or transferring radioactive material under 007.05 to:

007.13B1 Follow the instructions of the supervising authorized user;

007.13B2 Follow the written radiation safety procedures established by the licensee;

007.13B3 Follow the procedures established by the Radiation Safety Officer; and

007.13B4 Comply with these regulations and the license conditions with respect to the use of radioactive material.

007.13C A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

007.14 Reserved.

007.15 Mobile Nuclear Medicine Service Administrative Requirements.

007.15A The Agency will license mobile nuclear medicine services only in accordance with this section and other applicable requirements of these regulations. An authorized user or an on-site-physician who has met the training and experience requirements of 007.66, needs to be present during administration of radioactive material.

007.15B Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

007.15C If a mobile nuclear medicine service licensee provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this section while the mobile nuclear medicine service is under the client's direction.

007.15D A mobile nuclear medicine service licensee may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use.

007.16 Reserved.

007.17 Notifications, Records and Reports of Misadministrations.

007.17A For any misadministration of radioactive material or radiation:

007.17A1 The licensee shall notify the Agency by telephone no later than the next day after discovery of the misadministration.

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007.17A2 The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual or the individual's responsible relative or guardian, and if not, why not, and if there was notification, what information was provided. The report must not contain the individual's name or other information that could lead to identification of the individual. To meet the requirements of this subsection, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

007.17A3 The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee shall not delay appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

007.17A4 If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

007.17B Each licensee shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved in the event, including the prescribing physician, allied health personnel, the individual subject who received the misadministration, and the individual's referring physician, if applicable, the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken, to prevent recurrence.

007.17C Aside from the notification requirement, nothing in this Subsection affects any rights or duties of licensees, and physicians in relation to each other, individuals receiving misadministrations, or the individual's responsible relatives or guardians.

007.18 Suppliers. A licensee shall use for medical use only:

007.18A Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Section 003 and Parts 003.14J, K, and L of these regulations or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State;

007.18B Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration, the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; or

007.18C Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Section 003 of these regulations, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

SPECIFIC REQUIREMENTS

007.19 Possession, Use, Calibration, and Check of Dose Calibrators.

007.19A A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient and human research subject.

007.19B A licensee shall:

007.19B1 Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this Subpart, the check shall be done on a frequently used setting with a sealed source of not less than 370 kBq (10 microcuries) of radium-226 or 1.85 MBq (50 microcuries) of any other photon-emitting radionuclide with a half-life greater than 90 days;

007.19B2 Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 370 kBq (10 microcuries) for radium-226 and 1.85 MBq (50 microcuries) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

007.19B3 Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 MBq (30 microcuries) and the highest dosage that will be administered to a patient or human research subject; and

007.19B4 Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

007.19C A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 370 kBq (10 microcuries) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

007.19D A licensee shall also perform checks and tests required by 007.19B following adjustment or repair of the dose calibrator.

007.19E A licensee shall retain a record of each check and test required by 007.19 for 3 years. The records required by 007.19B shall include:

007.19E1 For 007.19B1, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

007.19E2 For 007.19B2, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the Radiation Safety Officer;

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007.19E3 For 007.19B3, the model and serial number of the dose calibrator, and the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

007.19E4 For 007.19B4, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

007.20 Calibration and Check of Survey Instruments.

007.20A A licensee shall ensure that the survey instruments used to show compliance with this section have been calibrated before first use, annually, and following repair.

007.20B To satisfy the requirements of 007.20A, the licensee shall:

007.20B1 Calibrate all required scale readings up to 10 mSv (1000 millirems) per hour with a radiation source;

007.20B2 Each scale shall be calibrated at 1/3 and 2/3 of the full scale reading.

007.20B3 Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

007.20C To satisfy the requirements of 007.20B, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent, and shall conspicuously attach a correction chart or graph to the instrument if the calibration is greater than ± 10 percent but less than ± 20 percent. Instruments greater than ± 20 percent shall be repaired or replaced.

007.20D A licensee shall check each survey instrument for proper operation with the dedicated check source before each day of use. The licensee is not required to keep records of these checks.

007.20E The licensee shall retain a record of each calibration required in 007.20A for three years. The record shall include:

007.20E1 A description of the calibration procedure; and

007.20E2 A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

007.20F To meet the requirements of 007.20A, B, and C, the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records of calibrations which contain information required by 007.20E shall be maintained by the licensee.

007.21 Possession, Use, Calibration, and Check of Instruments to Measure Dosage of Alpha- or Beta-emitting Radionuclides.

007.21A This section does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to Part 003.14J of these regulations or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

007.21B For other than unit dosages obtained pursuant to 007.21A of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each individual. In addition, the licensee shall:

007.21B1 Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

007.21B2 Check each instrument for constancy and proper operation at the beginning of each day of use.

007.22 Measurement of Unsealed Radioactive Material for Medical Use. A licensee shall:

007.22A Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

007.22B Measure, by direct measurement or by combination of measurement and calculations, the activity of each dosage of a alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 003.14J of these regulations or equivalent U.S. Nuclear Regulatory Commission or Agreement State Requirements;

007.22C Retain a record of the measurements required by 007.22A and B for three years. To satisfy this requirement, the record shall contain the:

007.22C1 Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

007.22C2 Patient's or human research subject's name, and identification number if one has been assigned;

007.22C3 Prescribed dosage and activity of the dosage at the time of measurement, or notation that the total activity is less than 1.1 MBq (30 microcuries);

007.22C4 Date and time of the administration measurement; and

007.22C5 Initials of the individual who made the record.

007.23 Authorization for Calibration and Reference Sources. Any person authorized by 007.05 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

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007.23A Sealed sources manufactured and distributed by persons specifically licensed pursuant to subsection 003.14L of these regulations or equivalent provisions of the U.S. Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 555 MBq (15 millicuries) each;

007.23B Any radioactive material authorized by 007.34 or 007.36 with a half-life of 100 days or less in individual amounts not to exceed 555 MBq (15 millicuries);

007.23C Any radioactive material authorized by 007.34 or 007.36 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 microcuries) each; and

007.23D Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).

007.24 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

007.24A A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

007.24B A licensee in possession of a sealed source shall assure that:

007.24B1 The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

007.24B2 The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission.

007.24C To satisfy the leak test requirements of 007.24B, the licensee shall assure that:

007.24C1 Leak tests are capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 Bq (0.001 microcuries) per 24 hours;

007.24C2 Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

007.24C3 Test samples are taken when the source is in the "off" position.

007.24D A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (microcuries), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer

007.24E If the leak test reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination, the licensee shall:

007.24E1 Immediately withdraw the sealed source from use and store it in accordance with the requirements of Section 004 of these regulations; and

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007.24E2 File a report with the Agency within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

007.24F A licensee need not perform a leak test on the following sources:

007.24F1 Sources containing only radioactive material with a half-life of less than 30 days;

007.24F2 Sources containing only radioactive material as a gas;

007.24F3 Sources containing 3.7 MBq (100 microcuries) or less of beta or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material;

007.24F4 Seeds of iridium-192 encased in nylon ribbon; or

007.24F5 Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

007.24G A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.

007.24H A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

007.24I A licensee shall retain a record of each survey required in 007.24H for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

007.25 Syringe Shields.

007.25A A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

007.25B A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

007.26 Syringe Labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, and the patient's or human research subject's name.

007.27 Vial Shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

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007.28 Vial Shield Labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

007.29 Surveys for Contamination and Ambient Radiation Dose Rate.

007.29A A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

007.29B A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

007.29C A licensee shall conduct the surveys required by 007.29A and B so as to be able to measure dose rates as low as 1 μ Sv (0.1 millirem) per hour.

007.29D A licensee shall establish dose rate action levels for the surveys required by 007.29A and B and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

007.29E A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and where radioactive materials are stored.

007.29F A licensee shall conduct the surveys required by 007.29E so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).

007.29G A licensee shall establish removable contamination action levels for the surveys required by 007.29E and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

007.29H A licensee shall retain a record of each survey required by 007.29A, B and E for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

007.30 Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

007.30A The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).¹

007.30B The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1

¹Regulatory Guide 7.1, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

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rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

007.30B1 Guidance on the interruption or discontinuation of breast-feeding and

007.30B2 Information on the consequences of failure to follow the guidance.

007.30C The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by:

007.30C1 Using the retained activity rather than the activity administered,

007.30C2 Using an occupancy factor less than 0.25 at 1 meter,

007.30C3 Using the biological or effective half-life, or

007.30C4 Considering the shielding by tissue.

007.30D The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

007.31 Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

007.31A Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

007.31B Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

007.31C Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

007.31D Check survey instruments and dose calibrators as required in 007.19 and 007.20, and check all other transported equipment for proper function before medical use at each address of use;

007.31E Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

007.31F Retain a record of each survey required by 007.31E for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (millirems) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

007.32 Storage of Volatiles and Gases.

007.32A A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

007.32B A licensee shall store and use a multidose container in a properly functioning fume hood.

007.33 Decay-In-Storage.

007.33A A licensee shall hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the waste disposal requirements of Section 004 of these regulations if the licensee:

007.33A1 Holds radioactive material for decay a minimum of ten half-lives;

007.33A2 Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

007.33A3 Removes or obliterates all radiation labels; and

007.33A4 Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

007.33B For radioactive material disposed in accordance with 007.33A, the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

**SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIALS
FOR UPTAKE, DILUTION, OR EXCRETION STUDIES**

007.34 Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies.

007.34A A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

007.34A1 Obtained from a manufacturer or preparer licensed pursuant 003.14J or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

007.34A2 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 007.66B, or an individual under the supervision of either as specified in 007.13.

007.35 Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μ Sv (0.1 millirem) per hour to 1000 μ Sv (100 millirems) per hour. The instrument shall be operable and calibrated in accordance with 007.20.

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**SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL, GENERATORS,
AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES**

007.36 Use of Unsealed Radioactive Material for Imaging and Localization Studies. A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

007.36A Obtained from a manufacturer or preparer licensed pursuant to 003.14J or equivalent Agreement State requirements; or

007.36B Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 007.66C, or an individual under the supervision of either as specified in 007.13.

007.37 Permissible Molybdenum-99 Concentration.

007.37A A licensee shall not administer to humans a radiopharmaceutical containing more than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 μ Ci of molybdenum-99 per mCi of technetium-99m).

007.37B A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

007.37C A licensee who must measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in MBq (mCi), the measured activity of molybdenum expressed in kBq (μ Ci), the ratio of the measures expressed as kBq (μ Ci) of molybdenum per MBq (mCi) of technetium, the time and date of the test, and the initials of the individual who performed the test.

007.37D A licensee shall report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 007.37A.

007.38 Control of Aerosols and Gases.

007.38A A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Section 004 of these regulations.

007.38B The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

007.38C A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

007.38D Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix 004-B of Section 004 of these regulations. The calculation shall be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

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007.38E A licensee shall post the time calculated in 007.38D at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

007.38F A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

007.38G A copy of the calculations required in 007.38D shall be recorded and retained for the duration of the license.

007.39 Possession of Survey Instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μ Sv (0.1 millirem) per hour to 500 μ Sv (50 millirems) per hour. If generators (Mo 99m/Tc 99m) are utilized, a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 007.20.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL FOR THERAPY

007.40 Use of Unsealed Radioactive Material for Therapeutic Administration. A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

007.40A Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction; or

007.40B Iodine-131 as iodide for treatment of thyroid carcinoma; or

007.40C Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases; or

007.40D Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

007.40E Gold-198 as colloid for intracavitary treatment of malignant effusions;

007.40F Strontium-89 as chloride for bone pain;

007.40G Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

007.41 Safety Instruction.

007.41A A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with subsection 007.30. Refresher training shall be provided at intervals not to exceed one year.

007.41B To satisfy 007.41A, the instruction shall describe the licensee's procedures for:

007.41B1 Patient or human research subject control;

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007.41B2 Visitor control;

007.41B3 Contamination control;

007.41B4 Waste control;

007.41B5 Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and

007.41B6 Section 010 training requirements.

007.41C A licensee shall keep a record of individuals receiving instruction required by 007.41A, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Agency for three years.

007.42 Safety Precautions.

007.42A For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 007.30, a licensee shall:

007.42A1 Provide a private room with a private sanitary facility;

007.42A2 Post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;

007.42A3 Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

007.42A4 Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Section 004 of these regulations and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in μSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

007.42A5 Monitor material and items removed from the patient's or the human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding. Items found to be above background may be cleaned to background levels, decayed to background by storage or disposed of as radioactive waste;

007.42A6 Reserved;

007.42A7 Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 3.33 Bq (200 dpm) per 100 square centimeters; and

007.42A8 Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by 004.51A of these regulations a record of each thyroid burden measurement, date of

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measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

007.42B A licensee shall notify the Radiation Safety Officer or the authorized user immediately if the patient or the human research subject dies or has a medical emergency.

007.43 Possession of Survey Instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 007.20.

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS

007.44 Use of Sealed Sources for Diagnosis. A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

007.44A Iodine-125, Americium-241, Gadolinium-153 as a sealed source in a device for bone mineral analysis; and

007.44B Iodine-125 as a sealed source in a portable device for imaging.

007.45 Availability of Survey Instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instrument shall be operable and calibrated in accordance with 007.20.

SPECIFIC REQUIREMENTS FOR THE USE OF SOURCES FOR BRACHYTHERAPY

007.46 Use of Sources for Brachytherapy. A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

007.46A Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

007.46B Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

007.46C Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

007.46D Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

007.46E Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

007.46F Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

007.46G Radon-222 as seeds for interstitial treatment of cancer;

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007.46H Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

007.46I Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

007.47 Safety Instruction.

007.47A The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or the human research subject receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

007.47B To satisfy 007.47A, the instruction shall describe:

007.47B1 Size and appearance of the brachytherapy sources;

007.47B2 Safe handling and shielding instructions in case of a dislodged source;

007.47B3 Procedures for patient or human research subject control;

007.47B4 Procedures for visitor control;

007.47B5 Procedures for notification of the Radiation Safety Officer or authorized user if the patient or the human research subject dies or has a medical emergency; and

007.47B6 Section 010 training requirements.

007.47C A licensee shall maintain for three years a record of individuals receiving instruction required by 007.47A and B, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

007.48 Safety Precautions.

007.48A For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to 007.30 of this part, a licensee shall:

007.48A1 Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy;

007.48A2 Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room. In addition, the posted sign shall indicate that pregnant women, or women who suspect that they are pregnant, shall contact the attendant staff for additional safety instructions or precautions. The bed, cubicle, or room of the hospital brachytherapy patient or human research subject shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions.

007.48A3 Authorize visits by individuals under 18 years of age only on a case-by-case basis with approval of the authorized user after consultation with the Radiation Safety Officer;

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007.48A4 Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with Section 004 of these regulations and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in μSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

007.48B A licensee shall notify the Radiation Safety Officer or authorized user immediately if the patient or the human research subject dies or has a medical emergency.

007.48C The following information shall be included in the patient's or human research subject's chart:

007.48C1 The radionuclide administered, number of sources, activity in GBq or mCi and time and date of administration;

007.48C2 The exposure rate at 1 meter, the time the determination was made, and name of the individual who made the determination;

007.48C3 The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 004.06 of these regulations, and;

007.48C4 The radiation symbol.

007.49 Brachytherapy Sources Inventory.

007.49A Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

007.49B A licensee shall make a record of brachytherapy source utilization which includes:

007.49B1 The names of the individuals permitted to handle the sources;

007.49B2 The number and activity of sources removed from storage, the room number of use and the patient's or the human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

007.49B3 The number and activity of sources returned to storage, the room number of use and patient's or the human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

007.49C Immediately after implanting sources in a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

007.49D A licensee shall maintain the records required in 007.49B and C for three years.

007.50 Release of Patients or Human Research Subjects Treated With Temporary Implants.

007.50A Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall perform a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

007.50B A licensee shall maintain for three years a record of patient or human research subject surveys which demonstrate compliance with 007.50A. Each record shall include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as μSv (millirems) per hour and measured within one meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

007.51 Possession of Survey Instruments. A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 007.20.

SPECIFIC REQUIREMENTS FOR THE USE OF A SEALED SOURCE IN TELETHERAPY

007.52 Use of a Sealed Source in a Teletherapy Unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

007.53 Maintenance and Repair Restrictions. Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

007.54 Amendments. In addition to the requirements specified in 007.07, a licensee shall apply for and receive a license amendment before:

007.54A Making any change in the treatment room shielding;

007.54B Making any change in the location of the teletherapy unit within the treatment room;

007.54C Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

007.54D Relocating the teletherapy unit; or

007.54E Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

007.55 Safety Instruction.

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007.55A A licensee shall conspicuously post instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:

007.55A1 The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

007.55A2 The procedure to be followed if the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

007.55A3 The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

007.55B A licensee shall provide instruction in the topics identified in 007.55A to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

007.55C A licensee shall maintain for three years a record of individuals receiving instruction required by 007.55B, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

007.56 Safety Precautions.

007.56A A licensee shall control access to the teletherapy room by a door at each entrance.

007.56B A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

007.56B1 Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

007.56B2 Turn the primary beam of radiation off immediately when an entrance door is opened; and

007.56B3 Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

007.56C A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

007.56D A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

007.56D1 Each radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

007.56D2 Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

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007.56D3 A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

007.56D4 A licensee shall maintain a record of the check required by 007.56D3 for three years. The record shall include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

007.56D5 If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 007.56D4.

007.56D6 A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

007.56E A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

007.57 Possession of Survey Instrument. A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 007.20.

007.58 Dosimetry Equipment.

007.58A A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

007.58A1 The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

007.58A2 The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

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007.58B The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 007.58A. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in 007.58A.

007.58C The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 007.58A and B, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM.

007.59 Full Calibration Measurements.

007.59A A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

007.59A1 Before the first medical use of the unit; and

007.59A2 Before medical use under the following conditions:

007.59A2a Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

007.59A2b Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

007.59A2c Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

007.59A3 At intervals not exceeding one year.

007.59B To satisfy the requirement of 007.59A, full calibration measurements shall include determination of:

007.59B1 The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

007.59B2 The coincidence of the radiation field and the field indicated by the light beam localizing device;

007.59B3 The uniformity of the radiation field and its dependence on the orientation of the useful beam;

007.59B4 Timer accuracy, constancy, and linearity over the range of use;

007.59B5 "On-off" error; and

007.59B6 The accuracy of all distance measuring and localization devices in medical use.

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007.59C A licensee shall use the dosimetry system described in 007.58A to measure the output for one set of exposure conditions. The remaining radiation measurements required 007.59B1 may then be made using a dosimetry system that indicates relative dose rates.

007.59D A licensee shall make full calibration measurements required by 007.59A in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p.213. Both of these documents are incorporated herein by reference and available for viewing at the Department of Health and Human Services Regulation and Licensure, 301 Centennial Mall South, 3rd floor, Lincoln, Nebraska 68509-5007.

007.59E A licensee shall correct mathematically the outputs determined in 007.59B1 for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.

007.59F Full calibration measurements required by 007.59A and physical decay corrections required by 007.59E shall be performed by a teletherapy physicist.

007.59G A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer, linearity and constancy, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

007.60 Periodic Spot-Checks.

007.60A A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed one month.

007.60B To satisfy the requirement of 007.60A, spot-checks shall include determination of:

007.60B1 Timer constancy and timer linearity over the range of use;

007.60B2 On-off error;

007.60B3 The coincidence of the radiation field and the field indicated by the light beam localizing device;

007.60B4 The accuracy of all distance measuring and localization devices used for medical use;

007.60B5 The output for one typical set of operating conditions; and

007.60B6 The difference between the measurement made in 007.60B5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

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007.60C A licensee shall use the dosimetry system described in 007.58 to make the spot-check required in 007.60B5.

007.60D A licensee shall perform spot checks required by 007.60A, B, and C in accordance with procedures established by the radiological physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

007.60E A licensee shall have the teletherapy physicist review the results of each output spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for three years.

007.60F A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed one month.

007.60G To satisfy the requirement of 007.60F, safety spot-checks shall assure proper operation of:

007.60G1 Electrical interlocks at each teletherapy room entrance;

007.60G2 Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism);

007.60G3 Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

007.60G4 Viewing systems;

007.60G5 Treatment room doors from inside and outside the treatment room; and

007.60G6 Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

007.60H A licensee shall arrange for prompt repair of any system identified in 007.60F and G that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

007.60J A licensee shall maintain a record of each spot-check required by 007.60A, B, C, and F and G for three years. The record shall include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

007.61 Radiation Surveys for Teletherapy Facilities.

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007.61A Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 007.54A through D, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 007.20 to verify that:

007.61A1 The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 μ Sv (10 millirems) per hour and 20 μ Sv (2 millirems) per hour, respectively; and

007.61A2 With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

007.61A2a Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 004.06 of these regulations; and

007.61A2b Radiation levels in unrestricted areas do not exceed the limits specified in 004.14 of these regulations.

007.61B If the results of the surveys required in 007.61A indicate any radiation levels in excess of the respective limit specified in that part, the licensee shall lock the control in the off position and not use the unit:

007.61B1 Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

007.61B2 Until the licensee has received a specific exemption pursuant to 004.14 of these regulations from the Agency.

007.61C A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in μ Sv (millirems) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

007.62 Safety Spot Checks for Teletherapy Facilities.

007.62A A licensee shall promptly check all systems listed in 007.60F and G for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 007.54A through D.

007.62B If the results of the safety spot checks required in 007.62A indicate the malfunction of any system specified in 007.60F and G, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

007.62C A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the Radiation Safety Officer.

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007.63 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

If the survey required by 007.61 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 004.14 of these regulations, before beginning the treatment program the licensee shall:

007.63A Either equip the unit with stops or add additional radiation shielding to ensure compliance with 004.14C of these regulations;

007.63B Perform the survey required by 007.61 again; and

007.63C Include in the report required by 007.64 the results of the initial survey, a description of the modification made to comply with 007.63A, and the results of the second survey; or

007.63D Request and receive a license amendment under 004.14C of these regulations that authorized radiation levels in unrestricted areas greater than those permitted by 004.14A2 of these regulations.

007.64 Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in 007.61, 007.62, 007.63 and the output from the teletherapy source expressed in roentgens, coulombs/kilogram, rads, or grays per hour at one meter from the source as determined during the full calibration required in 007.59 to the Agency within 30 days following completion of the action that initiated the record requirement.

007.65 Five-Year Inspection.

007.65A A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

007.65B This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State.

007.65C A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

SPECIFIC REQUIREMENTS FOR TRAINING

007.66 Training and Experience. The training and experience requirements for individuals using radioactive materials in this Section are as follows:

007.66A **Radiation Safety Officer.** The licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who:

007.66A1 Is certified by:

007.66A1a American Board of Health Physics in Comprehensive Health Physics;

007.66A1b American Board of Radiology;

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007.66A1c American Board of Nuclear Medicine;

007.66A1d American Board of Science in Nuclear Medicine;

007.66A1e Board of Pharmaceutical Specialties in Nuclear Pharmacy;

007.66A1f American Board of Medical Physics in radiation oncology physics;

007.66A1g Royal College of Physicians and Surgeons of Canada in nuclear medicine;

007.66A1h American Osteopathic Board of Radiology; or

007.66A1i American Osteopathic Board of Nuclear Medicine; or

007.66A2 Has had classroom and laboratory training and experience as follows:

007.66A2a Two-Hundred (200) hours of classroom and laboratory training that includes:

007.66A2a(1) Radiation physics and instrumentation;

007.66A2a(2) Radiation protection;

007.66A2a(3) Mathematics pertaining to the use and measurement of radioactivity;

007.66A2a(4) Radiation biology; and

007.66A2a(5) Radiopharmaceutical chemistry; and

007.66A2b One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission or an Agreement State license that authorizes the medical use of radioactive material; or

007.66A3 Be an authorized user identified on the licensee's license.

007.66B Training for Uptake, Dilution, and Excretion Studies. The licensee shall require the authorized user of a radiopharmaceutical in 007.34 to be a physician who:

007.66B1 Is certified in:

007.66B1a Nuclear medicine by the American Board of Nuclear Medicine; or

007.66B1b Diagnostic radiology by the American Board of Radiology; or

007.66B1c Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

007.66B1d Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;
or

007.66B1e American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

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007.66B2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

007.66B2a Forty (40) hours of classroom and laboratory training that includes:

007.66B2a(1) Radiation physics and instrumentation;

007.66B2a(2) Radiation protection;

007.66B2a(3) Mathematics pertaining to the use and measurement of radioactivity;

007.66B2a(4) Radiation biology; and

007.66B2a(5) Radiopharmaceutical chemistry; and

007.66B2b Twenty (20) hours of clinical experience under the supervision of an authorized user and includes:

007.66B2b(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

007.66B2b(2) Selecting an appropriate radiopharmaceutical and measuring the dosages;

007.66B2b(3) Administering dosages to patients or human research subjects using syringe radiation shields;

007.66B2b(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and

007.66B2b(5) Patient or human research subject follow-up; or

007.66B2c Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all topics identified in paragraph 007.66B2b of this Part.

007.66C Training for Imaging and Localization Studies. The licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in this group to be a physician who:

007.66C1 Is certified in:

007.66C1a Nuclear medicine by the American Board of Nuclear Medicine; or

007.66C1b Diagnostic radiology by the American Board of Radiology; or

007.66C1c Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

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007.66C1d Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;
or

007.66C1e American Osteopathic Board of Nuclear Medicine; or

007.66C2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

007.66C2a Two-Hundred (200) hours of classroom and laboratory training that includes:

007.66C2a(1) Radiation physics and instrumentation;

007.66C2a(2) Radiation protection;

007.66C2a(3) Mathematics pertaining to the use and measurement of radioactivity;

007.66C2a(4) Biological effects of radiation; and

007.66C2a(5) Radiopharmaceutical chemistry; and

007.66C2b Five-Hundred (500) hours of work experience under the supervision of an authorized user that includes:

007.66C2b(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

007.66C2b(2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

007.66C2b(3) Calculating and safely preparing patient or human research subject dosages;

007.66C2b(4) Using administrative controls to prevent the misadministration of radioactive material;

007.66C2b(5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

007.66C2b(6) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

007.66C2c Five-Hundred (500) hours of clinical experience under the supervision of an authorized user that includes:

007.66C2c(1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

007.66C2c(2) Selecting an appropriate radiopharmaceutical and measuring the dosages;

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007.66C2c(3) Administering dosages to patients or human research subjects using syringe radiation shields;

007.66C2c(4) Collaborating with the authorized user in the interpretation of radioisotope test results; and

007.66C2c(5) Patient or human research subject follow-up; or

007.66C3 Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph 007.66C2 of this Part.

NOTE: The requirements specified in sections 007.66C2a, 007.66C2b, and 007.66C2c may be satisfied concurrently if all three are included in the training program. Each physician named in Item 4 of Form NRH-5A (Medical/Teletherapy) must complete a separate Form NRH-5A (Medical/Teletherapy) Supplement A (Training and Experience, Authorized User or Radiation Safety Officer) and Form NRH-5A (Medical/Teletherapy) Supplement B (Preceptor Statement).

007.66D **Training for Therapeutic Use of Unsealed Radioactive Material.** The licensee shall require the authorized user of unsealed radioactive material in 007.40 to be a physician who:

007.66D1 Is certified by:

007.66D1a The American Board of Nuclear Medicine; or

007.66D1b The American Board of Radiology in radiology, therapeutic radiology or radiation oncology; or

007.66D1c Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

007.66D1d The American Osteopathic Board of Radiology after the effective date of these regulations; or

007.66D2 Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic unsealed radioactive materials, and supervised clinical experience as follows:

007.66D2a Training in basic radioisotope handling techniques of eighty (80 hours), including

007.66D2a(1) Radiation physics and instrumentation;

007.66D2a(2) Radiation protection;

007.66D2a(3) Mathematics pertaining to the use and measurement of radioactivity; and

007.66D2a(4) Radiation biology; and

007.66D2b Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

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007.66D2b(1) Use of Iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction 10 (ten) individuals; and

007.66D2b(2) Use of Iodine-131 for treatment of thyroid carcinoma in 3 (three) individuals.

007.66D2b(3) Use of Phosphorous-32 for treatment of polycythemia vera, leukemia and /or bone metastases in 3 (three) individuals.

007.66D2b(4) Use of Colloidal Phosphorous-32 for intracavitary treatment in 3 (three) individuals.

007.66D2b(5) Use of Colloidal Gold-198 for intracavitary treatment in 3 (three) individuals.

007.66D2b(6) Use of Strontium-89 for intracavitary treatment in 3 (three) individuals.

007.66D2b(7) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA), or an approved "Product License Approval" (PLA).

007.66E **Training For On-Site Physician.** The on-site physician shall have a minimum of forty (40) hours of formal training in basic radiological handling techniques.

007.66F **Training for Use of Brachytherapy Sources.** The licensee shall require the authorized user of a brachytherapy source listed in 007.46 for therapy to be a physician who is:

007.66F1 Certified in:

007.66F1a Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;

007.66F1b Radiation oncology by the American Osteopathic Board of Radiology;

007.66F1c Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology;" or "Fellow of the Royal College of Radiology"; or

007.66F1d Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

007.66F2 Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

007.66F2a Two-Hundred (200) hours of classroom and laboratory training that includes:

007.66F2a(1) Radiation physics and instrumentation

007.66F2a(2) Radiation protection

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007.66F2a(3) Mathematics pertaining to the use and measurement of radioactivity

007.66F2a(4) Radiation biology

007.66F2b Five-Hundred (500) hours of work experience under the supervision of an authorized user at a medical institution that includes:

007.66F2b(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

007.66F2b(2) Checking survey meters for proper operation;

007.66F2b(3) Preparing, implanting, and removing sealed sources;

007.66F2b(4) Maintaining running inventories of material on hand;

007.66F2b(5) Using administrative controls to prevent the misadministration of radioactive material; and

007.66F2b(6) Using emergency procedures to control radioactive material; and

007.66F2c Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

007.66F2c(1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

007.66F2c(2) Selecting the proper brachytherapy sources and dose and method of administration;

007.66F2c(3) Calculating the dose; and

007.66F2c(4) Post-administration follow-up and review of case histories in collaboration with the authorized user.

007.66G **Training for Ophthalmic Use of Strontium-90.** The licensee shall require the authorized user of only Strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

007.66G1 Twenty-Four (24) hours of classroom and laboratory training that includes:

007.66G1a Radiation physics and instrumentation;

007.66G1b Radiation protection;

007.66G1c Mathematics pertaining to the use and measurement of radioactivity; and

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007.66G1d Radiation biology;

007.66G2 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Strontium-90 for the ophthalmic treatment of five individuals that includes:

007.66G2a Examination of each individual to be treated;

007.66G2b Calculation of the dose to be administered;

007.66G2c Administration of the dose; and

007.66G2d Follow-up and review of each individuals case history.

007.66H **Training for Use of Sealed Sources for Diagnosis.** The licensee shall require the authorized user of a sealed source in a device listed in 007.44 to be a physician, dentist, or podiatrist who:

007.66H1 Is certified in:

007.66H1a Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;

007.66H1b Nuclear medicine by the American Board of Nuclear Medicine; or

007.66H1c Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

007.66H1d Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

007.66H2 Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

007.66H2a Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

007.66H2b Radiation biology;

007.66H2c Radiation protection; and

007.66H2d Training in the use of the device for the uses requested.

007.66I **Training for Teletherapy.** The licensee shall require the authorized user of a sealed source listed in 007.52 in a teletherapy unit to be:

007.66I1 A physician who is authorized to practice medicine in Nebraska.

007.66I2 Certified in:

007.66I2a Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;

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007.6612b Radiation oncology by the American Osteopathic Board of Radiology; or

007.6612c Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

007.6612d Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

007.6613 Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

007.6613a Two-Hundred (200) hours of classroom and laboratory training that includes:

007.6613a(1) Radiation physics and instrumentation;

007.6613a(2) Radiation protection;

007.6613a(3) Mathematics pertaining to the use and measurement of radioactivity; and

007.6613a(4) Radiation biology;

007.6613b Five-Hundred (500) hours of work experience under the supervision of an authorized user at a medical institution that includes:

007.6613b(1) Review of the full calibration measurements and periodic spot checks;

007.6613b(2) Preparing treatment plans and calculating treatment times;

007.6613b(3) Using administrative controls to prevent misadministrations;

007.6613b(4) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

007.6613b(5) Checking and using survey meters; and

007.6613c Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

007.6613c(1) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

007.6613c(2) Selecting the proper dose and how it is to be administered;

007.6613c(3) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by individuals' reaction to radiation; and

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007.66I3c(4) Post-administration follow-up and review of case histories.

007.66J Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to be an individual who:

007.66J1 Is certified by the American Board of Radiology in:

007.66J1a Therapeutic radiological physics;

007.66J1b Roentgen ray and gamma ray physics;

007.66J1c X-ray and radium physics; or

007.66J1d Radiological Physics; or

007.66J2 Is certified by the American Board of Medical Physics in radiation oncology physics;
or

007.66J3 Holds a master's or doctor's degree in physics, biophysics, radiological physics or health physics, and has completed one year full time training in therapeutic radiological physics and an additional year of full time experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in 007.24, 007.59, 007.60, and 007.61.

007.66K Physician Training in a Three Month Program. A physician who, before the effective date of these regulations, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of 007.66B or 007.66C.

007.66L Recentness of Training. The training and experience specified in this subpart must have been obtained within 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

007.66M Training And Experience Requirements For Nuclear Medicine Technologists.

007.66M1 The licensee shall require that a technologist who uses any radiopharmaceutical, generator, or reagent kit in 007.36 be an individual who:

007.66M1a Is certified in nuclear medicine by the:

007.66M1a(1) American Registry of Radiologic Technologists; or

007.66M1a(2) Nuclear Medicine Technology Certification Board; or

007.66M1b Has completed an integrated program of full-time training and experience that includes classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised handling experience, and supervised clinical experience as follows:

007.66M1b(1) 200 hours of classroom and laboratory training that include:

007.66M1b(1)(a) Radiation physics and instrumentation;

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007.66M1b(1)(b) Radiation protection policy, management, procedures, and regulations;

007.66M1b(1)(c) Mathematics of radiation and radioactivity;

007.66M1b(1)(d) Radiopharmaceutical chemistry;

007.66M1b(1)(e) Imaging technology; and

007.66M1b(1)(f) Radiation biology.

007.66M1b(2) Supervised handling experience under the supervision of an authorized user or practicing technologist that includes:

007.66M1b(2)(a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

007.66M1b(2)(b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

007.66M1b(2)(c) Calculating and safely preparing stock radiopharmaceuticals and individual dosages.

007.66M1b(2)(d) Using administrative controls to prevent the misadministration of radioactive material;

007.66M1b(2)(e) Containing spilled radioactive material and decontaminating; and

007.66M1b(2)(f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and assaying radiopharmaceuticals to determine the portion of radioactivity bound to the radiopharmaceutical.

007.66M1b(3) Supervised clinical experience under the supervision of an authorized user that includes:

007.66M1b(3)(a) Reviewing the case histories of individuals to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

007.66M1b(3)(b) Identifying radiopharmaceuticals for clinical procedures and calculating and measuring the dosages;

007.66M1b(3)(c) Administering dosages to individuals and using syringe radiation shields; and

007.66M1b(3)(d) Acquiring and manipulating diagnostic data.

007.66N Training And Experience Requirements For Radiation Therapists.

007.66N1 The licensee shall require that a radiation therapist who uses any source of radiation for therapy listed in Sections 006, 007 or 009 be an individual who:

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007.66N1a Is certified in radiation therapy technology by the American Registry of Radiologic Technologists; or

007.66N1b Has completed an integrated program of full-time training and experience that includes classroom and laboratory training applicable to the use of a source of radiation, supervised work experience, and supervised clinical experience as follow:

007.66N1b(1) 200 hours of classroom and laboratory training that include:

007.66N1b(1)(a) Radiation physics and instrumentation;

007.66N1b(1)(b) Radiation protection policy, management, procedures, and regulations;

007.66N1b(1)(c) Mathematics of radiation and radioactivity; and

007.66N1b(1)(d) Radiation biology;

007.66N1b(2) Supervised work experience under the supervision of an authorized user or practicing radiation therapist that includes;

007.66N1b(2)(a) Review of the full calibration measurements and periodic spot checks as appropriate;

007.66N1b(2)(b) Preparing treatment plans for prescriptions and calculating treatment times;

007.66N1b(2)(c) Using administrative controls to prevent misadministrations;

007.66N1b(2)(d) Implementing emergency procedures to be followed in the event of the abnormal operation of equipment; and

007.66N1b(2)(e) Checking and using survey meters; and

007.66N1b(3) Supervised clinical experience under the supervision of an authorized user or a practicing radiation therapist, that includes:

007.66N1b(3)(a) Reviewing the case histories of individuals to determine their suitability for treatment, and any limitations or contraindications;

007.66N1b(3)(b) Selecting the proper doses and how it is to be administered;

007.66N1b(3)(c) Reviewing calculations of radiation source doses for accuracy and completeness; and monitoring patients or human research subjects reaction to radiation, and bringing discrepancies to the authorized user's attention.

007.66N1b(3)(d) Application of radiation to individuals, including the use of beam modifying devices, based on the instructions in the individual's chart; and

007.66N1b(3)(e) Making and reviewing records of the medical use of radiation.

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007.66O Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

007.66O1 Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

007.66O2 Has completed seven-hundred (700) hours in structured educational program consisting of both:

007.66O2a Didactic training in the following areas:

007.66O2a(1) Radiation physics and instrumentation;

007.66O2a(2) Radiation protection;

007.66O2a(3) Mathematics pertaining to the use and measurement of radioactivity;

007.66O2a(4) Chemistry of radioactive material for medical use; and

007.66O2a(5) Radiation biology; and

007.66O2b Supervised experience in a nuclear pharmacy involving the following:

007.66O2b(1) Shipping, receiving, and performing related radiation surveys;

007.66O2b(2) Using and performing checks for proper operation of dose calibrators, and survey meters, and if appropriate, instruments used to measure alpha- or beta-emitting radionuclides

007.66O2b(3) Calculating, assaying and safely preparing dosages for individuals;

007.66O2b(4) Using administrative controls to avoid mistakes in the administration of radioactive material;

007.66O2b(5) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

007.66O3 Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

007.66P Training for Experienced Nuclear Pharmacists. A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 007.66O2 before the effective date of these regulations, and who is working in a nuclear pharmacy as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (007.66O3) and recentness of training (007.66L) to qualify as an authorized nuclear pharmacist.

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Section 008 RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

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008 RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

008.01 Purpose and Scope.

008.01A This section provides special requirements for analytical x-ray equipment.

008.01B The requirements of this section are in addition to, and not in substitution for applicable requirements in Sections 001, 002, 003, 004, 010, 015, 017 and 018 of these regulations.

008.02 Definitions. As used in this Section, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x or gamma rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of safety or warning device.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housing, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures which are related to radiation safety.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

008.03 Equipment Requirements.

008.03A Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the Agency for an exemption from the requirement of a safety device. Such exemption shall be granted provided that the Agency makes a finding that the exemption will not constitute a significant risk to the health and safety of the public. Such application shall include:

008.03A1 A description of the various safety devices that have been evaluated;

008.03A2 The reason each of these devices cannot be used; and

008.03A3 A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

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008.03B Warning Devices.

008.03B1 Open-beam configurations shall be provided with a readily discernible indication of:

008.03B1a X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

008.03B1b Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

008.03B2 Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after June 27, 1983, warning devices shall have fail-safe characteristics.

008.03C Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

008.03D Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

008.03D1 "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and

008.03D2 "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

008.03D3 "CAUTION - RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with Subsection 004.32 of these regulations if the radiation source is a radionuclide.

008.03E Shutters. On open-beam configurations installed after June 27, 1983, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

008.03F Warning Lights.

008.03F1 An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located:

008.03F1a Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

008.03F1b In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

008.03F2 On equipment installed after June 27, 1983, warning lights shall have fail-safe characteristics.

008.03G Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

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008.03G1 Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

008.03G2 Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 0.025 mSv (2.5 mrem) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

008.03H Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 2.5 uSv (0.25 mrem) in one hour.

008.04 Area Requirements.

008.04A Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Subsection 004.14 of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

008.04B Surveys.

008.04B1 Radiation surveys, as required by Subsection 004.22 of these regulations, of all analytical x-ray systems sufficient to show compliance with 008.04A shall be performed:

008.04B1a Upon installation of the equipment and at least once every 12 months thereafter;

008.04B1b Following any change in the initial arrangement, number, or type of local components in the system;

008.04B1c Following any maintenance requiring the disassembly or removal of a local component in the system;

008.04B1d During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

008.04B1e Any time a visual inspection of the local components in the system reveals an abnormal condition; and

008.04B1f Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in Subsection 004.06 of these regulations.

008.04B2 Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the Agency with 008.04A in some other manner.

008.04C Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION X-RAY EQUIPMENT" or words having a similar intent in accordance with Subsection 004.32 of these regulations.

008.05 Operating Requirements.

008.05A Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

008.05B Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed on the radiation source housing.

008.05C Repair or Modification of X-Ray Tube Systems. Except as specified in 008.05B, no operation involving removal of covers, shielding materials or tube housing or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

008.05D Radioactive Source Replacement, Testing, or Repair. Radioactive source housing shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

008.06 Personnel Requirements.

008.06A Instruction. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction in and demonstrated competence as to:

008.06A1 Identification of radiation hazards associated with the use of the equipment;

008.06A2 Significance of the various radiation warning and safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

008.06A3 Proper operating procedures for the equipment;

008.06A4 Recognition of symptoms of an acute localized exposure;

008.06A5 Proper procedures for reporting an actual or suspected exposure; and

008.06A6 Has met the training requirements specified in Subsection 015.28 of these regulations.

008.06B Personnel Monitoring.

008.06B1 Finger or wrist dosimetric devices shall be provided to and shall be used by:

008.06B1a Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

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008.06B1b Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

008.06B2 Reported dose values shall not be used for the purpose of determining compliance with Subsection 004.06 of these regulations unless evaluated by a qualified expert as specified in Part 015.13C of these regulations.

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Section 009 RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

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009 RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

009.01 Purpose and Scope.

009.01A This section establishes procedures for the registration and use of particle accelerators.

009.01B In addition to the requirements of this Section, all registrants are subject to the requirements of Sections 001, 002, 004, 010, 015, 017 and 018 of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Section 005 of these regulations. Registrants engaged in the healing arts are subject to the requirements of Section 006 and/or 007 of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Section 003 of these regulations.

REGISTRATION PROCEDURE

009.02 Registration Requirements. No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Section 002 of these regulations.

009.03 General Operating Requirements for the Issuance of a Registration for Particle Accelerators.

In addition to the requirements of Section 002 of these regulations, registration application for use of a particle accelerator will be approved only if the Agency determines that:

009.03A The applicant has appointed a radiation safety officer;

009.03B The applicant has established a radiation safety committee to approve, in advance, proposals for use of a particle accelerator(s);

009.03C The applicant's proposed or existing equipment, facilities and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property as required in Subsections 009.04 through 009.10;

009.03D The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Section and Sections 004 and 010 of these regulations in such a manner as to minimize danger to public health and safety or property;

009.03E The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 009.04;

009.03F The applicant and/or the applicant's staff has training and experience in the use of particle accelerators as specified in Section 015 of these regulations.

009.04 Human Use of Particle Accelerators. In addition to the requirements of Section 002 of these regulations, a registration for use of a particle accelerator in the healing arts will be issued only if:

009.04A The applicant has appointed a radiation safety committee of at least three members to oversee the use of the particle accelerator, and to review the institution's radiation safety program. Membership of the committee should include at least the following: an authorized user, a representative of the institution's management and the Radiation Safety Officer.

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009.04B The individuals designated on the application as the users have training and experience as designated in Subsection 015.05 in deep therapy techniques or in the use of particle accelerators to treat humans; and

009.04C The individuals designated on the application as the users are physicians.

009.04D Any applicant employing Radiation Therapists to perform radiation therapy procedures shall require that they have training and experience requirements as specified in Subsection 015.21 of these regulations.

RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

009.05 Operator Qualifications. No person shall operate an accelerator until they meet the training requirements of Subsection 015.24 (accelerators under 1 MeV) or Subsection 015.25 (non-human use accelerators above 1 MeV).

009.06 Limitations.

009.06A No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

009.06A1 Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

009.06A2 Has received copies of and instruction in this Section and the applicable requirements of Section 004 and Section 010 of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

009.06A3 Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

009.06B The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

009.07 Shielding and Safety Design Requirements.

009.07A A radiological physicist as specified in Parts 015.13A or 015.13B of these regulations shall be consulted in the design of a particle accelerator installation, shall submit a plan review prior to construction and shall perform a radiation survey when the accelerator is first capable of producing radiation. A copy of the survey results shall be submitted to the Agency for review.

009.07B Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with Subsections 004.06 and 004.14 of these regulations.

009.08 Particle Accelerator Controls and Interlock Systems.

009.08A Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

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009.08B Each entrance into a target room or other high radiation area shall be provided with a safety interlock(s) that shuts down the machine under conditions of barrier penetration.

009.08C When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

009.08D Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

009.08E All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

009.08F A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

009.09 Warning Devices.

009.09A Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

009.09B Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all radiation areas.

009.09C Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with Subsection 004.32 of these regulations.

009.10 Operating Procedures.

009.10A Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

009.10B The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

009.10C All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed six months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.

009.10D Electrical circuit diagrams of the accelerator and the associated interlock system shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.

009.10E If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

009.10E1 Authorized by the radiation safety committee and/or radiation safety officer;

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009.10E2 Recorded in a permanent log and a notice posted at the accelerator control console;
and

009.10E3 Terminated as soon as possible.

009.10F A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

009.11 Radiation Monitoring Requirements.

009.11A There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated, for the radiation being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

009.11B A radiation protection survey shall be performed, and documented by a radiological physicist as specified in Parts 015.13A or 015.13B of these regulations, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

009.11C Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electronically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

009.11D All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

009.11E Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

009.11F Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

009.11G All surveys shall be made in accordance with the written procedures established by a radiological physicist as specified in Parts 015.13A or 015.13B of the regulations, or the radiation safety officer.

009.11H Records of all radiation protection surveys, calibration and instrumentation tests, shall be maintained at the accelerator facility for inspection by the Agency.

009.12 Ventilation Systems.

009.12A Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Section 004, Appendix 004-B, Table I of these regulations.

009.12B A registrant, as required by Subsection 004.15 of these regulations, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceed the limits specified in Section 004, Appendix 004-B, Table II of these regulations, except as authorized pursuant to Subsections 004.39 or 004.15 of these regulations. For purposes of 009.12B, concentrations may be averaged over a period of not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

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Section 010 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS

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010 NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS

010.01 Purpose and Scope.

010.01A This section establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, orders and licenses issued there under regarding radiological working conditions.

010.01B The regulations in this section apply to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the Agency pursuant to Sections 002, 003, 005, 006, 007, 008, 009, 011, 012, 013 and 014 of these regulations.

010.02 Posting of Notices to Workers.

010.02A Each licensee or registrant shall post current copies of the following documents:

010.02A1 The regulations in this section and in Section 004 of these regulations;

010.02A2 The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

010.02A3 The operating procedures applicable to activities under the license or registration; and

010.02A4 Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Section 017 of these regulations, and any response from the licensee or registrant.

010.02B If posting of a document specified in 010.02A1, 2, or 3 is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

010.02C Agency Form NRH-3, "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

010.02D Agency documents posted pursuant to 010.02A4 shall be posted within 2 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

010.02E Documents, notices or forms posted pursuant to 010.02 shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

010.03 Instructions to Workers.

010.03A All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be:

010.03A1 Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

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010.03A2 Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

010.03A3 Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these regulations and licenses for the protection of personnel from exposures to radiation or radioactive material;

010.03A4 Instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to, constitute, or cause a violation of the Act, these regulations, and licenses or unnecessary exposure to radiation or radioactive material;

010.03A5 Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

010.03A6 Advised as to the radiation exposure reports which workers shall be furnished pursuant to 010.04.

010.03B In determining those individuals subject to the requirements of 010.03A of this section, licensees or registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensee's or registrant's facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place and shall be performed annually.

010.03C Records of the instructions to workers required by subsection 010.03 shall be maintained by the licensee and/or registrant until reviewed by the Agency.

010.04 Notifications and Reports to Individuals.

010.04A Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 010.04. The information reported shall include data and results obtained pursuant to these regulations, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 004.51 of these regulations. Each notification and report shall:

010.04A1 Be in writing;

010.04A2 Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

010.04A3 Include the individual's exposure information; and

010.04A4 Contain the following statement:

"This report is furnished to you under the provisions of Nebraska Regulations for Control of Radiation-Ionizing Section 010. You should preserve this report for further reference."

010.04B Each licensee or registrant shall furnish each worker annually a written report of the worker's dose as shown in records maintained by the licensee or registrant pursuant to Subsection 004.51 of these regulations.

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010.04C Each licensee or registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to Subsection 004.23 of these regulations. Such report shall be furnished within 30 days from the date of request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

010.04D Each licensee or registrant shall furnish to each worker a report of the worker's results of any measurements, analyses and calculations of radioactive material deposited or retained in the body. Such report shall be furnished to the worker within 30 days of such determination by the licensee or registrant.

010.04E When a licensee or registrant is required pursuant to 004.57, 004.58, or 004.59 of these regulations to report to the Agency any exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

010.04F At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

010.05 Presence of Representatives of Licensees or Registrants and Workers During Inspection.

010.05A Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

010.05B During an inspection, Agency inspectors may consult privately with workers as specified in 010.06. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

010.05C If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

010.05D Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 010.03.

010.05E Different representatives of licensees or 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.

010.05F With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example,

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a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

010.05G Notwithstanding the other provisions of 010.05, Agency 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 shall be an individual previously authorized by the licensee or registrant to enter that area.

010.06 Consultation with Workers During Inspections.

010.06A Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

010.06B 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, these regulations, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 010.07A.

010.06C The provisions of 010.06B shall not be interpreted as authorization to disregard instructions pursuant to 010.03.

010.07 Requests by Workers for Inspections.

010.07A Any worker or representative of workers who believes that a violation of the Act, these regulations or license conditions exists or has occurred in work under a license or registration to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

010.07B If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in 010.07A, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to 010.07 need not be limited to matters referred to in the complaint.

010.07C No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this section.

010.08 Inspections Not Warranted; Informal Review.

010.08A Review of determination that no inspection is warranted.

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010.08A1 If the Agency determines, with respect to a complaint under 010.07, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall 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 Regulation and Licensure, who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position to the Director of Regulation and Licensure, will provide the complainant with a copy of such statement by certified mail.

010.08A2 Upon the request of the complainant, the Director of Regulation and Licensure, may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or 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 Regulation and Licensure, shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

010.08B If the Agency determines that an inspection is not warranted because the requirements of 010.07A have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 010.07A.

Section 011

**REQUIREMENTS FOR RADON AND RADON PROGENY
MEASUREMENT AND MITIGATION SERVICES**

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011 REQUIREMENTS FOR RADON AND RADON PROGENY MEASUREMENT AND MITIGATION SERVICES.

011.01 Purpose and Scope.

011.01A This section provides for the licensure of radon measurement specialists, radon measurement technicians, radon measurement businesses, radon mitigation specialists, radon mitigation technicians, and radon mitigation businesses.

011.01B In addition to the requirements of this section, all licensees are subject to Sections 001, 004, 010, 017, and 018 and Subsections 003.10, 003.18, 003.19, 003.20 and 003.21 and Parts 003.11B and 003.11C.

011.02 Definitions. As used in this section, the following definitions apply.

011.02A "Diagnostic Tests" means tests performed or procedures used to determine appropriate radon mitigation systems for a building.

011.02B "Mitigation" means any action taken to reduce radon or radon progeny concentrations in the indoor atmosphere or to prevent entry of radon or radon progeny into the atmosphere, to include but not be limited to, application of materials, installation of systems, or any repair or alteration of a building or design.

011.02C "Mitigation System" means any system or materials installed for the purpose of reducing radon or radon progeny concentrations.

011.02D "Picocurie per liter" (pCi/l) means 2.22 transformations per minute of radioactive material per liter of air.

011.02E "Radon" means the radioactive noble gas radon-222 (Rn-222) and as used in these regulations includes radon progeny (see 011.02L).

011.02F "Radon Measurement Business" means a person, including a laboratory, who analyzes or tests for and measures radon or radon progeny concentrations and which employs one or more radon measurement specialist.

011.02G "Radon Measurement Specialist" means an individual who performs radon or radon progeny measurements; or provides professional advice on radon or radon progeny measurements, health risks, radon-related exposure, radon entry routes, or other radon-related activities; and may perform the duties of a radon measurement technician.

011.02H "Radon Measurement Technician" means an individual who performs radon or radon progeny measurement activities or provides information on test results.

011.02I "Radon Mitigation Business" means a person that mitigates radon.

011.02J "Radon Mitigation Specialist" means an individual who designs mitigation systems, or an individual who performs and evaluates diagnostic tests to determine appropriate radon or radon progeny mitigation systems and may perform the duties of a radon mitigation technician.

011.02K "Radon Mitigation Technician" means an individual who installs or supervises the installation of radon or radon progeny mitigation systems on existing buildings.

011.02L "Radon Progeny" means the short-lived radionuclides formed as a result of the decay of radon-222, including polonium-218, lead-214, bismuth-214, and polonium-214.

011.02M "Working Level (WL)" means the concentration of short-lived radon progeny that will result in $1.3E + 5$ million electron volts of potential alpha particle energy per liter of air.

011.03 Exemptions.

011.03A The licensure requirements of this section shall not apply to:

011.03A1 Individuals measuring or mitigating the premises in which they reside.

011.03A2 Federal, state, county and local health departments and their employees who provide professional advice on radon measurement or mitigation activities in the course of their assigned duties.

011.03A3 County extension agents and specialists of the Cooperative Extension Service of the University of Nebraska who provide professional advice on radon measurement or mitigation activities in the course of their assigned duties.

011.04 General Provisions.

011.04A Beginning on the effective date of these regulations, no person may provide services for the measurement or mitigation of the presence of radon in the State of Nebraska unless such person has been licensed as provided in this section. These regulations in no way exempt any person from other state or local occupational licensure requirements.

011.04B Any person who is informed of the results of radon measurements must also be informed of the date of the test, name, and license number of the person who made the measurements.

011.04C No license shall be approved unless the following conditions have been met:

011.04C1 The applicant has not been found to be in violation of the Act, or this section and has not had a license or certification terminated.

011.04C2 The applicant has filed an accurate and complete license application with the license fee.

011.04C3 The applicant is qualified to perform the activities for which she/he is seeking licensure, including the training and experience required in this section and that the applicant's proposed equipment and procedures are adequate to minimize danger to the public health and safety or property and are in compliance with municipal, county, state and federal laws and regulations.

011.04D Requirements for continued licensure shall include, at a minimum, the following conditions:

011.04D1 The licensee shall conduct his/her activities as described in the approved license and in accordance with provisions of the Act, all sections of these regulations, and all other related municipal, county, state, and federal laws and regulations.

011.04D2 The licensee shall allow authorized representatives of the Agency to have access during normal business hours to his/her facilities, offices and files for inspection and examination of radon-related records and test procedures. The licensee shall also allow authorized representatives of the Agency to accompany him/her while performing any radon measurement or mitigation activities for the purpose of inspecting these activities,

with the approval of the property owner or resident on whose property such activity is being performed.

011.04D3 The licensee shall remain in compliance with the Act, and this section. Any changes in the information provided in the original or renewal application, including changes in licensed personnel, shall be submitted as an amendment request to the Agency for approval prior to implementation.

011.04E A license will be valid for one year following the date of issuance. No radon measurement or mitigation activity shall be conducted after the expiration of the term of the license.

011.04F An application for annual license renewal shall be made on the same form, as that required for initial licensure and shall be accompanied by the fee specified in 011.15. A license renewal shall be issued or denied according to the criteria set forth in this section.

011.04G Applications for initial and renewal license shall be submitted along with the fees specified in 011.15 to the Department of Health and Human Services Regulation and Licensure, P.O. Box 95007, Lincoln, NE 68509-5007. Checks or money orders shall be made payable to Department of Health and Human Services Regulation and Licensure.

011.04H All applications should clearly label any information considered proprietary and segregate such information from non-proprietary information to the extent possible (Neb.Rev.Stat. § 84-712.05(3) and Neb.Rev.Stat. § 87-502).

011.05 License Requirements for Radon Measurement Specialists.

011.05A The following qualifications are required for licensure as a radon measurement specialist:

011.05A1 The individual shall submit an application that contains the following information to the Agency, along with the fee specified in 011.15.

011.05A1a Applicant name, mailing address (including city, state, ZIP) and phone number.

011.05A1b Radon related education, training and experience (including copies of certificates or letters of successful completion).

011.05A2 The individual shall have one year's experience in radiation or radioactivity measurements or any combination of two years of relevant college education or relevant work experience.

011.05A2a Relevant college education means a curriculum in physical sciences, biological sciences or engineering. Upon application the Agency may approve a related discipline.

011.05A2b Relevant work experience means the use of equipment to conduct measurement or analysis of a technical or environmental nature.

011.05A3 The individual shall have successfully completed a training course and passed an examination on radon measurements, approved by the Agency.

011.05A4 The individual shall participate in a radon proficiency program that the Agency has determined to meet the requirements of 011.12.

011.06 License Requirements for Radon Measurement Technicians.

011.06A The following qualifications are required for licensure as a radon measurement technician.

011.06A1 The individual shall submit an application that contains the following information to the Agency, along with the fee specified in 011.15.

011.06A1a Applicant name, mailing address (including city, state, ZIP) and phone number.

011.06A1b Radon related education, training and experience (including copies of certificates or letters of successful completion).

011.06A2 The individual shall have at least six months of experience in radiation or radioactivity measurements or any combination of one year of relevant college education or relevant work experience.

011.06A2a Relevant college education means a curriculum in physical sciences, biological sciences or engineering. Upon application the Agency may approve a related discipline.

011.06A2b Relevant work experience means the use of equipment to conduct measurement or analysis of a technical or environmental nature.

011.06A3 The individual shall have successfully completed a training course and passed an examination on radon measurements approved by the Agency.

011.06A4 The individual shall participate in a radon proficiency program that the Agency has determined to meet the requirements of 011.12.

011.07 License Requirements for Radon Mitigation Specialists.

011.07A The following qualifications are required for licensure as a radon mitigation specialist:

011.07A1 The individual shall submit an application that contains the following information to the Agency, along with the fee specified in 011.15.

011.07A1a Applicant name, mailing address (including city, state, ZIP) and phone number.

011.07A1b Radon related education, training and experience (including copies of certificates or letters of successful completion).

011.07A2 The applicant shall possess any combination of two years of relevant college education or relevant work experience.

011.07A2a Relevant college education means a curriculum in architecture, engineering, physical sciences, or related disciplines. A year of college education shall consist of a minimum of 24 credit hours or equivalent.

011.07A2b Relevant work experience means the design, construction and renovation of buildings, or associated heating, ventilation, and air conditioning systems.

011.07A3 The individual shall have successfully completed a training course and passed an examination on radon measurement and mitigation approved by the Agency.

011.07A4 The individual shall participate in a radon proficiency program that the Agency has determined to meet the requirements of 011.12.

011.08 License Requirements for Radon Mitigation Technicians.

011.08A The following qualifications are required for licensure as a radon mitigation technician.

011.08A1 The individual shall submit an application that contains the following information to the Agency, along with the fee specified in 011.15.

011.08A1a Applicant name, mailing address (including city, state, ZIP) and phone number.

011.08A1b Radon related education, training and experience (including copies of certificates or letters of successful completion).

011.08A2 The individual shall have attained a minimum of one year experience in the building or construction trades. For purposes of this section, experience in the installation of mitigation systems under the supervision of a radon mitigation specialist shall qualify as building experience.

011.08A3 The individual shall have successfully completed a training course and passed examination on radon mitigation approved by the Agency.

011.08A4 The individual shall participate in a radon proficiency program that the Agency has determined to meet the requirements of 011.12.

011.09 License Requirements for Radon Measurement Businesses.

011.09A The following are the requirements for licensure as a radon measurement business:

011.09A1 Submission of an application for a license which contains the Applicant name, business name, mailing address (including city, state, ZIP) and phone number to the Agency, along with the fee specified in 011.15.

011.09A2 Description of all radon and radon measurement techniques or related services to be offered, including the purpose of each measurement service, the type and purpose of measurement equipment to be used in performing the service, and an explanation of how that equipment and procedure will meet the intended purpose.

011.09A3 Identification of radon measurement specialists and radon measurement technicians to be used by the applicant. An applicant shall maintain on staff or retain as a consultant a radon measurement specialist. All radon testing will be performed only by radon measurement specialists or radon measurement technicians. This shall include the initial placement and final retrieval of all measurement devices. The radon measurement specialist shall direct the applicant's measurement activities and shall review, approve, sign, and submit monthly reports to the Agency containing the information specified in 011.13A, inform clients of radon levels in accordance with the provisions of 011.13, assess quality assurance and quality control measures, evaluate operating procedures, and ensure compliance with state and federal regulations. The radon measurement specialist shall be present during scheduled visits by the Agency and shall physically observe each

radon measurement technician in the performance of his/her measurement duties at least once each calendar quarter to ensure adequate supervision. If no radon measurements are performed during an entire calendar quarter by any of the radon measurement technicians working for a radon measurement business, the visit and observation by the specialist are not required for that quarter. The absence of radon measurements must be reported monthly to the Agency. The quarterly visit and observations by the specialist must be resumed within the same calendar quarter in which measurement activities are resumed. The interval between visits and observations by the specialist shall not exceed one year.

011.09A4 If a radon measurement business loses its radon measurement specialist, the radon measurement business shall notify the agency in writing within five business days. The radon measurement business shall obtain another radon measurement specialist within 30 days of the loss of the radon measurement specialist. Under this provision, the certified radon measurement business shall not operate more than 60 days in any one calendar year without a radon measurement specialist.

011.09A5 Identification of the analytical laboratory to be used that has been determined proficient by the Agency. The radon measurement business shall notify the Agency in writing within five business days of any change in the analytical laboratory used.

011.09A6 Development, disclosure, and adherence to a plan of quality control for each service and technique provided by the applicant to assure the reliability and validity of radon measurements.

011.09A7 Disclosure of all sample reporting forms mailed to clients, including any guidance provided concerning the need for further measurement or mitigation.

011.09A8 Disclosure of copies of current publications and advertisements of radon-related services made by the applicant.

011.09A9 Development, disclosure, and adherence to a health and safety program to determine employees' exposure to radon during the course of employment. Such a program shall include measures to keep each employee's exposure as low as reasonably achievable.

011.09A10 Maintenance of the following records for five years:

011.09A10a Records of all radon tests performed;

011.09A10b Records of instrument calibrations and quality control;

011.09A10c Records of participation in a proficiency program;

011.09A10d Records of employee exposure;

011.09A10e Copies of licenses for radon measurement specialists and radon measurement technicians employed or used as consultants.

011.10 License Requirements for Radon Mitigation Businesses.

011.10A The following are the requirements for licensure as a radon mitigation business:

011.10A1 Submission of an application for a license which contains the Applicant name, business name, mailing address (including city, state, ZIP) and phone number to the Agency, along with the fee specified in 011.15.

011.10A2 Description of all mitigation materials and systems offered, diagnostic tests performed, and other related services offered.

011.10A3 Identification of the radon mitigation specialists and radon mitigation technicians to be used by the business.

011.10A4 Identification of procedures and instrumentation used to perform diagnostic tests.

011.10A5 Disclosure of all reporting forms mailed to clients.

011.10A6 Disclosure of copies of current publications and advertisements of radon-related services made by the applicant.

011.10A7 Development, disclosure, and adherence to a health and safety program to limit employees' exposure to radon during the course of their employment. Such a program shall include measures to keep each employee's exposure as low as reasonably achievable.

011.10A8 The radon mitigation business shall maintain on staff or retain as a consultant a radon mitigation specialist. The radon mitigation specialist shall direct the applicant's mitigation activities, and shall review, approve, sign, and submit monthly reports to the Agency containing the information specified in 011.13D, evaluate operating procedures, ensure compliance with state and federal regulations, and be responsible for evaluating diagnostic tests in a building and designing mitigation systems. The mitigation specialist shall be present during scheduled visits by the agency and shall physically observe each radon mitigation technician in the performance of his/her mitigation duties at least once each calendar quarter to ensure adequate supervision.

011.10A9 If a radon mitigation business loses its radon mitigation specialist, the radon mitigation business shall notify the agency in writing within five business days. The radon mitigation business shall obtain another radon mitigation specialist within 30 days of the loss. Under this provision, the radon mitigation business shall not operate more than 60 days in any one calendar year without a radon mitigation specialist. If no radon mitigation activities are performed during an entire calendar quarter by any of the radon mitigation technicians working for a radon mitigation business, the visit and observation by the specialist are not required for that quarter. The absence of radon mitigation activities must be reported monthly to the Agency. The quarterly visit and observations by the specialist must be resumed within the same calendar quarter in which mitigation activities are resumed. The interval between visits and observations by the specialist shall not exceed one year.

011.10A10 The radon mitigation business shall assure that radon mitigation system installations are performed under the supervision of a radon mitigation specialist or radon mitigation technician.

011.10A11 The radon mitigation business shall provide all warranty information on the reduction of the radon level, or the proper functioning of mitigation equipment in writing to clients. If a firm warrants a system, the warranty must be honored and the precise coverage shall be explicitly stated in the contract offered to the client. Nothing in

011.10A11 shall limit warranties applicable to any client pursuant to any state or federal law.

011.10A12 The radon mitigation business shall maintain at a minimum the following records for five years:

011.10A12a Records of all mitigation work performed, including client name, address, initial and follow-up test results, diagnostic test results, a description of each mitigation system and materials installed, post-mitigation measurements including method of measurement and all pertinent dates.

011.10A12b Records of mitigation plans developed and signed by a radon mitigation specialist.

011.10A12c Records of all instrument calibrations and warranted equipment installed.

011.10A12d Copies of the licenses for radon mitigation specialists and radon mitigation technicians employed or used as consultants.

11.11 Mitigation System Installation Requirements.

011.11A The mitigation specialist shall review and assess the quality of any previous radon measurements made by or for the client and ascertain whether or not these measurements were made in accordance with the requirements of 011.09A5 or 011.12A of these regulations. If the mitigation specialist determines that the procedures outlined in the regulations were not followed, the mitigation specialist shall advise the client of this and retesting shall be recommended.

011.11B The radon mitigation specialist or radon mitigation technician shall perform visual and diagnostic tests as appropriate before system installation to determine the appropriate mitigation system to be installed. Observations made during visual inspections shall be documented.

011.11C In dwellings with levels exceeding 100 pCi/l, the mitigation specialist shall advise the client of temporary measures that can be used to reduce occupant exposure until a permanent mitigation system is installed. This may include temporary measures such as natural ventilation, or mechanical ventilation with unconditioned outside air, or limiting the occupants' exposure by minimizing the time spent in areas of the home with elevated radon levels, or any measures which effectively minimize occupant exposure.

011.11C1 The mitigation specialist shall not install a temporary radon reduction system in lieu of a permanent mitigation system.

011.11C2 Temporary radon reduction systems shall be labeled as such. The notice shall contain the following information:

011.11C2a The system should not be removed until a permanent mitigation system can be installed,

011.11C2b The permanent mitigation system should be installed within 30 days after the installation date of the temporary system, and

011.11C2c The mitigation business' name, license number, phone number, and the installation date.

011.11C3 If the equipment is not easily labeled, the notice shall be posted on the electric service panel, or other prominent location.

011.11D The mitigation business shall provide the following information to the client prior to initiating any work:

011.11D1 The mitigation business license number,

011.11D2 The scope of the work to be completed,

011.11D3 A statement indicating any known hazards associated with chemicals used in or as part of the installation,

011.11D4 A statement indicating compliance with provisions of the Act, all sections of these regulations, and all other related municipal, county, state and federal laws and regulations,

011.11D5 A statement indicating any required maintenance by the homeowner,

011.11D6 An estimate of the installation cost and annual operating cost of the system, and

011.11D7 Written instructions on the operation and maintenance of each component of the mitigation system.

011.11E The mitigation system shall be installed as a permanent, integral part of the building, unless an exemption is applied for and approved by the Agency. A permanent mitigation system shall include the following:

011.11E1 A mechanism to monitor system performance.

011.11E2 A label on all visible portions of the mitigation system to identify their function, including the system power or disconnect switch. One central label shall be placed on the mitigation system, electric panel or other prominent location and include a system description, a contact name and phone number.

011.11E3 If the mitigation system is designed to use fans for depressurization beneath a slab or membrane or within a block wall or drain tile system, the following conditions must be met:

011.11E3a The depressurization system fans shall not be installed in the conditioned (heated/cooled) space of a building, or in any basement, crawlspace, or other interior location directly beneath a conditioned space of a building.

011.11E3b Exhaust vents from depressurization system fans shall discharge according to all of the following requirements:

011.11E3b(1) The discharge point shall be ten feet or more above ground level,

011.11E3b(2) The discharge point shall be ten feet or more, measured directly (line-of-sight) from any window, door, or other openings in the structure (e.g., operable skylights or air intakes),

011.11E3b(3) The discharge point shall be ten feet or more away from any private or public access, and

011.11E3b(4) The discharge point shall be ten feet or more from any opening into an adjacent building.

011.11F The radon mitigation business shall ensure that each building is tested for radon levels before and after mitigation work is performed. Such tests shall be of sufficient type, duration and consistency to allow for comparison of before and after mitigation radon levels, and shall be performed by a radon measurement specialist. The post-mitigation test shall be started no sooner than 24 hours, nor longer than two weeks after mitigation. The results of both the pre-mitigation and the post-mitigation tests shall be sent to the Agency within 30 days. The mitigation business shall recommend retesting at least every two years. All measurements shall be conducted in accordance with the requirements of 011.12A of these regulations.

011.12 Radon Proficiency Program Requirements.

011.12A Radon Measurement Proficiency:

011.12A1 Require applicants to:

011.12A1a Submit and follow an approved quality assurance and quality control plan for the measurement device, including the use of duplicates, blanks, and spikes as described in the Protocols for Radon and Radon Decay Product Measurements in Homes, Publication No. EPA 402-R-92-003, June 1993, attached hereto as Attachment Number 12 and incorporated herein by this reference, and Indoor Radon and Radon Decay Product Measurement Device Protocols, Publication No. EPA 402-R-92-004, July 1992, incorporated herein by this reference and available for viewing at the Department of Health and Human Services Regulation and Licensure, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509-5007.

011.12A1b Have and use standard operating procedures (SOPs)

011.12A1c Provide proof of calibration(s) prior to use of the device

011.12A2 Contain a requirement for continuing education

011.12B Radon Mitigation Proficiency:

011.12B1 Require applicants to follow the Radon Mitigation Standards, Publication No. EPA 402-R-93-078, October 1993 (Revised April 1994), attached hereto as Attachment Number 13 and incorporated herein by this reference.

011.12B2 Contain a requirement for continuing education.

011.13 Reporting Requirements.

011.13A A radon measurement business must submit to the Agency, by the 30th of each month, the results of all available radon measurements performed in the State of Nebraska during the previous month.

011.13A1 Residential radon measurement reports shall contain the following:

011.13A1a Name of property owner, street address (including city, state, and Zip Code) and phone number.

011.13A1b Type of building, type of foundation, type of heating system, number of lived-in stories, and number of livable stories.

011.13A1c Name of person performing measurement, testing dates, total time of measurement in hours, location of test device (including story and room), type of test device, and radon test results.

011.13A1d Name and license number of radon measurement business and radon measurement specialist.

011.13A2 Nonresidential radon measurement reports shall contain the following:

011.13A2a Name of facility, type of facility, street address (including city, state, and Zip Code) and phone number, name of contact person, name and phone number of property owner.

011.13A2b Number of buildings per address, number of stories, number of occupied stories, type of foundation, type of HVAC system.

011.13A2c Name of person performing measurement, testing dates, total time of measurement in hours, location of test device (including story and room), type of test device, and radon test results.

011.13A2d Name and license number of radon measurement business and radon measurement specialist.

011.13B Radon measurement businesses and radon mitigation businesses shall report test results for radon to the client. Radon results shall be reported in picocuries per liter. Radon progeny results shall be reported in working levels.

011.13C In addition, the radon measurement business shall notify the client by telephone and mail within two business days of any measurement with results equal to or greater than 100 pCi/l or 0.5 WL and advise the client to contact the Agency at 1-800-334-9491 or at other telephone numbers provided by the Agency. The results of this measurement shall also be provided to the Agency by phone and mailed within the same two-business day period.

011.13D The radon mitigation business shall submit to the Agency, by the 30th day of each month, a report on all mitigation work completed during the previous month, including the floor plans and equipment arrangement of the mitigation system, or modifications of existing systems, and the mitigation fee(s) (per installation) as specified in 011.15G.

011.13D1 Residential radon mitigation reports shall contain the following:

011.13D1a Name of property owner, street address (including city, state, and Zip Code) and phone number.

011.13D1b Pre-mitigation testing dates, location of test device (including story and room), type of test device, radon test results, and measurement business responsible for tests (or occupant).

011.13D1c Post-mitigation testing dates, location of test device (including story and room), type of test device, radon test results, and measurement business responsible for tests (or occupant).

011.13D1d Date mitigation completed and type of mitigation system(s) installed.

011.13D1e Name and license number of radon mitigation business and radon mitigation specialist.

011.13D2 Nonresidential radon mitigation reports shall contain the following:

011.13D2a Name of facility, building street address (including city, state, and Zip Code), name and phone number of contact person, number of stories and number of occupied stories in building; name, address and phone number of property owner.

011.13D2b Pre-mitigation testing dates, location of test device (including story and room), type of test device, radon test results, and measurement business responsible for tests (or occupant).

011.13D2c Post-mitigation testing dates, location of test device (including story and room), type of test device, radon test results, and measurement business responsible for tests (or occupant).

011.13D2d Date mitigation completed and type of mitigation system(s) installed.

011.13D2e Name and license number of radon mitigation business and radon mitigation specialist.

11.14 Reciprocity. A person who has a valid license or certification from a state which licenses or certifies persons who measure or mitigate radon in a certification or licensing program with requirements determined by the Agency as comparable with the provisions of this may be licensed by the Agency upon submission of an application as specified in 011.05, 011.06, 011.07, 011.08, 011.09, and 011.10, with a copy of the certification or license from the other state, along with the fee specified in 011.15.

011.15 Fees.

<u>011.15A</u> Radon Measurement Specialist	
Initial Application Fee	\$ 50.00
Annual Renewal Fee	\$ 50.00
<u>011.15B</u> Radon Measurement Technician	
Initial Application Fee	\$ 50.00
Annual Renewal Fee	\$ 50.00
<u>011.15C</u> Radon Mitigation Specialist	
Initial Application Fee	\$ 50.00
Annual Renewal Fee	\$ 50.00
<u>011.15D</u> Radon Mitigation Technician	
Initial Application Fee	\$ 50.00
Annual Renewal Fee	\$ 50.00
<u>011.15E</u> Radon Measurement Business (Annual) Fee	\$100.00

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<u>011.15F</u> Radon Mitigation Business (Annual) Fee	\$250.00
<u>011.15G</u> Mitigation Fee per installation	\$ 50.00

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Section 012 LICENSING REQUIREMENTS FOR MANAGEMENT OF RADIOACTIVE WASTE

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012 LICENSING REQUIREMENTS FOR MANAGEMENT OF RADIOACTIVE WASTE

GENERAL PROVISIONS

012.01 Purpose and Scope.

012.01A The regulations in this section establish procedures, criteria, and terms and conditions upon which the Agency issues licenses for the management of wastes received from other persons. Applicability of the requirements in this section to Agency licenses for waste management facilities in effect on the effective date of this regulation will be determined on a case-by-case basis and implemented through terms and conditions of the license or by orders issued by the Agency.

012.01B This section establishes procedural requirements and performance objectives applicable to any method of waste management. It establishes specific technical requirements for management of radioactive waste which involves disposal above ground of the earth.

012.01C The requirements of this section are in addition to, and not in substitution for requirements in Sections 001, 003, 004, 010, 013, 015, 017 and 018 of these regulations.

012.02 Definitions. As used in this Section.

"Active maintenance" means any significant activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in 012.21 and 012.22 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers, and general management site upkeep such as mowing grass.

"Buffer zone" means a portion of the management site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

"Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a management facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the management site or the protection of environmental values.

"Custodial agency" means an agency of the government designated to act on behalf of the government owner of the management site.

"Custodial care" means the continued observation, monitoring, and care of a management facility for a minimum of one hundred years following transfer of ownership of the management facility from the operator to the Agency.

"Disposal" means the permanent isolation of radioactive wastes from the biosphere inhabited by man and his food chain by emplacement in a management facility.

"Disposal facility" means a management facility in which radioactive waste is disposed of in a structure above the earth's surface.

"Disposal site" means that portion of a disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

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"Disposal unit" means a discrete portion of the management site into which waste is placed for disposal. For surface disposal, the unit is usually a permanent structure above ground.

"Engineered barrier" means a man-made structure or device that is intended to improve the management facility's ability to meet the performance objectives in this section.

"Hydrogeologic unit" means any soil or rock unit or zone which by virtue of its porosity or permeability, or lack thereof, has a distinct influence on the storage or movement of groundwater.

"Inadvertent intruder" means a person who might occupy the management site after closure and engage in normal activities, such as agriculture, dwelling construction, or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

"Institutional control" means the institutional control program to physically control access to the disposal site. The institutional control program shall also mean, but not be limited to, custodial care and other requirements as determined by the Agency.

"Intruder barrier" means a sufficient cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this section or engineered structures that provide equivalent protection to the inadvertent intruder.

"Management facility" means the land, buildings, and equipment which is intended to be used for the management of radioactive wastes. A near-surface disposal facility would be a type of management facility.

"Monitoring" in addition to the definition of monitoring in Subsection 001.02 of these regulations monitoring means observing and making measurements to provide data to evaluate the performance and characteristics of the management site.

"Near-surface disposal facility" means a facility built above grade, provided with a protective earthen cover, used for disposal of waste.

"Site closure and stabilization" means those actions that are taken upon completion of operations that prepare the management site for custodial care and that assure that the management site will remain stable and will not need ongoing active maintenance.

"Stability" means structural stability.

"Surveillance" means monitoring and observation of the management site for purposes of vital detection of need for maintenance, custodial care, evidence of intrusion, and compliance with other license and regulatory requirements.

012.03 Exemptions. The regulations in this section do not apply to disposal of byproduct material as defined in Subpart 001.02 of these regulations in quantities greater than 10,000 kilograms containing more than 185 MBq (5 millicuries) of radium-226 or disposal of radioactive material as provided for in Section 004 of these regulations.

012.04 License Required.

012.04A No person may receive, possess, and dispose of waste received from other persons at a management facility unless authorized by a license issued by the Agency pursuant to this section and Section 003 of these regulations.

012.04B Each person shall file an application with the Agency pursuant to Subsection 003.10 of these regulations and obtain a license as provided in this section before commencement of

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construction of a management facility. Failure to comply with this requirement may be grounds for denial of a license.

012.05 Term. Licenses shall be issued for a period of thirty (30) years subject to review every five (5) years.

012.06 Content of Application. In addition to the requirements set forth in 003.11 of these regulations, an application to receive from others, possess, and dispose of wastes shall consist of general information, specific technical information, institutional information, and financial information as set forth in 012.07 through 012.11.

012.07 General Information. The general information shall include each of the following:

012.07A Identity of the applicant including:

012.07A1 The full name, address, telephone number, and description of the business or occupation of the applicant;

012.07A2 If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

012.07A3 If the applicant is a corporation or an unincorporated association:

012.07A3a The state where it is incorporated or organized and the principal location where it does business, and

012.07A3b The names and addresses of its directors and principal officers; and

012.07A4 If the applicant is acting as an agent or representative of another person in filing the application, all information required under 012.07A must be supplied with respect to the other person.

012.07B Qualifications of the applicant:

012.07B1 The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

012.07B2 The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in 012.07B1 must be provided, and meet the requirements of Subsection 015.32.

012.07B3 A description of the applicant's personnel training program; and

012.07B4 The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling, and management operations in a safe manner.

012.07C A description of:

012.07C1 The location of the proposed management site;

012.07C2 The general character of the proposed activities;

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012.07C3 The types and quantities of waste to be received, possessed, and disposed of:

012.07C4 Plans for use of the management facility for purposes other than management of radioactive wastes; and

012.07C5 The proposed facilities and equipment.

012.07D Proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed management facility.

012.08 Specific Technical Information. The specific technical information shall include the following information needed for demonstration that the performance objectives and the applicable technical requirements of this section will be met:

012.08A A description of the natural and demographic disposal site characteristics as determined by management site selection and characterization activities. The description shall include geologic, geochemical, geotechnical, hydrologic, ecologic, archaeologic, meteorologic, climatologic, and biotic features of the management site and vicinity.

012.08B A description of the design features of the management facility and the disposal units. For surface disposal, the description shall include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, wastes, and covers; contact of wastes with standing water; management site drainage; management site closure and stabilization; elimination to the extent practicable of long-term management site maintenance; inadvertent intrusion; occupational exposures; management site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

012.08C A description of the principal design criteria and their relationship to the performance objectives.

012.08D A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

012.08E A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land management facilities.

012.08F A description of the construction and operation of the management facility. The description shall include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water access to the wastes. The description shall also include a description of the methods to be employed in the handling and management of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives of this section.

012.08G A description of the management site closure plan, including those design features which are intended to facilitate management site closure and to eliminate the need for ongoing active maintenance.

012.08H An identification of the known natural resources at the management site, whose exploitation could result in inadvertent intrusion into the low-level wastes after removal of active institutional control.

012.08I A description of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed, and disposed of at the management facility.

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012.08J. A description of the quality assurance program, tailored to low level waste disposal, developed and applied by the applicant for the determination of natural disposal site characteristics and for quality assurance during the design, construction, operation, and closure of the management facility and the receipt, handling, and emplacement of waste.

012.08K A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in 012.22 and occupational radiation exposure to ensure compliance with the requirements of Section 004 of these regulations and to control contamination of personnel, vehicles, equipment, buildings, and the management site. Both routine operations and accidents shall be addressed. The program description must include procedures, instrumentation, facilities, and equipment.

012.08L A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration of radionuclides is indicated.

012.08M A description of the administrative procedures that the applicant will apply to control activities at the management facility.

012.08N A description of the facility electronic recordkeeping system as required in 012.36.

012.09 Technical Analyses. The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of this section will be met:

012.09A Pathways analyzed in demonstrating protection of the general population from releases of radioactivity shall include air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is reasonable assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in 012.22.

012.09B Analyses of the protection of individuals from inadvertent intrusion shall include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

012.09C Analyses of the protection of individuals during operations shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage, and management of waste. The analyses shall provide reasonable assurance that exposures will be controlled to meet the requirements of Section 004 of these regulations.

012.09D Analyses of the long-term stability of the management site and the need for ongoing active maintenance after closure shall be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, container or building defects, infiltration through covers over management areas, adjacent soils, and surface drainage of the management site. The analyses shall provide reasonable assurance that there will not be a need for ongoing active maintenance of the management site following closure.

012.10 Institutional Information. The institutional information submitted by the applicant shall include.

012.10A A certification by the Federal or State government which owns the management site that the Federal or State government is prepared to accept transfer of the license when the provisions of 012.19 are met and will assume responsibility for custodial care after site closure and post-closure observation and maintenance.

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012.10B Where the proposed management site is on land not owned by the Federal or a State government, the applicant shall submit evidence that arrangements have been made for assumption of ownership-in fee by the Federal or a State agency before the Agency issues a license.

012.11 Financial Information. The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements of this section.

012.12 Requirements for Issuance of a License. A license for the receipt, possession, and management of waste containing or contaminated with radioactive material will be issued by the Agency upon finding that:

012.12A The application is complete.

012.12B The issuance of the license will not constitute an unreasonable risk to the health and safety of the public;

012.12C The applicant is qualified by reason of training and experience to carry out the management operations requested in a manner that protects health and minimizes danger to life or property;

012.12D The applicant's proposed management site, management design, management facility operations, including equipment, facilities, and procedures, management site closure, and post-closure institutional control are adequate to protect the public health and safety in that they provide reasonable assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in 012.22;

012.12E The applicant's proposed management site, management site design, management facility operations, including equipment, facilities, and procedures, management disposal site closure, and post-closure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that individual inadvertent intruders are protected in accordance with the performance objective in 012.23;

012.12F The applicant's proposed management facility operations, including equipment, facilities, and procedures, are adequate to protect the public health and safety in that they will provide reasonable assurance that the standards for radiation protection set out in Section 004 of these regulations will be met;

012.12G The applicant's proposed management site, management site design, management facility operations, management site closure, and post-closure institutional control are adequate to protect the public health and safety in that they will provide reasonable assurance that long-term stability of the disposed waste and the management site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the management site following closure;

012.12H The applicant's demonstration provides reasonable assurance that the applicable technical requirements of this section will be met;

012.12I The applicant's proposal for institutional control provides reasonable assurance that such control will be provided for the length of time found necessary to ensure the findings in 012.12D through G and that the institutional control meets the requirements of 012.31; and

012.12J The financial or surety arrangements meet the requirements of this section.

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012.12K The requirements of 10 CFR Chapter I, Part 51, Subpart A, Section 51.20(b) (11) and (12) and Appendix A, attached hereto as Attachment Number 9 and incorporated herein by this reference have been met.

012.12L Any additional information submitted, as requested by the Agency, is adequate.

012.13 Conditions of Licenses.

012.13A A license issued under this section, or any right thereunder, may be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, only if the Agency finds, after securing full information, that the transfer is in accordance with Title 180 Chapter 1 NAC and the Act and gives its consent in writing in the form of a license amendment.

012.13B The licensee shall submit written statements under oath upon request of the Agency, at any time before termination of the license, to enable the Agency to determine whether the license should be modified, suspended, or revoked.

012.13C The license will be terminated only on the full implementation of the final closure plan as approved by the Agency, including post-closure observation and maintenance.

012.13D The licensee shall be subject to the provisions of the Act now or hereafter in effect, and to all rules, regulations, and orders of the Agency. The terms and conditions of the license are subject to amendment, revision, or modification, by reason of amendments to, or by reason of rules, regulations, and orders issued in accordance with the terms of Title 180 Chapter 1 NAC and the Act.

012.13E Each person licensed by the Agency pursuant to the regulations in this section shall confine possession and use of materials to the locations and purposes authorized in the license.

012.13F The licensee shall not dispose of waste until the Agency has inspected the management facility and has found it to be in conformance with the description, design, and construction described in the application for a license.

012.13G The Agency may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession, and management of waste as it deems appropriate or necessary in order to:

012.13G1 Protect health or to minimize danger to life or property;

012.13G2 Require reports and the keeping of records, and to provide for inspections of activities under the license that may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

012.13H The authority to dispose of wastes expires on the date stated in the license. Any expiration date on a license applies only to the above ground activities and to the authority to management of waste. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post-closure observation, and transfer of the license to the site owner.

012.13I Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (Bankruptcy) of the United States Code by or against:

012.13I1 The licensee;

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012.13I2 An entity (as that term is defined in 11 U.S.C. 101 (14) Attachment Number 7 herein) controlling the licensee or listing the license or licensee as property of the estate; or

012.13I3 An affiliate (as that term is defined in 11 U.S.C. 101 (2) Attachment Number 7 herein) of the licensee.

012.13I4 This notification must indicate:

012.13I4a The bankruptcy court in which the petition for bankruptcy was filed; and

012.13I4b The date of the filing of the petition.

012.14 Changes.

012.14A Except as provided for in specific license conditions, the licensee shall not make changes in the management facility or procedures described in the license application. The license will include conditions restricting subsequent changes to the facility and procedures authorized which are important to the public health and safety. These license restrictions will fall into three categories of descending importance to public health and safety as follows:

012.14A1 Those features and procedures which may not be changed without:

012.14A1a 60 days prior notice to the Agency;

012.14A1b 30 days prior notice of opportunity for a prior hearing; and

012.14A1c Prior Agency approval.

012.14A2 Those features and procedures which may not be changed without:

012.14A2a 60 days prior notice to the Agency; and

012.14A2b Prior Agency approval; and

012.14A3 Those features and procedures which may not be changed without 60 days prior notice to the Agency. Features and procedures falling in 012.14A3 of this Section may not be changed without prior Agency approval if the Agency, after having received the required notice, so orders.

012.14B Amendments authorizing site closure, license transfer or license termination shall be included in 012.14A1 of this section.

012.15 Amendment of License.

012.15A An application for amendment of a license shall be filed in accordance with Subsection 003.21 of these regulations.

012.16 Application for Renewal or Closure.

012.16A An application for renewal or an application for closure under 012.17 must be filed at least 90 days prior to license expiration. Failure to renew the license shall not relieve the licensee of responsibility for implementing site closure, post closure observation, and transfer of the license to the site owner.

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012.16B Applications for renewal of a license must be filed in accordance with 012.06 through 012.11. Applications for closure must be filed in accordance with 012.17. Information contained in previous applications, statements, or reports filed with the Agency under the license may be incorporated by reference if the references are clear and specific.

012.16C In any case in which a licensee has timely filed an application in proper form for renewal of a license, the license does not expire until the Agency has taken final action on the application for renewal.

012.16D In determining whether a license will be renewed, the Agency will apply the criteria set forth in 012.12.

012.17 Contents of Application for Site Closure and Stabilization.

012.17A Prior to final closure of the management site, or as otherwise directed by the Agency, the applicant shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the management site closure plan included as part of the license application submitted under 012.08G that includes each of the following:

012.17A1 Any additional geologic, hydrologic, or other data pertinent to the long-term containment of emplaced radioactive wastes obtained during the operational period.

012.17A2 The results of tests, experiments, or other analyses relating to closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments, or analysis pertinent to long-term containment of emplaced waste within the management site.

012.17A3 Any proposed revision of plans for:

012.17A3a Decontamination and/or dismantlement of surface facilities;

012.17A3b Backfilling of excavated areas; or

012.17A3c Stabilization of the management site for post-closure care.

012.17A4 Any significant new information regarding the environmental impact of closure activities and long-term performance of the management site.

012.17B Upon review and consideration of an application to amend the license for closure submitted in accordance with 012.17A, the Agency shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of this section will be met.

012.18 Post-Closure Observation and Maintenance. The licensee shall observe, monitor, and carry out necessary maintenance and repairs at the management site until the site closure is complete and the license is transferred by the Agency in accordance with 012.19. Responsibility for the management site must be maintained by the licensee for 5 years. A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

012.19 Transfer of License. Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the management site owner. The license shall be transferred when the Agency finds:

012.19A That the closure of the management site has been made in conformance with the licensee's management site closure plan, as amended and approved as part of the license;

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012.19B That reasonable assurance has been provided by the licensee that the performance objectives of this section are met;

012.19C That any funds for care and records required by 012.36D and F have been transferred to the management site owner;

012.19D That the post-closure monitoring program is operational for implementation by the management site owner; and

012.19E That the Federal or State agency which will assume responsibility for institutional control of the management site is prepared to assume responsibility and ensure that the institutional requirements found necessary under 012.12I will be met.

012.20 Termination of License.

012.20A Following any period of institutional control needed to meet the requirements found necessary under 012.12, the licensee may apply for an amendment to terminate the license.

012.20B This application will be reviewed in accordance with the provisions of Subsection 003.10 of these regulations.

012.20C A license shall be terminated only when the Agency finds:

012.20C1 That the institutional control requirements found necessary under 012.12I have been met;

012.20C2 That any additional requirements resulting from new information developed during the institutional control period have been met; and

012.20C3 That permanent monuments or markers warning against intrusion have been installed.

012.20C4 That any funds for care and records required by 012.36D and E have been transferred to the management site owner.

PERFORMANCE OBJECTIVES

012.21 General Requirement. Management facilities shall be sited, designed, operated, closed, and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in 012.22 through 012.25. Subsection 012.22 applies only to a near-surface land disposal facility.

012.22 Protection of the General Population from Releases of Radioactivity. Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall not result in an annual dose exceeding an equivalent of 0.25 mSv (25 millirems) to the whole body, 0.75 mSv (75 millirems) to the thyroid, and 0.25 mSv (25 millirems) to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

012.23 Protection of Individuals from Inadvertent Intrusion. Design, operation, and closure of the management facility shall ensure protection of any individual inadvertently intruding into the management site and occupying the site or contacting the waste at any time after active institutional controls over the management site are removed.

012.24 Protection of Individuals During Operations. Operations at the management facility shall be conducted in compliance with the standards for radiation protection set out in Section 004 of these regulations, except for releases of radioactivity in effluents from the management facility, which shall be governed by 012.22. Every reasonable effort should be made to maintain radiation exposures as low as is reasonably achievable.

012.25 Stability of the Management Site After Closure. The management facility shall be sited, designed, used, operated, and closed to achieve long-term stability of the management site and to eliminate, to the extent practicable, the need for ongoing active maintenance of the management site following closure so that only surveillance, monitoring, or minor custodial care are required.

TECHNICAL REQUIREMENTS FOR MANAGEMENT FACILITIES

012.26 Management Site Suitability Requirements.

012.26A Management Site Suitability for Disposal. The primary emphasis in management site suitability is given to isolation of wastes and to management site features that ensure that the long-term performance objectives are met.

012.26A1 The management site shall be capable of being characterized, modeled, analyzed and monitored.

012.26A2 Within the region where the facility is to be located, a management site should be selected so that projected population growth and future developments are not likely to affect the ability of the management facility to meet the performance objectives of this section.

012.26A3 Areas shall be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of this section.

012.26A4 The management site shall be generally well drained and free of areas of flooding or frequent ponding. Waste management shall not take place in a 100-year flood plain, meaning that area subject to a one percent or greater chance of flooding in any given year.

012.26A5 Upstream drainage areas shall be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

012.26A6 The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the management site.

012.26A7 Areas shall be avoided where tectonic processes such as faulting, folding, seismic activity, or vulcanism may occur with such frequency and extent to significantly affect the ability of the management site to meet the performance objectives of this section, or may preclude defensible modeling and prediction of long-term impacts.

012.26A8 Areas shall be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the management site to meet the performance objectives of this section, or may preclude defensible modeling and prediction of long-term impact.

012.26A9 The management site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of this section or significantly mask the environmental monitoring program.

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012.27 Management Site Design.

012.27A Disposal Site Design.

012.27A1 Site design features shall be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

012.27A2 The management site design and operation shall be compatible with the management site closure and stabilization plan and lead to management site closure that provides reasonable assurance that the performance objectives will be met.

012.27A3 The management site shall be designed to complement and improve, where appropriate, the ability of the management site's natural characteristics to assure that the performance objectives will be met.

012.27A4 Covers shall be designed to minimize to the extent water infiltration, to direct percolating or surface water away from the disposed waste, and to resist degradation by surface geologic processes and biotic activity.

012.27A5 Surface features shall direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

012.27A6 The management site shall be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during management and the contact of percolating or standing water with wastes after disposal.

012.27B Reserved.

012.28 Management Facility Operation and Management Site Closure.

012.28A Disposal Facility Operation and Management Site Closure.

012.28A1 Wastes designated as Class A pursuant to Appendix 004-E of Section 004 of these regulations shall be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives of this section. This segregation is not necessary for Class A wastes if they meet the stability requirements in Appendix 004-E of Section 004 of these regulations.

012.28A2 Wastes designated as Class C pursuant to Appendix 004-E of Section 004 of these regulations shall be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

012.28A3 Except as provided in 012.28A11, only waste classified as Class A, B, C shall be acceptable for disposal. All waste shall be disposed of in accordance with requirements of 012.28A4 through 10.

012.28A4 Wastes shall be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages, and permits the void spaces to be filled.

012.28A5 Waste shall be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all

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provisions of Subsection 004.14 of these regulations at the time the license is transferred pursuant to 012.19.

012.28A6 The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Disposal units shall be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

012.28A7 A buffer zone of land shall be maintained between any waste and the management site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in 012.29D and take mitigative measures if needed.

012.28A8 Closure and stabilization measures as set forth in the approved site closure plan shall be carried out as each disposal unit is filled.

012.28A9 Active waste management operations shall not have an adverse effect on completed closure and stabilization measures.

012.28A10 Only wastes containing or contaminated with radioactive material shall be disposed of at the management site.

012.28A11 Proposals for management of waste that is not generally acceptable for disposal because the waste form and disposal methods must be different and, in general, more stringent than those specified for Class C waste, may be submitted to the Agency for approval.

012.28B Reserved.

012.29 Environmental Monitoring.

012.29A At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the management site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology of the management site. For those characteristics that are subject to seasonal variation, data must cover at least a 12-month period.

012.29B During the management facility site construction and operation, the licensee shall maintain an environmental monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of waste from the management site before they leave the site boundary.

012.29C After the management site is closed, the licensee responsible for post-operational surveillance of the management site shall maintain a monitoring system based on the operating history and the closure and stabilization of the management site. The monitoring system must be capable of providing early warning of releases of waste from the management site before they leave the site boundary.

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012.29D The licensee shall have plans for taking corrective measures and implementing these plans if the environmental monitoring program detects migration of waste which would indicate that the performance objectives may not be met.

012.30 Alternative Requirements for Design and Operations. The Agency may, upon request or on its own initiative, authorize provisions other than those set forth in 012.27 through 012.29 for the segregation and management of waste and for the design and operation of a management facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of this section.

012.31 Institutional Requirements.

012.31A Land Ownership. Disposal of waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

012.31B Institutional Control. The land owner or custodial agency shall conduct an institutional control program to physically control access to the management site following transfer of control of the disposal site from the disposal site operator. The institutional control program shall also include, but not be limited to, conducting an environmental monitoring program at the management site, periodic surveillance, minor custodial care, and other requirements as determined by the Agency; and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Agency, but institutional controls may not be relied upon for more than 100 years following transfer of control of the management site to the owner.

012.31C A map of the type, location and quantity of low-level radioactive waste disposed of at the site shall be filed, within 60 days of transfer of the license to the Agency, with the Register of Deeds of the County where such land is located and with the Agency.

012.32 Reserved.

FINANCIAL ASSURANCES

012.33 Applicant Qualifications and Assurances. Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and management.

012.34 Funding for Management Site Closure and Stabilization.

012.34A The applicant shall provide assurances prior to the commencement of operations that sufficient funds will be available to carry out disposal site closure and stabilization, including: (1) Decontamination or dismantlement of management facility structures; and (2) closure and stabilization of the management site so that following transfer of the management site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Agency-approved cost estimates reflecting the Agency-approved plan for management site closure and stabilization. The applicant's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

012.34B In order to avoid unnecessary duplication and expense, the Agency will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of Federal or other State agencies (and/or local governmental bodies) for such decontamination, closure, and stabilization. The Agency will accept these arrangements only if they are considered adequate to satisfy the requirements of 012.34 and that the portion of the surety which

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covers the closure of the management site is clearly identified and committed for use in accomplishing these activities.

012.34C The licensee's financial or surety arrangement shall be submitted annually for review by the Agency to assure that sufficient funds will be available for completion of the closure plan.

012.34D The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation, increases in the amount of distributed land, changes in engineering plans, closure and stabilization that has already been accomplished, and any other conditions affecting costs. The financial or surety arrangement shall be sufficient at all times to cover the costs of closure and stabilization of the disposal units that are expected to be used before the next license renewal.

012.34E The financial or surety arrangement shall be written for a specified period of time and shall be automatically renewed unless the person who issues the surety notifies the Agency, the beneficiary (the site owner), and the principal (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Agency, the beneficiary may collect on the original surety.

012.34F Proof of forfeiture shall not be necessary to collect the surety so that, in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above shall be clearly stated on any surety instrument.

012.34G Financial or surety arrangements generally acceptable to the Agency include surety bonds, cash deposits, certificates of deposit, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds, and combinations of the above or such other types of arrangements as may be approved by the Agency. Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement for private sector applicants.

012.34H The licensee's financial or surety arrangement shall remain in effect until the closure and stabilization program has been completed and approved by the Agency, and the license has been transferred to the site owner.

012.35 Financial Assurances for Institutional Controls.

012.35A Prior to the issuance of the license, the applicant shall provide for Agency approval, a binding arrangement, between the applicant and the management site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the institutional control period. The binding arrangement shall be reviewed annually by the Agency to ensure that changes in inflation, technology, and management facility operations are reflected in the arrangements.

012.35B Subsequent changes to the binding arrangement specified in 012.35A relevant to institutional control shall be submitted to the Agency for prior approval.

RECORDS, REPORTS, TESTS, AND INSPECTIONS

012.36 Maintenance of Records, Reports, and Transfers.

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012.36A Each licensee shall maintain any records and make any reports in connection with the licensed activities as may be required by the conditions of the license or by the rules, regulations, and orders of the Agency.

012.36B Records which are required by these regulations or by license conditions shall be maintained for a period specified by the appropriate regulations or by license condition. If a retention period is not otherwise specified, these records must be maintained and transferred to the officials specified in 012.36D as a condition of license termination unless the Agency otherwise authorizes their disposition.

012.36C Records which shall be maintained pursuant to this section may be the original or a reproduced copy or microfilm if this reproduced copy or microfilm is capable of producing copy that is clear and legible at the end of the required retention period.

012.36D Notwithstanding 012.36A through C, copies of records of the location and the quantity of wastes contained in the management site must be transferred upon license termination to the chief executive of the nearest municipality, the chief executive of the county in which the facility is located, the county zoning board or land development and planning agency, the state governor, and other State, local and Federal governmental agencies as designated by the Agency at the time of license termination.

012.36E Following receipt and acceptance of a shipment of radioactive waste, the license shall record the date that the shipment is received at the disposal facility, the date of disposal of the waste, a traceable shipment manifest number, a description of any engineered barrier or structural overpack provided for disposal of the waste, the location of disposal and the disposal site, the containment integrity of the waste disposal containers as received, any discrepancies between materials listed on the manifest and those received, the volume of any pallets, bracing, or other shipping or onsite generated materials that are contaminated, and are disposed of as contaminated or suspect materials, and any evidence of leaking or damaged disposal containers or radiation or contamination levels in excess of limits specified in Department of Transportation and Agency regulations. The licensee shall briefly describe any repackaging operations of any of the disposal containers included in the shipment, plus any other information required by the Agency as a license condition. The licensee shall retain these records until the Agency transfers or terminated the license that authorizes the activities described in this section.

012.36F Each licensee authorized to dispose of radioactive waste received from other persons shall file a copy of its financial report or a certified financial statement annually with the Agency in order to update the information base for determining financial qualifications.

012.36G Each licensee authorized to dispose of waste received from other persons, pursuant to this section, shall submit annual reports to the Agency. Reports shall be submitted by the end of the first calendar quarter of each year for the preceding year.

012.36G1 The reports shall include:

012.36G1a Specification of the quantity of each of the principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding year,

012.36G1b The results of the environmental monitoring program,

012.36G1c A summary of licensee disposal unit survey and maintenance activities,

012.36G1d A summary, by waste class, of activities and quantities of radionuclides disposed of,

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012.36G1e Any instances in which observed site characteristics were significantly different from those described in the application for a license; and

012.36G1f Any other information the Agency may require.

012.36G2 If the quantities of radioactive waste released during the reporting period, monitoring results, or maintenance performed are significantly different from those predicted, the report must cover this specifically.

012.36H In addition to the other requirements of this section, the licensee shall store, or have stored, manifest and other information pertaining to the receipt and disposal of radioactive waste in an electronic recordkeeping system.

012.36H1 The manifest information that must be electronically stored is:

012.36H1a That information required in 180 NAC 1, Appendix 004-D, with the exception of shipper and carrier telephone numbers and shipper and consignee certifications; and

012.36H1b That information required in Subsection 012.36E of this section.

012.36H2 As specified in facility license conditions, the licensee shall report the stored information, or subsets of this information, on a computer-readable medium.

012.37 Tests on Management Facilities. Each licensee shall perform, or permit the Agency to perform, any tests the Agency deems appropriate or necessary for the administration of the regulations in this section, including, but not limited to, tests of:

012.37A Wastes;

012.37B Facilities used for the receipt, storage, treatment, handling or management of wastes;

012.37C Radiation detection and monitoring instruments; or

012.37D Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage, or management of waste.

012.37E Geohydrologic, hydrologic, soil, or other environmental conditions or parameters.

012.38 Agency Inspections of Management Facilities.

012.38A Each licensee shall afford to the Agency at all reasonable times opportunity to inspect waste not yet disposed of, and the premises, equipment, operations, and facilities in which wastes are received, possessed, handled, treated, stored, or disposed of.

012.38B Each licensee shall make available to the Agency for inspection, upon reasonable notice, records kept by it pursuant to these regulations. Authorized representatives of the Agency may copy and take away copies of, for the Agency's use, any record required to be kept pursuant to these regulations.

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Section 013 TRANSPORTATION OF RADIOACTIVE MATERIAL

013.01 Purpose and Scope. The regulations in this section establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

013.02 Definitions. As used in this section, the following definitions apply:

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Certificate holder" means a person who has been issued a certificate of compliance or other package approval by the Agency.

"Close reflection by water" means immediate contact by water of sufficient thickness for maximum reflection of neutrons.

"Containment system" means the assembly of components of packaging intended to retain the radioactive material during transport.

"Conveyance" means:

For transport by public highway or rail any transport vehicle or large freight container;

For transport by water any vessel, or any hold compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

For transport by aircraft any aircraft.

"Exclusive use" means the sole use of a conveyance by a single consignor for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls and include them with the shipping paper information provided to the carrier by the consignor.

"Fissile material" means plutonium-238, plutonium-239, plutonium-241, uranium-233, uranium-235, or any combination of these radionuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in this definition.¹

"Low specific activity (LSA) Material" means radioactive material with limited specific activity that satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material must be in one of three groups:

"LSA-I": Ores containing only naturally occurring radionuclides (e.g., uranium, thorium) and uranium or thorium concentrates of such ores; or

¹Agency jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in Subsection 001.02 of these regulations.

Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures; or

Radioactive material other than fissile material, for which the A_2 value is unlimited; or

Mill tailings, contaminated earth, concrete, rubble, other bulk debris and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed $10^{-4} A_2/g$.

LSA-II: Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

Material in which the active material is distributed throughout, and the average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

LSA-III solids (e.g., consolidated wastes, activated materials) in which:

The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.); and

The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package leaching, when placed in water for 7 days, would not exceed $0.1 A_2$; and

The average specific activity of the solid does not exceed $2 \text{ E-}3 A_2/g$.

"Low toxicity alpha emitters" means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates; or alpha emitters with a half-life of less than 10 days.

"Natural thorium" means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

"Normal form radioactive material" radioactive material which has not been demonstrated to qualify as "special form radioactive material." "Special form radioactive material" is defined in Subsection 001.02 of these regulations..

"Optimum interspersed hydrogenous moderation" means the presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

"Fissile material package means a fissile material packaging together with its fissile material contents."

"Type B package" means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless that package has a maximum normal operating pressure or more than 700 kPa (100 lb/in²) gauge or pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR Part 71.73 (hypothetical accident conditions), in which it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is not distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see U. S. Department of Transportation (DOT) regulations, 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified 013.08.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie down system, and auxiliary equipment may be designated as part of the packaging.

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Surface contaminated object" (SCO) means a solid object that is not itself classed as radioactive material but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

SCO-1: A solid object on which:

The non-fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 4 Bq/cm² (10⁻⁴ μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm² (10⁻⁵ μCi/cm²) for all other alpha emitters.

The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 4 E4 Bq/cm² (1.0 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E3 Bq/cm² (0.1 μCi/cm²) for all other alpha emitters; and

The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 4 E4 Bq/cm² (1.0 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 4 E3 Bq/cm² (0.1 μCi/cm²) for all other alpha emitters.

SCO-II: A solid object on which the limits for SCO-1 are exceeded and on which:

The non-fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 400 Bq/cm² (10⁻² μCi/cm²) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm² (10⁻³ μCi/cm²) for all other alpha emitters;

The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 8 E5 Bq/cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E4 Bq/cm² (2 μCi/cm²) for all other alpha emitters;

The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 8 E5 Bq/cm² (20 μCi/cm²) for beta and gamma and low toxicity alpha emitters, or 8 E4 Bq/cm² (2 μCi/cm²) for all other alpha emitters.

"Transport index" means the dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. The transport index is determined as follows:

For non-fissile material packages, the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft)); or

For fissile material packages, the number determined by multiplying the maximum radiation level in millisievert per hour at one meter (3.3 ft) from the external surface of the package by 100 (equivalent

to the maximum radiation level in millirem per hour at one meter (3.3 ft), or, for criticality control purposes, the number obtained as described in 10 CFR Part 71.59, whichever is larger.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix A of this section, or may be determined by procedures described in Appendix A of this section.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

" Uranium - natural, depleted, enriched"

"Natural uranium" means uranium with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

"Depleted uranium" means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

"Enriched Uranium" means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

013.03 Requirement for License. No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Agency or as exempted in 013.04 of these regulations.

013.04 Exemptions.

013.04A Common and contract carriers, freight forwarders, and warehouse workers which are subject to the requirements of the DOT in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), incorporated by reference, at 39 CFR 111.1 (1997), are exempt from the requirements of this section to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the DOT or U.S. Postal Service are subject to 013.03 and other applicable requirements of these regulations.

013.04B Any physician licensed by the State of Nebraska to dispense drugs in the practice of medicine is exempt from 013.03 with respect to transport by the physician of radioactive material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Section 003 of these regulations.

013.04C Any licensee is exempt from the requirements of this section to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 70 Bq/gm (0.002 μ Ci/g).

013.04D A licensee is exempt from all requirements of this section, other than 013.05 and 013.16, with respect to shipment or carriage of the following:

013.04D1 Packages containing no more than Type A quantities of radioactive material if the package contains no fissile material; or

013.04D2 A package containing radioactive materials that is low specific activity (LSA) material in group LSA-1, or surface contaminated objects (SCO) in group SCO-1.

013.05 Transportation of Licensed Material.

013.05A Each licensee who transports licensed material outside of the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall:

013.05A1 Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the DOT, particularly regulations of the DOT in the following areas:

013.05A1a Packaging - 49 CFR Part 173: Subparts A and B and I.

013.05A1b Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.440, and Subpart E.

013.05A1c Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.

013.05A1d Accident Reporting - 49 CFR Part 171: §§ 171.15 and 171.16.

013.05A1e Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.

013.05A1f Hazardous material employee training - 49 CFR Part 172: Subpart H.

013.05A1g Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

013.05A2 The licensee shall also comply with applicable DOT regulations pertaining to the following modes of transportation:

013.05A2a Rail - 49 CFR Part 174: Subparts A through D and K.

013.05A2b Air - 49 CFR Part 175

013.05A2c Vessel - 49 CFR Part 176: Subparts A through F and M.

013.05A2d Public Highway - 49 CFR Part 177 and Parts 390 through 397.

013.05A3 Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with Part 004.37 of these regulations.

013.05B If, for any reason, the regulations of the DOT are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 170 through 189 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations.

013.06 General Licenses for Carriers.

013.06A A general license is hereby issued to any common or contract carrier not exempt under 013.04 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements

relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting².

013.06B A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.

013.06C Persons who transport radioactive material pursuant to the general licenses in 013.06A or B are exempt from the requirements of Sections 004 and 010 of these regulations to the extent that they transport radioactive material.

013.07 General License: NRC-Approved Packages.

013.07A A general license is hereby issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC.

013.07B This general license applies only to a licensee who:

013.07B1 Has a copy of the specific license, certificate of compliance, or other approval by the NRC of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

013.07B2 Complies with the terms and conditions of the license, certificate, or other approval by the NRC, as applicable, and the applicable requirements of this Section;

013.07B3 Prior to the licensee's first use of the package, has registered with the NRC; and

013.07B4 Has a quality assurance program required by 013.21.

013.07C The general license in 013.07A applies only when the package approval authorizes use of the package under this general license.

013.07D For a Type B or fissile material package, the design of which was approved before April 1, 1996 the general license is subject to the additional restrictions of 013.08.

013.08 General License: Previously Approved Packages.

013.08A A Type B package previously approved by the NRC, but not designated as B(U) or B(M) in the identification number of the NRC Certificate of Compliance, may be used under the general license of 013.07 with the following additional conditions:

013.08A1 Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with NRC regulations at 10 CFR 71.85(c);

013.08A2 A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in DOT regulations at 49 CFR 173.403; and

²Notification of incidents shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of and in addition to notification made to DOT or other agencies.

013.08A3 A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

013.08B A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the NRC but without the designation "-85" in the identification number of the NRC Certificate of Compliance, may be used under the general license of 013.07 with the following additional conditions:

013.08B1 Fabrication of the package is satisfactorily completed by April 1, 1996, as demonstrated by application of its model number in accordance with NRC regulations at 10 CFR 71.85(c).

013.08B2 A package used for a shipment to a location outside the United States is subject to multilateral approval except approved under special arrangement in accordance with DOT regulations at 49 CFR 173.403; and

013.08B3 A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

013.09 General License: DOT Specification Container.

013.09A A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

013.09B This general license applies only to a licensee who:

013.09B1 Has a copy of the specification;

013.09B2 Complies with the terms and conditions of the specification and the applicable requirements of this section; and

013.09B3 Has a quality assurance program required by 013.21.

013.09C The general license in 013.09A is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

013.10 General License: Use of Foreign Approved Package.

013.10A A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.12.

013.10B This general license applies only to international shipments.

013.10C This general license applies only to a licensee who:

013.10C1 Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

013.10C2 Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this section.

013.10C3 Has a quality assurance program approved by the Agency.

013.11 General License; Fissile Material, Limited Quantity Per Package.

013.11A A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this Subsection.

013.11B The general license applies only to a licensee who has a quality assurance program approved by the Agency.

013.11C Except as provided in 013.11D, this general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

013.11C1 Up to 40 grams of uranium-235;

013.11C2 Up to 30 grams of uranium-233;

013.11C3 Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A₁ quantity of plutonium may be present; or

013.11C4 A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 013.11C(1), (2) and (3) does not exceed unity.

013.11D For packages where fissile material is mixed with substances having an average hydrogen density greater than water, this general license applies only when a package contains no more than a Type A quantity of radioactive material, including one of the following:

013.11D1 Up to 29 grams of uranium-235;

013.11D2 Up to 18 grams of uranium-233;

013.11D3 Up to 18 grams of fissile radionuclides of plutonium, or

013.11D4 A combination of fissile radionuclides in which the sums of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 013.11D(1), (2) and (3) does not exceed unity.

013.11E Except for the beryllium contained within the special form plutonium-beryllium sources authorized in 013.11C, this general license applies only when beryllium, graphite, or hydrogenous material enriched in deuterium is not present in quantities exceeding 0.1% of the fissile material mass.

013.11F Except as specified in 013.11F1 of this Subsection for encapsulated plutonium-beryllium sources, this general license applies only when, a package is labeled with a transport index not less than the number given by the following equation, where the package contains x grams of uranium-235, y grams of uranium-233, and z grams of the fissile radionuclides of plutonium:

$$\text{Minimum Transport Index} = (0.25x + 0.33y + 0.4z)$$

013.11F1 For a package in which the only fissile material is in the form of encapsulated plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.025 times the number of grams of the fissile radionuclides of plutonium.

013.11F2 Packages which have a transport index greater than 10 are not authorized under the general license provisions of this Subsection.

013.12 General License: Fissile Material, Limited Moderator Per Package.

013.12A A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this subsection.

013.12B This general license applies only when all of the following requirements are met:

013.12B1 The package contains no more than a Type A quantity of radioactive material;

013.12B2 Neither beryllium nor hydrogenous material enriched in deuterium is present;

013.12B3 The total mass of graphite present does not exceed 7.7 times the total mass of uranium-235 plus plutonium;

013.12B4 Substances having a higher hydrogen density than water, for example certain hydrocarbon oils are not present, except that polyethylene may be used for packing or wrapping;

013.12B5 Uranium-233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium-235;

013.12B6 The amount of uranium-235 is limited as follows:

013.12B6a If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium-235 per package may not exceed the value given in TABLE I of this Subsection; or

013.12B6b If the fissile radionuclides are distributed uniformly, for example, can not form a lattice arrangement within the packaging, the maximum amount of uranium-235 per package may not exceed the value given in TABLE II of this subsection; and

013.12B7 The transport index of each package based on criticality considerations is taken as 10 times the number of grams of uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with TABLE I or TABLE II of this subsection as applicable.

013.12C Has a quality assurance program approved by the Agency.

**TABLE I - Permissible Mass of Uranium-235
Per Fissile Material Package
[Nonuniform Distribution]**

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
1.35	320
1	680*
0.92	1,200*

**TABLE II - Permissible Mass of Uranium-235
Per Fissile Material Package
[Uniform Distribution]**

Uranium enrichment in weight percent of uranium-235 not exceeding	Permissible maximum grams of uranium-235 per package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560*
1.35	800*

*Pursuant to the Agency's agreement with the NRC, jurisdiction extends only to 350 grams of uranium-235.

013.13 Assumptions as to Unknown Properties.

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

013.14 Preliminary Determinations.

Prior to the first use of any packaging for the shipment of radioactive material:

013.14A The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

013.14B Where the maximum normal operating pressure will exceed 35 kilopascal (5lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

013.14C The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the NRC; and

013.14D The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC.

013.15 Routine Determinations. Prior to each shipment of licensed material, the licensee shall determine that:

013.15A The package is proper for the contents to be shipped;

013.15B The package is in unimpaired physical condition except for superficial defects such as marks or dents;

013.15C Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

013.15D Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

013.15E Any pressure relief device is operable and set in accordance with written procedures;

013.15F The package has been loaded and closed in accordance with written procedures;

013.15G Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

013.15H The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 013.15H(1), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in TABLE I of this Subsection at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are

used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in TABLE I of this Subsection.

013.15H1 In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed 10 times the levels prescribed in 013.15H. The levels at the beginning of transport must not exceed the levels in 013.15H;

013.15I External radiation levels around the package and around the vehicle, if applicable, will not exceed 2 mSv/h (200 mrem/hr) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10.;

013.15J For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 013.15I but shall not exceed any of the following:

013.15J1 2 mSv/h (200 mrem/hr) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/hr);

013.15J1a The shipment is made in a closed transport vehicle,

013.15J1b Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

013.15J1c There are no loading or unloading operations between the beginning and end of the transportation.

013.15J2 2 mSv/h (200 mrem/hr) at any point on the outer surface of the vehicle, including the upper and top and underside of the vehicle, or, in the case of a flat-bed style vehicle, with a personnel barrier³, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load [or enclosure, if used], and on the lower external surface of the vehicle³;

013.15J3 0.1 mSv/h (10 mrem/hr) at any point 2 meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point 2 meters from the vertical planes projected from the outer edges of the vehicle; and

013.15J4 0.02 mSv/h (2 mrem/hr) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with Subsection 010.03 of these regulations; and

013.15K A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 185 degrees Fahrenheit (85 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

³A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 2 mSv/h (200 mrem/hr) at the surface.*

013.15L A package may not incorporate a feature intended to allow continuous venting during transport.

TABLE I
Removable External Radioactive Contamination Wipe Limits

Contaminant	Maximum	Permissible	Limits
	Bq/cm ²	μCi/cm ²	dpm/cm ²
Beta and gamma emitters and low toxicity alpha emitters	0.41	1.0 E-5	22
All other alpha emitting radionuclides	0.04	1.0 E-6	2.2

013.16 Air Transport of Plutonium.

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of the DOT regulations, as may be applicable, the licensee shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

013.16A The plutonium is contained in a medical device designed for individual human application; or

013.16B The plutonium is contained in a material in which the specific activity is not greater than 70 Bq/g (0.002 μCi/g) of material and in which the radioactivity is essentially uniformly distributed; or

013.16C The plutonium is shipped in a single package containing no more than an A₂ quantity of plutonium in any isotope or form and is shipped in accordance with 013.05; or

013.16D The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC; or

013.16E For a shipment of plutonium by air which is subject to 013.16D, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, the DOT regulations applicable to the air transport of plutonium.

013.17 Opening Instructions. Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with Subsection 004.37 of these regulations.

013.18 Shipment Records. Each licensee shall maintain for a period of three years after shipment a record of each shipment of licensed material not exempt under 013.04, showing, where applicable:

013.18A Identification of the packaging by model number and serial number;

013.18B Verification that the packaging, as shipped, has no significant defects;

013.18C Volume and identification of coolant;

013.18D Type and quantity of licensed material in each package, and the total quantity of each shipment;

013.18E Date of the shipment;

013.18F Name and address of the transferee;

013.18G Address to which the shipment was made; and

013.18H Results of the determinations required by 013.15 and by the conditions of the package approval.

013.19 Reports.

The licensee shall report to the Agency within 30 days:

013.19A Any instance in which there is significant reduction in the effectiveness of any packaging during use;

013.19B Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.; or

013.19C Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

013.20 Advance Notification of Transport of Nuclear Waste.

013.20A Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee,* of each state within or through which the waste will be transported.⁴

013.20B Advance notification is required only when:

013.20B1 The nuclear waste is required to be in Type B packaging for transportation;

013.20B2 The nuclear waste is being transported into, within, or through, a state en route to a disposal facility or to a collection point for transport to a disposal facility; and

013.20B3 The quantity of licensed material in a single package exceeds:

013.20B3a 3000 times the A_1 value of the radionuclides as specified in Appendix A, Table I for special form radioactive material;

013.20B3b 3000 times the A_2 value of the radionuclides as specified in Appendix A, Table I for normal form radioactive material; or

013.20B3c 1000 TBq (27,000 Ci).

⁴A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, NRC, Washington, D.C. 20555. The list will be published annually in the Federal register on or about June 30 to reflect any changes in information.

013.20C Each advance notification required by Section 013.20A shall contain the following information:

013.20C1 The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

013.20C2 A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

013.20C3 The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

013.20C4 The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

013.20C5 The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

013.20C6 A point of contact with a telephone number for current shipment information.

013.20D The notification required by 013.20A shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

013.20E The licensee shall notify each appropriate governor, or governor's designee, and the Agency of any changes to schedule information provided pursuant to 013.20A. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.

013.20F Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice, identifying the advance notification that is being canceled, to the governor, or governor's designee, of each appropriate state and to the Agency. A copy of the notice shall be retained by the licensee for one year.

013.21 Quality Assurance Requirements.

013.21A Unless otherwise authorized by the Agency, each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

013.21B The licensee shall identify the material and components to be covered by the quality assurance program.

013.21C Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

013.21D Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the Agency of its quality assurance program.

013.21E The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of three years after shipment.

013.22 Incorporation of Federal Regulations.

013.22 The following federal regulations cited in section 013 and in effect on the effective date of these regulations are hereby incorporated by reference. Copies of these regulations may be obtained from:

U.S. Government Printing Office
Superintendent of Documents
P.O. Box 371954
Pittsburgh, PA 15250-7954

Or Call Order Desk in Washington, D.C. (202)512-1800

Or Internet at http://www.access.gpo.gov/su_docs

013.22A 49 CFR Part 107

013.22B 49 CFR Parts 170 through 189

013.22C 49 CFR Parts 390 through 397

013.22D Postal Service Manual (Domestic Mail Manual), section which is incorporated by reference at 39 CFR 111.1.

013.23 The following regulations are hereby attached and incorporated by reference. They may be obtained from the above listed locations.

013.23A 10 CFR Sections 71.53, 71.59, 71.85(c) and 71.45

013 - APPENDIX A
DETERMINATION OF A_1 AND A_2

- I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is one tenth of one percent or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.
- II. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A_1 and A_2 requires Department approval, except that the values of A_1 and A_2 in Table A-2 may be used without obtaining Agency Approval.
- III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 and A_2 value to be applied shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.
- IV For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:
 - (a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_1(i)} \quad \text{Less than or equal to 1}$$

- (b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\sum_i \frac{B(i)}{A_2(i)} \quad \text{Less than or equal to 1}$$

Where $B(i)$ is the activity of radionuclide (i) and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide i, respectively.

Alternatively, an A_1 value for **mixtures of special form material** may be determined as follows:

$$A_1 = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

Where $f(i)$ is the fraction of activity of nuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide (i) .

An A value for **mixtures of normal form material** may be determined as follows:

$$A_2 = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

Where $f(i)$ is the fraction of activity of nuclide (i) in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide i .

When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formula in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Symbol of Radionuclides	Element and Atomic Number	A ₁ (TBq)	A ₁ (Ci)	A ₂ (TBq)	A ₂ (Ci)	Specific (TBq/g)	Activity (Ci/g)
Ac-225	Actinium (89)	0.6	16.2	1 E-2	0.270	2.1 E+3	5.8 E+4
Ac-227		40	1080	2 E-5	5.41 E-4	2.7	7.2 E+1
Ac-228		0.6	16.2	0.4	10.8	8.4 E+4	2.2 E+6
Ag-105	Silver (47)	2	54.1	2	54.1	1.1 E+3	3.0 E+4
Ag-108m		0.6	16.2	0.6	16.2	9.7 E-1	2.6 E+1
Ag-110m		0.4	10.8	0.4	10.8	1.8 E+2	4.7 E+3
Ag-111		0.6	16.2	0.5	13.5	5.8 E+3	1.6 E+5
Al-26	Aluminum (13)	0.4	10.8	0.4	10.8	7.0 E-4	1.9 E-2
Am-241	Americium (95)	2	54.1	2 E-4	5.41 E-3	1.3 E-1	3.4
Am-242m		2	54.1	2 E-4	5.41 E-3	3.6 E-1	1.0 E+1
Am-243		2	54.1	2 E-4	5.41 E-3	7.4 E-3	2.0 E-1
Ar-37	Argon (18)	40	1080	40	1080	3.7 E+3	9.9 E+4
Ar-39		20	541	20	541	1.3	3.4 E+1
Ar-41		0.6	16.2	0.6	16.2	1.5 E+6	4.2 E+7
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6 E+2
As-72	Arsenic (33)	0.2	5.41	0.2	5.41	6.2 E+4	1.7 E+6
As-73		40	1080	40	1080	8.2 E+2	2.2 E+4
As-74		1	27	0.5	13.5	3.7 E+3	9.9 E+4
As-76		0.2	5.41	0.2	5.41	5.8 E+4	1.6 E+6
As-77		20	541	0.5	13.5	3.9 E+4	1.0 E+6
At-211	Astatine (85)	30	811	2	54.1	7.6 E+4	2.1 E+6
Au-193	Gold (79)	6	162	6	162	3.4 E+4	9.2 E+5
Au-194		1	27	1	27.0	1.5 E+4	4.1 E+5
Au-195		10	270	10	270	1.4 E+2	3.7 E+3
Au-196		2	54.1	2	54.1	4.0 E+3	1.1 E+5
Au-198		3	81.1	0.5	13.5	9.0 E+3	2.4 E+5
Au-199		10	270	0.9	24.3	7.7 E+3	2.1 E+5
Ba-131	Barium (56)	2	54.1	2	54.1	3.1 E+3	8.4 E+4
Ba-133m		10	270	0.9	24.3	2.2 E+4	6.1 E+5
Ba-133		3	81.1	3	81.1	9.4	2.6 E+2
Ba-140		0.4	10.8	0.4	10.8	2.7 E+3	7.3 E+4
Be-7	Beryllium (4)	20	541	20	541	1.3 E+4	3.5 E+5
Be-10		20	541	0.5	13.5	8.3 E-4	2.2 E-2
Bi-205	Bismuth (83)	0.6	16.2	0.6	16.2	1.5 E-3	4.2 E+4
Bi-206		0.3	8.11	0.3	8.11	3.8 E+3	1.0 E+5
Bi-207		0.7	18.9	0.7	18.9	1.9	5.2 E+1
Bi-210m		0.3	8.11	3 E-2	0.811	2.1 E-5	5.7 E-4
Bi-210		0.6	16.2	0.5	13.5	4.6 E+3	1.2 E+5
Bi-212		0.3	8.11	0.3	8.11	5.4 E+5	1.5 E+7
Bk-247	Berkelium (97)	2	54.1	2 E-4	5.41 E-3	3.8 E-2	1.0
Bk-249		40	1080	8 E-2	2.16	6.1 E+1	1.6 E+3
Br-76	Bromine (35)	0.3	8.11	0.3	8.11	9.4 E+4	2.5 E+6
Br-77		3	81.1	3	81.1	2.6 E+4	7.1 E+5

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Br-82		0.4	10.8	0.4	10.8	4.0 E+4	1.1 E+6
C-11	Carbon (6)	1	27	0.5	13.5	3.1 E+7	8.4 E+8
C-14		40	1080	2	54.1	1.6 E-1	4.5
Ca-41	Calcium (20)	40	1080	40	1080	3.1 E-3	8.5 E-2
Ca-45		40	1080	0.9	24.3	6.6 E+2	1.8 E+4
Ca-47		0.9	24.3	0.5	13.5	2.3 E+4	6.1 E+5
Cd-109	Cadmium (48)	40	1080	1	27.0	9.6 E+1	2.6 E+3
Cd-113m		20	541	9 E-2	2.43	8.3	2.2 E+2
Cd-115m		0.3	8.11	0.3	8.11	9.4 E+2	2.5 E+4
Cd-115		4	108	0.5	13.5	1.9 E+4	5.1 E+5
Ce-139	Cerium (58)	6	162	6	162	2.5 E+2	6.8 E+3
Ce-141		10	270	0.5	13.5	1.1 E+3	2.8 E+4
Ce-143		0.6	16.2	0.5	13.5	2.5 E+4	6.6 E+5
Ce-144		0.2	5.41	0.2	5.41	1.2 E+2	3.2 E+3
Cf-248	Californium (98)	30	811	3 E-3	8.11 E-2	5.8 E+1	1.6 E+3
Cf-249		2	54.1	2 E-4	5.41 E-3	1.5 E-1	4.1
Cf-250		5	135	5 E-4	1.35 E-2	4.0	1.1 E+2
Cf-251		2	54.1	2 E-4	5.41 E-3	5.9 E-2	1.6
Cf-252		0.1	2.70	1 E-3	2.70 E-2	2.0 E+1	5.4 E+2
Cf-253		40	1080	6 E-2	1.62	1.1 E+3	2.9 E+4
Cf-254		3 E-3	8.11 E-2	6 E-4	1.62 E-2	3.1 E+2	8.5 E+3
Cl-36	Chlorine (17)	20	541	0.5	13.5	1.2 E-3	3.3 E-2
Cl-38		0.2	5.41	0.2	5.41	4.9 E+6	1.3 E+8
Cm-240	Curium (96)	40	1080	2 E-2	0.541	7.5 E+2	2.0 E+4
Cm-241		2	54.1	0.9	24.3	6.1 E+2	1.7 E+4
Cm-242		40	1080	1 E-2	0.270	1.2 E+2	3.3 E+3
Cm-243		3	81.1	3 E-4	8.11 E-3	1.9 E-3	5.2 E+1
Cm-244		4	108	4 E-4	1.08 E-2	3.0	8.1 E+1
Cm-245		2	54.1	2 E-4	5.41 E-3	6.4 E-3	1.7 E-1
Cm-246		2	54.1	2 E-4	5.41 E-3	1.1 E-2	3.1 E-1
Cm-247		2	54.1	2 E-4	5.41 E-3	3.4 E-6	9.3 E-5
Cm-248		4 E-2	1.08	5 E-5	1.35 E-3	1.6 E-4	4.2 E-3
Co-55	Cobalt (27)	0.5	13.5	0.5	13.5	1.1 E+5	3.1 E+6
Co-56		0.3	8.11	0.3	8.11	1.1 E+3	3.0 E+4
Co-57		8	216	8	216	3.1 E+2	8.4 E+3
Co-58m		40	1080	40	1080	2.2 E+5	5.9 E+6
Co-58		1	27	1	27.0	1.2 E+3	3.2 E+4
Co-60		0.4	10.8	0.4	10.8	4.2 E+1	1.1 E+3
Cr-51	Chromium (24)	30	811	30	811	3.4 E+3	9.2 E+4
Cs-129	Cesium (55)	4	108	4	108	2.8 E+4	7.6 E+5
Cs-131		40	1080	40	1080	3.8 E+3	1.0 E+5
Cs-132		1	27	1	27.0	5.7 E+3	1.5 E+5
Cs-134m		40	1080	9	243	3.0 E+5	8.0 E+6
Cs-134		0.6	16.2	0.5	13.5	4.8 E+1	1.3 E+3
Cs-135		40	1080	0.9	24.3	4.3 E-5	1.2 E-3
Cs-136		0.5	13.5	0.5	13.5	2.7 E+3	7.3 E+4

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Cs-137		2	54.1	0.5	13.5	3.2	8.7 E+1
Cu-64	Copper (29)	5	135	0.9	24.3	1.4 E+5	3.9 E+6
Cu-67		9	243	0.9	24.3	2.8 E+4	7.6 E+5
Dy-159	Dysprosium (66)	20	541	20	541	2.1 E+2	5.7 E+3
Dy-165		0.6	16.2	0.5	13.5	3.0 E+5	8.2 E+6
Dy-166		0.3	8.11	0.3	8.11	8.6 E+3	2.3 E+5
Er-169	Erbium (68)	40	1080	0.9	24.3	3.1 E+3	8.3 E+4
Er-171		0.6	16.2	0.5	13.5	9.0 E+4	2.4 E+6
Es-253	Einsteinium (99)	200	5400	2 E-2	5.41 E-1		
Es-254		30	811	3 E-3	8.11 E-2		
Es-254m		0.6	16.2	0.4	10.8		
Es-255							
Eu-147	Europium (63)	2	54.1	2	54.1	1.4 E+3	3.7 E+4
Eu-148		0.5	13.5	0.5	13.5	6.0 E+2	1.6 E+4
Eu-149		20	541	20	541	3.5 E+2	9.4 E+3
Eu-150		0.7	18.9	0.7	18.9	6.1 E+4	1.6 E+6
Eu-152m		0.6	16.2	0.5	13.5	8.2 E+4	2.2 E+6
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8 E+2
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6 E+2
Eu-155		20	541	2	54.1	1.8 E+1	4.9 E+2
Eu-156		0.6	16.2	0.5	13.5	2.0 E+3	5.5 E+4
F-18	Fluorine (9)	1	27	0.5	13.5	3.5 E+6	9.5 E+7
Fe-52	Iron (26)	0.2	5.41	0.2	5.41	2.7 E+5	7.3 E+6
Fe-55		40	1080	40	1080	8.8 E+1	2.4 E+3
Fe-59		0.8	21.6	0.8	21.6	1.8 E+3	5.0 E+4
Fe-60		40	1080	0.2	5.41	7.4 E-4	2.0 E-2
Fm-255	Fermium (100)	40	1080	0.8	21.6		
Fm-257		10	270	8 E-3	2.16 E-1		
Ga-67	Gallium (31)	6	162	6	162	2.2 E+4	6.0 E+5
Ga-68		0.3	8.11	0.3	8.11	1.5 E+6	4.1 E+7
Ga-72		0.4	10.8	0.4	10.8	1.1 E+5	3.1 E+6
Gd-146	Gadolinium (64)	0.4	10.8	0.4	10.8	6.9 E+2	1.9 E+4
Gd-148		3	81.1	3 E-4	8.11 E-3	1.2	3.2 E+1
Gd-153		10	270	5	135	1.3 E+2	3.5 E+3
Gd-159		4	108	0.5	13.5	3.9 E+4	1.1 E+6
Ge-68	Germanium (32)	0.3	8.11	0.3	8.11	2.6 E+2	7.1 E+3
Ge-71		40	1080	40	1080	5.8 E+3	1.6 E+5
Ge-77		0.3	8.11	0.3	8.11	1.3 E+5	3.6 E+6
H-3	Hydrogen (1)	See	Tritium				
Hf-172	Hafnium (72)	0.5	13.5	0.3	8.11	4.1 E+1	1.1 E+3
Hf-175		3	81.1	3	81.1	3.9 E+2	1.1 E+4
Hf-181		2	54.1	0.9	24.3	6.3 E+2	1.7 E+4
Hf-182		4	108	3 E-2	0.811	8.1 E-6	2.2 E-4

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Hg-194	Mercury (80)	1	27	1	27.0	1.3 E-1	3.5
Hg-195m		5	135	5	135	1.5 E+4	4.0 E+5
Hg-197m		10	270	0.9	24.3	2.5 E+4	6.7 E+5
Hg-197		10	270	10	270	9.2 E+3	2.5 E+5
Hg-203		4	108	0.9	24.3	5.1 E+2	1.4 E+4
Ho-163	Holmium (67)	40	1080	40	1080	2.7	7.6 E+1
Ho-166m		0.6	16.2	0.3	8.11	6.6 E-2	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6 E+4	7.0 E+5
I-123	Iodine (53)	6	162	6	162	7.1 E+4	1.9 E+6
I-124		0.9	24.3	0.9	24.3	9.3 E+3	2.5 E+5
I-125		20	541	2	54.1	6.4 E+2	1.7 E+4
I-126		2	54.1	0.9	24.3	2.9 E+3	8.0 E+4
I-129		Unlimited	Unlimited	Unlimited	Unlimited	6.5 E-6	1.8 E-4
I-131		3	81.1	0.5	13.5	4.6 E+3	1.2 E+5
I-132		0.4	10.8	0.4	10.8	3.8 E+5	1.0 E+7
I-133		0.6	16.2	0.5	13.5	4.2 E+4	1.1 E+6
I-134		0.3	8.11	0.3	8.11	9.9 E+5	2.7 E+7
I-135		0.6	16.2	0.5	13.5	1.3 E+5	3.5 E+6
In-111	Indium (49)	2	54.1	2	54.1	1.5 E+4	4.2 E+5
In-113m		4	108	4	108	6.2 E+5	1.7 E+7
In-114m		0.3	8.11	0.3	8.11	8.6 E+2	2.3 E+4
In-115m		6	162	0.9	24.3	2.2 E+5	6.1 E+6
Ir-189	Iridium (77)	10	270	10	270	1.9 E+3	5.2 E+4
Ir-190		0.7	18.9	0.7	18.9	2.3 E+3	6.2 E+4
Ir-192		1	27.0	0.5	13.5	3.4 E+2	9.2 E+3
Ir-193m		10	270	10	270	2.4 E+3	6.4 E+4
Ir-194		0.2	5.41	0.2	5.41	3.1 E+4	8.4 E+5
K-40	Potassium (19)	0.6	16.2	0.6	16.2	2.4 E-7	6.4 E-6
K-42		0.2	5.41	0.2	5.41	2.2 E+5	6.0 E+6
K-43		1.0	27	0.5	13.5	1.2 E+5	3.6 E+6
Kr-81	Krypton (36)	40	1080	40	1080	7.8 E-4	3.1 E-2
Kr-85m		6	162	6	162	3.0 E+5	8.2 E+6
Kr-85		20	541	10	270	1.5 E+1	3.9 E+2
Kr-87		0.2	5.41	0.2	5.41	1.0 E+6	2.8 E+7
La-137	Lanthanum (57)	40	1080	2	54.1	1.6 E-3	4.4 E-2
La-140		0.4	10.8	0.4	10.8	2.1 E+4	5.6 E+5
Lu-172	Lutetium (71)	0.5	13.5	0.5	13.5	4.2 E+3	1.1 E+5
Lu-173		8	216	8	216	5.6 E+1	1.5 E+3
Lu-174m		20	541	8	216	2.0 E+2	5.3 E+3
Lu-174		8	216	4	108	2.3 E+1	6.2 E+2
Lu-177		30	811	0.9	24.3	4.1 E+3	1.1 E+5
MFP	For mixed fission products, use formula for mixtures or Table A-3						
Mg-28	Magnesium (12)	0.2	5.41	0.2	5.41	2.0 E+5	5.4 E+6
Mn-52	Manganese (25)	0.3	8.11	0.3	8.11	1.6 E+4	4.4 E+5
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	6.8 E-5	1.8 E-3
Mn-54		1.0	27	1	27.0	2.9 E+2	7.7 E+3

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Mn-56		0.2	5.41	0.2	5.41	8.0 E+5	2.2 E+7
Mo-93	Molybdenum (42)	40	1080	7	189	4.1 E-2	1.1
Mo-99		0.6	16.2	0.5	13.5	1.8 E+4	4.8 E+5
N-13	Nitrogen (7)	0.6	16.2	0.5	13.5	5.4 E+7	1.5 E+9
Na-22	Sodium (11)	0.5	13.5	0.5	13.5	2.3 E+2	6.3 E+3
Na-24		0.2	5.41	0.2	5.41	3.2 E+5	8.7 E+6
Nb-92m	Niobium (41)	0.7	18.9	0.7	18.9	5.2 E+3	1.4 E+5
Nb-93m		40	1080	6	162	8.8	2.4 E+2
Nb-94		0.6	16.2	0.6	16.2	6.9 E-3	1.9 E-1
Nb-95		1	27	1	27.0	1.5 E+3	3.9 E+4
Nb-97		0.6	16.2	0.5	13.5	9.9 E+5	2.7 E+7
Nd-147	Neodymium (60)	4	108	0.5	13.5	3.0 E+3	8.1 E+4
Nd-149		0.6	16.2	0.5	13.5	4.5 E+5	1.2 E+7
Ni-59	Nickel (28)	40	1080	40	1080	3.0 E-3	8.0 E-2
Ni-63		40	1080	30	811	2.1	5.7 E+1
Ni-65		0.3	8.11	0.3	8.11	7.1 E+5	1.9 E+7
Np-235	Neptunium (93)	40	1080	40	1080	5.2 E+1	1.4 E+3
Np-236		7	189	1 E-3	2.70 E-2	4.7 E-4	1.3 E-2
Np-237		2	54.1	2 E-4	5.41 E-3	2.6 E-5	7.1 E-4
Np-239		6	162	0.5	13.5	8.6 E+3	2.3 E+5
Os-185	Osmium (76)	1	27	1	27.0	2.8 E+2	7.5 E+3
Os-191m		40	1080	40	1080	4.6 E+4	1.3 E+6
Os-191		10	270	0.9	24.3	1.6 E+3	4.4 E+4
Os-193		0.6	16.2	0.5	13.5	2.0 E+4	5.3 E+5
Os-194		0.2	5.41	0.2	5.41	1.1 E+1	3.1 E+2
P-32	Phosphorus (15)	0.3	8.11	0.3	8.11	1.1 E+4	2.9 E+5
P-33		40	1080	0.9	24.3	5.8 E+3	1.6 E+5
Pa-230	Protactinium (91)	2	54.1	0.1	2.70	1.2 E+3	3.3 E+4
Pa-231		0.6	16.2	6 E-5	1.62 E-3	1.7 E-3	4.7 E-2
Pa-233		5	135	0.9	24.3	7.7 E+2	2.1 E+4
Pb-201	Lead (Pb)	1	27	1	27.0	6.2 E+4	1.7 E+6
Pb-202		40	1080	2	54.1	1.2 E-4	3.4 E-3
Pb-203		3	81.1	3	81.1	1.1 E+4	3.0 E+5
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	4.5 E-6	1.2 E-4
Pb-210		0.6	16.2	9 E-3	0.243	2.8	7.6 E+1
Pb-212		0.3	8.11	0.3	8.11	5.1 E+4	1.4 E+6
Pd-103	Palladium (46)	40	1080	40	1080	2.8 E+3	7.5 E+4
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	1.9 E-5	5.1 E-4
Pd-109		0.6	16.2	0.5	13.5	7.9 E+4	2.1 E+6
Pm-143	Promethium (61)	3	81.1	3	81.1	1.3 E+2	3.4 E+3
Pm-144		0.6	16.2	0.6	16.2	9.2 E+1	2.5 E+3
Pm-145		30	811	7	189	5.2	1.4 E+2
Pm-147		40	1080	0.9	24.3	3.4 E+1	9.3 E+2
Pm-148m		0.5	13.5	0.5	13.5	7.9 E+2	2.1 E+4
Pm-149		0.6	16.2	0.5	13.5	1.5 E+4	4.0 E+5
Pm-151		3	81.1	0.5	13.5	2.7 E+4	7.3 E+5

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Po-208	Polonium (84)	40	1080	2 E-2	0.541	2.2 E+1	5.9 E+2
Po-209		40	1080	2 E-2	0.541	6.2 E-1	1.7 E+1
Po-210		40	1080	2 E-2	0.541	1.7 E+2	4.5 E+3
Pr-142	Praseodymium (59)	0.2	5.41	0.2	5.41	4.3 E+4	1.2 E+6
Pr-143		4	108	0.5	13.5	2.5 E+3	6.7 E+4
Pt-188	Platinum (78)	0.6	16.2	0.6	16.2	2.5 E+3	6.8 E+4
Pt-191		3	81.1	3	81.1	8.7 E+3	2.4 E+5
Pt-193m		40	1080	9	243	5.8 E+3	1.6 E+5
Pt-193		40	1080	40	1080	1.4	3.7 E+1
Pt-195m		10	270	2	54.1	6.2 E+3	1.7 E+5
Pt-197m		10	270	0.9	24.3	3.7 E+5	1.0 E+7
Pt-197		20	541	0.5	13.5	3.2 E+4	8.7 E+5
Pu-236	Plutonium (94)	7	189	7 E-4	1.89 E-2	2.0 E+1	5.3 E+2
Pu-237		20	541	20	541	4.5 E+2	1.2 E+4
Pu-238		2	54.1	2 E-4	5.41 E-3	6.3 E-1	1.7 E+1
Pu-239		2	54.1	2 E-4	5.41 E-3	2.3 E-3	6.2 E-2
Pu-240		2	54.1	2 E-4	5.41 E-3	8.4 E-3	2.3 E-1
Pu-241		40	1080	1 E-2	0.270	3.8	1.0 E+2
Pu-242		2	54.1	2 E-4	5.41 E-3	1.5 E-4	3.9 E-3
Pu-244		0.3	8.11	2 E-4	5.41 E-3	6.7 E-7	1.8 E-5
Ra-223	Radium (88)	0.6	54.1	3 E-2	0.811	1.9 E+3	5.1 E+4
Ra-224		0.3	8.11	6 E-2	1.62	5.9 E+3	1.6 E+5
Ra-225		0.6	16.2	2 E-2	0.541	1.5 E+3	3.9 E+4
Ra-226		0.3	8.11	2 E-2	0.541	3.7 E-2	1.0
Ra-228		0.6	16.2	4 E-2	1.08	1.0 E+1	2.7 E+2
Rb-81	Rubidium (37)	2	54.1	0.9	24.3	3.1 E+5	8.4 E+6
Rb-83		2	54.1	2	54.1	6.8 E+2	1.8 E+4
Rb-84		1	27	0.9	24.3	1.8 E+3	4.7 E+4
Rb-86		0.3	8.11	0.3	8.11	3.0 E+3	8.1 E+4
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	3.2 E-9	8.6 E-8
Rb(natural)		Unlimited	Unlimited	Unlimited	Unlimited	6.7 E-10	1.8 E-8
Re-183	Rhenium (75)	5	135	5	135	3.8 E+2	1.0 E+4
Re-184m		3	81.1	3	81.1	1.6 E+2	4.3 E+3
Re-184		1	27	1	27.0	6.9 E+2	1.9 E+4
Re-186		4	108	0.5	13.5	6.9 E+3	1.9 E+5
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	1.4 E-9	3.8 E-8
Re-188		0.2	5.41	0.2	5.41	3.6 E+4	9.8 E+5
Re-189		4	108	0.5	13.5	2.5 E+4	6.8 E+5
Re(natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.8 E-10	2.4 E-8
Rh-99	Rhodium (45)	2	54.1	2	54.1	3.0 E+3	8.2 E+4
Rh-101		4	108	4	108	4.1 E+1	1.1 E+3
Rh-102m		2	54.1	0.9	24.3	2.3 E+2	6.2 E+3
Rh-102		0.5	13.5	0.5	13.5	4.5 E+1	1.2 E+3
Rh-103m		40	1080	40	1080	1.2 E+6	3.3 E+7
Rh-105		10	270	0.9	24.3	3.1 E+4	8.4 E+5
Rn-222	Radon (86)	0.2	5.41	4 E-3	0.108	5.7 E+3	1.5 E+5

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Ru-97	Ruthenium (44)	4	108	4	108	1.7 E+4	4.6 E+5
Ru-103		2	54.1	0.9	24.3	1.2 E+3	3.2 E+4
Ru-105		0.6	16.2	0.5	13.5	2.5 E+5	6.7 E+6
Ru-106		0.2	5.41	0.2	5.41	1.2 E+2	3.3 E+3
S-35	Sulfur (16)	40	1080	2	54.1	1.6 E+3	4.3 E+4
Sb-122	Antimony (51)	0.3	8.11	0.3	8.11	1.5 E+4	4.0 E+5
Sb-124		0.6	16.2	0.5	13.5	6.5 E+2	1.7 E+4
Sb-125		2	54.1	0.9	24.3	3.9 E+1	1.0 E+3
Sb-126		0.4	10.8	0.4	10.8	3.1 E+3	8.4 E+4
Sc-44	Scandium (21)	0.5	13.5	0.5	13.5	6.7 E+5	1.8 E+7
Sc-46		0.5	13.5	0.5	13.5	1.3 E+3	3.4 E+4
Sc-47		9	243	0.9	24.3	3.1 E+4	8.3 E+5
Sc-48		0.3	8.11	0.3	8.11	5.5 E+4	1.5 E+6
Se-75	Selenium (34)	3	81.1	3	81.1	5.4 E+2	1.5 E+4
Se-79		40	1080	2	54.1	2.6 E-3	7.0 E-2
Si-31	Silicon (14)	0.6	16.2	0.5	13.5	1.4 E+6	3.9 E+7
Si-32		40	1080	0.2	5.41	3.9	1.1 E+2
Sm-145	Samarium (62)	20	541	20	541	9.8 E+1	2.6 E+3
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	8.5 E-10	2.3 E-8
Sm-151		40	1080	4	108	9.7 E-1	2.6 E+1
Sm-153		4	108	0.5	13.5	1.6 E+4	4.4 E+5
Sn-113	Tin (50)	4	108	4	108	3.7 E+2	1.0 E+4
Sn-117m		6	162	2	54.1	3.0 E+3	8.2 E+4
Sn-119m		40	1080	40	1080	1.4 E+2	3.7 E+3
Sn-121m		40	1080	0.9	24.3	2.0	5.4 E+1
Sn-123		0.6	16.2	0.5	13.5	3.0 E+2	8.2 E+3
Sn-125		0.2	5.41	0.2	5.41	4.0 E+3	1.1 E+5
Sn-126		0.3	8.11	0.3	8.11	1.0 E-3	2.8 E-2
Sr-82	Strontium (38)	0.2	5.41	0.2	5.41	2.3 E-3	6.2 E+4
Sr-85m		5	135	5	135	1.2 E+6	3.3 E+7
Sr-85		2	54.1	2	54.1	8.8 E+2	2.4 E+4
Sr-87m		3	81.1	3	81.1	4.8 E+5	1.3 E+7
Sr-89		0.6	16.2	0.5	13.5	1.1 E+3	2.9 E+4
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4 E+2
Sr-91		0.3	8.11	0.3	8.11	1.3 E+5	3.6 E+6
Sr-92		0.8	21.6	0.5	13.5	4.7 E+5	1.3 E+7
T	Tritium (1)	40	1080	40	1080	3.6 E+2	9.7 E+3
Ta-178	Tantalum (73)	1	27	1	27.0	4.2 E+6	1.1 E+8
Ta-179		30	811	30	811	4.1 E+1	1.1 E+3
Ta-182		0.8	21.6	0.5	13.5	2.3 E+2	6.2 E+3
Tb-157	Terbium (65)	40	1080	10	270	5.6 E-1	1.5 E+1
Tb-158		1	27	0.7	18.9	5.6 E-1	1.5 E+1
Tb-160		0.9	24.3	0.5	13.5	4.2 E+2	1.1 E+4
Tc-95m	Technetium (43)	2	54.1	2	54.1	8.3 E+2	2.2 E+4
Tc-96m		0.4	10.8	0.4	10.8	1.4 E+6	3.8 E+7
Tc-96		0.4	10.8	0.4	10.8	1.2 E+4	3.2 E+5

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

Tc-97m		40	1080	40	1080	5.6 E+2	1.5 E+4
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	5.2 E-5	1.4 E-3
Tc-98		0.7	18.9	0.7	18.9	3.2 E-5	8.7 E-4
Tc-99m		8	216	8	216	1.9 E+5	5.3 E+6
Tc-99		40	1080	0.9	24.3	6.3 E-4	1.7 E-2
Te-118	Tellurium (52)	0.2	5.41	0.2	5.41	6.8 E+3	1.8 E+5
Te-121m		5	135	5	135	2.6 E+2	7.0 E+3
Te-121		2	54.1	2	54.1	2.4 E+3	6.4 E+4
Te-123m		7	189	7	189	3.3 E+2	8.9 E+3
Te-125m		30	811	9	243	6.7 E+2	1.8 E+4
Te-127m		20	541	0.5	13.5	3.5 E+2	9.4 E+3
Te-127		20	541	0.5	13.5	9.8 E+4	2.6 E+6
Te-129m		0.6	16.2	0.5	13.5	1.1 E+3	3.0 E+4
Te-129		0.6	16.2	0.5	13.5	7.7 E+5	2.1 E+7
Te-131m		0.7	18.9	0.5	13.5	3.0 E+4	8.0 E+5
Te-132		0.4	10.8	0.4	10.8	1.1 E+4	3.0 E+5
Th-227	Thorium (90)	9	243	1 E-2	0.270	1.1 E+3	3.1 E+4
Th-228		0.3	8.11	4 E-4	1.08 E-2	3.0 E+1	8.2 E+2
Th-229		0.3	8.11	3 E-5	8.11 E-4	7.9 E-3	2.1 E-1
Th-230		2	54.1	2 E-4	5.41 E-3	7.6 E-4	2.1 E-2
Th-231		40	1080	0.9	24.3	2.0 E+4	5.3 E+5
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	4.0 E-9	1.1 E-7
Th-234		0.2	5.41	0.2	5.41	8.6 E+2	2.3 E+4
Th(natural)		Unlimited	Unlimited	Unlimited	Unlimited	8.1 E-9	2.2 E-7
Ti-44	Titanium (22)	0.5	13.5	0.2	5.41	6.4	1.7 E+2
Tl-200	Thallium (81)	0.8	21.6	0.8	21.6	2.2 E+4	6.0 E+5
Tl-201		10	270	10	270	7.9 E+3	2.1 E+5
Tl-202		2	54.1	2	54.1	2.0 E+3	5.3 E+4
Tl-204		4	108	0.5	13.5	1.7 E+1	4.6 E+2
Tm-167	Thulium (69)	7	189	7	189	3.1 E+3	8.5 E+4
Tm-168		0.8	21.6	0.8	21.6	3.1 E+2	8.3 E+3
Tm-170		4	108	0.5	13.5	2.2 E+2	6.0 E+3
Tm-171		40	1080	10	270	4.0 E+1	1.1 E+3
U-230	Uranium (92)	40	1080	1 E-2	0.270	1.0 E+3	2.7 E+4
U-232		3	81.1	3 E-4	8.11 E-3	8.3 E-1	2.2 E+1
U-233		10	270	1 E-3	2.70 E-2	3.6 E-4	9.7 E-3
U-234		10	270	1 E-3	2.70 E-2	2.3 E-4	6.2 E-3
U-235		Unlimited	Unlimited	Unlimited	Unlimited	8.0 E-8	2.2 E-6
U-236		10	270	1 E-3	2.70 E-2	2.4 E-6	6.5 E-5
U-238		Unlimited	Unlimited	Unlimited	Unlimited	1.2 E-8	3.4 E-7
U (natural)		Unlimited	Unlimited	Unlimited	Unlimited	2.6 E-8	7.1 E-7
U(enriched 5% or less)		Unlimited	Unlimited	Unlimited	Unlimited	(See Table A-3)	
U(enriched more than 5%)		10	270	1 E-3	2.70 E-2	(See Table A-3)	
U(depleted)		Unlimited	Unlimited	Unlimited	Unlimited	(See Table A-3)	

TABLE A-1: A₁ AND A₂ VALUES FOR RADIONUCLIDES

V-48	Vanadium (23)	0.3	8.11	0.3	8.11	6.3 E+3	1.7 E+5
V-49		40	1080	40	1080	3.0 E+2	8.1 E+3
W-178	Tungsten (74)	1	27	1	27.0	1.3 E+3	3.4 E+4
W-181		30	811	30	811	2.2 E+2	6.0 E+3
W-185		40	1080	0.9	24.3	3.5 E+2	9.4 E+3
W-187		2	54.1	0.5	13.5	2.6 E+4	7.0 E+5
W-188		0.2	5.41	0.2	5.41	3.7 E+2	1.0 E+4
Xe-122	Xenon (54)	0.2	5.41	0.2	5.41	4.8 E+4	1.3 E+6
Xe-123		0.2	5.41	0.2	5.41	4.4 E+5	1.2 E+7
Xe-127		4	108	4	108	1.0 E+3	2.8 E+4
Xe-131m		40	1080	40	1080	3.1 E+3	8.4 E+4
Xe-133		20	541	20	541	6.9 E+3	1.9 E+5
Xe-135		4	108	4	108	9.5 E+4	2.6 E+6
Y-87	Yttrium (39)	2	54.1	2	54.1	1.7 E+4	4.5 E+5
Y-88		0.4	10.8	0.4	10.8	5.2 E+2	1.4 E+4
Y-90		0.2	5.41	0.2	5.41	2.0 E+4	5.4 E+5
Y-91m		2	54.1	2	54.1	1.5 E+6	4.2 E+7
Y-91		0.3	8.11	0.3	8.11	9.1 E+2	2.5 E+4
Y-92		0.2	5.41	0.2	5.41	3.6 E+5	9.6 E+6
Y-93		0.2	5.41	0.2	5.41	1.2 E+5	3.3 E+6
Yb-169	Ytterbium (70)	3	81.1	3	81.1	8.9 E+2	2.4 E+4
Yb-175		30	811	0.9	24.3	6.6 E+3	1.8 E+5
Zn-65	Zinc (30)	2	54.1	2	54.1	3.0 E+2	8.2 E+3
Zn-69m		2	54.1	0.5	13.5	1.2 E+5	3.3 E+6
Zn-69		4	108	0.5	13.5	1.8 E+6	4.9 E+7
Zr-88	Zirconium (40)	3	81.1	3	81.1	6.6 E+2	1.8 E+4
Zr-93		40	1080	0.2	5.41	9.3 E-5	2.5 E-3
Zr-95		1	27	0.9	24.3	7.9 E+2	2.1 E+4
Zr-97		0.3	8.11	0.3	8.11	7.1 E+4	1.9 E+6

TABLE A-2: GENERAL VALUES FOR A₁ AND A₂

CONTENTS	A ₁		A ₂	
	TBq	Ci	TBq	Ci
Only beta- or gamma-emitting nuclides are known to be present	0.2	5	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available	0.10	2.70	2 E-5	5.4 E-4

TABLE A-3: ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment*- weight % U-235 present	Specific Activity	
	Ci/g	TBq/g
0.45	1.8 E-8	5.0 E-7
0.72	2.6 E-8	7.1 E-7
1.0	2.8 E-8	7.6 E-7
15	3.7 E-8	1.0 E-6
5.0	1.0 E-7	2.7 E-6
10.0	1.8 E-7	4.8 E-6
20.0	3.7 E-7	1.0 E-5
35.0	7.4 E-7	2.0 E-5
50.0	9.3 E-7	2.5 E-5
90.0	2.2 E-6	5.8 E-5
93.0	2.6 E-6	7.0 E-5
95.0	3.4 E-6	9.1 E-5

* The figures for uranium include representative values for the activity of the uranium-234 which is concentrated during the enrichment process.

must be taken of the behavior of materials under irradiation.

(e) A package valve or other device, the failure of which would allow radioactive contents to escape, must be protected against unauthorized operation and, except for a pressure relief device, must be provided with an enclosure to retain any leakage.

(f) A package must be designed, constructed, and prepared for shipment so that under the tests specified in § 71.71 ("Normal conditions of transport") there would be no loss or dispersal of radioactive contents, no significant increase in external surface radiation levels, and no substantial reduction in the effectiveness of the packaging.

(g) A package must be designed, constructed, and prepared for transport so that in still air at 38°C (100°F) and in the shade, no accessible surface of a package would have a temperature exceeding 50°C (122°F) in a nonexclusive use shipment, or 85°C (185°F) in an exclusive use shipment.

(h) A package may not incorporate a feature intended to allow continuous venting during transport.

§ 71.45 Lifting and tie-down standards for all packages.

(a) Any lifting attachment that is a structural part of a package must be designed with a minimum safety factor of three against yielding when used to lift the package in the intended manner, and it must be designed so that failure of any lifting device under excessive load would not impair the ability of the package to meet other requirements of this subpart. Any other structural part of the package that could be used to lift the package must be capable of being rendered inoperable for lifting the package during transport, or must be designed with strength equivalent to that required for lifting attachments.

(b) Tie-down devices:

(1) If there is a system of tie-down devices that is a structural part of the package, the system must be capable of withstanding, without generating stress in any material of the package in excess of its yield strength, a static force applied to the center of gravity of the package having a vertical component of 2 times the weight of the package with its contents, a horizontal component along the direction in which the vehicle travels of 10 times the weight of the package with its contents, and a horizontal component in the transverse direction of 5 times the weight of the package with its contents.

(2) Any other structural part of the package that could be used to tie down the package must be capable of being

rendered inoperable for tying down the package during transport, or must be designed with strength equivalent to that required for tie-down devices.

(3) Each tie-down device that is a structural part of a package must be designed so that failure of the device under excessive load would not impair the ability of the package to meet other requirements of this part.

§ 71.47 External radiation standards for all packages.

(a) Except as provided in paragraph (b) of this section, each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

(b) A package that exceeds the radiation level limits specified in paragraph (a) of this section must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

(i) The shipment is made in a closed transport vehicle;

(ii) The package is secured within the vehicle so that its position remains fixed during transportation; and

(iii) There are no loading or unloading operations between the beginning and end of the transportation;

(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

(3) 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry

designed and constructed and its contents so limited that it would be subcritical if water were to leak into the containment system, or liquid contents were to leak out of the containment system so that, under the following conditions, maximum reactivity of the fissile material would be attained:

(1) The most reactive credible configuration consistent with the chemical and physical form of the material;

(2) Moderation by water to the most reactive credible extent; and

(3) Close full reflection of the containment system by water on all sides, or such greater reflection of the containment system as may additionally be provided by the surrounding material of the packaging.

(c) The Commission may approve exceptions to the requirements of paragraph (b) of this section if the package incorporates special design features that ensure that no single packaging error would permit leakage, and if appropriate measures are taken before each shipment to ensure that the containment system does not leak.

(d) A package used for the shipment of fissile material must be so designed and constructed and its contents so limited that under the tests specified in § 71.71 ("Normal conditions of transport")—

(1) The contents would be subcritical;

(2) The geometric form of the package contents would not be substantially altered;

(3) There would be no leakage of water into the containment system unless, in the evaluation of undamaged packages under 10 CFR 71.59(a)(1), it has been assumed that moderation is present to such an extent as to cause maximum reactivity consistent with the chemical and physical form of the material; and

(4) There will be no substantial reduction in the effectiveness of the packaging, including:

(i) No more than 5 percent reduction in the total effective volume of the packaging on which nuclear safety is assessed;

(ii) No more than 5 percent reduction in the effective spacing between the fissile contents and the outer surface of the packaging; and

(iii) No occurrence of an aperture in the outer surface of the packaging large enough to permit the entry of a 10 cm (4 in) cube.

(e) A package used for the shipment of fissile material must be so designed and constructed and its contents so limited that under the tests specified in § 71.73 ("Hypothetical accident conditions"), the package would be

subcritical. For this determination, it must be assumed that:

(1) The fissile material is in the most reactive credible configuration consistent with the damaged condition of the package and the chemical and physical form of the contents;

(2) Water moderation occurs to the most reactive credible extent consistent with the damaged condition of the package and the chemical and physical form of the contents; and

(3) There is full reflection by water on all sides, as close as is consistent with the damaged condition of the package.

§ 71.57 [Reserved]

§ 71.59 Standards for arrays of fissile material packages.

(a) A fissile material package must be controlled by either the shipper or the carrier during transport to assure that an array of such packages remains subcritical. To enable this control, the designer of a fissile material package shall derive a number "N" based on all the following conditions being satisfied, assuming packages are stacked together in any arrangement and with close full reflection on all sides of the stack by water:

(1) Five times "N" undamaged packages with nothing between the packages would be subcritical;

(2) Two times "N" damaged packages if each package were subjected to the tests specified in § 71.73 ("Hypothetical accident conditions") would be subcritical with optimum interspersed hydrogenous moderation; and

(3) The value of "N" cannot be less than 0.5.

(b) The transport index based on nuclear criticality control must be obtained by dividing the number 50 by the value of "N" derived using the procedures specified in paragraph (a) of this section. The value of the transport index for nuclear criticality control may be zero provided that an unlimited number of packages is subcritical such that the value of "N" is effectively equal to infinity under the procedures specified in paragraph (a) of this section. Any transport index greater than zero must be rounded up to the first decimal place.

(c) Where a fissile material package is assigned a nuclear criticality control transport index—

(1) Not in excess of 10, that package may be shipped by any carrier, and that carrier provides adequate criticality control by limiting the sum of the transport indexes to 50 in a non-exclusive use vehicle, and to 100 in exclusive use vehicle.

(2) In excess of 10, that package may only be shipped by exclusive use

vehicle or other shipper controlled system specified by DOT for fissile material packages. The shipper provides adequate criticality control by limiting the sum of the transport indexes to 100 in an exclusive use vehicle.

§ 71.61 Special requirement for irradiated nuclear fuel shipments.

A package for irradiated nuclear fuel with activity greater than 37 PBq (10^6 Ci) must be so designed that its undamaged containment system can withstand an external water pressure of 2 MPa (290 psi) for a period of not less than one hour without collapse, buckling, or leakage of water.

§ 71.63 Special requirements for plutonium shipments.

(a) Plutonium in excess of 0.74 TBq (20 Ci) per package must be shipped as a solid.

(b) Plutonium in excess of 0.74 TBq (20 Ci) per package must be packaged in a separate inner container placed within outer packaging that meets the requirements of Subparts E and F of this part for packaging of material in normal form. If the entire package is subjected to the tests specified in § 71.71 ("Normal conditions of transport"), the separate inner container must not release plutonium as demonstrated to a sensitivity of 10^{-6} A₂/h. If the entire package is subjected to the tests specified in § 71.73 ("Hypothetical accident conditions"), the separate inner container must restrict the loss of plutonium to not more than A₂ in 1 week. Solid plutonium in the following forms is exempt from the requirements of this paragraph:

- (1) Reactor fuel elements;
- (2) Metal or metal alloy;
- (3) Vitrified high-level waste contained in a sealed canister designed to maintain waste containment during handling activities associated with transport. As one method of meeting these design requirements, the NRC will consider acceptable a canister which is designed in accordance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure

Vessel Code, Section VIII, 1995 Edition (earlier editions may be used in lieu of the 1995 Edition). However, this canister need not be designed in accordance with the requirements of Section VIII, Parts UG-46, UG-115 through UG-120, UG-125 through UG-136, UW-60, UW-65, UHA-60, and UHA-65 and the canister's final closure weld need not be designed in accordance with the requirements of Section VIII, Parts UG-99 and UW-11. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of the ASME Boiler and Pressure Vessel Code, Section VIII, 1995 Edition, may be purchased from the American Society of Mechanical Engineers, Service Center, 22 Law Drive, P.O. Box 2900, Fairfield, NJ 07007. It is also available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, MD 20852-2738 or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.; and

(4) Other plutonium bearing solids that the Commission determines should be exempt from the requirements of this section.

§ 71.64 Special requirements for plutonium air shipments.

(a) A package for the shipment of plutonium by air subject to § 71.88(a)(4), in addition to satisfying the requirements of §§ 71.41 through 71.63, as applicable, must be designed, constructed, and prepared for shipment so that under the tests specified in—

- (1) Section 71.74 ("Accident conditions for air transport of plutonium")—
 - (i) The containment vessel would not be ruptured in its post-tested condition; and the package must provide a sufficient degree of containment to restrict accumulated loss of plutonium contents to not more than an A₂ quantity in a period of 1 week;

(ii) The external radiation level would not exceed 10 mSv/h (1 rem/h) at a distance of 1 m (40 in) from the surface of the package in its post-tested condition in air; and

(iii) A single package and an array of packages are demonstrated to be subcritical in accordance with this part, except that the damaged condition of the package must be considered to be that which results from the plutonium accident tests in § 71.74, rather than the hypothetical accident tests in § 71.73; and

(2) Section 71.74(c), there would be no detectable leakage of water into the containment vessel of the package.

(b) With respect to the package requirements of paragraph (a), there must be a demonstration or analytical assessment showing that—

(1) The results of the physical testing for package qualification would not be adversely affected to a significant extent by—

(i) The presence, during the tests, of the actual contents that will be transported in the package; and

(ii) Ambient water temperatures ranging from 0.6°C (+33°F) to 38°C (+100°F) for those qualification tests involving water, and ambient atmospheric temperatures ranging from -40°C (-40°F) to +54°C (+130°F) for the other qualification tests.

(2) The ability of the package to meet the acceptance standards prescribed for the accident condition sequential tests would not be adversely affected if one or more tests in the sequence were deleted.

§ 71.65 Additional requirements.

The Commission may, by rule, regulation, or order, impose requirements on any licensee, in addition to those established in this part, as it deems necessary or appropriate to protect public health or to minimize danger to life or property.

Subpart F—Package, Special Form, and LSA-III Tests²

§ 71.71 Normal conditions of transport.

(a) *Evaluation.* Evaluation of each package design under normal conditions of transport must include a determination of the effect on that design of the conditions and tests specified in this section. Separate specimens may be used for the free drop test, the compression test, and the penetration test, if each specimen is subjected to the water spray test before being subjected to any of the other tests.

² The package standards related to the tests in this subpart are contained in subpart E of this part.

(b) *Initial conditions.* With respect to the initial conditions for the tests in this section, the demonstration of compliance with the requirements of this part must be based on the ambient temperature preceding and following the tests remaining constant at that value between -29°C (-20°F) and +38°C (+100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system must be considered to be the maximum normal operating pressure, unless a lower internal pressure consistent with the ambient temperature considered to precede and follow the tests is more unfavorable.

(c) *Conditions and tests.*

(1) *Heat.* An ambient temperature of 38°C (100°F) in still air, and insulation according to the following table:

INSULATION DATA

Form and location of surface	Total insulation for a 12-hour period (g cal/cm ²)
Flat surfaces transported horizontally:	
Base	None
Other surfaces	800
Flat surfaces not transported horizontally.	200
Curved surfaces	400

(2) *Cold.* An ambient temperature of -40°C (-40°F) in still air and shade.

(3) *Reduced external pressure.* An external pressure of 25 kPa (3.5 lbf/in²) absolute.

(4) *Increased external pressure.* An external pressure of 140 kPa (20 lbf/in²) absolute.

(5) *Vibration.* Vibration normally incident to transport.

(6) *Water spray.* A water spray that simulates exposure to rainfall of approximately 5 cm/h (2 in/h) for at least 1 hour.

(7) *Free drop.* Between 1.5 and 2.5 hours after the conclusion of the water spray test, a free drop through the distance specified below onto a flat, essentially unyielding, horizontal surface, striking the surface in a position for which maximum damage is expected.

CRITERIA FOR FREE DROP TEST (WEIGHT/DISTANCE)

Package weight		Free drop distance	
Kilograms	(Pounds)	Meters	(Feet)
Less than 5,000.	(Less than 11,000).	1.2	(4)
5,000 to 10,000.	(11,000 to 22,000).	0.9	(3)
10,000 to 15,000.	(22,000 to 33,100).	0.6	(2)
More than 15,000.	(More than 33,100).	0.3	(1)

(8) *Corner drop.* A free drop onto each corner of the package in succession, or in the case of a cylindrical package onto each quarter of each rim, from a height of 0.3 m (1 ft) onto a flat, essentially unyielding, horizontal surface. This test applies only to fiberboard, wood, or fissile material rectangular packages not exceeding 50 kg (110 lbs) and fiberboard, wood, or fissile material cylindrical packages not exceeding 100 kg (220 lbs).

(9) *Compression.* For packages weighing up to 5000 kg (11,000 lbs), the package must be subjected, for a period of 24 hours, to a compressive load applied uniformly to the top and bottom of the package in the position in which the package would normally be transported. The compressive load must be the greater of the following:

- (i) The equivalent of 5 times the weight of the package; or
- (ii) The equivalent of 13 kPa (2 lbf/in²) multiplied by the vertically projected area of the package.

(10) *Penetration.* Impact of the hemispherical end of a vertical steel cylinder of 3.2 cm (1.25 in) diameter and 6 kg (13 lbs) mass, dropped from a height of 1 m (40 in) onto the exposed surface of the package that is expected to be most vulnerable to puncture. The long axis of the cylinder must be perpendicular to the package surface.

§ 71.73 Hypothetical accident conditions.

(a) *Test procedures.* Evaluation for hypothetical accident conditions is to be based on sequential application of the tests specified in this section, in the order indicated, to determine their cumulative effect on a package or array of packages. An undamaged specimen may be used for the water immersion tests specified in paragraph (c)(6) of this section.

(b) *Test conditions.* With respect to the initial conditions for the tests, except for the water immersion tests, to demonstrate compliance with the requirements of this part during testing, the ambient air temperature before and after the tests must remain constant at that value between -29°C (-20°F) and

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+38°C (+100°F) which is most unfavorable for the feature under consideration. The initial internal pressure within the containment system must be the maximum normal operating pressure, unless a lower internal pressure, consistent with the ambient temperature assumed to precede and follow the tests, is more unfavorable.

(c) *Tests.* Tests for hypothetical accident conditions must be conducted as follows:

(1) *Free Drop.* A free drop of the specimen through a distance of 9 m (30 ft) onto a flat, essentially unyielding, horizontal surface, striking the surface in a position for which maximum damage is expected.

(2) *Crush.* Subjection of the specimen to a dynamic crush test by positioning the specimen on a flat, essentially unyielding, horizontal surface so as to suffer maximum damage by the drop of a 500 kg (1100 pound) mass from 9 m (30 ft) onto the specimen. The mass must consist of a solid mild steel plate 1 m (40 in) by 1 m and must fall in a horizontal attitude. The crush test is required only when the specimen has a mass not greater than 500 kg (1100 lbs), an overall density not greater than 1000 kg/m³ (62.4 lbs/ft³) based on external dimensions, and radioactive contents greater than 1000 A₂ not as special form radioactive material.

(3) *Puncture.* A free drop of the specimen through a distance of 1 m (40 in) in a position for which maximum damage is expected, onto the upper end of a solid, vertical, cylindrical, mild steel bar mounted on an essentially unyielding, horizontal surface. The bar must be 15 cm (6 in) in diameter, with the top horizontal and its edge rounded to a radius of not more than 6 mm (0.25 in), and of a length as to cause maximum damage to the package, but not less than 20 cm (8 in) long. The long axis of the bar must be vertical.

(4) *Thermal.* Exposure of the specimen fully engulfed, except for a simple support system, in a hydrocarbon fuel/air fire of sufficient extent, and in sufficiently quiescent ambient conditions, to provide an average emissivity coefficient of at least 0.9, with an average flame temperature of at least 800°C (1475°F) for a period of 30 minutes, or any other thermal test that provides the equivalent total heat input to the package and which provides a time averaged environmental temperature of 800°C. The fuel source must extend horizontally at least 1 m (40 in), but may not extend more than 3 m (10 ft), beyond any external surface of the specimen, and the specimen must be positioned 1 m (40 in) above the surface of the fuel source. For purposes

of calculation, the surface absorptivity coefficient must be either that value which the package may be expected to possess if exposed to the fire specified or 0.8, whichever is greater; and the convective coefficient must be that value which may be demonstrated to exist if the package were exposed to the fire specified. Artificial cooling may not be applied after cessation of external heat input, and any combustion of materials of construction, must be allowed to proceed until it terminates naturally.

(5) *Immersion—fissile material.* For fissile material subject to § 71.55, in those cases where water leakage has not been assumed for criticality analysis, immersion under a head of water of at least 0.9 m (3 ft) in the attitude for which maximum leakage is expected.

(6) *Immersion—all packages.* A separate, undamaged specimen must be subjected to water pressure equivalent to immersion under a head of water of at least 15 m (50 ft). For test purposes, an external pressure of water of 150 kPa (21.7 lbf/in²) gauge is considered to meet these conditions.

§ 71.74 Accident conditions for air transport of plutonium.

(a) *Test conditions—Sequence of tests.* A package must be physically tested to the following conditions in the order indicated to determine their cumulative effect.

(1) Impact at a velocity of not less than 129 m/sec (422 ft/sec) at a right angle onto a flat, essentially unyielding, horizontal surface, in the orientation (e.g., side, end, corner) expected to result in maximum damage at the conclusion of the test sequence.

(2) A static compressive load of 31,800 kg (70,000 lbs) applied in the orientation expected to result in maximum damage at the conclusion of the test sequence. The force on the package must be developed between a flat steel surface and a 5 cm (2 in) wide, straight, solid, steel bar. The length of the bar must be at least as long as the diameter of the package, and the longitudinal axis of the bar must be parallel to the plane of the flat surface. The load must be applied to the bar in a manner that prevents any members or devices used to support the bar from contacting the package.

(3) Packages weighing less than 227 kg (500 lbs) must be placed on a flat, essentially unyielding, horizontal surface, and subjected to a weight of 227 kg (500 lbs) falling from a height of 3 m (10 ft) and striking in the position expected to result in maximum damage at the conclusion of the test sequence.

§ 71.77 Qualification of LSA-III Material

(a) LSA-III material must meet the test requirements of paragraph (b) of this section. Any differences between the specimen to be tested and the material to be transported must be taken into account in determining whether the test requirements have been met.

(b) *Leaching Test.* (1) The specimen, representing no less than the entire contents of the package, must be immersed for 7 days in water at ambient temperature;

(2) The volume of water to be used in the test must be sufficient to ensure that at the end of the test period the free volume of the unabsorbed and unreacted water remaining will be at least 10% of the volume of the specimen itself;

(3) The water must have an initial pH of 6–8 and a maximum conductivity 10 micromho/cm at 20°C (68°F); and

(4) The total activity of the free volume of water must be measured following the 7 day immersion test and must not exceed 0.1 A₂.

Subpart G—Operating Controls and Procedures**§ 71.81 Applicability of operating controls and procedures.**

A licensee subject to this part, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this subpart G, with the quality assurance requirements of subpart H of this part, and with the general provisions of subpart A of this part.

§ 71.83 Assumptions as to unknown properties.

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

§ 71.85 Preliminary determinations.

Before the first use of any packaging for the shipment of licensed material—

(a) The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging;

(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating

pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

(c) The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by NRC. Before applying the model number, the licensee shall determine that the packaging has been fabricated in accordance with the design approved by the Commission.

§ 71.87 Routine determinations.

Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this part and of the license. The licensee shall determine that—

(a) The package is proper for the contents to be shipped;

(b) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(c) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(d) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(e) Any pressure relief device is operable and set in accordance with written procedures;

(f) The package has been loaded and closed in accordance with written procedures;

(g) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(h) Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of § 71.45;

(i) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(j) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in § 71.47 at any time during transportation; and

(k) Accessible package surface temperatures will not exceed the limits specified in § 71.43(g) at any time during transportation.

§ 71.88 Air transport of plutonium.

(a) Notwithstanding the provisions of any general licenses and

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SUBCHAPTER C—POST OFFICE SERVICES [DOMESTIC MAIL]

General Information on Postal Service

PART 111—GENERAL INFORMATION ON POSTAL SERVICE

Sec.

- 111.1 Domestic Mail Manual: incorporation by reference of regulations governing domestic mail services.
- 111.2 Availability of the Domestic Mail Manual.
- 111.3 Amendments to the Domestic Mail Manual.
- 111.4 Approval of the Director of the Federal Register.
- 111.5 Contents of the Domestic Mail Manual.

AUTHORITY: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 3001-3011, 3201-3219, 3403-3406, 3621, 3626, 5001.

SOURCE: 44 FR 39852, July 6, 1979, unless otherwise noted.

§ 111.1 Domestic Mail Manual: incorporated by reference of regulations governing domestic mail services.

Section 552(a) of title 5, U.S.C., relating to the public information requirements of the Administrative Procedure Act, provides in pertinent part that " * * matter reasonably available to the class of persons affected thereby is deemed published in the FEDERAL REGISTER when incorporated by reference therein with the approval of the Director of the Federal Register." In conformity with that provision, and with 39 U.S.C. section 410(b)(1), and as provided in this part, the U.S. Postal Service hereby incorporates by reference in this part, the Domestic Mail Manual, a looseleaf document published twice each year in January and July, unless otherwise determined by the Postal Service.

[62 FR 14827, Mar. 28, 1997]

§ 111.2 Availability of the Domestic Mail Manual.

(a) Copies of the Domestic Mail Manual, both current and previous issues, are available during regular business hours for reference and public inspection at the U.S. Postal Service Library, National Headquarters in Washington,

DC. Copies of only the current issue are available during regular business hours for public inspection at area and district offices of the Postal Service and at all post offices, classified stations, and classified branches.

(b) A copy of the current Domestic Mail Manual is on file with the Director, Office of the Federal Register, National Archives and Records Administration, 800 North Capitol Street, NW, Suite 700, Washington, DC.

(c) A 1-year subscription to the Domestic Mail Manual for two consecutive issues can be purchased by the public from the Superintendent of Documents, Washington, DC 20402-9375.

[62 FR 14827, Mar. 28, 1997]

§ 111.3 Amendments to the Domestic Mail Manual.

(a) Except for interim or final regulations published as provided in paragraph (b) of this section, only notices rather than complete text of changes made to the Domestic Mail Manual are published in the FEDERAL REGISTER. These notices are published in the form of one summary transmittal letter for each issue of the Domestic Mail Manual. A complete issue of the Domestic Mail Manual, including the text of all changes published to date, will be filed with the Director, Office of the Federal Register. Subscribers to the Domestic Mail Manual receive the latest issue of the Domestic Mail Manual from the Government Printing Office.

(b) When the Postal Service invites comments from the public on a proposed change to the Domestic Mail Manual, the proposed change and, if adopted, the full text of the interim or the final regulation is published in the FEDERAL REGISTER.

(c) The Postal Bulletin contains the full text of all interim and final regulations published as provided in paragraph (b) of this section, and the full text of all other changes to the Domestic Mail Manual that are summarized in the notices published under paragraph (a) of this section, except for nonsubstantive changes and corrections of typographical errors. The

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014 RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING AND SUBSURFACE TRACER STUDIES

014.01 Purpose and Scope.

014.01A This section establishes radiation safety requirements for persons using sources of radiation in these operations. This section applies to all licensees who use radioactive material including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well.

014.01B The provisions and requirements of this section are in addition to, and not in substitution for, other requirements of these regulations. In particular, the provisions of Sections 001, 002, 003, 004, 010, 013, 015, 017 and 018 of these regulations apply to applicants and licensees subject to this section.

014.02 Definitions. As used in this section, the following definitions apply:

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

"Fresh water aquifer," for the purpose of this section, means a geologic formation that is capable of yielding fresh water to a well or spring, except those aquifers exempted pursuant to 40 CFR 122.35.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Irretrievable well logging source" means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 014.17.

"Logging supervisor" means an individual who uses radioactive material or provides personal supervision in the use of radioactive material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the regulations and the conditions of the license.

"Logging tool" means a device used subsurface to perform well logging.

"Personal supervision" means guidance and instruction by a logging supervisor, who is physically present at a temporary jobsite, who is in personal contact with logging assistants, and who can give immediate assistance.

"Radioactive marker" means radioactive material used for depth determination or direction orientation. For purposes of this section, this term includes radioactive collar markers and radioactive iron nails.

"Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

"Source holder" means a housing or assembly into which a sealed source is placed to facilitate the handling and use of the source in well logging.

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"Subsurface tracer study" means the release of unsealed radioactive material or a substance labeled with radioactive material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

"Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

"Temporary jobsite" means a place where radioactive material are present for the purpose of performing well logging or subsurface tracer studies.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

"Well" means a drilled hole in which well logging may be performed. As used in this section, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater, or geological exploration.

"Well logging" means all operations involving the lowering and raising of measuring devices or tools which contain radioactive material or are used to detect radioactive materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater, or geological exploration.

014.03 Agreement With Well Owner or Operator.

014.03A A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements.

014.03A1 If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

014.03A2 A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

014.03A3 The radiation monitoring required in 014.18A will be performed;

014.03A4 If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release from the site or release for unrestricted use; and

014.03A5 If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within 30 days:

014.03A5a Each irretrievable well logging source must be immobilized and sealed in place with a cement plug.

014.03A5b A mechanical device to prevent inadvertent intrusion on the source must be set at some point in the well above the cement plug, unless the cement plug, and source are not accessible to any subsequent drilling operations; and

014.03A5c A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless

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the mounting of the plaque is not practical. The size of the plaque must be at least 7 inches (17 cm) square and 1/8-inch (3mm) thick. The plaque must contain:

- 014.03A5c(1) The word "Caution";
- 014.03A5c(2) The radiation symbol (the color requirement in 004.32A of these regulations need not be met);
- 014.03A5c(3) The date the source was abandoned;
- 014.03A5c(4) The name of the well owner or well operator as appropriate;
- 014.03A5c(5) The well name and well identification number(s) or other designation;
- 014.03A5c(6) An identification of the sealed source(s) by radionuclide and quantity;
- 014.03A5c(7) The depth of the source and depth to the top of the plug; and
- 014.03A5c(8) An appropriate warning such as "DO NOT RE-ENTER THIS WELL".

014.03A5d If a radioactive source is classified as irretrievably lost in any well or test hole, the licensee shall, within 15 days, file with the Register of Deeds of the County in which the well or test hole is located, a map of the location, including the legal description where the source was irretrievably lost, and a statement identifying the type and quantity of the radioactive source. Certified copies of the filing shall be submitted to the Agency within 30 days of the filing.

014.03B The licensee shall retain a copy of the written agreement for 3 years after the completion of the well logging operation.

014.03C If a radioactive source is irretrievably lost in a fresh water aquifer or down a liquified petroleum products storage cavity, then a drilling safety zone shall be established by the Agency upon review of the geology and hydrology of the site. All wells and storage cavities in the drilling safety zone shall be abandoned and no fluids shall be removed except upon approval by the Agency. In addition of the notice requirements in Subpart 014.03A5, within 15 days after receipt of notice of the establishment of a drilling safety zone by the Agency, the licensee shall prepare a map of the drilling safety zone indicating the type and quantity of radioactive source, and the map shall be filed with the Register of Deeds of any County which forms a portion of the drilling safety zone. Certified copies of the filing shall be submitted to the Agency within 30 days after the filing.

014.03D A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements in 014.03A1 through 014.03A5.

Equipment

014.04 Labels, Security, and Transportation Precautions.

014.04A Labels.

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014.04A1 The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in Subsection 004.32A of these regulations, without the conventional color requirements, and the wording:

**CAUTION¹
RADIOACTIVE MATERIAL**

014.04A2 The licensee may not use a container to store radioactive material unless the container has securely attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol specified in Subsection 004.32A of these regulations and the wording:

**CAUTION²
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)**

014.04A3 The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Section 013 of these regulations.

014.04B Security, Precautions During Storage and Transportation.

014.04B1 The licensee shall store each source containing radioactive material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of radioactive material from storage by unauthorized personnel. The licensee shall store radioactive material in a manner which will minimize danger from explosion or fire.

014.04B2 The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

014.05 Radiation Survey Instruments.

014.05A The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this section and by Section 004 of these regulations. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 milliroentgen (2.58E - 8 C/kg) per hour through at least 50 milliroentgens (1.29E - 5 C/kg) per hour.

014.05B The licensee shall have available additional calibrated and operable radiation survey instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

¹Or "Danger".

²Ibid. p. 14 - 5

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014.05C The licensee shall have each radiation survey instrument required under paragraph 014.05A of this section calibrated:

014.05C1 At intervals not to exceed 6 months and after instrument servicing;

014.05C2 For linear scale instruments, at two points located approximately 1/3 and 2/3 of full scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at approximate points;

014.05C3 So that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale; and

014.05C4 At energies and radiation levels appropriate for use.

014.05D The licensee shall retain calibration records for a period of 3 years after the date of calibration for inspection by the Agency.

014.06 Leak Testing of Sealed Sources.

014.06A Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.

014.06B Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

014.06C Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

014.06D Removal of Leaking Source from Service.

014.06D1 If the test conducted pursuant to 014.06A and B of this section reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by a U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions.

014.06D2 The licensee shall submit a report to the Agency within 5 days of receiving the test results. The report must describe the equipment involved in the leak test, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

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014.06E Exemptions from Testing Requirements. The following sealed sources are exempt from the periodic leak test requirements set out in 014.06A through D of this section:

014.06E1 Hydrogen-3 sources;

014.06E2 Sources containing radioactive material with a half-life of 30 days or less;

014.06E3 Sealed sources containing radioactive material in gaseous form;

014.06E4 Sources of beta- or gamma- emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

014.06E5 Sources of alpha- or neutron- emitting radioactive material with an activity of 10 microcuries (0.37 MBq) or less.

014.07 Physical Inventory. Each licensee shall conduct a quarterly physical inventory to account for all radioactive material received and possessed under the license. The licensee shall retain records of the inventory for 3 years from the date of the inventory for inspection by the Agency. The inventory must indicate the quantity and kind of radioactive material, the location of the radioactive material, the date of the inventory, and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

014.08 Records of Material Use.

014.08A Each licensee shall maintain records for each use of radioactive material showing:

014.08A1 The make, model number, and a serial number or a description of each sealed source used;

014.08A2 In the case of unsealed radioactive material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;

014.08A3 The identity of the logging supervisor who is responsible for the radioactive material and the identity of logging assistants present; and

014.08A4 The location and date of use of the radioactive material.

014.08B The licensee shall make the records required by 014.08A of this section available for inspection by the Agency. The licensee shall retain the records for 3 years from the date of the recorded event.

014.09 Design, Performance Criteria for Sealed Sources.

014.09A A licensee shall not use a sealed source in well logging unless the sealed source:

014.09A1 Is doubly encapsulated;

014.09A2 Contains radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

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014.09A3 The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

014.09A3a Temperature. The test source must be held at 40°C (104°F) or 20 minutes, 600°C (1112°F) for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600°C (1112°F) to 20°C (68°F) within 15 seconds.

014.09A3b Impact Test. A 5 kg steel hammer, 2.5cm in diameter, must be dropped from a height of 1m onto the test source.

014.09A3c Vibration Test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5g amplitude for 30 minutes:

014.09A3d Puncture Test. A 1 gram hammer and pin, 0.3cm pin diameter, must be dropped from a height of 1m onto the test source.

014.09A3e Pressure Test. The test source must be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695E+7 pascals).

014.09B The requirements in 014.09A of this section do not apply to sealed sources that contain radioactive material in gaseous form.

014.10 Inspection, Maintenance, and Opening of a Source or Source Holder.

014.10A Each licensee shall visually check source holders, logging tools, and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment shall be removed from service until repaired and a record must be made listing: the date of check, name of inspector, equipment involved, defects found, and repairs made. These records shall be retained for 3 years after the defect is found.

014.10B Each licensee shall conduct, at intervals not to exceed 6 months, a program of visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment shall be removed from service until repaired, and a record shall be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. These records shall be retained for 3 years after the defect is found.

014.10C Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure pursuant to 014.15 has been developed by the licensee and approved by the Agency based upon compliance with Sections 004 and 010 of these regulations.

014.10D If a sealed source is stuck in the source holder, the licensee may not perform any operation on the source holder, such as drilling, cutting, or chiseling, unless the licensee is specifically approved by the Agency; approval shall be based upon training and experience of the licensee and upon compliance with Sections 004 and 010 of these regulations.

014.10E The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State.

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014.11 Subsurface Tracer Studies.

014.11A The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the licensee, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

014.11B A licensee may not knowingly inject radioactive material into fresh water aquifers.

014.12 Uranium Sinker Bars. The licensee may use a uranium sinker bar in well logging only if it is legibly impressed with the words "CAUTION - RADIOACTIVE - DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND".

014.13 Use of a Sealed Source.

014.13A In a Well With a Surface Casing. No sealed source may be used in any well unless the well is cased pursuant to the rules and regulations of the Nebraska Oil and Gas Conservation Commission Title 267 Chapter 3, 012.01 through 012.03 and 012.09 and Chapter 4, 006.01B.

014.13B In a Well Without a Surface Casing. The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Agency.

Radiation Safety Requirements

014.14 Training and Experience Qualification Requirements for Well Logging Personnel. Are specified in Subsection 015.30 of these regulations.

014.15 Operating and Emergency Procedures. Each licensee shall develop and follow written operating and emergency procedures that cover:

014.15A The handling and use of radioactive materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

014.15B The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

014.15C Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by 014.17B-E;

014.15D Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive tracer materials;

014.15E Methods and occasions for locking and securing stored radioactive materials;

014.15F Personnel monitoring and the use of personnel monitoring equipment;

014.15G Transportation of sources of radiation to field stations or temporary jobsites, packaging of sources of radiation for transport in vehicles, placarding of vehicles when needed, and physically securing sources of radiation in transport vehicles during transportation to prevent accidental loss, tampering or unauthorized removal;

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014.15H Picking up, receiving, and opening packages containing radioactive materials, in accordance with Subsection 004.37 of these regulations;

014.15I For the use of tracers, decontamination of the environment, equipment, and personnel;

014.15J Maintenance of records generated by logging personnel at temporary jobsites;

014.15K The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by 014.10;

014.15L Actions to be taken if a sealed source is lodged in a well;

014.15M Notifying proper persons in the event of an accident; and

014.15N Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination, to minimize inhalation and ingestion of radioactive materials, and actions to obtain suitable radiation survey instruments as required by Part 014.05B.

014.16 Personnel Monitoring.

014.16A The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of radioactive materials, either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

014.16B The licensee shall provide bioassay services to individuals using radioactive materials in subsurface tracer studies if required by the license.

014.16C The licensee shall retain records of film badge, TLD and bioassay results until inspected by the Agency.

014.17 Radiation Surveys.

014.17A The licensee shall make radiation surveys, including but not limited to the surveys required under 014.17B through 014.17E of this section, of each area where radioactive materials are used and stored.

014.17B Before transporting radioactive materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.

014.17C If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

014.17D If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

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014.17E The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

014.17F The results of surveys required under 014.17A through 014.17E of this section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee shall retain records of survey for inspection by the Agency for 3 years after they are made.

014.18 Radioactive Contamination Control.

014.18A If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by 014.15.

014.18B If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

014.18C During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

Precautionary Procedures in Logging and Subsurface Tracer Operations

014.19 Handling Tools. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

014.20 Particle Accelerators. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of Subsections 004.06 and 004.14 of these regulations, as appropriate, are met.

Security, Records, Notifications

014.21 Security.

014.21A A logging supervisor must be physically present at a temporary jobsite whenever radioactive material is being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

014.21B During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 001.02 in these regulations.

014.22 Documents and Records Required at Field Stations. Each licensee shall maintain the following documents and records at the field station:

014.22A A copy of Sections 004, 010 and 014 of these regulations;

014.22B The license authorizing the use of radioactive material;

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- 014.22C Operating and emergency procedures required by 014.15;
- 014.22D The record of radiation survey instrument calibrations required by 014.05;
- 014.22E The record of leak tests required by 014.06;
- 014.22F Physical inventory records required by 014.07;
- 014.22G Utilization records required by 014.08;
- 014.22H Records of inspection and maintenance required by 014.10;
- 014.22I Training records required by 014.14; and
- 014.22J Survey records required by 014.17.

014.23 Documents and Records Required at Temporary Jobsites. Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

- 014.23A Operating and emergency procedures required by 014.15;
- 014.23B Evidence of latest calibration of the radiation survey instruments in use at the site required by 014.05;
- 014.23C Latest survey records required by 014.17B, C and E;
- 014.23D The shipping papers for the transportation of radioactive materials required by Subsection 013.05 of these regulations; and
- 014.23E When operating under reciprocity pursuant to Subsection 003.28 of these regulations, a copy of the U.S. Nuclear Regulatory Commission or Agreement State License authorizing use of radioactive materials.

014.24 Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources.

014.24A The licensee shall immediately notify the Agency by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the escape of radioactive materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

014.24B The licensee shall notify the Agency of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by Subsections 004.56, 004.57, 004.58 and 003.26 of these regulations.

014.24C If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:

014.24C1 Notify the appropriate Agency by telephone of the circumstances that resulted in the inability to retrieve the source and obtain approval to implement abandonment procedures;

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014.24C2 Advise the well owner or operator, as appropriate, of the abandonment procedures under 014.03A or C; and

014.24C3 Either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

014.24D The licensee shall, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the Agency. The report must contain the following information:

014.24D1 Date of occurrence;

014.24D2 A description of the irretrievable well logging source involved including the radionuclide and its quantity, chemical, and physical form;

014.24D3 Surface location and identification of the well;

014.24D4 Results of efforts to immobilize and seal the source in place;

014.24D5 A brief description of the attempted recovery effort;

014.24D6 Depth of the source;

014.24D7 Depth of the top of the cement plug;

014.24D8 Depth of the well; and

014.24D9 Any other information, such as a warning statement, contained on the permanent identification plaque.

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Section 015 TRAINING AND EXPERIENCE REQUIREMENTS FOR USE OF RADIATION SOURCES

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SECTION 015 TRAINING AND EXPERIENCE REQUIREMENTS FOR USE OF RADIATION SOURCES

015.01 Purpose and Scope.

015.01A This section establishes the training and experience requirements of personnel in Sections 003, 005, 006, 008, 009, 012 and 014 of these regulations.

015.01B It establishes the criteria which courses of instruction must possess prior to being approved by the Agency for the certification training programs.

015.02 Definitions. As used in this section, the following definitions apply.

"Approved Program" means an education and training program which the Agency has determined meets the minimum requirements of the Radiation Control Act.

"Clinical Education" means the direct participation of the student in completion of diagnostic studies.

"Experience" means active participation in events or activities, leading to accumulation of knowledge.

"Formal Training" means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

015.03 Exemptions.

015.03A Individuals who are currently licensed in the State of Nebraska as podiatrists, chiropractors, dentists, physicians and surgeons, osteopathic medicine and surgery, or as osteopathic physicians and veterinarians or certified as physician assistants shall be exempt from the rules and regulations of the department pertaining to the training requirements for the use of x-ray radiation-generating equipment operated for medical diagnostic purposes.

015.03B Individuals who are currently authorized under Neb. Rev. Stat. Sections 71-193.15 and 71-193.17 to practice in the State of Nebraska as dental hygienists are deemed to meet the requirements of this section. Other dental auxiliaries must meet the requirements of Neb. Rev. Stat. Section 71-193.13.

015.04 Reserved.

015.05 Training And Experience Requirements For Use Of Medical Teletherapy.

015.05A Shall be a physician who is authorized to practice medicine in Nebraska.

015.05B Is certified in:

015.05B1 Radiology or therapeutic radiology by the American Board of Radiology; or

015.05B2 Radiation oncology by the American Osteopathic Board of Radiology; or

015.05B3 Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

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015.05B4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;
or

015.05B5 If not certified as indicated above, the physician's training and experience qualifications shall include active practice in therapeutic radiology with a minimum of three years experience gained from an institutional program:

015.05B5a A signed preceptor statement shall be submitted from the chairman of the institutional program under whom the training and experience was obtained describing the scope and extent of training and competency to use a teletherapy unit; or

015.05C Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

015.05C1 Two-Hundred (200) hours of classroom and laboratory training that includes:

015.05C1a Radiation physics and instrumentation;

015.05C1b Radiation protection;

015.05C1c Mathematics pertaining to the use and measurement of radioactivity; and

015.05C1d Biological effects of radiation;

015.05C2 Five-Hundred (500) hours of work experience under the supervision of an authorized user at a medical institution that includes:

015.05C2a Review of the full calibration measurements and periodic spot checks;

015.05C2b Preparing treatment plans and calculating treatment times;

015.05C2c Using administrative controls to prevent misadministrations;

015.05C2d Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

015.05C2e Checking and using survey meters; and

015.05C3 Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

015.05C3a Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

015.05C3b Selecting and administering the proper doses;

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015.05C3c Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

015.05C3d Post-administration follow-up and review of case histories.

015.06 Reserved.

015.07 Training And Experience Requirements For Ophthalmic Use Of Strontium-90.

015.07A The licensee shall require the authorized user of only Strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

015.07A1 Twenty-Four (24) hours of classroom and laboratory training that includes:

015.07A1a Radiation physics and instrumentation;

015.07A1b Radiation protection;

015.07A1c Mathematics pertaining to the use and measurement of radioactivity; and

015.07A1d Biological effects of radiation;

015.07A2 Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Strontium-90 for the ophthalmic treatment of five individuals that includes:

015.07B2a Examination of each individual to be treated;

015.07B2b Calculation of the dose to be administered;

015.07B2c Administration of the dose; and

015.07B2d Follow-up and review of each individuals case history.

015.08 Reserved.

015.09 Reserved.

015.10 Reserved.

015.11 Recentness Of Training. The training and experience specified in this section must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

015.12 Reserved.

015.13 Minimum Qualifications For Radiological Medical Physicist, Radiological Health Physicist And Qualified Expert.

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015.13A Radiological Medical Physicist means a person having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. This person shall have training and experience in the clinical applications of radiation physics to radiation therapy (for example, persons certified in Radiological Physics or Therapeutic Radiological Physics by the American Board of Radiology, or those having equivalent qualifications).

015.13A1 Has at least the following:

015.13A1a Is certified by the American Board of Health Physics or the American Board of Radiology in Therapeutic Radiological Physics; Roentgen Ray and Gamma Ray Physics; X-Ray and Radium Physics; or Radiological Physics; or the American Board of Science, in Nuclear Medicine; or

015.13A1b Holds a Master's or Doctor's Degree in physics, biophysics, radiological physics, or health physics and has completed one (1) year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a Radiological Medical Physicist at the radiotherapy facility, including personally conducting a calibration and spot-check of at least one teletherapy unit.

015.13B Radiological Health Physicist with reference to radiation protection, means a person having the knowledge and training to advise regarding radiation protection needs to measure ionizing radiation, and to evaluate safety techniques (for example, persons having relevant certification from the American Board of Radiology or American Board of Health Physics, or those having equivalent qualifications). With reference to shielding design, a person having particular knowledge and training in the field of medical x-ray and gamma-ray shielding.

015.13B1 Has at least the following:

015.13B1a Is certified by the American Board of Health Physics or the American Board of Radiology in Therapeutic Radiological Physics; Roentgen Ray and Gamma Ray Physics; X-Ray and Radium Physics; or Radiological Physics; or the American Board of Science, in Nuclear Medicine; or

015.13B1b A Master's or a Doctor's degree in a physical or natural science or equivalent, biophysics, radiological physics or health physics, plus one (1) year of experience in radiation protection and measurements, or

015.13B1c A Bachelor's Degree in a physical or natural science or equivalent, science plus three (3) years of training and experience in radiation protection and measurements and a written statement from a radiological health physicist as defined in 015.13B1a or 015.13B1b that two (2) years of training and experience in radiation protection and measurements were obtained under his or her supervision.

015.13C Qualified Expert means an individual who has demonstrated to the satisfaction of the Agency that he/she possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

015.13C1 Has at least the following:

015.13C1a A Bachelor's Degree in a physical or natural science, and one (1) year of experience in radiation protection and measurements, or

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015.13C1b A Certificate or an Associate Degree from an accredited radiological technology school and one (1) year of experience in radiation protection and measurements.

015.14 Reserved.

015.15 Training And Experience Requirements For Personnel For Institutional Broad Scope Type License A, B and C Listed In Subsection 003.13.

015.15A The minimum qualifications shall be:

015.15A1 Radiation Safety Officer.

015.15A1a A college degree at the bachelor level, in physical or biological sciences or in engineering plus four (4) years work experience in health physics, radiological health or another field equivalent to the above fields; or

015.15A1b A master's degree of graduate work in health physics or radiological health with two (2) years of work experience in health physics or radiological health.

015.15A2 Authorized User.

015.15A2a A college degree at the bachelor level, or equivalent training or experience, in the physical or biological sciences or in engineering; and

015.15A2b At least forty (40) hours of formal instruction in:

015.15A2b(1) Radiation physics and instrumentation;

015.15A2b(2) Radiation protection;

015.15A2b(3) Mathematics pertaining to the use and measurement of radioactivity; and

015.15A2b(4) Biological effects of radiation; and

015.15A2c One-Hundred and Sixty (160) hours experience in the safe handling of radioactive material.

015.16 Personnel Training And Experience Requirements For Licensee's In An Educational Institution Other Than Broad Scope Licenses.

015.16A Radiation Safety Officer and/or Authorized User:

015.16A1 A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

015.16A2 Forty (40) hours of formal instruction in:

015.16A2a Radiation physics and instrumentation;

015.16A2b Radiation protection;

015.16A2c Mathematics pertaining to the use and measurement of radioactivity, and

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015.16A2d Biological effects of radiation; and

015.16A3 Demonstrate an understanding of institution radiation safety policy and procedures and Nebraska Regulations for Control of Radiation-Ionizing or their equivalent.

015.17 Training And Experience Requirements For Laboratory And Industrial Use Of Radioactive Material Personnel.

015.17A For Millicurie Quantities.

015.17A1 Radiation Safety Officer and/or Authorized User:

015.17A1a A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

015.17A1a(1) Forty (40) hours of formal instruction in:

015.17A1a(1)(a) Radiation physics and instrumentation;

015.17A1a(1)(b) Radiation protection;

015.17A1a(1)(c) Mathematics pertaining to the use and measurement of radioactivity; and

015.17A1a(1)(d) Biological effects of radiation; and

015.17A1a(2) Demonstrate an understanding of operating and emergency procedures and Nebraska Regulations for Control of Radiation-Ionizing or their equivalent.

015.17B For Microcurie Quantities.

015.17B1 Radiation Safety Officer and/or Authorized User:

015.17B1a Forty (40) hours of formal instruction in:

015.17B1a(1) Radiation physics and instrumentation;

015.17B1a(2) Radiation protection;

015.17B1a(3) Mathematics pertaining to the use and measurement of radioactivity; and

015.17B1a(4) Biological effects of radiation; and

015.17B1b Demonstrate an understanding of operating and emergency procedures and Nebraska Regulations for Control of Radiation-Ionizing or their equivalent.

015.18 Personnel Training And Experience Requirements For Licenses To Manufacture Or Introduction Of Radioactive Material Into Manufactured Products And Devices Specified In Parts 003.14A, B, C, D, E, F, I, L, And M.

015.18A Radiation Safety Officer and/or Authorized User:

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015.18A1 A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering; and

015.18A2 Forty (40) hours of formal instruction in:

015.18A2a Radiation physics and instrumentation;

015.18A2b Radiation protection;

015.18A2c Mathematics pertaining to the use and measurement of radioactivity;

015.18A2d Biological effects of radiation; and

015.18A3 Demonstrate an understanding of company radiation safety policy and procedures and Nebraska Regulations for Control of Radiation-Ionizing or their equivalent.

015.19 Personnel Training And Experience Requirements For Licenses To Manufacture And Introduce Radioactive Material Into Radiopharmaceuticals As Specified In Part 003.14H.

015.19A Radiation Safety Officer and/or Authorized User:

015.19A1 A registered pharmacist;

015.19A2 Basic radioisotope handling techniques of two- hundred (200) hours, including:

015.19A2a Radiation physics and instrumentation;

015.19A2b Radiation protection;

015.19A2c Mathematics pertaining to the use and measurement of radioactivity;

015.19A2d Biological effects of radiation; and

015.19A2e Radiopharmaceutical chemistry.

015.19A3 Three-hundred (300) hours experience as a radiopharmaceutical chemist.

015.20 Reserved.

015.21 Training And Experience Requirements For Radiation Therapists.

015.21A The licensee shall require that a radiation therapist who uses any source of radiation for therapy listed in Sections 006 or 009 be an individual who:

015.21A1 Is certified in radiation therapy technology by the American Registry of Radiologic Technologists; or

015.21A2 Has completed an integrated program of full-time training and experience that includes classroom and laboratory training applicable to the use of a source of radiation, supervised work experience, and supervised clinical experience as follow:

015.21A2a 200 hours of classroom and laboratory training that include:

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015.21A2a(1) Radiation physics and instrumentation;

015.21A2a(2) Radiation protection policy, management, procedures, and regulations;

015.21A2a(3) Mathematics of radiation and radioactivity; and

015.21A2a(4) Radiation biology;

015.21A2b Supervised work experience under the supervision of an authorized user or practicing technologist that includes;

015.21A2b(1) Review of the full calibration measurements and periodic spot checks as appropriate;

015.21A2b(2) Preparing treatment plans for prescriptions and calculating treatment times;

015.21A2b(3) Using administrative controls to prevent misadministrations;

015.21A2b(4) Implementing emergency procedures to be followed in the event of the abnormal operation of equipment; and

015.21A2b(5) Checking and using survey meters; and

015.21A2c Supervised clinical experience under the supervision of an authorized user or a practicing technologist, that includes:

015.21A2c(1) Reviewing the case histories of patients to determine their suitability for treatment, and any limitations or contraindications;

015.21A2c(2) Selecting the proper doses and how it is to be administered;

015.21A2c(3) Reviewing calculations of radiation source doses for accuracy and completeness; and monitoring patients reaction to radiation, and bringing discrepancies to the authorized user's attention.

015.21A2c(4) Application of radiation to patients, including the use of beam modifying devices, based on the instructions in the patient's chart; and

015.21A2c(5) Making and reviewing records of the medical use of radiation.

015.22 Reserved.

015.23 Reserved.

015.24 Minimum Training Requirements For Operators Of Non-Human X-Ray Or Particle Accelerators Under 1 MeV.

015.24A The registrant shall require that the operator shall receive a minimum of eight (8) hours of instruction in the following areas:

015.24A1 Fundamentals of Radiation Safety.

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015.24A1a Characteristics of radiation

015.24A1b Units of radiation measurement

015.24A1c Significance of radiation dose and exposure

015.24A1c(1) Radiation protection standards

015.24A1c(2) Biological effects of radiation

015.24A1d Sources and levels of radiation

015.24A1e Methods of controlling radiation dose

015.24A1e(1) Working time

015.24A1e(2) Working distances

015.24A1e(3) Shielding

015.24A2 Radiation Detection Instrumentation to be Used.

015.24A2a Use of radiation survey instruments

015.24A2a(1) Operation

015.24A2a(2) Calibration

015.24A2a(3) Limitations

015.24A2b Survey techniques

015.24A2c Use of personnel monitoring equipment

015.24A2c(1) Film badges

015.24A2c(2) Thermoluminescent dosimeters

015.24A2c(3) Pocket dosimeters

015.24A3 Radiographic Equipment to be Used.

015.24A3a Remote handling equipment

015.24A3b Radiographic exposure devices and sealed sources

015.24A3c Operation and control of x-ray equipment

015.24A4 The Requirements of Pertinent Federal and State Regulations.

015.24A5 The Registrant's Written Operating and Emergency Procedures.

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015.24A6 Case Histories of Radiography Accidents.

Training shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Agency inspection.

015.25 Training And Experience Requirements For Particle Accelerators (Above 1 MeV) Personnel - Non-Human Use.

015.25A Radiation Safety Officer or Supervisor shall have a Bachelor of Science Degree plus one (1) year experience in the use and operation of particle accelerators which includes forty (40) hours formal training as specified for particle accelerator operators.

015.25B Operators shall have forty (40) hours formal training in subject matter listed below and 3 months experience, the first one month on-the-job training shall be under direct supervision.

015.25B1 Forty (40) Hours of Formal Training of Particle Accelerator Operators - (Non-Human Use)

015.25B1a All operators shall be instructed in the fundamentals of radiation.

015.25B1a(1) Characteristics of beta, gamma and x-radiation.

015.25B1a(2) Units of radiation dose (rem).

015.25B1a(3) Biological effects of radiation.

015.25B1a(4) Levels of radiation from particle accelerators.

015.25B1a(5) Methods used to prevent radiation exposure at the specific facility to be operated:

015.25B1a(5)(a) Shielding

015.25B1a(5)(b) Interlock system

015.25B1a(5)(c) Safety rules

015.25B1a(5)(d) Radiation monitoring equipment

015.25B2 All operators shall:

015.25B2a Be instructed on the use and care of personnel monitoring equipment employed at the facility.

015.25B2b Be familiar with the location and use of all operating controls.

015.25B2c Be familiar with the requirements of pertinent State regulations.

015.25B2d Be familiar with the registrant's written operating and emergency procedures.

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015.25B2e Receive at least one (1) month of on-the-job training before assuming operational responsibility.

015.25B3 All operator's assistants or helpers shall receive the training listed in paragraphs 015.25B1a through 015.25B2a above at not less than twenty (20) hours.

015.26 Reserved.

015.27 Training And Experience Requirements For Industrial Gauge Personnel.

015.17A Licensed User.

015.27A1 Demonstrate competency in use, maintenance and transfer of device by satisfactory completion of eight (8) hour course provided by the manufacturer of the device or any agency approved course.

015.28 Training And Experience Requirements For Analytical X-Ray Equipment Personnel.

015.28A At least twenty (20) hours of instruction in the fundamentals of:

015.28A1 Radiation physics and instrumentation;

015.28A2 Radiation protection;

015.28A3 Radiation units of measurement;

015.28A4 Biological effects of radiation; and

015.28A5 Equipment operation

015.28A5a Operation of analytical x-ray equipment

015.28A5b Safety devices

015.28A5c Labeling

015.28A5d Registrant's operations and emergency procedures; and

015.28A5e Case histories of analytical x-ray accidents.

015.29 Training And Experience Requirements For Gas Chromatograph Personnel.

015.29A Licensed User.

015.29A1 Has received and is competent in operating procedures and manufacturer's instructions.

015.30 Training And Experience Requirements For Well Logging Personnel.

015.30A Radiation Safety Officer.

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015.30A1 A college degree at the bachelor level, or equivalent training and experience in the physical or biological sciences or in engineering;

015.30A2 Qualified well logger or six (6) weeks on-the-job training under an authorized user; and

015.30A3 Forty (40) hours of formal instruction in:

015.30A3a Principles and practices of radiation protection;

015.30A3b Radioactivity measurements standardization and monitoring techniques and instruments;

015.30A3c Mathematics and calculations basic to the use of and measurement of radioactivity;

015.30A3d Biological effects of radiation, and

015.30A3e Operating and emergency procedures and federal and state radiation control regulations.

015.30B The licensee shall not permit an individual to act as a logging supervisor until that person:

015.30B1 Has completed forty (40) hours of formal training in the subjects outlined in paragraph 015.30F of this section;

015.30B2 Has received copies of, and instruction in:

015.30B2a The regulations contained in the applicable Sections of 004, 010, and 014 of these regulations;

015.30B2b The license under which the logging supervisor will perform well logging; and

015.30B2c The licensee's operating and emergency procedures required by 014.16;

015.30B3 Has completed six (6) weeks of on-the-job training under a logging supervisor and demonstrated competence in the use of radioactive materials, remote handling tools, and radiation survey instruments by a field evaluation; and

015.30B4 Has demonstrated understanding of the requirements in paragraphs 015.30B, 015.30B1, and 015.30B2 of this section by successfully completing a written test.

015.30C The licensee shall not permit an individual to act as a logging assistant until that person:

015.30C1 Has received instruction in applicable Sections of 004 and 010 of these regulations;

015.30C2 Has received copies of, and instruction in, the licensee's operating and emergency procedures required by 014.15;

015.30C3 Has demonstrated understanding of the materials listed in paragraphs 015.30C1 and 015.30C2 of this section by successfully completing the test; and

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015.30C4 Has received instruction in the use of radioactive materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

015.30D The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

015.30E The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests. The training records must be retained for 3 years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for 3 years.

015.30F The licensee shall include the following subjects in the training required in paragraph 015.30B1 of this section:

015.30F1 Fundamentals of radiation safety including:

015.30F1a Characteristics of radiation;

015.30F1b Units of radiation dose and quantity of radioactivity;

015.30F1c Hazards of exposure to radiation;

015.30F1d Levels of radiation from radioactive material;

015.30F1e Methods of controlling radiation dose (time, distance, and shielding); and

015.30F1f Radiation safety practices, including prevention of contamination, and methods of decontamination.

015.30F2 Radiation detection instruments including:

015.30F2a Use, operation, calibration, and limitations of radiation survey instruments;

015.30F2b Survey techniques; and

015.30F2c Use of personnel monitoring equipment;

015.30F3 Equipment to be used including:

015.30F3a Operation of equipment, including source handling equipment and remote handling tools;

015.30F3b Storage, control, and disposal of radioactive material; and

015.30F3c Maintenance of equipment.

015.30F4 The requirements of pertinent regulations. And

015.30F5 Case histories of accidents in well logging.

015.31 Reserved.

015.32 Training And Experience Requirements For Management Of Radioactive Waste Personnel.

015.32A Radiation Safety Officer (RSO).

015.32A1 The RSO shall have experience in applied radiation protection at nuclear facilities or waste disposal sites dealing with radiation protection problems. The individual should be familiar with the design features and operations of LLW sites that affect the potential for exposures of site personnel to radiation. In addition, the RSO should have the technical competence to establish radiation protection programs and the supervisory capability to direct the work of radiation protection technicians.

015.32A2 The RSO should have a bachelor's degree in science or engineering (or equivalent), including formal training in radiation protection. Minimum acceptable substitutes for a bachelor's degree are a high school diploma or its equivalent and one of the following: (1) four years of formal schooling in science or engineering, (2) four years of applied experience at a nuclear facility in the area of radiation protection, or (3) any combination of the above totaling four years, and

015.32A3 The RSO should have at least three years of experience in radiation protection, one year of which should be at a LLW disposal site. If the RSO does not have a bachelor's degree, then a total of seven years experience is recommended. A master's degree and doctor's degree may be considered equivalent to one and two years experience, respectively, if the course work is related to radiation protection.

015.32B Radiation Protection Technician.

015.32B1 The senior radiation protection technician should have three years of working experience in radiation protection of which one year should be from an LLW disposal site. The technician should possess a high degree of manual dexterity and ability, and should be capable of learning and applying basic skills.

015.32B2 Individuals in training or apprentice positions should not be considered technicians, but should be permitted to perform work for which qualification has been demonstrated. The classification of radiation protection technicians should be as follows:

015.32B2a In training (minimal experience) - apprentice technician.

015.32B2b 0-3 years experience - technician.

015.32B2c Greater than 3 years experience - senior technician.

However, time alone is not enough. Any training and advancement program should also require technicians to pass written and oral examinations before advancing to different technician levels.

015.32C Radiation Protection Training Instructor.

015.32C1 At the time of appointment to the instructor position, the responsible individual shall have experience in applied radiation at nuclear facilities dealing with the radiation protection problems and programs similar to those at LLW disposal sites. The individual should be familiar with the design features and operations of LLW sites that affect the potential for exposure of site personnel to radiation.

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015.32C2 The instructor should have an associate's degree in science or engineering (or equivalent), including formal training in radiation protection. Minimum acceptable substitutes for an associate degree are a high school diploma or its equivalent and one of the following: (1) two years of formal schooling in science or engineering, (2) two years of applied experience at a nuclear facility in the area of radiation protection, or (3) any combination of the above totaling two years. The instructor should have one year of experience in radiation protection at an LLW disposal site. If the instructor does not have an associate's degree, then a total of three years experience is recommended.

015.32D General Employee.

015.32D1 Information on the LLW site's radiation protection policy and program should be presented to all new employees during the general employee orientation training. The orientation training should consist of classroom instruction and may be supplemented by other training methods. Written material covering the basic topics of the training should be distributed to the new employees for future reference. Visitor and contractor personnel should be given the same training, if it is expected that they may encounter radioactive material or radiation levels above background. It is recommended that the classroom instruction phase of this training be at least eight (8) hours in length.

015.32E Radiation Worker.

015.32E1 Personnel who work in a radiation area are termed radiation workers and their radiation worker training shall be received prior to entering or beginning work in a radiation area. The classroom instruction phase of this training shall be at least twenty (20) hours in length.

015.33 Training And Experience Requirements For Installation And/Or Servicing Of Radiation Generating Equipment And Associated Radiation Generating Equipment As Supplied By The Employer.

015.33A A minimum of 8 hours of formal course work or as approved by the Agency should be completed and include the following:

015.33A1 Radiation physics and instrumentation

015.33A2 Radiation protection

015.33A3 Mathematics pertaining to the use and measurement of radioactivity

015.33A4 Biological effects of radiation

015.33B On-the-job training should include hands-on experience installing and/or servicing radiation generating equipment and associated radiation generating equipment components. On-the-job training shall be for six (6) months under the supervision of an individual who has completed the training in this Subsection.

015.34 Training And Experience Requirements For Personnel Dosimetry Services Personnel.

015.34A Personnel must work for a dosimetry processor who holds a current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards.

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Section 016 LICENSURE OF PERSONS PERFORMING MEDICAL RADIOGRAPHY

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016 LICENSURE OF PERSONS PERFORMING MEDICAL RADIOGRAPHY.

016.01 Scope of Regulations.

016.01A This section establishes requirements for persons providing diagnostic radiographic services under the direction of licensed practitioners. It specifies the minimum standards of education and/or testing required of persons performing Medical Radiography. This section also provides for the licensure of Medical Radiographers, Temporary Medical Radiographers, Limited Radiographers, and Provisional Limited Radiographers as defined by Neb. Rev. Stat. §§71-3501 to 71-3515.02 and 71-3517.

016.02 Definitions.

016.02A "Act" means the Radiation Control Act. Sections 71-3501 to 71-3520, Reissue Revised Statutes of Nebraska, 1943. As amended.

016.02B "Approved Educational Program" means an educational program for Medical Radiographers, provided by any accredited community college, university or hospital-based program that awards a certificate of completion or an academic degree to its graduates, which consists of twenty-four (24) months of instruction in radiography which includes, but is not limited to, radiographic procedures, imaging equipment, image production and evaluation, film processing, radiation physics, radiation protection, radiation biology, radiographic pathology, and quality assurance activities. Programs which meet the programmatic accreditation requirements or equivalent of the ARRT as qualification for registration in radiography will be approved by the Department.

016.02C "ARRT" means the American Registry of Radiologic Technologists.

016.02D "CEU", for the purpose of these regulations, means one hour of continuing education.

016.02E "Completed Application" means an application with all of the information requested on the application filled in, the signature of the applicant verified, fees and all required documentation submitted.

016.02F "Department" means the Department of Health and Human Services Regulation and Licensure.

016.02G "Hour" means a period of 50 to 60 minutes of formal instruction, otherwise known as a "contact hour."

016.02H "Interpretative Fluoroscopic Procedures", for the purpose of these regulations, means the use of radiation in continuous mode to provide information, data and film or hardcopy images for diagnostic review and interpretation by a licensed practitioner as the images are being produced.

016.02I "Licensed Practitioner" means a person licensed to practice medicine, dentistry, podiatry, chiropractic, osteopathic medicine and surgery, or as an osteopathic physician.

016.02J "Licensure" means the process by which the Department grants permission to persons meeting the requirements of the Radiation Control Act and the Department's rules and regulations to apply radiation to humans.

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016.02K "Medical Radiography" means the application of radiation to humans for diagnostic purposes, including but not limited to: adjustment or manipulation of x-ray systems and accessories, including image receptors; positioning of patients; processing of films; and any other action that materially affects the radiation dose to patients.

016.02L "Routine Radiographic Procedures", for the purpose of these regulations, means those procedures accomplished to produce hard copy or plane images using a general radiographic unit. These procedures include examinations of structures as identified in Subparts 016.05C1 through 016.05C6 and exclude those examinations where images are obtained using mammography, angiography or nuclear medicine units.

016.02M "Rural Area" means located within any county in Nebraska having a population of less than fifteen thousand inhabitants.

016.02N "Student" means a person who is enrolled and participating in an educational program in medical radiography and has completed at least twelve (12) months of that educational program.

016.02O "Use of Contrast Media", for the purpose of these regulations, means the administration of contrast media by invasive procedures such as insertion of the enema tip, catheter, establishment of an intravenous line, or direct injection.

016.03 General Requirements.

016.03A Documentation of current licensure shall be maintained at each facility where an individual licensed by the Department performs Medical Radiography.

016.03B Non-exempt individuals shall not perform Medical Radiography without a valid license.

016.04 Exemptions.

016.04A Persons authorized under Neb. Rev. Stat. §§71-193.15 and 71-193.17 to practice as dental hygienists and dental auxiliaries who meet the requirements of Neb. Rev. Stat. §71-193.13 are exempt from the requirements of Section 016 of these regulations.

016.04B Persons certified pursuant to Neb. Rev. Stat. §71-176.01 who are employed exclusively in the office or clinic of a licensed podiatrist are exempt from the requirements of Section 016 of these regulations.

016.04C Licensed practitioners and certified physician assistants are exempt from the requirements of Section 016 of these regulations.

016.04D Students enrolled and participating in an educational program in medical radiography who, as a part of this educational program, apply radiation to humans while under the supervision of the Licensed Practitioners or Medical Radiographers associated with the educational program are exempt from the requirements of this section.

016.05 Categories of Licensure.

016.05A Medical Radiographer. A Medical Radiographer is permitted to apply radiation to any part of the human anatomy for diagnostic purposes. The performance of radiographic procedures

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shall be at the request of, and for interpretation by, a licensed practitioner. These radiographic procedures shall not include interpretative fluoroscopic procedures.

016.05B Temporary Medical Radiographer. A Temporary Medical Radiographer is permitted to perform the duties of a Limited Radiographer licensed in the categories of Sections 016.05C1 through 016.05C6 (Chest, Extremities, Skull and Sinus, Spine, Ankle and Foot, and Abdomen) of these regulations.

016.05C Limited Radiographer. A Limited Radiographer is permitted to apply radiation to limited regions of the human anatomy for diagnostic purposes. The performance of radiographic procedures shall be at the request of, and for interpretation by, a licensed practitioner. These radiographic procedures shall not include computed tomography, the use of contrast media, the use of fluoroscopic or mammographic equipment, and are limited to routine radiographic procedures. The Limited Radiographer may be licensed in one or more of the following categories:

016.05C1 Limited Radiographer - Chest. A Limited Radiographer licensed to apply radiation to the chest shall be permitted to perform radiography of the chest. Chest refers to the lung fields including the cardiac shadow, as well as the ribs and sternum.

016.05C2 Limited Radiographer - Extremities. A Limited Radiographer licensed to apply radiation to the extremities shall be permitted to perform radiography of the extremities. The upper extremity refers to those body parts from the distal phalanges of the hand to the head of the humerus, including the clavicle and scapula. The lower extremity refers to those body parts from the distal phalanges of the foot to the head of the femur and its articulation with the pelvic girdle, including the hip.

016.05C3 Limited Radiographer - Skull and Sinus. A Limited Radiographer licensed to apply radiation to the skull and sinus shall be permitted to perform radiography of the skull and sinuses. Skull refers to the cranium - including facial bones - the paranasal sinuses and the mandible.

016.05C4 Limited Radiographer - Spine. A Limited Radiographer licensed to apply radiation to the spine shall be permitted to perform radiography of the spine. Spine refers to cervical, thoracic, and lumbar vertebrae and their articulations, as well as the pelvis, sacrum, and coccyx.

016.05C5 Limited Radiographer - Ankle and Foot. A Limited Radiographer licensed to apply radiation to the ankle and foot shall be permitted to perform radiography of the ankle and foot. The ankle and foot refers to those body parts from the distal phalanges of the foot to the distal one third of the fibula and tibia.

016.05C6 Limited Radiographer - Abdomen. A Limited Radiographer licensed to apply radiation to the abdomen shall be permitted to perform radiography of the abdomen. Abdomen refers to those organs contained within the peritoneum. The Department shall authorize a limited radiographer to perform radiography of the abdomen if:

016.05C6a The applicant has passed the Core and Spine sections of the Examination for the Limited Scope of Practice in Radiography given by the ARRT; and

016.05C6b Upon finding by the Department that continued provision of service for a community would be in jeopardy if this applicant were not authorized to perform radiography of the abdomen;

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016.05C6b(1) An applicant whose practice site is located within a medical profession shortage area as determined by the Nebraska Rural Health Advisory Commission shall be deemed authorized to perform radiography of the abdomen. No further documentation authorizing such practice will be provided by the Department.

016.05D Provisional Limited Radiographer. A Provisional Limited Radiographer shall be permitted to perform the duties of a Limited Radiographer licensed in the categories of Sections 016.05C1 through 016.05C6 (Chest, Extremities, Skull and Sinus, Spine, Ankle and Foot, and Abdomen) of these regulations. A Provisional Limited Radiographer shall not radiograph children under the age of six months, except:

016.05D1 Upon a finding by the Department that continued provision of service for a community would be in jeopardy if this provision were to be enforced;

016.05D1a An applicant whose practice site is located within a medical profession shortage area as determined by the Nebraska Rural Health Advisory Commission shall be deemed authorized to radiograph children under the age of six months. No further documentation authorizing such practice will be provided by the Department;

016.05D2 For an employee of a hospital licensed in good standing by the Department and located in a rural area; or

016.05D3 In a bona fide emergency situation, as determined by the licensed practitioner.

016.06 Requirements for Issuance of License. Any person, except those referred to in Section 016.04 of these regulations, who wishes to perform Medical Radiography and/or represent himself or herself as a Medical Radiographer, Temporary Medical Radiographer, Limited Radiographer, or Provisional Limited Radiographer must be licensed as such. The criteria for issuance of these licenses and the documentation required by the Department are set forth below.

016.06A Procedures for Licensure as a Medical Radiographer. An applicant for a license to practice as a Medical Radiographer must:

016.06A1 Complete an approved educational program in radiography;

016.06A2 Pass the Examination in Radiography given by the ARRT with a score of at least 75;
and

016.06A3 Submit to the Department:

016.06A3a A verified, complete application on a form provided by the Department, a copy of which is attached hereto as Attachment A and incorporated in these regulations by this reference. Only applications which are complete will be considered;

016.06A3b The following documentation:

016.06A3b(1) Proof of registration in radiography with the ARRT (photocopy of ARRT card or ARRT certificate), meeting the requirements for licensure as a Medical Radiographer;

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016.06A3b(1)(a) Such registration must not have any record of previous adverse action taken by the ARRT; or

016.06A3b(2) A certificate of completion from an approved educational program in radiography indicating successful completion of the program; and

016.06A3b(3) Official documentation of having passed a Department approved examination with a score of at least 75 which meets the requirements of Section 016.07 of these regulations.

016.06A3c The required licensure fee.

016.06A3d If an applicant has performed medical radiography in another jurisdiction which regulated such practice either by licensure, certification or registration, the applicant must submit from the regulatory agency where the applicant is currently regulated:

016.06A3d(1) A certification that the applicant is duly licensed, certified or registered, that his/her license, certification or registration was based on an examination, that his/her license, certification or registration has never been suspended, revoked or otherwise disciplined, and that so far as the record of the agency is concerned, the applicant is entitled to its endorsement; and

016.06A3d(2) The nature of disciplinary actions, if any, taken against the applicant's license, certification or registration.

016.06B As an alternative to the requirement of Subpart 016.06A2 of these regulations, persons seeking licensure as a Medical Radiographer shall take and achieve a passing score of at least 75 on a Department approved examination which meets the requirements of Section 016.07 of these regulations.

016.06C The Department shall act within one hundred fifty (150) days upon all completed applications for licensure.

016.06D Procedures for Licensure as a Temporary Medical Radiographer. A student, as defined in Section 016.02N of these regulations, who applies for a license as a Temporary Medical Radiographer must:

016.06D1 Have completed at least twelve (12) months of an approved educational program in radiography; and

016.06D2 Submit to the Department:

016.06D2a A verified, complete application on a form provided by the Department, a copy of which is attached hereto as Attachment A and incorporated in these regulations by this reference. Only applications which are complete will be considered;

016.06D2b Official documentation from an approved educational program in radiography indicating that at least twelve (12) months of the program have been completed; and

016.06D2c The required licensure fee.

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016.06D3 The licensed Temporary Medical Radiographer shall be permitted to perform the duties of a Limited Radiographer licensed in the categories of Sections 016.05C1 through 016.05C6 (Chest, Extremities, Skull and Sinus, Spine, Ankle and Foot, and Abdomen) of these regulations.

016.06D4 The Temporary Medical Radiographer License shall expire eighteen (18) months after the date of issuance and is not renewable.

016.06E The Department shall act within one hundred fifty (150) days upon all completed applications for licensure.

016.06F Procedures for Licensure as a Limited Radiographer. An applicant for a license to practice as a Limited Radiographer must:

016.06F1 Pass the Examination for the Limited Scope of Practice in Radiography given by the ARRT as follows:

016.06F1a Achieve a passing score of seventy percent (70%) or above on the Core section of the exam; and

016.06F1b Achieve a passing score of sixty-five percent (65%) or above on each of the following sections of the exam for which licensure is sought:

016.06F1b(1) Chest;

016.06F1b(2) Extremities;

016.06F1b(3) Skull and Sinus;

016.06F1b(4) Spine; or

016.06F1b(5) Ankle and Foot.

016.06F2 Submit to the Department:

016.06F2a A verified, complete application on a form provided by the Department, a copy of which is attached hereto as Attachment A and incorporated in these regulations by this reference. Only applications which are complete will be considered;

016.06F2b If the Examination for the Limited Scope of Practice in Radiography given by the ARRT was taken in a state other than Nebraska, the applicant must request that the ARRT send the examination scores directly to the Department; and

016.06F2c The required licensure fee.

016.06F2d If an applicant has performed medical radiography in another jurisdiction which regulated such practice either by licensure, certification or registration, the applicant must submit from the regulatory agency where the applicant is currently regulated:

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016.06F2d(1) A certification that the applicant is duly licensed, certified or registered, that his/her license, certification or registration was based on an examination, that his/her license, certification or registration has never been suspended, revoked or otherwise disciplined, and that so far as the record of the agency is concerned, the applicant is entitled to its endorsement; and

016.06F2d(2) The nature of disciplinary actions, if any, taken against the applicant's license, certification or registration.

016.06F3 The Department shall authorize a Limited Radiographer to perform radiography of the abdomen if:

016.06F3a The applicant has passed the Core and Spine sections of the Examination for the Limited Scope of Practice in Radiography given by the ARRT; and

016.06F3b Upon a finding by the Department that continued provision of service for a community would be in jeopardy if this applicant were not authorized to perform radiography of the abdomen;

016.06F3b(1) An applicant whose practice site is located within a medical profession shortage area as determined by the Nebraska Rural Health Advisory Commission shall be deemed authorized to perform radiography of the abdomen.

016.06F4 As an alternative to the requirement of Section 016.06F1 of these regulations, persons seeking licensure as a Limited Radiographer shall take and achieve a passing score of at least seventy percent (70%) on the Core section and a passing score of at least sixty-five percent (65%) on each of the anatomical categories on a Department approved examination which meets the requirements of Section 016.07 of these regulations.

016.06F5 No applicant for a license as a Limited Radiographer shall take the examination for licensure, or for licensure for any specific anatomical region, more than three times without:

016.06F5a Waiting a period of one year after the last unsuccessful attempt of the examination; and

016.06F5b Submitting proof to the Department of completion of twelve (12) hours of continuing education meeting the requirements of Section 016.09 of these regulations for each subsequent attempt.

016.06G The Department shall act within one hundred fifty (150) days upon all completed applications for licensure.

016.06H Criteria for Licensure as a Provisional Limited Radiographer.

016.06H1 A Provisional Limited Radiographer must have submitted to the Department of Health on or before January 1, 1996, the required licensure fee and verified documentation that he or she was performing medical radiography before and on June 2, 1995.

016.06H2 A Provisional Limited Radiographer shall not concurrently hold a license in any other category of medical radiography.

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016.06H3 All Provisional Limited Radiographer licenses shall expire on January 1, 2005, and are not renewable after that date.

016.06I The Department shall act within one hundred fifty (150) days upon all completed applications for licensure.

016.07 Department Approval of Alternative Examinations

016.07A The Department shall approve examinations which it determines:

016.07A1 Are based upon national standards regarding:

016.07A1a Administration and procedures followed for examinations;

016.07A1b The method of grading and the passing grades; and

016.07A1c Security protection for questions and answers;

016.07A1d Educational and psychological testing as recommended by the American Psychological Association, the American Educational Research Association, and the National Council of Measurement in Education; and

016.07A2 Are equivalent to:

016.07A2a The Examination in Radiography from the American Registry of Radiologic Technologists for Medical Radiographers; or

016.07A2b The Examination for the Limited Scope of Practice in Radiography from the American Registry of Radiologic Technologists for Limited Radiographers.

016.07B Department approved examinations for the Limited Radiographer shall include, but are not limited to the following topics:

016.07B1 Radiation protection;

016.07B2 Equipment maintenance and operation;

016.07B3 Image production and evaluation;

016.07B4 Patient care and management; and

016.07B5 The anatomy of, and positioning for, specific regions of the human anatomy. The anatomical regions shall include at least one of the following anatomical categories:

016.07B5a Chest;

016.07B5b Extremities;

016.07B5c Skull and Sinus;

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016.07B5d Spine; or

016.07B5e Ankle and Foot.

016.07C The Department shall review the procedures to be followed for examination, the method of grading and security protection for questions and answers.

016.07C1 The Department shall establish the passing grades for such examinations which ensures appropriate knowledge base has been met.

016.07D Any costs incurred by the Department in determining the extent to which examinations meet the requirements of this subsection shall be paid by the individual or organization proposing the Department approve such examination.

016.08 Procedures for Renewal of License. All initial licenses, except Temporary Medical Radiographer licenses, issued by the Department under Neb. Rev. Stat. §§71-3501 to 71-3515.02 and these regulations shall expire two years from the date of issuance.

016.08A Any licensee who wishes to renew his or her license must:

016.08A1 Meet continuing education requirements as specified in Section 016.09 of these regulations;

016.08A2 Pay the renewal fee as prescribed in section 018 of these regulations; and

016.08A3 Submit to the Department:

016.08A3a The renewal notice;

016.08A3b The renewal fee; and

016.08A3c Documentation of completion of an average of twenty-four (24) hours of approvable continuing education that meets the criteria for approval by the Department, earned prior to the date of expiration.

016.08A3c(1) For Medical Radiographers, presentation of proof of current registration in Radiography with the ARRT (photocopy of current ARRT card) shall be deemed proof of meeting the requirements of Subsection 016.08A3c of these regulations.

016.08B **First Notice.** At least sixty (60) days before the expiration date of the license, the Department shall send a renewal notice, an affidavit for continuing education, a copy of which is attached hereto as Attachment B and incorporated in these regulations by this reference, to each licensee at the licensee's last place of residence as noted in the records of the Department. It is the responsibility of the licensee prior to the renewal period to notify the Department of any name and/or address changes.

016.08B1 The renewal notice shall specify:

016.08B1a The name of the licensee;

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016.08B1b The licensee's last known address of record;

016.08B1c The license number;

016.08B1d The expiration date of the license; and

016.08B1e The renewal fee as prescribed in Section 018 of these regulations.

016.08C **Second Notice.** The Department shall send to each licensee who fails to renew his or her license in response to the first notice, a second notice of renewal in accordance with the requirements of Section 016.08B of these regulations that specify:

016.08C1 That the licensee failed to pay the renewal fee;

016.08C2 That the license has expired; and

016.08C3 That upon receipt of the renewal fee and completed affidavit of continuing education, no order of revocation will be entered.

016.08D When any licensee fails within thirty (30) days of expiration of a license, to meet the renewal requirement of payment of the renewal fee or to meet the continuing education requirement, the Department shall revoke such license after notice and opportunity for hearing according to 184 NAC 1.

016.09 Continuing Education

016.09A **General Requirements for Medical Radiographers, Limited Radiographers and Provisional Limited Radiographers.** On or before the expiration date of his/her license, each Medical Radiographer, Limited Radiographer and Provisional Limited Radiographer who is licensed in the State of Nebraska shall as a condition for renewal of his/her license:

016.09A1 Complete an average of twenty-four (24) hours of approvable continuing education during the preceding twenty-four (24) month period;

016.09A2 Submit to the Department:

016.09A2a For Medical Radiographers who maintain registration with the ARRT, presentation of proof of current registration in Radiography with the ARRT (photocopy of current ARRT card); or

016.09A2b For Medical Radiographers who do not maintain registration with the ARRT, Limited Radiographers and Provisional Limited Radiographers, an affidavit of continuing education hours on a form provided by the Department. Such form is attached to these regulations as Attachment B and is incorporated by this reference. The completed affidavit must include the following information:

016.09A2b(1) The topic of the program;

016.09A2b(2) Name of provider;

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016.09A2b(3) Location of continuing education;

016.09A2b(4) The date(s) of the program; and

016.09A2b(5) The number of hours received for the program.

016.09A3 Be responsible for:

016.09A3a Maintaining in his/her personal files such certificates or records of credit from approved continuing education activities attended and must submit such certificates or records to the Department upon request.

016.09A3a(1) One hour of attendance equals one hour of credit.

016.09A3a(2) A licensee must attend the complete continuing education offering in order to report it for credit.

016.09A3a(2)(a) Partial credit shall not be claimed by the licensee.

016.09A3a(3) Maintaining documentation of presentation of an approved continuing education program. Credit will not be given for subsequent presentations of the same program.

016.09B When any licensee meets the renewal requirement of payment of the renewal fee and meets the continuing education requirement, the Department shall renew such license.

016.09C Criteria for Approvable Continuing Education Programs.

016.09C1 In addition to meeting the specifications for type of program outlined in Section 016.09D of these regulations to be an approvable program for license renewal, a continuing education program must also meet the following criteria:

016.09C1a The program must be at least fifty to sixty minutes in duration;

016.09C1b The program's topic and/or objectives must relate to Medical Radiography, which includes but is not limited to mammography, MRI, computed tomography, cardiovascular technology, quality management, nuclear medicine, radiation therapy, ultrasound and medical dosimetry, as set out in Section 016.09D of these regulations; and

016.09C1c Programs must be open to all Medical Radiographers, Limited Radiographers, and Provisional Limited Radiographers licensed in Nebraska.

016.09C1c(1) Participation in such programs may be restricted if there is a legitimate reason such as a required knowledge base.

016.09D Acceptable Continuing Education Programs.

016.09D1 The Department will accept as continuing education for licensure renewal:

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016.09D1a Programs which meet the quality standards established by nationally recognized organizations or associations of radiography, such as the ARRT or the American Society of Radiologic Technologists (ASRT);

016.09D1a(1) Passing an advanced level examination in mammography, MRI, computed tomography, cardiovascular technology, quality management, nuclear medicine, radiation therapy or ultrasound during the biennial-renewal period may be used to satisfy the 24-hour continuing education requirement.

016.09D1b Learning experiences provided they are planned and conducted for individuals performing Medical Radiography which are related to the practice of Medical Radiography;

016.09D1c Academic courses in an accredited post-secondary institution which are related to the specific knowledge and/or technical skills required for the practice of Medical Radiography;

016.09D1d Courses, lectures or offerings related to the technical and scientific knowledge for the practice of Medical Radiography which includes but is not limited to:

016.09D1d(1) Radiation protection;

016.09D1d(2) Equipment maintenance and operation;

016.09D1d(3) Image production and evaluation;

016.09D1d(4) Patient care and management; and

016.09D1d(5) Quality assurance activities.

016.09D1e A course in cardiopulmonary resuscitation (CPR) which results in certification by the American Heart Association or the American Red Cross. Such certification shall be valid at the time of renewal.

016.09D1e(1) Only four (4) credit hours of this type of course may be counted within the biennial renewal period; and

016.09D1e(2) A copy of the current certification card shall be deemed-adequate in meeting the documentation a licensee must provide in the event of an audit of continuing education by the Department as set out in Subsection 016.09E of these regulations.

016.09D1f Home study with testing mechanism. If there is no testing mechanism or certificate of completion, the licensee must submit an abstract or resume of the material covered to the Department. Said abstract or resume must be written by only the licensee and will be reviewed for approval by the Department.

016.09D1f(1) The only home study courses allowed shall be those courses which have been assigned a specific number of continuing education credit hours by the home study provider.

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016.09D1g Continuing Education obtained to meet continuing education requirements of a health care profession other than medical radiography licensed, certified, or registered by the Department may be acceptable if such continuing education has a rational connection to the practice of medical radiography and meets the requirements of Subpart 016.09D1d of these regulations.

016.09D1g(1) No more than four (4) hours of this type of continuing education may be counted within each year of the twenty-four (24) month renewal period.

016.09E **Audit of Continuing Education.** The Department may biennially select, in a random manner, a sample of the license renewal applications for audit of continuing education credits. Each licensee shall be responsible for maintaining in his/her personal files such certificates or records of credit from approvable continuing education activities. Licensees selected for audit shall be required to produce documentation of his/her attendance at those continuing education activities listed on his/her renewal application.

016.09E1 The Department will send to each licensee selected for audit notification of audit.

016.09E2 When selected for audit, the licensee must provide satisfactory documentation of attendance at or participation in the approvable continuing education activities listed on the licensee's sworn affidavit.

016.09E2a Satisfactory documentation includes but is not limited to certificates of attendance or written verification of attendance from the provider of the course which contain the information referenced in Subdivisions 016.09A2b(1) through 016.09A2b(5) of these regulations.

016.09E3 Failure to comply with the audit may be grounds for non-renewal of the license.

16.10 Duration and Renewal of Licensure.

016.10A A license as a Medical Radiographer shall be valid for a period of two (2) years. The license shall be renewable every two (2) years in accordance with the requirements of Section 016.08 of these regulations.

016.10B A license as a Temporary Medical Radiographer shall be valid for a period of eighteen (18) months and cannot be renewed.

016.10C A license as a Limited Radiographer shall be valid for a period of two (2) years. The license shall be renewable every two (2) years in accordance with the requirements of Section 016.08 of these regulations.

016.10D A license as a Provisional Limited Radiographer shall be valid for a period of two (2) years. The license shall be renewable every two (2) years in accordance with the requirements of Section 016.08 of these regulations. All Provisional Limited Radiographer licenses shall expire on January 1, 2005, and are not renewable after that date.

016.10D1 A Provisional Limited Radiographer shall not concurrently hold a license in any other category of medical radiography.

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016.11 Suspension and Revocation of Licensure.

016.11A The Department may act to suspend or revoke an individual license for any one or a combination of the following causes:

016.11A1 Knowingly causing a material misstatement or misrepresentation to be made in the application for a license or renewal of such license if such misstatement would impair the Department's ability to evaluate the applicant's qualifications or compliance with renewal requirements;

016.11A2 Willfully aiding another person in violating the Act or these regulations;

016.11A3 Violating the statute or regulations pertaining to the Act;

016.11A4 Performing procedures in Medical Radiography beyond the scope of practice authorized by Section 016.05 of these regulations;

016.11A5 Failure to comply with the continuing education requirements applicable to the specific classification of licensure; and

016.11A6 Nonpayment of renewal fees.

016.11B Disciplinary actions shall be carried out in accordance with the requirements of Section 17 of these regulations.

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If you are applying for a Medical Radiographer license by submitting proof of ARRT registration, you are not required to complete this form. Submit a photocopy of your current ARRT card with the renewal notice and your payment.

Attachment B

STATE OF _____)
COUNTY OF _____)

Affidavit of Completion of
Medical Radiography
Continuing Education

Before me, the undersigned authority, personally appeared _____ (name),
who, being first duly sworn, deposes and says:

1. That he/she is _____
(name)
2. That his/her mailing address is _____
(street address)

(city) (state) (Zip code) (phone number - optional)
3. That he/she holds a license, issued by the Department of Health and Human Services Regulation and Licensure to practice as a (Check one) Medical Radiographer ____, as a Limited Radiographer ____, or as a Provisional Limited Radiographer ____.
4. That for the period between _____, 19 ____, and _____, 19 ____,
he/she has completed the required twenty-four (24) hours of approvable continuing education activities on the dates, at the locations, and for the number of hours set forth below:

Program Topic and Provider	Program Location (City/State)	Program Dates (MM/DD/YY)	Hours Earned

Further affiant saith not.

(Signature of License Holder) (License Number)

Sworn to and subscribed before me on the ____ Day of _____, 19 ____.

(SEAL)

(Signature of Notary Public)
My Commission Expires: _____

This form **MUST** be signed in the presence of a Notary Public. There is no exemption from notarization.

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Section 017 ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING
PROCEDURES FOR LICENSEES AND REGISTRANTS; PENALTIES

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017 ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING PROCEDURES FOR LICENSEES AND REGISTRANTS; PENALTIES.

017.01 Purpose and Scope. This section governs the conduct of proceeding under the Radiation Control Act, the administrative procedures of the Agency and the Formal Hearing Procedures of the Department of Health and Human Services Regulation and Licensure, for the issuing, denying, renewing, transferring, amending, suspending, revoking of any license, registration or certification of persons to use radiation sources and for determining compliance with or granting of exemptions from Agency rule, order, or condition of license or certification of persons; for assessing administrative penalties; and for determining content of other agency 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 Regulation and Licensure, 184 NAC 1, except as provided below.

017.02 Definitions. Terms used in this section have the following definitions:

"Act" means the Radiation Control Act as defined in the Nebraska Revised Statutes.

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

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

"Civil Penalty" means a monetary penalty assessed by the Agency under 71-3517 of the Act.

"Contested Case" means a proceeding in which the Agency determines the legal rights, duties, or privileges of a party after an opportunity for adjudicative hearing.

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

"Disposal facility" refers to a facility licensed to dispose of radioactive waste received from other persons.

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

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

"Hearing Examiner" means a person selected by the Director of Regulation and Licensure to conduct hearings.

"Interested person" is a person who participates in a hearing concerning a contested case but who is not admitted as a party by the Hearing Examiner.

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

Corrective steps taken by the licensee/registrant, and the results achieved;

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Corrective steps to be taken to prevent recurrence; and

The projected date for achieving full compliance.

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

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

The Agency;

An applicant/licensee/registrant; and

Any person affected.

"Person affected" means a person:

Who is a resident of a county, or a county adjacent to the county, in which radioactive materials subject to the Act are or will be located, including any person who is doing business or who has a legal interest in land in the county or adjacent county, and any local government in the county; and

Who shall demonstrate that he/she has suffered or will suffer actual injury or economic damage.

"Preliminary Report" is a document prepared by the Agency containing:

A statement of facts on which the Agency bases the conclusion that a violation has occurred;
Recommendations that an administrative penalty be imposed on the person charged; and

Recommendations for the amount of that proposed penalty.

"Public Hearing", means a proceeding which shall 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.

"Requestor" is the designation of a person claiming party status as a person affected.

"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.

"Violation" is an infringement of any rule, license or registration condition, order of the Agency, or any provision of the Act.

017.03 Public Hearings.

017.03A The Agency shall hold public hearings in the following instances:

017.03A1 In any proceeding for the issuance or modification of rules or regulations relating to control of sources of radiation, the agency shall provide an opportunity for public participation through written comments and a public hearing.

017.03B Public Hearing on Applications.

017.03B1 Procedure

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017.03B1a The Agency shall provide a public hearing for an application for a license for licensing ores processed for their source material content and management of byproduct material and source material mill tailings, or for licensing management of low-level radioactive waste.

017.03B1b The Agency shall issue public notice of the public hearing and provide opportunity for written comments. A transcript of the hearing and a written determination shall be available of the action to be taken based on the findings of the evidence presented during the public hearing and public comment period. Agency staff, the hearing officer and applicant may ask questions of any witness testifying at the public hearing.

017.03B2 Environmental Impact Analysis

017.03B2a When the Agency determines that the issuance, amendment or renewal of a license to manage, process or dispose of low-level radioactive waste as defined in 71-3503(23) of the Act or process materials resulting in byproduct material as defined in Section 71-3503(13)(b) of the Act will have a significant impact on the public health and safety and environment, the Agency shall secure a written analysis of the impact from the applicant or licensee, and the Agency shall prepare a written statement on the analysis and make them available to the public for written comment at least thirty (30) days before holding the public hearing on the issuance, amendment or renewal of a license.

017.03B2b The analysis shall assess the radiological and nonradiological impact on the public health and the impact on the total environment. It shall consider the alternatives to the issuance, amendment or renewal of the license, including long term impacts of the licensing action may have on radioactive materials remaining at the site after decommissioning and reclamation.

017.03B2c The Agency shall prohibit any major construction of the applicant for a license before the environmental impact analysis has been completed and a report filed and a license issued.

017.03B3 Prior to termination of a license issued after public hearing in compliance with 017.03B1, the Agency shall assure that the licensee has complied with:

017.03B3a The decontamination, decommissioning and reclamation standards established by the Agency, as set out in Section 012 of these regulations.

017.03B3b The ownership of the site shall be the State of Nebraska or the United States Government.

017.03B3c That adequate funding arrangements have been made to provide for long term surveillance and care of the site.

017.04 Right to a Hearing. When the Agency denies an application for a license or an amendment to the license or exemption to licensing requirements or suspends or revokes a license, it shall provide the applicant or licensee a hearing, according to 184 NAC 1.

017.05 Discipline.

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017.05A 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 license, registration, or certificate issued pursuant to such Act shall be subject to:

Revocation, suspension, modification, condition or limitation;

The imposition of a civil penalty; or

The terms of an appropriate order issued by the Agency.

017.05B Compliance.

017.05B1 In all instances other than the issuance of emergency sanctions pursuant to 017.08, prior to setting a hearing on discipline as set out in Section 017.06, the Agency may afford the licensee, registrant or certificate holder the opportunity to:

017.05B1a Correct violations and show compliance with applicable provisions of the Act, or the rules and regulations, license or registration requirements, and any orders of the Agency issued thereunder, or

017.05B1b Attend an enforcement conference to discuss with the Agency methods and schedules for correcting the violation(s) or to show compliance with the Act, rules and regulations and license conditions. Notice of any enforcement conference shall be sent by personal service or certified mail, return receipt requested. An enforcement conference is not a prerequisite for any action.

017.05B1b(1) Licensees or registrants other than low-level radioactive waste and uranium mining and milling which correct violation of regulations of the Act within the time specified in the notice of violation/non-compliance shall not be subject to civil penalties.

017.05B2 The Agency shall permit the licensee or registrant, or certified individual to respond in writing to the alleged violation of the Act, rule, regulation, order, or any term, conditions of limitation of license or registration.

017.05B3 Failure of a licensee or registrant to respond shall be cause for the Agency to proceed with disciplinary action.

017.06 Hearings on Discipline. Whenever the Agency proposes to subject a licensee or registrant to the provisions of 017.05A, the Agency shall 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 section, rule, regulation, order, license or registration certificate involved in the violation, (c) the time, date and place at which a hearing will be had on such charge, (d) that the Agency may revoke, suspend, modify, condition, or limit a license or registration, impose a civil penalty, or enter an appropriate order, and (e) that upon failure to pay the civil penalty, if any, as determined by the Agency, the penalty may be collected by civil action. The notice shall be delivered to each alleged violator not less than ten (10) days before the time set for the hearing by personal service, or by certified or registered mail to his or her last known address, or by publication. Notice by publication is permissible if other notification means cannot be accomplished. Hearings on discipline shall be conducted in accordance with the provisions of 184 NAC 1.

017.07 Sanctions.

017.07A The Director shall consider the following:

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017.07A1 Criteria in determining what sanctions are appropriate:

017.07A1a Previous history of noncompliance;

017.07A1b Action necessary to deter future violations;

017.07A1c Lack of reasonable efforts to correct the violation(s);

017.07A1d Willfulness; and

017.07A1e Any other aggravating factors.

017.07A2 The severity levels. The seriousness of violations shall be categorized by one of the following severity levels:

017.07A2a 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.

017.07A2b Severity Level II - Violations that are very significant and have an impact on occupational and/or public health and safety or on the environment.

017.07A2c Severity Level III - Violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.

017.07A2d 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.

017.07A2e Severity Level V - Violations that are of minor public health and safety or environmental significances.

017.07A3 Examples of violations in each severity level(s) are set out in Appendix 017-A.

017.07B Application of Sanctions. The Director may impose differing levels of penalties for different severity level violations. In addition, the Director may impose more severe penalties within a given severity level in accordance with the existence of any of the criteria set out in 017.07A1.

017.07B1 For any Severity Level I violation(s), the Director may revoke the license and impose any lesser sanction(s) that the Director may find to be necessary.

017.07B2 For any Severity Level II violation(s), the Director may: (1) revoke the license, (2) Suspend the license, (3) modify, condition or limit the license, (4) impose a civil penalty, (5) enter an appropriate order to further the purposes of the Act, or (6) impose a combination of the sanctions set out above.

017.07B3 For any Severity Level III violation(s), the Director may: (1) revoke the license, if any aggravating criteria of 017.07A1 are found, (2) suspend the license, (3) modify, condition or limit the license, (4) impose a civil penalty, (5) enter an appropriate order to further the purposes of the Act, or (6) impose a combination of the sanctions set out above.

017.07B4 For any Severity Level IV violation(s), the Director may: (1) suspend the license, if any aggravating criteria of 017.07A1 are found, (2) modify, condition or limit the license, (3) impose a

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civil penalty, (4) enter an appropriate order to further the purposes of the Act, or (5) impose a combination of the sanctions set out above.

017.07B5 For any Severity Level V violation(s), the Director may: (1) impose a civil penalty, if any aggravating criteria of 017.07A1 are found, (2) enter an appropriate order to further the purposes of the Act, or (3) issue a declaratory order finding the charges to be true, but not imposing any penalty or directing any action to be taken.

017.07C Civil Penalties. Any civil penalty imposed shall be in an amount not to exceed ten thousand dollars (\$10,000) a day for a person who violates the Act or a rule, order, license, registration or regulations issued under the Act. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

TABLE I

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

017.07C1 Adjustments to the amounts in Table I may be made for the presence of the criteria set out in 017.07A1.

017.07D Suspension and Revocation of a License or Registration. In addition to the other factors set out in 017.07, used by the Director to determine appropriateness of license revocation or suspension, the Director may Act to suspend or revoke a license or a registration if a person:

017.07D1 Knowingly causes a material misstatement or misrepresentation to be made in the application for license or registration if such misstatement would impair the Agency's ability to evaluate the applicant's qualifications, or

017.07D2 Willfully aid another person in violating the Act or these regulations.

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

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017.08A Issue a regulation or order citing the existence of such emergency and require that certain actions be taken as it shall direct to meet the emergency.

017.08A1 An emergency regulation or order takes effect immediately upon service on the person to whom the order is directed.

017.08A2 Any person receiving such emergency regulation or order shall comply immediately.

017.08B If the Agency 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 Agency may impound or order the impounding of the sources of radiation.

017.08B1 An order of impoundment takes effect immediately upon service on the person to whom the order is directed. An impoundment takes effect immediately, and service on the affected person of notice of impoundment or of an order of impoundment shall be made as soon as is practical under the circumstances.

017.08B2 Any person receiving an order of impoundment shall comply immediately.

017.08C Service of any regulation order, or other notice or pleading under this section shall be by personal service or by certified mail, return receipt requested. Affidavit of service, proof of mailing to the proper address, or the return receipt shall be evidence of service.

017.08D Hearings on Emergency Sanctions

017.08D1 A hearing shall be held on an emergency regulation or order pursuant to 017.08A or upon an impoundment or order of impoundment pursuant to 017.08B, if the person to whom the regulation or order or impoundment is directed makes a written application to the Agency for a hearing; said application must be filed within fifteen (15) days of receipt of the emergency regulation or order of impoundment or notice of impoundment.

017.08D2 The hearing shall be held not less than fifteen (15) days nor more than thirty (30) days after filing the written application for hearing.

017.08D3 Whenever a person has requested a hearing pursuant to 017.08D, the Agency shall notify the person in writing, setting forth the time, date and place at which a hearing will be held. The notice shall be served in accord with 017.08C on the applicant not less than ten (10) days before the time set for the hearing.

017.08D4 On the basis of the evidence presented at the hearing, the Director or his/her designee shall, within thirty (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 shall send the applicant a copy of its findings of fact and determination.

017.08E Any final department action on emergency regulations or orders or impoundment of sources of radiation shall be subject to judicial review pursuant to the Administrative Procedure Act.

Appendix 017-A

EXAMPLES OF SEVERITY LEVELS

The following examples of severity levels apply to licensees or registrants and are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

A. Severity I - Most Significant Violations.

1. Exposure of a worker in excess of 250 mSv (25 rems) of radiation to the whole body, or 1.50 Sv (150 rems) to the skin of the whole body, or 3.75 Sv (375 rems) to the feet, ankles, hands, or forearms;
2. Annual whole body exposure in excess of 25 mSv (2.5 rems) of radiation to a non-radiation worker or a radiation worker who is a minor;
3. Release of radioactive material to an unrestricted area(s) in excess of ten times the limits specified in the rules;
4. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the rules;
5. Disposal of licensed material into a sanitary sewage system in quantities or concentrations which exceed ten times the limits of 004.40;
6. Exposure of a worker in a restricted area(s) to ten times the limits of 004.06;
7. A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or not operable due to a deliberate act by the licensee or registrant (e.g., bypassing an interlock);
8. A material false statement. This is a written or sworn statement that is false and is relevant to the regulatory process;
9. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency 010.07C;
10. Deliberate exposure of an individual except by or under the supervision of an individual licensed to engage in the healing arts;
11. Refusing authorized Agency personnel access to facilities and/or equipment to conduct inspections or investigations; or
12. Possession of licensable quantities of radioactive material without a license.

B. Severity II - Very Significant Violations.

1. Single exposure of a worker in excess of 50 mSv (5 rems) of radiation to the whole body, 300 mSv (30 rems) to the skin of the whole body, or 750 mSv (75 rems) to the feet, ankles, hands or forearms;
2. Annual whole body exposure in excess of 50 mSv (0.5 rem) of radiation to a non-radiation worker or radiation worker who is a minor;

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3. Release of radioactive material to an unrestricted area in excess of five times the limits of 004.15;
4. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the rules;
5. Failure to immediately notify the Agency as required by 004.56, 004.57A1 and 004.57A2;
6. Unauthorized disposal of licensed material in quantities or concentrations in excess of five times the limits of 004.40;
7. Exposure of a worker in a restricted area in excess of five times the limits 004.06;
8. A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable;
9. Failure to obtain appropriate Agency approval before moving to a new use and/or storage location;
10. A material false statement. This is a statement that is false by omission and is relevant to the regulatory process;
11. Radiation output on fluoroscopic devices which exceed the limits in 006.05C1.
12. Absence of patient exposure reduction equipment required by Nebraska Regulation for Control of Radiation - Ionizing.
13. Refusing authorized Agency personnel access to records during an inspection or investigation upon reasonable notice;
14. Loss of control of a source of radiation; or
15. Failure to register sources of radiation or services as required by these rules.

C. Severity III - Significant Violations.

1. Single exposure of a worker in excess of 30 mSv (3 rems) of radiation to the whole body, or 75 mSv (7.5 rems) to the skin of the whole body, or 187.5 mSv (18.75 rems) to the feet, ankles, hands or forearms;
2. A radiation level in an unrestricted area such that an individual could receive greater than 1.0 mSv (100 millirems) in a one-hour period or 5.0 mSv (500 millirems) in any seven consecutive days;
3. Failure to notify the Agency within 24 hours as required by 004.57B or failure to notify the Agency immediately as required by 004.57A and 004.57;
4. Substantial potential for an exposure or release in excess of the limits of Nebraska Regulation for Control of Radiation - Ionizing Section 004 (e.g., entry into high radiation areas without performing an adequate survey; operation of a radiation facility with a nonfunctioning interlock system);
5. Release of radioactive material to an unrestricted area in excess of the limits of 004.15;
6. Unauthorized disposal of licensed material not covered in Severity Levels I or II;

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7. Exposure of a worker in restricted areas in excess of the limits of 004.06;
8. Release for unrestricted use of radioactive material or contaminated equipment which poses a potential for significant exposure to members of the public, or which reflects a programmatic rather than isolated weakness in the radiation safety program;
9. Cumulative worker exposure above Nebraska's Regulations for Control of Radiation - Ionizing limits when such exposure reflects a programmatic rather than an isolated weakness in the radiation safety program;
10. Conduct of licensee or registrant activities by an unauthorized or an unqualified person;
11. Any noncompliance with posting, labeling, placarding, shipping papers, packaging loading, or other transporting requirements that could result in the following:
 - a. Improper identification of the type, quantity, or form of material,
 - b. Failure of the carrier or recipient to exercise adequate controls, or
 - c. Substantial potential for personnel exposure or contamination, or improper transfer of material;
12. Failure to control access to licensed materials as specified by Agency rules;
13. Possession or use by licensee or registrant of unauthorized radiation machine or radioactive material in conducting registrant or licensee activities;
14. Radiation levels, contamination levels, or releases that exceed the limits specified in the license;
15. Failure to use exposure reduction devices properly (e.g., collimators, filtration); or
16. Failure to hospitalize patients who have sealed source implants or therapeutic quantities of radioactive material in accordance with the license or license conditions;

D. Severity IV - Violations.

1. Exposure in excess of the limits of 004.06 not constituting Severity I, II, or III violations;
2. A radiation level in an unrestricted area such that an individual could receive greater than 0.02 mSv (2 millirems) in any one-hour period or 1.0 mSv (100 millirems) in any seven consecutive days;
3. Failure to notify the Agency Within 30 days as required by 004.58.
4. Failure to make a follow-up written report to the Agency as required by 004.56B, 004.62 or 010.04;
5. Failure to conduct required leakage or contamination tests or to use properly calibrated equipment.
6. Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (e.g., change of address, expiration of certificate of registration); or
7. Failure to maintain complete records and/or forms required by Nebraska's Regulations for Control of Radiation - Ionizing.

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E. Severity V - Minor Violations.

1. Failure to maintain a current copy of the Nebraska's Regulations for Control of Radiation - Ionizing and current copies of active licenses and/or certificates of registration;
2. Failure to post Nebraska's Regulations for Control of Radiation - Ionizing notices required by 180 NAC 1-010.02; or
3. Other violations that have minor safety or environmental significance.

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Section 018 **FEEES FOR CERTIFICATES OF REGISTRATION, RADIOACTIVE MATERIAL(S) LICENSES, ENVIRONMENTAL SURVEILLANCE, EMERGENCY RESPONSE AND OTHER REGULATORY SERVICES.**

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018 **FEES FOR CERTIFICATES OF REGISTRATION, RADIOACTIVE MATERIAL(S) LICENSES, ENVIRONMENTAL SURVEILLANCE, EMERGENCY RESPONSE AND OTHER REGULATORY SERVICES.**

018.01 **Purpose and Scope.**

018.01A This section establishes the fees for licensing, registration, environmental surveillance and implementation, emergency planning, emergency response and implementation, and other regulatory services and provide for their payment.

018.01B Except as otherwise specifically provided, the rules and requirements in this section apply to any person who is

018.01B1 An applicant for, or holder of:

018.01B1a A radioactive material license issued pursuant to Sections 003, 005, 007, 011, 012, 014 or 016 of these regulations; or

018.01B1b A certificate of registration for radiation machines/facilities and/or services issued pursuant to Sections 002 or 005 of these regulations.

018.01B2 The holder of a fixed nuclear facility construction permit or operating license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 50; or

018.01B3 The operator of any other fixed nuclear facility under a license issued by the U.S. Nuclear Regulatory Commission Pursuant to 10 CFR Parts 30, 31, 32, 33, 34, 35, 40 and/or 70.

018.01B4 The operator of any other nuclear facility.

018.01B5 The operator of any facility that during the course of operation results in the release of radioactive material to the environment.

018.02 **Definitions.** For the purposes of Section 018 of these regulations, the following definitions apply:

"Carrier" means any common carrier, contract carrier, private carrier, railway freight carrier or railway express carrier handling, storing or transporting radioactive material.

"Emergency Planning, Emergency Response and Implementation" means the development and application of those capabilities necessary for the protection of the public and the environment from the effects of an accidental or uncontrolled exposure dose or release of radioactive materials, including the equipping, training and periodic retraining of emergency response personnel.

"Environmental Surveillance and Implementation" means the development and application of those capabilities necessary to assess the radiological impact of activities conducted by licensees and registrants on public health and safety and the environment.

"Facility" means any facility other than that defined in this subsection.

"Fixed Nuclear Facility" means:

Any nuclear reactor(s) at a single site;

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Any facility designed or used for the assembly or disassembly of nuclear weapons;

Any other facility using or possessing source material, special nuclear material, byproduct material and/or any other radioactive material for which the agency conducts off-site environmental surveillance to protect the public health and safety or the environment.

"Shipper" means a person who packages the radioactive material and presents the package for transport.

018.03 Exemptions.

018.03A No application or annual fee shall be required for any common carrier, contract carrier, private carrier, railway freight carrier, or railway express carrier handling, storing or transporting any of the materials described in the Radiation Control Act in the ordinary course of such carrier's business.

018.03B No fee shall be required for the Department of Health and Human Services Regulation and Licensure.

018.04 Payment of Fees.

018.04A Application fees. Each application for a license or certificate of registration for which a fee is prescribed shall be accompanied by a non-refundable fee equal to the appropriate annual fee, except as otherwise specified in Section 018 or that an application for a license covering more than one fee category shall be accompanied by the prescribed fee for the highest fee category.

018.04A1 An application for a certificate of registration shall be accompanied by the base fee and the total fee for all applicable categories.

018.04A2 No application will be accepted for filing or processing prior to full fee payment, as specified, and the application will be returned to the applicant.

018.04A3 All application fees will be charged irrespective of the Agency's disposition of the application or a withdrawal of the application.

018.04B Annual Fees for Licenses, and Certificates of Registration.

018.04B1 A non-refundable fee, pursuant to 018.05, 018.06, 018.07, or 018.08 shall be paid annually for each radioactive material license and for each certificate of registration or radioactive material certificate of registration, which ever is applicable, is required.

018.04B1a The fee shall be paid in full each year on or before the last day of the expiration anniversary month of the license or certificate of registration.¹

018.04B2 In the case of a single license which authorizes more than one category of use, only one fee shall be paid.

¹Example: If the license or certificate of registration expires on June 30, 1992, annual fees are due on or before June 30, of each year.

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018.04B3 A non-refundable fee, pursuant to 018.05 or 018.08, shall be paid annually for each radioactive material license and/or certificate of registration, which ever is applicable, for radiation services and/or servicing.

018.04B3a The fee shall be paid in full each year on or before the last day of the expiration (anniversary) month of the certificate of registration.²

018.04B3a(1) In the case of a single registration which authorizes more than one category of use, the applicable fee for each category shall be paid.

018.04B4 A non-refundable fee, pursuant to 018.08, shall be paid annually for each certificate of registration for radiation machines.

018.04B4a The fee consists of a base fee for all registrants plus a fee for each machine possessed.

018.04B4b The machine fee is modified by the inspection interval (years between routine inspections) of the facility category as specified in Appendix 018-A. The formula for calculation is as follows:

$$\text{Annual Fee} = \frac{\text{Base Fee} + (\text{Sum of Machine and/or Service Fees})}{\text{Inspection Interval(s)}}^3$$

018.04B5 An application for an amendment to a license or certificate of registration which results in a change to a category with a higher fee shall result in a fee being charged equal to the prorated difference between the fee for the current category and the one to which the amended license or certificate will escalate.

018.04B5a The prorated costs shall 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.⁴

018.04B5b The agency will bill the licensee or registrant.

018.04B5c The replacement of part(s) for an existing radiation machine will not result in an additional fee.

018.04C Reciprocity Fees.

018.04C1 Each application for reciprocal recognition of an out-of-state license under Subsection 003.28 of these regulations shall be accompanied by the applicable annual fee

018.04C2 Each application for recognition of an out-of-state registration under Subsection 002.12 of these regulations shall be accompanied by the applicable annual fee, provided that no

²Ibid. p. 18-3

³An example of a fee calculation is shown in Appendix 018-B.

⁴Example: If a waste processing license amendment to change the licensee's classification from Class A to Class B becomes effective July 1, 1985, and the expiration month of the license is December, the licensee will be billed.

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such fee has been submitted within 12 months of the date of commencement of the proposed activity.

018.04D Environmental Surveillance Fees.

018.04D1 Each holder of a fixed nuclear facility construction permit or operating license, or an operator of any other fixed nuclear facility, or any other facility as defined in 018.02 shall submit the fee pursuant to 018.09 for services received.

018.04D2 This fee shall recover for the Department of Health and Human Services Regulation and Licensure, the expenses arising from environmental surveillance and implementation activities.

018.04D3 Payment shall be made within 90 days following the date of invoice.

018.04E Emergency Planning, Emergency Response and Implementation Fees.

018.04E1 Each holder of a fixed nuclear facility construction permit or operating license, or an operator of any other fixed nuclear facility, or any other facility as defined in 018.02 shall submit the fee, pursuant to 018.10, for services received.

018.04E2 This fee shall recover for the Department of Health and Human Services Regulation and Licensure, the expenses arising from emergency planning, emergency response and implementation activities.

018.04E3 Payment shall be made within 90 days following the date of invoice.

018.04F Method of Payment.

018.04F1 Fee payments shall be by check or money order made payable to the Department of Health and Human Services Regulation and Licensure.

018.04F2 The payments may be made by personal delivery to the office, State of Nebraska Department of Health and Human Services Regulation and Licensure in Lincoln, Nebraska, or mailed to the, Department of Health and Human Services Regulation and Licensure, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509.

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018.05 Schedule of Annual Fees for Radioactive Material Licenses.

1. Uranium Recovery - See 018.06 Schedule of Fees for Uranium Recovery Facility Licenses.
2. Low-Level Radioactive Waste Management - See 018.07 Schedule of Fees for Low-Level Radioactive Waste Management Licenses.
3. Manufacturing/Processing of Radioactive Material \$4,830.00
4. Industrial Radiography \$2,925.00
5. Broad License (Educational and/or Medical) \$14,300.00
6. Irradiator, Unshielded During Irradiation \$4,960.00
7. Nuclear Pharmacy \$3,815.00
8. License for Distributor to distribute to persons generally licensed, persons exempt from licensing and/or persons specifically licensed. \$1,950.00
9. Commercial collection and laundry of items contaminated with radioactive, byproduct, source or special nuclear material. \$1,425.00
10. Manufacturer and distribution of encapsulated radioactive material, byproduct, source, or special nuclear material in a device that uses decay heat as a source of power. \$3,460.00
11. Wireline Service Operations \$1,145.00
12. Irradiator, Self-Contained \$1,075.00
13. Mobile Scanning \$1,495.00
14. Nuclear Medicine/Brachytherapy
 - a. 180 NAC 1-007.34A, 007.36 , and/or 007.40 \$1,495.00
 - b. 180 NAC 1-007.46 and/or Remote Controlled Brachytherapy Device \$1,495.00
15. Teletherapy (180 NAC 1-007.52) \$1,495.00
16. Research and development (Human Use). \$1,495.00
17. Processing or manufacture and distribution of radiopharmaceuticals by other than a nuclear pharmacy. \$840.00
18. Possession and use of radioactive materials (Ra-226) in luminous paint or products containing such paint. \$1,000.00
19. Sealed Sources for Diagnosis (180 NAC 1-007.44) \$850.00
20. Research and Development (Non-Human Use) \$850.00

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21. Educational (Instructional Only)	\$865.00
22. Industrial Gauge	\$850.00
23. Emergency Management (Civil Defense)	\$790.00
24. Services (e.g. Leak Testing, Instrument Calibration, Gauge Installations or Maintenance)	\$850.00
25. Gas Chromatograph Detector	\$790.00
26. Other Specific License.	\$790.00
a. If license involves use of radioactive material at temporary job sites, an additional fee of:	\$95.00
b. If license involves use of radioactive material in other than sealed source form, an additional fee of	\$60.00
27. Additional permanent sites where radioactive material is stored or used under same license	20% of applicable fee not to exceed an additional 100%
28. General license which requires registration.	\$70.00
29. Reciprocity	
a. Industrial Radiography	\$2,160.00
b. Wireline Service Operations	\$660.00
c. Mobile Scanning	\$765.00
d. Industrial Gauge	\$230.00
e. Services	\$235.00
f. Gas Chromatograph Detector	\$255.00
30. Review of a device, product, or sealed source containing radioactive, byproduct, source or special nuclear material for which no prior review has been performed. Each device, product or sealed source shall be considered an individual review. ⁵	\$2,400.00

⁵This fee shall be considered a one-time fee which is to be submitted upon the initial review request. Each and any modifications to the device product or sealed source would require a new review and the appropriate fee must be paid.

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31. Application for New License ⁶	
a. License of type listed in 3 through 10 above.	\$1,910.00
b. License of type listed in 11 through 18 above.	\$1,525.00
c. License of type listed in 19 through 26 above.	\$955.00
32. Agency-Approved Training Courses ⁷	\$350.00

⁶The fee for new license application is a one-time fee for application review which is valid as long as the application is not abandoned.

⁷The fees for course approvals applies to all training courses regardless of who is offering such courses. There is a one-time fee for course review which is valid as long as the original course remains unchanged. Courses qualifying for deemed status shall not be subject to fee.

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018.06 Schedule of Fees for Uranium Recovery Facility Licenses.⁸

018.06A Annual Fees.

<u>Category</u>	<u>New Application</u>	<u>Operational Year Including Renewal</u>	<u>Restoration or Reclamation Only</u>	<u>Long Term Care</u>
1. In Situ	\$109,200	\$109,200	\$87,360	\$65,000
2. Disposal only	\$104,000	\$104,000	\$87,360	\$65,000

018.06B Adjustments to Annual Fees.

018.06B1 If additional non-contiguous uranium recovery facility sites are authorized under the same license, the appropriate annual fee shall be increased by 20 percent for each additional site.

018.06B2 Facilities proposing to conduct or conducting irrigation or surface discharge shall pay the following additional annual fee for each irrigation plot or surface discharge point:

<u>New Application</u>	<u>Operational Year</u>	<u>Restoration or Reclamation Only</u>	<u>Long Term Care</u>
\$3,435.00	\$4,300.00	\$3,435.00	\$2,580.00

018.06C One-time Fee Adjustments for the addition of items listed below after an Environmental Assessment has been completed on a facility, a one-time fee corresponding to the item shall be paid:

1. New In Situ Uranium Recover Facility	\$35,875.00
2. In Situ Well Field on Non-Contiguous Property	\$35,875.00
3. In Situ Satellite	\$35,875.00
4. Well Field on Contiguous Property	\$14,295.00
5. Irrigation/Surface Discharge	\$3,345.00
6. Non-Vacuum Dryer	\$25,315.00

018.06D In addition to any other fees, in Subsection 018.06, prior to the issuance of the license the applicant shall deposit with the state cash, negotiable government securities, or an irrevocable assignment of certificates of deposit for Site Closure and Reclamation Cash Fund in the amount of \$5,000.

018.06E The licensee shall pay annually, in addition to all other fees in Subsection 018.06 an amount specified in Part 018.06A for deposit by the State Treasurer in the Nebraska Department of Health and Human Services Regulation and Licensure, Radiation Long-Term Care Cash Fund.

⁸Examples of the fee calculation are shown in Appendix 018-C.

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018.06F Interpretive Rules and Definitions.

018.06F1 "Contiguous" properties are those locations adjacent to an existing licensed or permitted area.

018.06F2 A "new in situ uranium recover facility" is one which has one or more well fields, an ion exchange uranium recovery facility, and facilities for concentrating yellow cake.

018.06F3 Once facilities under a license have entered restoration or reclamation, the appropriate annual fee will continue to be the restoration/reclamation annual fee (subject to adjustment for non-contiguous sites) without regard to whether the license term is subject to renewal.

018.06F4 The one-time fee adjustment shall apply only to those facilities not licensed as of the effective date of these regulations.

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018.07 Fees for Low-Level Radioactive Waste Management Pursuant to Section 012.

018.07A License Processing Fees

018.07A1 A fee shall be assessed from license applicants to process, issue, amend or renew licenses including amendments for the purpose of site closure and stabilization.

018.07A2 In determining the fees, the Agency shall calculate and itemize the direct costs associated with license evaluation, processing, and monitoring, including application review, meetings and correspondence with the license applicant, license research and drafting time, necessary travel, technical and administrative review of the drafted license, clerical preparation of the license and related tasks, advertising costs for public notice, review of public comments, hearing costs, license processing fee billing, and final license issuance. The Agency shall apply the current indirect rate to its total direct wages and salary expenses. This method is the approved agency-wide procedure for recovering indirect costs from its federal programs.

018.07A3 The Agency shall maintain itemized records of staff time and costs incurred in the processing of a license application. License processing fees shall apply without regard to whether a license is issued, denied or requested to be inactivated prior to issuance or thereafter.

018.07A4 Each application for a license shall be accompanied by a filing fee of two-hundred seventy-five thousand dollars (\$275,000.).

018.07A5 All fees shall be made payable to the Nebraska Department of Health and Human Services Regulation and Licensure.

018.07A5a Where the fees assessed in accordance with 018.07A2 above are less than the filing fee set forth in 018.07A4 above, the Agency shall refund the balance to the applicant.

018.07A5b Where the fees assessed in accordance with 018.07A2 above exceed the filing fee set forth in 018.07A4 above, the applicant shall be billed the balance.

018.07B Annual License Administration Fees

018.07B1 An administration fee shall be assessed to licensees based upon direct and indirect costs annually during the term of operation and during site closure and stabilization until the license has been terminated.

018.07B2 In determining the annual fees, the Agency shall calculate and itemize the cost of monitoring the licensed facility, inspections of the facility or other site visits, reviewing the compliance of facilities with the associated license conditions, general legal costs incurred by the Agency, or other tasks related to administering the license program.

018.07B3 The Agency shall maintain itemized records of staff time and costs incurred in the administration of a license.

018.07B4 An annual fee of \$200,000 shall be made payable to the State of Nebraska Department of Health and Human Services Regulation and Licensure and shall be due July 1.

018.07B4a Where the fees assessed in accordance with 018.07B2 above are less than the fee set forth in 018.07B4 above, the Agency shall refund the balance to the licensee.

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018.07B4b Where the fees assessed in accordance with 018.07B2 above exceed the fee set forth in 018.07B4 above, the licensee shall be billed the balance and shall pay the balance within 30 days of receipt.

018.07C Fees charged under 018.07A and 018.07B are for the purpose of reimbursing the Agency for direct and indirect costs and are not for the purpose of meeting any financial assurance requirements set out in Section 012, which financial assurance requirements must be met in addition to all fees being paid.

018.07D Institutional Care and Control Monitoring

018.07D1 In addition to any other fees, in 018.07, prior to the issuance of the license, the applicant shall pay a fee for the purpose of providing funds in the event of a default by the licensee to provide adequate funds to comply with regulations and license conditions and to maintain health and safety standards. The fee for commercial storage and disposal of low-level radioactive waste is to be invested and the principal and interest applied to the Long-Term Care Cash Fund of institutional care and control monitoring, which shall mean the maintenance of decommissioned structures, facilities and grounds and the environmental monitoring to assure no releases of entombed materials to the environment for the lifetime of entombed materials. The applicant shall pay the amounts specified below:

a. Commercial Storage/Disposal	\$10,000,000
b. Incineration	\$3,000,000
c. Compacting	\$3,000,000
d. Storage or Processing	
Class A Storage or Processing Facility	\$ 1,000,000
Class B Storage Facility	\$2,000,000
Class B Processing Facility	\$3,000,000
Class C Storage and Processing Facility	\$5,000,000

018.07D2 In addition to the initial fee set out in 018.07D1 licensees shall pay an annual fee as specified below:

Commercial Storage/Disposal	\$250,000
Incineration	\$35,000
Compacting	\$20,000
Processing	\$20,000
Receipt of Packaged Waste (Broker)	\$5,000
Handling/Packaging Waste (Broker)	\$10,000

018.07D3 Additional fee for Commercial Storage/Disposal of radioactive waste.

018.07D3a In addition to the annual fees charged to Commercial Storage/Disposal licensees under Subpart 018.07D2, a fee of \$3.00 per cubic foot of radioactive waste received, possessed, stored or processed from other persons shall be assessed.

018.07D3b The fee per cubic foot of radioactive waste shall be increased by the amount of \$.50 per cubic foot commencing two years after the date of issuance of the license, additional

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increases of \$.50 per cubic foot shall be added on the biennial anniversary date of the license thereafter until termination.

018.07D3c Fees assessed under this section shall be paid to the Agency no later than the tenth day of each month following the month of collection.

018.07D4 All fees collected under 018.07D shall be deposited into the State of Nebraska Department of Health and Human Services Regulation and Licensure, Radiation Long-Term Care Cash Fund.

018.07E Interpretive Rules and Definitions.

018.07E1 Radioactive waste processing and storage facilities are classified according to the radionuclides, received, possessed, or processed and the total possession limit shall not exceed the quantities specified in Section 013 Table A-1 Column A, or A(2). The Class possession limits are as follows:

018.07E1a Class A facility not to exceed the Column A(2) quantity.

018.07E1b Class B facility not to exceed the Column A, quantity.

018.07E1c Class C facility quantities in excess of those specified in Column A.

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018.08 Schedule of Annual Fees for Certificates of Registration for Radiation Generating Equipment and Services and Licenses to Practice Medical Radiography

<u>Base Fee</u>	\$ 25.00
<u>Category of Machine (Radiation Generating Equipment)</u>	<u>Fee Per Unit</u>
1. Accelerator	\$115.00
2. Airport Baggage X-ray	\$70.00
3. Electron Beam Welding	\$70.00
4. Chiropractic	\$70.00
5. CT Scanners	\$70.00
6. Dental Diagnostic	\$20.00
7. Radiographic/Fluoroscopic Combination	\$70.00
8. X-Ray Diffraction	\$40.00
9. X-Ray Fluorescence	\$40.00
10. Fluoroscopy Diagnostic	\$70.00
11. Fluoroscopy X-Ray - Industrial	\$70.00
12. Industrial Gauge - X-Ray	\$70.00
13. Ion Implantation Device	\$70.00
14. Medical Diagnostic X-ray	\$70.00
15. Electron Microscope	\$70.00
16. Package X-Ray	\$70.00
17. Particle Size Analyzer - X-Ray (Analytical)	\$70.00
18. Podiatric Diagnostic - X-Ray	\$40.00
19. Spectroscopy/Spectrography X-Ray	\$70.00
20. Therapeutic X-Ray	\$70.00
21. Veterinary Diagnostic X-Ray	\$40.00
22. Radiography Cabinet X-Ray (per registration)	\$70.00
23. Industrial Radiography - In-Plant Only (per registration) ⁹	\$240.00
24. Industrial Radiography - Temporary Field Site Authorization (per registration) ¹⁰	\$300.00
25. Research and Development	\$80.00
26. Registration of Out-of-State radiation generating equipment brought into Nebraska for temporary use	Annual Fee of Applicable Category
27. Reciprocity	Annual Fee of Applicable Category
28. Other Registered Sources	\$95.00

⁹Those registrants possessing a radioactive material license and industrial x-ray equipment, the fee is reduced two-thirds.

¹⁰Ibid. p. 18-14

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<u>Category of Service</u>	<u>Annual Fee Except As Stated Otherwise</u>
1. Assembler/Installer - Radiation Generating Equipment	\$85.00
2. Facility Shielding Review	\$85.00
3. Calibration - Radiation Generating Equipment	\$85.00
4. Demonstration/Sales	\$85.00
5. Health Physics Services	
a. Any Combination of two (2) of the Above	\$170.00
b. Any Combination of three (3) of the Above	\$250.00
c. Any Combination of four (4) of the Above	\$300.00
6. Personnel Monitoring Services	\$ 95.00

FEES FOR LICENSES TO PRACTICE MEDICAL RADIOGRAPHY

SCHEDULE OF FEES. The following fees have been set by the Department of Health and Human Services Regulation and Licensure, by this regulation to be paid as a condition of issuance of licensure as a Medical Radiographer, a Temporary Medical Radiographer, a Limited Radiographer or a Provisional Limited Radiographer.

1. Examination Fee for Limited Radiographer license, thirty dollars (\$30.00).
2. By an applicant for a license to practice as a Medical Radiographer, the fee of fifty-five dollars (\$55.00).
3. By an applicant for a license to practice as a Temporary Medical Radiographer, the fee of fifteen dollars (\$15.00).
4. By an applicant for a license to practice as a Limited Radiographer, the fee of fifty-five dollars (\$55.00).
5. By an applicant for a license to practice as a Provisional Limited Radiographer, the fee of fifty-five dollars (\$55.00).
6. By an applicant for renewal on a biennial basis of a license to practice as a Medical Radiographer, the fee of fifty-five dollars (\$55.00).
7. By an applicant for renewal on a biennial basis of a license to practice as a Limited Radiographer, the fee of fifty-five dollars (\$55.00).
8. By an applicant for renewal on a biennial basis of a license to practice as a Provisional Limited Radiographer, the fee of fifty-five dollars (\$55.00).
9. The applicable fee set by the State of Nebraska Department of Health and Human Services Regulation and Licensure pursuant to this regulation shall accompany the application.

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018.09 Environmental Surveillance Fees. Whenever the Agency conducts environmental surveillance the following fees shall be charged.

<u>Category</u>	<u>Fees per Analysis Type</u>
1. Air Filter	
Gross Alpha	\$20.00
Gross Beta	\$20.00
Gross Alpha/Beta	\$25.00
Gamma Scan	\$60.00
2. Charcoal Cartridge	
Gamma Scan	\$60.00
Iodine 131	\$60.00
3. Silver Zeolite Cartridge	
Gamma Scan	\$60.00
Iodine 131	\$60.00
4. Water (Surface/Ground)	
Gross Alpha	\$20.00
Gross Beta	\$20.00
Gross Alpha/Beta	\$25.00
Gamma Scan	\$60.00
Tritium	\$25.00
Iodine 131	\$60.00
Strontium 89/90	\$90.00
Strontium 90	\$90.00
Radon	\$50.00
Total Uranium	\$40.00
Thorium	\$90.00
Total Radium	\$40.00
Radium 226	\$55.00
Radium 228	\$55.00
5. Milk	
Strontium 89/90	\$90.00
Strontium 90	\$90.00
Gamma Scan	\$60.00
Iodine 131	\$60.00
6. Food Product and Vegetation	
Gamma Scan	\$60.00
Iodine 131	\$60.00
Strontium 89/90	\$90.00
Strontium 90	\$90.00
7. Soil and Sediments	
Gross Alpha	\$20.00
Gross Beta	\$20.00
Gamma Scan	\$60.00
Strontium 89/90	\$90.00

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Strontium 90	\$90.00
8. Biota	
Gamma Scan	\$60.00
9. Any Other Sample	
Gross Alpha	\$20.00
Gross Beta	\$20.00
Gross Alpha/Beta	\$25.00
Gamma Scan	\$60.00
10. Radon Measurement	\$50.00
11. Any Other Analysis Not Specified Above ¹¹	As necessary to cover the costs
12. Environmental Dosimetry	
TLD Bulb	\$50.00 Each
TLD Bulb Analysis	\$20.00
13. Personal Services	\$50.00/Hour
14. Equipment/Supplies	As necessary to cover the cost of adequately assessing the radiological impact of activities conducted by licensees and registrants on public health and safety and the environment.
15. Smears (wipes) for Removable Contamination (Radioactive Material)	\$20.00
16. Leak Test of Sealed Sources	\$20.00

018.10 Emergency Response Fees. Whenever the Agency provides emergency response capability a fee shall be charged equal to the cost, to include personnel, equipment and supplies.

018.11 Nuclear Power Plant Fees. Any fee(s) collected pursuant to Subsections 018.09 and 018.10 from any Nuclear Power Plant, shall not exceed the lesser of the actual annual costs of such activities or \$36,000.

018.12 Failure to Pay Prescribed Fees.

018.12A In any case where the agency finds that an applicant for a license or certificate of registration has failed to pay the fee prescribed in this section, the Agency will not process that application until such fee is paid.

018.12B In any case where the agency finds that a licensee or registrant has failed to pay a fee prescribed by this section by the due date, the Agency may implement the appropriate compliance procedures.

¹¹In determining such fees, the Agency shall, as an objective obtain sufficient funds from the fees to pay for a portion of the direct and indirect costs of administering the Radiation Control Act without loss or reduction of the General Fund Allocation to the Agency.

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018.12C In any case where the Agency finds that a fixed nuclear facility has failed to pay fees for environmental surveillance and/or emergency planning, emergency response and implementation pursuant to contract within 90 days following date of invoice, the Agency may issue an order to show cause why the services should not be terminated for breach of contract.

018.12D In the event the Agency has performed services for or expended funds on behalf of a person who has not reimbursed the Agency after demand, then the Agency may take appropriate legal action to recover amounts.

APPENDIX 018-A

Routine Inspection Intervals For Determination of the Machine Fee, the Routine Inspection Frequency For Radiation Generating Equipment and the Assigned Priority.

<u>Facility/Type</u>	<u>Column 1</u> <u>Priority</u> ¹²	<u>Column 2</u> <u>Inspection Interval In</u> <u>Years For Fee</u> <u>Determination</u> ¹³	<u>Column 3</u> <u>Inspection Interval In</u> <u>Years For Radiation</u> <u>Machine</u> ¹⁴
Hospital	I-II	2	1-2
Radiology Clinic	I, II or III	2	1-3
Private Practice	II or III	2	2-3
Chiropractic	II or III	2	2-3
Dental	IV	4	4
Veterinary	IV	4	4
Podiatrists	IV	4	4
Industrial	I-II	1	1-2
Osteopathic	II or III	2	2-3
Colleges & Schools	I or II	2	1-2
Regional Center	II or III	2	2-3
Miscellaneous	I, II or III	2	1-3

¹²The priority in Column 1 is determined on the basis of facility size, number of patients, number of tubes and personnel. The priority number assigned would coincide with the inspection frequency and may be adjusted in accordance with inspection findings.

¹³The inspection interval in years in Column 2 for fee determination is only used to establish the annual fee that is due. This interval is used in the formula specified in 018.04B4b and is shown in the example of a fee calculation in Appendix 018-B.

¹⁴The inspection interval in years in Column 3 for radiation machines establishes when the routine inspection frequency is expected. For example, a hospital has a 1-2 year frequency which means that inspections routinely would be conducted within that time frame. However, more frequent inspections may be made if and when conditions and situations warrant the accelerated inspection frequency.

APPENDIX 018-B

Example of Fee Calculation.

The Annual Fee For Each Certificate of Registration is Calculated Using the Following Formula:

$$\text{Annual Fee} = \text{Base Fee} + \frac{\text{Sum of machines and/or Service fees}}{\text{Inspection Interval}}$$

The Inspection Interval for the Fee determination is Specified in Column 2 in Appendix 018-A.

Example:

1. There are three machines located in a clinic.
 - 1 dental diagnostic x-ray unit
 - 1 diagnostic x-ray unit (radio/fluoro combination)
 - 1 medical diagnostic x-ray unit

The fee would be calculated as follows:

$$\$25 + \frac{(1 \times \$20)}{4} + \frac{(1 \times \$70)}{2} + \frac{(1 \times \$70)}{2} =$$

$$\$25 + \frac{\$20}{4} + \frac{\$140}{2} =$$

$$\$25 + \$5 + \$70 = \$100$$

The annual fee = \$100

2. There are four machines located in a dental office.
 - 4 dental diagnostic x-ray units

The fee would be calculated as follows:

$$25 + \frac{(4 \times \$20)}{4} =$$

$$\$25 + \frac{\$80}{4} =$$

$$\$25 + \$20 = \$45$$

The annual fee = \$45

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3. There is one machine located in a dental office.
1 dental diagnostic x-ray unit

The fee would be calculated as follows:

$$\$25 + \frac{(1 \times \$20)}{4} =$$

$$\$25 + \frac{\$20}{4} =$$

$$\$25 + \$5 = \$30$$

The annual fee = \$30

Appendix 018-C

Examples of Fee Calculation for Uranium Recovery Facility Licenses.

This Example is the same for either an In Situ or a Disposal License.

1. New Application - This is a one-time fee paid upon the submission of the license application. This fee may be adjusted by the appropriate amount specified in Part 018.06-C.

Example:

In Situ License Application	\$109,200
<u>In Situ Satellite</u>	<u>\$ 35,875</u>
Total for Application	\$145,075

If this application contains the request for surface discharge then an additional \$3,435.00 must also be submitted. The total would then be \$148,512.

2. Operational Year Including Renewal. The annual fee consist of the following:

Annual Operational Fee	\$109,200
Long-Term Care Fund Payment	\$ 65,000
If Surface Discharge is Requested	\$ 4,300
<u>Long-Term Care Fund Payment</u>	<u>\$ 2,580</u>
Annual Total	\$181,080

3. Site Restoration or Reclamation. The annual fee consists of the following:

Annual Restoration Fee	\$ 87,360
Long-Term Care Fund Payment	\$ 65,000
If Surface Discharge is Requested	\$ 3,435
<u>Long-Term Care Fund Payment</u>	<u>\$ 2,580</u>
Annual Total	\$158,375

This fee is paid annually starting with the commencement of site restoration or reclamation at the conclusion of the operational licensed activities. The operational fee terminates at the conclusion of the operational licensed activities. The fees for site restoration or reclamation are to be paid annually until the restoration or reclamation has been completed.

4. The long-term care fees may be assessed by the Agency beyond the cessation of operational licensed activities, site restoration or reclamation, if necessary, but before termination of the license and closure of the site.

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019 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

019.01 Purpose and Scope.

019.01A This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators. The requirements of this section are in addition to other requirements in these regulations. In particular, the provisions of Sections 001, 003, 004, 010, 013, 017 and 018 of these regulations apply to applications and licenses subject to this section. Nothing in this section relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

019.01B The regulations in this section apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Section.

019.01C The regulations in this section do not apply to self contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

019.02 Definitions. As used in this Section:

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

"Double encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device are not accessible to personnel.

"Irradiator operator" means an individual who has successfully completed the training and testing described in 019.18 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

"Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

"Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

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"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

"Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Radiation safety officer" means an individual with responsibility for the overall radiation safety program at the facility.

"Sealed source" means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

SPECIFIC LICENSING REQUIREMENTS

019.03 Application for a Specific License. A person, as defined in Subsection 001.02 of these regulations, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRH-5, "Application for Material License." Each application for a license, must be accompanied by the fee prescribed in Subsection 018.05 of these regulations. The application and one copy must be sent to:

Department of Health and Human Services
Regulation and Licensure
Radioactive Materials Program
P.O. Box 95007
301 Centennial Mall South
Lincoln, NE 68509

019.04 Specific Licenses for Irradiators. The Agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this Subsection.

019.04A The applicant shall satisfy the general requirement specified in Subsection 003.11 of these regulations and the requirements contained in this Section.

019.04B The application must describe the training provided to irradiator operators including:

019.04B1 Classroom training;

019.04B2 On-the-job or simulator training;

019.04B3 Safety reviews;

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019.04B4 Means employed by the applicant to test each operator's understanding of the Agency's regulations and licensing requirements and the irradiator operating and emergency procedures; and

019.04B5 Minimum training and experience of personnel who may provide training.

019.04C The application must include an outline of the written operating and emergency procedures listed in 019.19 that describes the radiation safety aspects of the procedures.

019.04D The application must describe the organizational structure for managing the irradiator, specifically, the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

019.04E The application must include a description of the access control systems required by 019.08, the radiation monitors required by 019.11, the method of detecting leaking sources required by 019.22 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

019.04F If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Agency. The description must include the:

019.04F1 Instruments to be used;

019.04F2 Methods of performing the analysis; and

019.04F3 Pertinent experience of the individual who analyzes the samples.

019.04G If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading of its facility, the loading or unloading must be done by an organization specifically authorized by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.

019.04H The applicant shall describe the inspection and maintenance checks including the frequency of the checks required by 019.23.

019.05 Start of Construction. The applicant may not begin construction of a new irradiator prior to the submission to the Agency of both an application for a license for the irradiator and the fee required by Subsection 018.05. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of site, site surveys or soil testing, site preparation, site evacuation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of license with respect to the requirements of the Nebraska Radiation Control Act, as amended, and rules, regulations, and orders issued under the Act.

019.06 Applications for Exemptions. In addition to the exemption in Part 001.03A, any application for a license or for amendment of a license authorizing use of teletherapy-type unit for irradiation of materials

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or objects may include proposed alternatives for the requirements of this Section. The Agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

019.07 Performance Criteria for Sealed Sources.

019.07A Requirements. Sealed sources installed after the effective date of these regulations:

019.07A1 Must have a certificate of registration issued under the U. S. Nuclear Regulatory Commission or an Agreement State for evaluation of radiation safety information about its product.

019.07A2 Must be doubly encapsulated;

019.07A3 Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

019.07A4 Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

019.07A5 In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (B) through (G) of this Subsection.

019.07B Temperature. The test source must be held at - 40° celsius for 20 minutes, 600° celsius for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600° celsius to 20° celsius within 15 seconds.

019.07C Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

019.07D Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

019.07E Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

019.07F Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

019.07G Bend, if the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

019.08 Access Control

019.08A Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as

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a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

019.08B In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

019.08C A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 019.08B. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

019.08D Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

019.08E Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

019.08F Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

019.08G Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "CAUTION, RADIOACTIVE MATERIAL(S) "or" DANGER, RADIOACTIVE MATERIAL(S)." Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

019.08H If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

019.08I Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

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019.09 Shielding.

019.09A The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over any area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

019.09B The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

019.09C The radiation dose rate at 1 meter from the shield of a dry-source- storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

019.10 Fire Protection.

019.10A The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

019.10B The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

019.11 Radiation Monitors.

019.11A Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this Part.

019.11B Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

019.12 Control of Source Movement.

019.12A The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

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019.12B The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

019.12C The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

019.12D Each control for a panoramic irradiator must be clearly marked as to its function.

019.13 Irradiator Pools.

019.13A For licenses initially issued after the effective date of these regulations, irradiator pools must either:

019.13A1 Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pools; or

019.13A2 Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

019.13B For licenses initially issued after the effective date of these regulations, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

019.13C A means must be provided to replenish water losses from the pool.

019.13D A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

019.13E Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens (ohms) per centimeter or less and with a clarity so that the sources can be seen clearly.

019.13F A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

019.13G If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

019.14 Source Rack Protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

019.15 Power Failures.

019.15A If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

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019.15B The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

019.15C During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

019.16 Design Requirements. Irradiators whose construction begins after the effective date of these regulations, must meet the design requirements of this Subsection.

019.16A Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 019.09. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

019.16B Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

019.16C Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 019.13B, and that metal components are metallurgically compatible with other components in the pool.

019.16D Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of

019.13E The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

019.16E Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 019.11A. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 019.22B, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

019.16F Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

019.16G Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 019.08.

019.16H Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the

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detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

019.16I Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

019.16J Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

019.16K Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

019.17 Construction Monitoring and Acceptance Testing. The requirements of this Subsection must be met for irradiators whose construction begins after the effective dated of these regulations. The requirements must be met prior to loading sources.

019.17A Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that the construction meets design specifications and generally accepted building code requirement for reinforced concrete.

019.17B Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

019.17C Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of 019.13B.

019.17D Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

019.17E Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 019.11A. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet 019.22B. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitors, alarms, and interlocks required by 019.11B.

019.17F Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 019.14 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

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019.17G Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

019.17H Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing systems.

019.17I Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

019.17J Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

019.17K Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

OPERATION OF IRRADIATORS

019.18 Training

019.18A Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

019.18A1 The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Agency dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how a irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

019.18A2 The requirements of Sections 010 and 019 of these regulations that are relevant to the irradiator;

019.18A3 The operation of the irradiator;

019.18A4 Those operating and emergency procedures listed in 019.19 that the individual is responsible for performing; and

019.18A5 Case histories of accidents or problems involving irradiators.

019.18B Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individuals responsible for performing and other operations necessary to safely operate the irradiator without supervision.

019.18C Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as

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described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

019.18D The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

- 019.18D1 Changes in operating and emergency procedures since the last review, if any;
- 019.18D2 Changes in regulations and license conditions since the last review, if any;
- 019.18D3 Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
- 019.18D4 Relevant results of inspections of operator safety performance;
- 019.18D5 Relevant results of the facility's inspection and maintenance checks; and
- 019.18D6 A drill to practice an emergency or abnormal event procedure.

019.18E The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

019.18F Individuals that will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 019.19 that they are expected to perform or comply with, and their proper response to alarms required in this Section. Tests may be oral.

019.18G Individuals who must be prepared to respond to alarms required by 019.08B, 019.08I, 019.10A, 019.11A, 019.11B, and 019.22B shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

019.19 Operating and Emergency Procedures.

019.19A The licensee shall have and follow written operating procedures for:

- 019.19A1 Operation of the irradiator, including entering and leaving the radiation room;
- 019.19A2 Use of personnel dosimeters;
- 019.19A3 Surveying the shielding of panoramic irradiators;
- 019.19A4 Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- 019.19A5 Leak testing of sources;
- 019.19A6 Inspection and maintenance checks required by 019.23;

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019.19A7 Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

019.19A8 Inspection of movable shielding required by 019.08H, if applicable.

019.19B The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

019.19B1 Sources stuck in the unshielded position;

019.19B2 Personnel overexposures;

019.19B3 A radiation alarm from the product exit portal monitor or pool monitor;

019.19B4 Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

019.19B5 A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

019.19B6 A prolonged loss of electrical power;

019.19B7 A fire alarm or explosion in the radiation room;

019.19B8 An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

019.19B9 Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

019.19B10 The jamming of automatic conveyor systems.

019.19C The licensee may revise operating and emergency procedures without Agency approval only if all of the following conditions are met:

019.19C1 The revisions do not reduce the safety of the facility,

019.19C2 The revisions are consistent with the outline or summary of procedures submitted with the license application,

019.19C3 The revisions have been reviewed and approved by the radiation safety officer; and

019.19C4 The users or operators are instructed and tested on the revised procedures before they are put into use.

019.20 Personnel Monitoring

019.20A Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see Part

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004.22). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLD's must be processed at least quarterly.

019.20B Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this part, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

019.21 Radiation Surveys.

019.21A A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modifications to the radiation room shielding or structure that might increase dose rates.

019.21B If the radiation levels specified in 019.09 are exceeded, the facility must be modified to comply with the requirements in 019.09.

019.21C Portable radiation survey meters must be calibrated at least annually to an accuracy of ± 20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

019.21D Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Section 004, Table 2, Column 2 or Table 3 of Appendix 004-B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

019.21E Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

019.22 Detection of Leaking Sources.

019.22A Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State to perform the test.

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019.22B For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

019.22C If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agency, U. S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or product are found, the licensee shall arrange to have them decontaminated or disposed of by an Agency, U.S. Nuclear Regulatory Commission or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Section 004, Table 2, Column 2. Appendix 004-B. (See Subsection 003.26 for reporting requirements.)

019.23 Inspection and Maintenance.

019.23A The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

- 019.23A1** Operability of each aspect of the access control system required by 019.08.
- 019.23A2** Functioning of the source position indicator required by 019.12B.
- 019.23A3** Operability of the radiation monitor for radioactive contamination in pool water required by 019.22B using a radiation check source, if applicable.
- 019.23A4** Operability of the over-pool radiation monitor at underwater irradiators as required by 019.11B.
- 019.23A5** Operability of the product exit monitor required by 019.11A.
- 019.23A6** Operability of the emergency source return control required by 019.12C.
- 019.23A7** Leak-tightness of systems through which pool water circulates (visual inspection).
- 019.23A8** Operability of the heat and smoke detectors and extinguisher system required by 019.10 (but without turning extinguishers on).
- 019.23A9** Operability of the means of pool water replenishment required by 019.13C.

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019.23A10 Operability of the indicators of high and low pool water levels required by 019.13D.

019.23A11 Operability of the intrusion alarm required by 019.08I, if applicable.

019.23A12 Functioning and wear of the systems, mechanisms, and cables used to raise and lower sources.

019.23A13 Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 019.14.

019.23A14 Amount of water added to the pool to determine if the pool is leaking.

019.23A15 Electrical wiring on required safety systems for radiation damage.

019.23A16 Pool water conductivity measurements and analysis as required by 019.24B.

019.23B Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

019.24 Pool Water Purity.

019.24A Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

019.24B The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens (ohms) per centimeter. Conductivity meters must be calibrated at least annually.

019.25 Attendance During Operation.

019.25A Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite;

019.25A1 Whenever the irradiator is operated using an automatic product conveyor system; and

019.25A2 Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

019.25B At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in 019.18G must be onsite.

019.25C At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 019.18F and 019.18G. Static irradiations may be performed without a person present at the facility.

019.26 Entering and Leaving the Radiation Room.

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019.26A Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

019.26B Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

019.26B1 Visually inspect the entire radiation room to verify that no one else is in it; and

019.26B2 Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

019.26C During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 019.11B is operating with backup power.

019.27 Irradiation of Explosive or Flammable Materials.

019.27A Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

019.27B Irradiation of more than small quantities of flammable material (flash point below 140° F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

RECORDS

019.28 Records and Retention Periods. The licensee shall maintain the following records at the irradiator for the periods specified.

019.28A A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Agency terminates the license for documents not superseded.

019.28B Records of each individual's training, tests, and safety reviews provided to meet the requirements of 019.18A, B, C, D, F and G until 3 years after the individual terminates work.

019.28C Records of the annual evaluations of the safety performance of irradiator operators required by 019.18E for 3 years after the evaluation.

019.28D A copy of the current operating and emergency procedures required by 019.19 until superseded or the Agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 019.19C3 retained for 3 years from the date of the change.

019.28E Film badge and TLD results required by 019.20 until the Agency terminates the license.

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- 019.28F Records of radiation surveys required by 019.21 for 3 years from the date of the survey.
- 019.28G Records of radiation survey meter calibrations required by 019.21 and pool water conductivity meter calibrations required by 019.24B until 3 years from the date of calibration.
- 019.28H Records of the results of leak tests required by 019.22A and the results of contamination checks required by 019.22B for 3 years from the date of each test.
- 019.28I Records of inspection and maintenance checks required by 019.23 for 3 years.
- 019.28J Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.
- 019.28K Records of the receipt, transfer and disposal, of all licensed sealed sources as required by Subsection 003.30 and Subsection 003.25.
- 019.28L Records on the design checks required by 019.16 and the construction control checks as required by 019.17 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.
- 019.28M Records related to decommissioning of the irradiator as required by Part 003.18G.

019.29 Reports.

019.29A In addition to the reporting requirements in other parts of Agency regulations, the licensee shall report the following events if not reported under of parts of Agency regulations:

- 019.29A1 Source stuck in an unshielded position.
- 019.29A2 Any fire or explosion in a radiation room.
- 019.29A3 Damage to the source racks.
- 019.29A4 Failure of the cable or drive mechanism used to move the source racks.
- 019.29A5 Inoperability of the access control system.
- 019.29A6 Detection of radiation source by the product exit monitor.
- 019.29A7 Detection of radioactive contamination attributable to licensed radioactive material.
- 019.29A8 Structural damage to the pool liner or walls.
- 019.29A9 Abnormal water loss or leakage from the source storage pool.
- 019.29A10 Pool water conductivity exceeding 100 microsiemens (ohms) per centimeter.

019.29B The report must include a telephone report within 24 hours as described in Subpart 003.26C1 and a written report within 30 days as described in Subpart 003.26C2.

Nebraska Department of Health and Human Services Regulation and Licensure

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CUMULATIVE OCCUPATIONAL EXPOSURE HISTORY

1. NAME (LAST, FIRST, MIDDLE INITIAL)				2. IDENTIFICATION NUMBER		3. ID TYPE		4. SEX MALE <input type="checkbox"/> FEMALE <input type="checkbox"/>		5. DATE OF BIRTH	
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
6. MONITORING PERIOD		7. LICENSEE OR REGISTRANT NAME		8. LICENSE OR REGISTRATION NUMBER		9. RECORD ESTIMATE NO RECORD		10. ROUTINE PSE			
11. DDE	12. LDE	13. SDE, WB	14. SDE, ME	15. CEDE	16. CDE	17. TEDE		18. TODE			
19. SIGNATURE OF MONITORED INDIVIDUAL		20. DATE SIGNED		21. CERTIFYING ORGANIZATION		22. SIGNATURE OF DESIGNEE		23. DATE SIGNED			

**INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE
COMPLETION OF NRH-1
(All doses should be stated in rems)**

- | <p>1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).</p> <p>2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.</p> <p>3. Enter the code for the type of identification used as shown below:</p> <table border="1"> <thead> <tr> <th>CODE</th> <th>ID TYPE</th> </tr> </thead> <tbody> <tr> <td>SSN</td> <td>U.S. Social Security Number</td> </tr> <tr> <td>PPN</td> <td>Passport Number</td> </tr> <tr> <td>CSI</td> <td>Canadian Social Insurance Number</td> </tr> <tr> <td>WPN</td> <td>Work Permit Number</td> </tr> <tr> <td>IND</td> <td>INDEX Identification Number</td> </tr> <tr> <td>OTH</td> <td>Other</td> </tr> </tbody> </table> <p>4. Check the box that denotes the sex of the individual being monitored.</p> <p>5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.</p> <p>6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.</p> <p>7. Enter the name of the licensee, registrant, or facility not licensed by the Agency that provided monitoring.</p> <p>8. Enter the Agency license or registration number or numbers.</p> <p>9. Place an "X" in Record, Estimate, or No Record. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee or registrant intends to assign the record dose on the basis of TLD results that are not yet available.</p> | CODE | ID TYPE | SSN | U.S. Social Security Number | PPN | Passport Number | CSI | Canadian Social Insurance Number | WPN | Work Permit Number | IND | INDEX Identification Number | OTH | Other | <p>10. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring period. If more than one PSE was received in a single year, the licensee should sum them and report the total of all PSEs.</p> <p>11. Enter the deep dose equivalent (DDE) to the whole body.</p> <p>12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.</p> <p>13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE, WB).</p> <p>14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE, ME).</p> <p>15. Enter the committed effective dose equivalent (CEDE).</p> <p>16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ.</p> <p>17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.</p> <p>18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.</p> <p>19. Signature of the monitored individual. The signature of the monitored individual on this form indicates that the information contained on the form is complete and correct to the best of his or her knowledge.</p> <p>20. Enter the date this form was signed by the monitored individual.</p> <p>21. [OPTIONAL] Enter the name of the licensee, registrant or facility not licensed by the Agency, providing monitoring for exposure to radiation (such as a DOE facility) or the employer if the individual is not employed by the licensee or registrant and the employer chooses to maintain exposure records for its employees.</p> | <p>22. [OPTIONAL] Signature of the person designated to represent the licensee, registrant or employer entered in item 21. The licensee, registrant or employer who chooses to countersign the form should have on file documentation of all the information on the Agency Form Y being signed.</p> <p>23. [OPTIONAL] Enter the date this form was signed by the designated representative.</p> |
|--|----------------------------------|---------|-----|-----------------------------|-----|-----------------|-----|----------------------------------|-----|--------------------|-----|-----------------------------|-----|-------|---|---|
| CODE | ID TYPE | | | | | | | | | | | | | | | |
| SSN | U.S. Social Security Number | | | | | | | | | | | | | | | |
| PPN | Passport Number | | | | | | | | | | | | | | | |
| CSI | Canadian Social Insurance Number | | | | | | | | | | | | | | | |
| WPN | Work Permit Number | | | | | | | | | | | | | | | |
| IND | INDEX Identification Number | | | | | | | | | | | | | | | |
| OTH | Other | | | | | | | | | | | | | | | |

Nebraska Department of Health and Human Services Regulation and Licensure

NRH-2
1997

OCCUPATIONAL EXPOSURE RECORD FOR A MONITORING PERIOD

1. NAME (LAST, FIRST, MIDDLE INITIAL)	2. IDENTIFICATION NUMBER	3. ID TYPE	4. SEX MALE _____ FEMALE _____	5. DATE OF BIRTH
6. MONITORING PERIOD	7. LICENSEE OR REGISTRANT NAME	8. LICENSE OR REGISTRATION NUMBER(S)	9A. RECORD _____ ESTIMATE _____	9B. ROUTINE _____ PSE _____

INTAKES				DOSES (in rem)	
10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μ CI		
				DEEP DOSE EQUIVALENT (DDE)	11.
				EYE DOSE EQUIVALENT TO THE LENS OF THE EYE (LDE)	12.
				SHALLOW DOSE EQUIVALENT, WHOLE BODY (SDE,WB)	13.
				SHALLOW DOSE EQUIVALENT, MAX EXTREMITY (SDE,ME)	14.
				COMMITTED EFFECTIVE DOSE EQUIVALENT (CEDE)	15.
				COMMITTED DOSE EQUIVALENT, MAXIMALLY EXPOSED ORGAN (CDE)	16.
				TOTAL EFFECTIVE DOSE EQUIVALENT (BLOCKS 11+15) (TEDE)	17.
				TOTAL ORGAN DOSE EQUIVALENT, MAX ORGAN (BLOCKS 11+16) (TODE)	18.
				19. COMMENTS	

20. SIGNATURE – LICENSEE OR REGISTRANT	21. DATE PREPARED
--	-------------------

**INSTRUCTIONS AND ADDITIONAL INFORMATION PERTINENT TO THE
COMPLETION OF NRH-2
(All doses should be stated in rems)**

1. Type or print the full name of the monitored individual in the order of last name (include "Jr," "Sr," "III," etc.), first name, middle initial (if applicable).
2. Enter the individual's identification number, including punctuation. This number should be the 9-digit social security number if at all possible. If the individual has no social security number, enter the number from another official identification such as a passport or work permit.
3. Enter the code for the type of identification used as shown below:

CODE	ID TYPE
SSN	U.S. Social Security Number
PPN	Passport Number
CSI	Canadian Social Insurance Number
WPN	Work Permit Number
IND	INDEX Identification Number
OTH	Other
4. Check the box that denotes the sex of the individual being monitored.
5. Enter the date of birth of the individual being monitored in the format MM/DD/YY.
6. Enter the monitoring period for which this report is filed. The format should be MM/DD/YY - MM/DD/YY.
7. Enter the name of the licensee or registrant.
8. Enter the Agency license or registration number or numbers.
- 9A. Place an "X" in Record or Estimate. Choose "Record" if the dose data listed represent a final determination of the dose received to the best of the licensee's or registrant's knowledge. Choose "Estimate" only if the listed dose data are preliminary and will be superseded by a final determination resulting in a subsequent report. An example of such an instance would be dose data based on self-reading dosimeter results and the licensee intends to assign the record dose on the basis of TLD results that are not yet available.
- 9B. Place an "X" in either Routine or PSE. Choose "Routine" if the data represent the results of monitoring for routine exposures. Choose "PSE" if the listed dose data represents the results of monitoring of planned special exposures received during the monitoring

- period. If more than one PSE was received in a single year, the licensee or registrant should sum them and report the total of all PSEs.
- 10A. Enter the symbol for each radionuclide that resulted in an internal exposure recorded for the individual, using the format "Xx-##x," for instance, Cs-137 or Tc-99m.
 - 10B. Enter the lung clearance class as listed in Appendix B to Part D (D, W, Y, V, or O for other) for all intakes by inhalation.
 - 10C. Enter the mode of intake. For inhalation, enter "H." For absorption through the skin, enter "B." For oral ingestion, enter "G." For injection, enter "J."
 - 10D. Enter the intake of each radionuclide in μCi .
 11. Enter the deep dose equivalent (DDE) to the whole body.
 12. Enter the eye dose equivalent (LDE) recorded for the lens of the eye.
 13. Enter the shallow dose equivalent recorded for the skin of the whole body (SDE,WB).
 14. Enter the shallow dose equivalent recorded for the skin of the extremity receiving the maximum dose (SDE,ME).
 15. Enter the committed effective dose equivalent (CEDE) or "NR" for "Not Required" or "NC" for "Not Calculated".
 16. Enter the committed dose equivalent (CDE) recorded for the maximally exposed organ or "NR" for "Not Required" or "NC" for "Not Calculated".
 17. Enter the total effective dose equivalent (TEDE). The TEDE is the sum of items 11 and 15.
 18. Enter the total organ dose equivalent (TODE) for the maximally exposed organ. The TODE is the sum of items 11 and 16.

19. Signature of the person designated to represent the licensee or registrant.
20. Enter the date this form was prepared.
21. **COMMENTS.**
In the space provided, enter additional information that might be needed to determine compliance with limits. An example might be to enter the note that the SDE,ME was the result of exposure from a discrete hot particle. Another possibility would be to indicate that an overexposed report has been sent to the Agency in reference to the exposure report.

Department of Health and Human Services Regulation and Licensure
Public Health Assurance Division
301 Centennial Mall South
Lincoln, Nebraska 68509

NOTICE TO EMPLOYEES

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

In the Nebraska Regulations for Control of Radiation-Ionizing, the Nebraska Department of Health and Human Services Regulation and Licensure has established standards for your protection against radiation hazards and has established certain provisions for the options of workers engaged in work under an agency 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 the Nebraska Regulations for Control of Radiation - Ionizing, 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 the Nebraska Regulations for Control of Radiation - Ionizing 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 and radioactive material 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 Agency Inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY:

1. The Nebraska Regulations for Control of Radiation - Ionizing 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 Subsections 004.06, 004.12 and 004.13 of the regulations. 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 Services Regulation and Licensure, Public Health Assurance Division. 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 Regulation and Licensure. 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, Agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he/she 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 Sections 002 and 003 by the Nebraska Department of Health and Human Services Regulation and Licensure, 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.

DO NOT WRITE IN THIS SPACE

REGISTRATION NO _____

STATE _____ COUNTY _____

DATE FEE PAID _____

DATE OF EXPIRATION _____

PRIORITY _____ FEE DET. NO. _____

NEBRASKA DEPARTMENT OF HEALTH
DIVISION OF RADIOLOGICAL HEALTH
REGISTRATION OF RADIATION GENERATING EQUIPMENT

- 1. NAME OF FACILITY: _____
- 2. OWNER(S) (USER/OR POSSESSOR) OF RADIATION SOURCE(S) (FIRST, MIDDLE INITIAL, LAST).
A. _____
B. _____
- 3. LOCATION OF RADIATION SOURCE(S) (NUMBER, STREET, CITY, STATE, ZIP CODE).

_____ COUNTY _____ PHONE NUMBER _____
- 4. PERSON RESPONSIBLE FOR RADIATION PROTECTION _____
- 5. TYPE OF PRACTICE _____
- 6. RADIATION GENERATING EQUIPMENT (USE ADDITIONAL SHEETS IF NECESSARY).

List each machine on a separate line.

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

REGISTRATION DOES NOT IMPLY APPROVAL OR DISAPPROVAL OF THIS FACILITY NOR IS IT A LICENSE.

TO THE BEST OF MY KNOWLEDGE THE ABOVE INFORMATION IS TRUE AND CORRECT.

NAME (TYPE OR PRINT)

SIGNATURE

DATE

return all copies to Nebraska Department of Health, Division of Radiological Health. 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509. The pink copy will be returned for your files.

INSTRUCTION FOR COMPLETION OF FORM NRH-4

1. **NAME OF FACILITY** means the name of the facility where the x-ray equipment is located.
2. **OWNER (USER OR POSSESSOR)** means the person(s) or organization having administrative control of the source(s) of radiation, where owner, lessee or otherwise.
3. **LOCATION** the location at which one or more radiation machines or sources are installed and/or located within one building, vehicle or under one roof and are under the same administrative control, e.g., hospitals, laboratories, physician's offices, industrial plants, etc. (Enter complete address including city and zip code.)
4. **PERSON RESPONSIBLE FOR RADIATION PROTECTION** means an individual who possesses the knowledge and training to measure and evaluate the safety of radiation emitting equipment and techniques and to advise regarding radiation protection needs.
5. **TYPE OF PRACTICE** enter code that identifies the facilities type of practice from table below:

1. Chiropractic	7. Orthopedist	13. Urologist	19. Dental
2. Dermatology	8. Osteopath	14. Multiple Specialty Clinic	20. Educational Inst.
3. General Practice	9. Pediatrics	15. Nursing Home	21. Veterinary
4. Gastroenterology	10. Podiatrist	16. Mobile Van	22. Industrial
5. Internal Medicine	11. Radiologist	17. Hospital	23. Medical Other
6. ENT	12. Surgeon	18. Regional Center	24. Other
			40. Out-of-State Registration

6. **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.

Under TYPE enter the code of applicable equipment from table below:

<u>HEALING ARTS DIAGNOSTIC GENERAL RADIATION MACHINES (CONT)</u>	<u>HEALING ARTS DIAGNOSTIC-GENERAL (CONT)</u>	<u>HEALING ARTS-THERAPY</u>	<u>NON-HEALING ARTS</u>
101 Medical Diagnostic X-Ray General Purpose (Radiographic)	112 Mobile C-Arm	301 Superficial	408 Package X-Ray
410 Fluoroscopy X-Ray-Industrial	113 CT Scanner - Head	302 X-Ray Deep Therapy	409 Industrial Gauge X-Ray
102 Fluoroscopy Diagnostic General Purpose	114 CT Scanner - W.B.	303 Accelerator-Therapy	
103 Radiographic/Fluoroscopic	115 Veterinary Radiographic	304 Veterinary Therapy	411 X-Ray Fluorescence
104 Tomographic	116 Veterinary Fluoroscopic	310 Other	412 X-Ray Diffraction
105 Angiographic	117 Stationary C-Arm		413 Electron Beam Welding
107 Urologic	118 Simulator	<u>NON-HEALING ARTS RADIATION MACHINES</u>	414 Industrial Rad.-in-Plant Only
108 Mammographic	119 Chiropractic	401 Accelerators	415 Industrial Rad Therapy
109 Chest	<u>HEALING ARTS DIAGNOSTIC-DENTAL</u>	402 Radiographic Cabinet X-Ray	416 Ion Implantation Device
110 Head and Neck	201 Intra-Oral	403 Analytic X-Ray	417 Other-Non Healing Arts
111 Mobile Radiographic	202 Panoramic	404 Electron Microscope	<u>OTHER</u>
	203 Cephalometric	405 Airport Baggage X-Ray	501
	210 Other-Dental	406 Spectroscopy/ Spectrography X-Rays	
		407 Particle Size Analyzer-X-Ray	

Under # TUBES - Self-explanatory

Under CONTROL MANUFACTURER identify the name of the manufacturer.

Under MODEL NO. - Self-explanatory

Under SERIAL NO. - Self-explanatory

Under DATE INSTALLED - Self-explanatory

Under DATE OF MFG. - Self-explanatory

Under CONTROL LOCATION - Self-explanatory

SIGNATURE: No registration form will be processed without the proper signature of the person responsible for the facility e.g., OWNER (user or possessor).

Nebraska Regulations for Control of Radiation - Ionizing

- 002.09 Report of changes.
(The registrant shall notify the agency in writing within thirty (30) days of any change which would render the information contained in the application for registration no longer accurate.)
- 002.11 Assembler an/or transfer obligation.
- 002.11A Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment in this State shall notify the Agency within fifteen (15) days of:
 - 002.11A1 The name and address of persons who have received equipment;
 - 002.11A2 The manufacturer, model and serial number of each radiation generating equipment transferred; and
 - 002.11A3 The date of transfer of each radiation generating equipment.

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS - (Use additional sheets where necessary.)

New or Renewal Application - Complete Items 1. through 15.

Amendment to License - Complete Items 1.a, 3., and 15. And indicate other changes as appropriate.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Nebraska Regulations for the control of Radiation - Ionizing and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.) Applicant Name: _____ Address: _____ City, State Zip +4: _____ Telephone #: _____ FAX #: _____ eMail Address: _____													
1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a) (1) <u>Permanent</u> Address: _____ City, State Zip+4: _____ (2) <u>Temporary Job Sites Throughout Nebraska?</u> <input type="checkbox"/> Yes <input type="checkbox"/> No													
2. Department to Use Radioactive Material _____ Person to Contact: _____ Telephone #: _____	3. This is an application for: <input type="checkbox"/> New License <input type="checkbox"/> Amendment to License No. _____ <input type="checkbox"/> Renewal of License No. _____												
4. Individual User(s) <input type="checkbox"/> <u>Individual users approved by the Licensee's radiation safety committee.</u> <input type="checkbox"/> <u>Individual users approved by the Licensee's radiation safety officer.</u> <input type="checkbox"/> <u>Individual users satisfy the requirements of 180 NAC 1-003.13</u> OR <input type="checkbox"/> <u>Name and Title of individual(s) who will use or directly supervise use of Radioactive Materials. Give training and experience in Items 7. And 8.</u> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%; text-align: left;">First Name + Middle Initial</th> <th style="width: 33%; text-align: left;">Last Name</th> <th style="width: 33%; text-align: left;">Title</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	First Name + Middle Initial	Last Name	Title										5. Radiation Safety Officer (RSO) (Name and Title of Individual designated as Radiation Safety Officer.) _____ Telephone #: _____ Attach documentation of his/her training and experience as in Items 7. and 8. <div style="text-align: center; border: 1px solid black; padding: 5px; margin: 5px 0;">*Agency Use Only*</div> <div style="text-align: center; border: 1px solid black; padding: 5px; margin: 5px 0;">Date Received Stamp</div>
First Name + Middle Initial	Last Name	Title											

6. Radioactive Material Data				
<input type="checkbox"/> Type B Broad Scope, 180 NAC 1-003.13A2				
<input type="checkbox"/> Type C Broad Scope, 180 NAC 1-003.13A3				
<input type="checkbox"/> Specific License, Radioactive Material Listed below.				
<u>6.a. Element and Mass Number</u>	<u>6.b. Chemical or Physical Form (Make and Model if sealed source)</u>	<u>6.c. Maximum Activity Requested (Expressed as Curies, Millicuries or Microcuries)</u>	<u>6.d. Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)</u>	
7. Training of Individuals in Items 4. and 5.				
<u>Name of Individual:</u>				
	<u>Formal Course Title</u>	<u>Location and Date(s) of Training</u>	<u>Clock Hours in Lecture or Laboratory</u>	
<u>7.a. Radiation Physics and Instrumentation</u>				
<u>7.b. Radiation Protection</u>				
<u>7.c. Mathematics Pertaining to the Use and Measurement of Radioactivity</u>				
<u>7.d. Biological Effects of Radiation</u>				
8. Experience with Radiation of Individuals in Items 4. and 5. (Actual use of Radioisotopes or Equivalent Experience)				
<u>Name of Individual:</u>				
<u>Isotope</u>	<u>Maximum Activity</u>	<u>Where Experience Was Gained</u>	<u>Months/Years</u>	<u>Type of Use</u>

9. Radiation Detection Instruments					
<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model Number</u>	<u>Number Available</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
10. Calibration of Instruments Listed in Item 9.					
<input type="checkbox"/> a. Calibrated by Service Company Name and Address of Service Company and Frequency of Calibration			<input type="checkbox"/> b. Calibrated by Applicant		
11. Personnel Monitoring Devices (Check and/or complete as appropriate)					
<u>Type</u>	<u>Supplier (Service Company)</u>	<u>Exchange Frequency</u>			
<input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> DOSL <input type="checkbox"/> Other (Specify): _____		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other (Specify): _____			

Information to be Submitted on Additional Sheets

12. Facilities and Equipment

Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Attach an explanatory sketch of the facility.

13. Radiation Protection Program

Describe the radiation protection program as appropriate for the material to be used, including: the duties and responsibilities of the Radiation Safety Officer (RSO); control measures; bioassay procedures (if needed); day-to-day general safety instructions to be followed; etc. If the application is for sealed sources also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

14. Waste Disposal

If a commercial waste disposal service is employed, specify the name and address of the company. Otherwise, submit a detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. If the application is for sealed sources and devices and they will be returned to the manufacturer, so state.

15. 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 Regulation and Licensure Regulations for the Control of Radiation - Ionizing and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.a.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

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

Date Received Stamp

6. Radioactive Material Data

6. Radioactive Material for Medical Use

Radioactive Material Listed In:	Items Desired (X)	Maximum Possession Limits (In millicuries)
Title 180 NAC 1-003.08I for Invitro Studies		
Title 180 NAC 1-007.34A		
Title 180 NAC 1-007.36		
Title 180 NAC 1-007.40		
Title 180 NAC 1-007.44		
Title 180 NAC 1-007.46		
Additional Items		
Xenon-133 as gas or gas in saline for blood flow studies and pulmonary function studies		
Technetium-99m aerosolized DTPA for pulmonary function studies		
High dose rate remote afterloading brachytherapy device		

6.b. Radioactive Material for Uses not Listed in Item 6.a.

<u>6.b.(1)</u> Element and Mass Number	<u>6.b.(2)</u> Chemical or Physical Form (Make and Model if sealed source)	<u>6.b.(3)</u> Maximum Activity Requested (Expressed as Curies, Millicuries, or Microcuries)	<u>6.b.(4)</u> Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

Instructions for Items 7. Through 23.

For Items 7. through 23., check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet, identifying the item number and the date of the application in the lower right hand corner of each page.

If you indicate that you will follow an Appendix to the *Guide for Preparation of Applications for Medical Programs 7.0*, do not submit the pages, but specify the revision number and date of the *Guide*.

The Most current *Guide* is: Revision: _____ Date: _____

Instructions for Items 7. Through 23.

For items 7. through 23., check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet, identifying the item number and the date of the application in the lower right hand corner of each page.

If you indicate that you will follow an Appendix to the *Guide for Preparation of Applications for Medical Programs 7.0*, do not submit the pages, but specify the revision number and date of the *Guide*.

The Most current *Guide* is: Revision: _____ Date: _____

- 7. Radiation Safety Committee**
 Names and Specialities attached; AND
 Duties as in Appendix B; OR
Equivalent Duties attached
- 8. Training and Experience**
 Supplements A and B attached for each individual user; AND
 Supplement A attached for RSO
- 9. Instrumentation**
 Appendix C Form attached; OR
 List by Name and Model Number
- 10. Calibration of Instruments**
a. Survey Instruments
 Appendix D Procedures followed; OR
 Equivalent Procedures attached

AND
b. Dose Calibrator
 Appendix D Procedures followed; OR
 Equivalent Procedures attached
- 11. Facilities and Equipment**
 Description or diagram attached; OR
 See Supplements C - Teletherapy Requirements
- 12. Personnel Training Program**
 Description of training attached
- 13. Procedures for Ordering and Receiving Radioactive Materials**
 Detailed Information Attached
- 14. Procedures for Safely Opening Packages Containing Radioactive Materials**
 Appendix F Procedures followed; OR
 Equivalent Procedures attached
- 15. General Rules for the safe use of Radioactive Material**
 Appendix G Procedures followed; OR
 Equivalent Procedures attached
- 16. Emergency Procedures**
 Appendix H Procedures followed; OR
 Equivalent Procedures attached
- 17. Area Survey Procedures**
 Appendix I Procedures followed; OR
 Equivalent Procedures attached
- 18. Waste Disposal**
 Appendix J Form attached; OR
 Equivalent Information attached
- 19. Therapeutic Use of Radiopharmaceuticals**
 Appendix K Procedures followed; OR
 Equivalent Procedures attached
- 20. Therapeutic Use of Sealed Sources**
 Detailed Information attached; AND
 Appendix L Procedures followed; OR
 Equivalent Procedures attached
- 21. Procedures and Precautions for use of Radioactive Gases (e.g., Xenon-133)**
 Detailed Information attached
- 22. Procedures and Precautions for Use of Radioactive Material in Animals**
 Detailed Information attached
- 23. Procedures and Precautions for Use of Radioactive Material Specified in Item 6.b.**
 Detailed Information attached

24. Personnel Monitoring Devices (Check and/or complete as appropriate)		
Type	Supplier/Service Company	Exchange Frequency
24.a. Whole Body <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> DOSL <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24.b. Finger <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24.c. Wrist <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
24d. Other (Specify)		
25. Private Practice Applicants Only		
25.a. Hospital Agreeing to accept patients containing Radioactive Material: Name: _____ Mailing Address: _____ _____ City, State Zip+4: _____		
25.b. Attach a copy of the agreement letter signed by the hospital administrator.		
25.c. When requesting Therapy Procedures, attach a copy of Radiation Safety Precautions to be taken and list available radiation detection instruments.		

26. 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 Regulation and Licensure Regulations for the Control of Radiation - Ionizing and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.a.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT A

Training and Experience
Authorized User or Radiation Safety Officer (RSO)

1. Name of Individual <hr/> <input type="checkbox"/> Authorized User <input type="checkbox"/> Radiation Safety Officer		2. Physician who is licensed to dispense drugs in the practice of medicine in Nebraska? <input type="checkbox"/> YES <input type="checkbox"/> NO		
3. Certification				
3.a. Specialty Board	3.b. Category	3.c. Month and Year Certified		
4. Training Received in Basic Radioisotope Handling Techniques				
	<u>Location and Dates of Training</u>	<u>Clock Hours in Lecture or Laboratory</u>	<u>Clock Hours of Supervised Laboratory Experience</u>	
4.a. Radiation Physics and Instrumentation				
4.b. Radiation Protection				
4.c. Mathematics Pertaining to the Use and Measurement of				
4.d. Biological Effects of Radiation				
4.e. Radiopharmaceutical Chemistry				
5. Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience)				
<u>Isotope</u>	<u>Maximum Activity</u>	<u>Where Experience Was Gained</u>	<u>Months/Years</u>	<u>Type of Use</u>

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

Medical or Teletherapy

SUPPLEMENT B

Preceptor Statement

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. Full Name and Street Address of Applicant Physician			
Full Name:			
Address:			
City, State Zip+4			

2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
<u>Isotope</u>	<u>Conditions Diagnosed or Treated</u>	<u>Number of Cases Involving Personal Participation¹</u>	<u>Comments²</u>
I-125 or I-131	Diagnosis of Thyroid Function		
	Determination of Blood and Blood Plasma Volume		
	Liver Function Studies		
	Fat Absorption Studies		
	Kidney Function Studies		
	In vitro Studies		
Other			
I-125	Detection of Thrombosis		
I-131	Thyroid Imaging		
P-32	Eye Tumor Localization		
Se-75	Pancreas Imaging		
Yb-169	Cisternography		
Xe-133	Blood Flow Studies and Pulmonary Function Studies		
Other			
Tc-99m	Brain Imaging		
	Cardiac Imaging		
	Thyroid Imaging		
	Salivary Gland Imaging		
	Blood Pool Imaging		
	Placenta Localization		
	Liver and Spleen Imaging		
	Lung Imaging		
Bone Imaging			

2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
<u>Isotope</u>	<u>Conditions Diagnosed or Treated</u>	<u>Number of Cases Involving Personal Participation¹</u>	<u>Comments²</u>
Other			
P-32 (Soluble)	Treatment of Polycythemia Vera, Leukemia, and Bone Metastases		
P-32 (Colloidal)	Intracavitary Treatment		
I-131	Diagnosis of Thyroid Function		
	Treatment of Hyperthyroidism		
Au-198	Intracavitary Treatment		
Co-60 or Cs-137	Interstitial Treatment		
	Intracavitary Treatment		
I-125 or Ir-192	Interstitial Treatment		
Ra-226	Intracavitary Treatment		
	Interstitial Treatment		
	Superficial Treatment		
Co-60 or Cs-137	Teletherapy Treatment		
Sr-90	Treatment of Eye Disease		
	Radiopharmaceutical Preparation		
Mo-99/Tc-99m	Generator		
Sn-113/In-113m	Generator		
Tc-99m	Reagent Kits		
X-Ray and Accelerator Therapy	Courses of Therapy Treatment		
Other			

¹ Key to column

Personal Participation should consist of:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

² Additional information or comments may be submitted in duplicate on separate sheets.

3. Dates and Total Number of Hours Received in Clinical Radioisotope Training

(Submit in duplicate on separate sheets)

4. Training and Experience Obtained Under the Supervision of:

Supervisor's
Name:

Institution
Name:

Address

City, State
Zip+4

Radioactive material License Number(s):

5. Preceptor's Verification

Preceptor's Name: _____
(Type or Print)

Preceptor's Name: _____ (Date) _____
(Type or Print)

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT C

Requirements Specific to Teletherapy

1. Facilities and Equipment

- Description and drawing of facilities attached; AND
- Description of patient viewing and communicating systems attached; AND
- Description of area safeguards attached

2. Beam Stops

- Description of stops used to restrict beam orientation attached

3. Shielding Evaluation

- Evaluation of proposed shielding attached

4. Operating and Emergency Procedures

- Description of operating procedures attached; AND
- Copy of emergency procedures attached

5. Instruction of Personnel

- Training program and schedule in Appendix A followed; OR
- Description of instruction program for employees attached

6. Leak Tests of Sealed Sources

- Description of leak test procedures attached

7. Teletherapy Physicist (Use only if individual fails to meet 007.66J requirements)

- Statement of qualifications of the physicist who will perform teletherapy calibrations attached.

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR REGISTRATION OF SERVICES FOR RADIATION SOURCES

INSTRUCTIONS - (Use additional sheets where necessary.)

Type or Print except where indicated.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Nebraska Regulations for the control of Radiation - Ionizing and the Nebraska Radiation Control Act.

1. Name and Street Address of Applicant (Individual or Company) Applicant Name: _____ Address: _____ City, State Zip+4 _____ Telephone #: _____ FAX#: _____ E-mail Address: _____	
2. Person to Contact Regarding this Application _____ Telephone # _____	3. Individual User(s) Submit in duplicate on a separate sheet(s) the Name and Title of individual(s) qualified to perform each service listed below. Document training and experience in accordance with 180 NAC 1-015.
4. Services Provided (check as appropriate) <u>Radioactive Material Services Requiring Registration and an Agency, NRC or Agreement State Specific License:</u> <input type="checkbox"/> Analysis of Samples for Radioactivity <input type="checkbox"/> Bioassay <input type="checkbox"/> Calibration of Radiation monitoring Instruments <input type="checkbox"/> Decommissioning of Facilities <input type="checkbox"/> Decontamination of Facilities <input type="checkbox"/> Device Services (Industrial Gauge, Irradiator, HDR, Teletherapy, etc.) <input type="checkbox"/> Facility/Packaging Shielding Determination (Use of Radioactive Material) <input type="checkbox"/> Leak Test Service <input type="checkbox"/> Waste Disposal Services (Receipt of Waste)	

(continued)

4. Services Provided (check as appropriate) (Continued)

Radioactive Material Services Requiring Registration:

- Waste Disposal Consultation Services (No Receipt of Waste)

Radiation Generating Equipment Services Requiring Registration:

- Device Sales
- Device Services (Demonstration, Installation, Electronic Calibration, Repair, Survey)

General Radiation Services Requiring Registration:

- Facility/Packaging Shielding Review (Calculation Only) - Submit Procedures
- Radiation Protection or Health Physics Consultation
- Radiation Survey - Submit Instrumentation and Procedures
- Personnel Monitoring - Submit NVLAP Certification
- Other

5. 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., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure Regulations for the Control of Radiation - Ionizing and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____
Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant

Registration Does Not Imply Approval or Disapproval of Service

**NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION**

**CERTIFICATE - USE OF DEPLETED URANIUM
UNDER GENERAL LICENSE**

Part 003.07D of Nebraska Regulations for Control of Radiation - Ionizing establishes a general license authorizing a person to receive, acquire, possess, use, or transfer in accordance with the provisions of 003.07D 2, 3, 4, and 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

Possession of depleted uranium is not authorized under 003.07D until a licensee has filed Form NRH-11 and received from the Agency a validated copy of NRH-11 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 003.07D

003.07D Depleted Uranium in Industrial Products and Devices

003.07D1 A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 003.07D, 2, 3, 4, and 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

003.07D2 The general license in 003.07D1 applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 003.13M or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

003.07D3 Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 003.07D1 shall:

003.07D3a File Agency Form NRH-11 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form NRH-11 the following information and such other information as may be required by that form:

003.07D3a(1) Name and address of the general licensee;

003.07D3a(2) A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 003.07D1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

003.07D3a(3) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 003.07D3a(2).

003.07D3b Report in writing to the Agency any changes in information furnished by registrant in Agency Form NRH-11 "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

003.07D4 A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 003.07D1:

003.07D4a Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

003.07D4b Shall not abandon such depleted uranium.

003.07D4c Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 003.25. In the case where the transferee receives the depleted uranium pursuant to the general license established by 003.07D1, the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form NRH-11. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 003.07D1, the transferor shall furnish the transferee a copy of this regulation and a copy of Agency Form NRH-11 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this regulation.

003.07D4d Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

003.07D5 Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 003.07D1 is exempt from the requirements of Sections 004 and 010 of these regulations with respect to the depleted uranium covered by that general license.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

A certification number will be assigned and a validated copy of NRH-11 will be returned.

(Print or Type)

1. Licensee Information

Legal Name: _____

Address: _____

City, State and Zip+4 _____

Person Authorized to sign binding
documents for the Licensee _____

2. I hereby apply for a Certificate number pursuant to 003.07D of Section 003 on behalf of the above Licensee.

3. Certification:

I certify that:

- a. All information in this certificate is true and complete.
- b. I understand the Department regulations require that any change in the information furnished on this certificate be reported to the Department within 30 days from the date of such change.
- c. I have read and understand the provisions of Part 003.07D of Section 003 of the Department regulations, and I understand that I am required to comply with those provisions as to the depleted uranium which I receive, possess, use, or transfer under the general license.

(Signature of Person listed in Item 1.)

(Date)

4. To be completed by the Agency:

Certification Number _____ ***Date:*** _____

Radioactive Materials Program Manager _____

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
PUBLIC HEALTH ASSURANCE DIVISION

CERTIFICATE - IN VITRO TESTING
WITH RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

Part 003.08I of Section 003 of the Nebraska Regulations for Control of Radiation - Ionizing establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for In Vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under Part 003.08I is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed Form NRH-17 and received from the Agency a validated copy of Form NRH-17 with a certification number.

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 003.08I

003.08I General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

003.08I1 A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 003.08I 2, 3, 4, 5, and 6, the following radioactive materials in prepackaged units for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

003.08I1a Iodine-125, Iodine-131, Selenium-75, Cobalt-57, and Carbon-14 in units not exceeding 370 kBq (10 microcuries) each.

003.08I1b Hydrogen-3 (Tritium), in units not exceeding 1.85 MBq (50 microcuries) each.

003.08I1c Iron-59, in units not exceeding 740 kBq (20 microcuries) each.

003.08I1d Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of Iodine-129 and 1.85 Bq (0.005 microcurie) of Americium-241 each.

003.08I2 No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 003.08I1 until he has filed Agency Form NRH-17, "Certificate - In Vitro Testing with Radioactive Material Under General License", with the Agency and received from the Agency a validated copy of Agency Form NRH-17 with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on Agency Form NRH-17 the following information and such other information as may be required by that form:

003.08I2a Name and address of the physician, veterinarian, clinical laboratory or hospital;

003.08I2b The location of use; and

003.08I2c A statement that the physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out In Vitro clinical or laboratory tests with radioactive material as authorized under the general license in 003.08I1 and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

003.08I3 A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 003.08I1 shall comply with the following:

003.0813a The general licensee shall not possess at any one time, pursuant to the general license in 003.0811 at any one location of storage or use a total amount of Iodine-125, Iodine-131, Iron-59, Cobalt-57, and/or Selenium-75 in excess of 7.4 MBq (200 microcuries).

003.0813b The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

003.0813c The general licensee shall use the radioactive material only for the uses authorized by 003.0811.

003.0813d The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

003.0813e The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 003.0811d as required of Subsection 004.38 of these regulations.

003.0814 The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 003.0811:

003.0814a Except as prepackaged units which are labeled in accordance with the provisions of applicable specific license issued pursuant to 003.14H or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (Tritium), Iron-59, Selenium-75, Cobalt-57 or Mock Iodine-125 to persons generally licensed under 003.081 or its equivalent, and

003.0814b Unless the following statement, or substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for In Vitro clinical or laboratory tests not involving internal or external administration of the material, or in the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of Manufacturer

003.815 The physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital possessing or using radioactive material under the general license of 003.0811 shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - In Vitro testing with Radioactive Material Under General License", Agency Form NRH-17. The report shall be furnished within 30 days after the effective date of such change.

003.816 Any person using radioactive material pursuant to the general license of 003.0811 is exempt from the requirements of Section 004 and Section 010 of these regulations with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 003.081d shall comply with the provisions of 004.38, 004.56, and 004.57 of these regulations.

INSTRUCTIONS

Submit this form in duplicate to the Department of Health and Human Services Regulation and Licensure, Public Health Assurance Division, 301 Centennial Mall South, P.O. Box 95007, Lincoln, Nebraska 68509-5007.

A certification number will be assigned and a validated copy of NRH-17 will be returned.

(Print or Type)

1. Licensee Information

Legal Name:
(Physician, Veterinarian, Clinical
Laboratory or Hospital)

Address:

City, State and Zip+4

Person Authorized to sign binding
documents for the Licensee

2. I hereby apply for a Certificate Number pursuant to 003.008I of Section 003 for use of radioactive materials for:

- a. Myself, a duly licensed physician authorized to dispense drugs in the practice of medicine, or a veterinarian licensed to practice veterinary medicine.
- b. The above named clinical laboratory.
- c. The above named hospital.

3. If place of use is different from address in Item 1, please give complete address:

4. Certification:

I certify that:

- a. All information in this certificate is true and complete.
- b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 003.08I of Section 003. The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive materials.
- c. I understand that Agency regulations require that any change in the information furnished on this certificate be reported to the Agency within 30 days from the date of such change.

d. I have read and understand the provisions of Part 003.08I of Section 003 of the Agency regulations; and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certification number is filed with the Agency.

(Signature of Person listed in Item 1.)

(Date)

4. To be completed by the Agency:

<p><i>Certification Number</i> _____ <i>Date:</i> _____</p> <p>Radioactive Materials Program Manager _____</p>

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
 DIVISION OF PUBLIC HEALTH ASSURANCE
 RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)

Type or Print except where indicated.

Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.

Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Nebraska Regulations for the control of Radiation - Ionizing and the Nebraska Radiation Control Act.

<p>1. Licensee Information</p> <p>Licensee Number: _____</p> <p>License Expiration Date: _____</p> <p>Licensee Name and Street Address:</p> <p style="padding-left: 40px;">Applicant Name: _____</p> <p style="padding-left: 40px;">Address: _____</p> <p style="padding-left: 40px;">City, State Zip+4 _____</p> <p style="padding-left: 40px;">Telephone #: _____</p> <p style="padding-left: 40px;">FAX#: _____</p> <p style="padding-left: 40px;">E-mail Address: _____</p>	<p>2. Person to Contact Regarding this Application</p> <p>_____</p> <p>Telephone #: _____</p>
<p>3. Materials Data</p> <p><input type="checkbox"/> No Materials have ever been procured or possessed by the Licensee under this License.</p> <p><input type="checkbox"/> All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner:</p> <p style="padding-left: 20px;"><input type="checkbox"/> <u>Transfer</u> Specify the date of the transfer, the name of the licensed recipient and the recipient's Agency, NRC or Agreement State license number. Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.</p> <p style="padding-left: 20px;"><input type="checkbox"/> <u>Disposed of directly by Licensee</u> Describe specific disposal procedures (e.g. decay in storage).</p>	
<p>4. Other Data</p> <p><input type="checkbox"/> Our License has not yet expired, please terminate it. A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license:</p> <p style="padding-left: 20px;"><input type="checkbox"/> NO (Attach Explanation)</p> <p style="padding-left: 20px;"><input type="checkbox"/> YES, the results:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Are attached</p> <p style="padding-left: 40px;"><input type="checkbox"/> Were forwarded to the Agency on (Date) _____</p>	

4. Other Data (Continued)

Address all future correspondence regarding this license to:

Name: _____

Address: _____

City, State Zip+4: _____

Telephone #: _____

FAX#: _____

E-mail Address: _____

5. 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., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure Regulations for the Control of Radiation - Ionizing and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____

Signature

Date: _____

Print Name and Title of certifying official authorized to act on behalf of the applicant