25 TEXAS ADMINISTRATIVE CODE

§289.231

General Provisions and Standards for Protection Against Machine-Produced Radiation

(revisions effective December 29, 2011 are shown as shaded text)

25 TAC §289.231

General Provisions and Standards for ProtectionAgainst Machine-Produced Radiation (Continued)

§289.231 General Provisions and Standards for Protection Against Machine-Produced Radiation.

(a) Purpose.

(1) This section establishes standards for protection against ionizing radiation resulting from the use of radiation machines.

(2) The requirements in this section are designed to control the receipt, possession, use, and transfer of radiation machines by any person so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency. A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer radiation machines. The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with this chapter, or to voluntary participation in medical research programs. However, no radiation may be deliberately applied to human beings except by or under the supervision of an individual authorized by and licensed in accordance with Texas' statutes to engage in the healing arts.

(2) Registrants who are also licensed by the agency to receive, possess, use, and transfer radioactive materials must also comply with the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material) and §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material).

(c) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise.

(1) Absorbed dose--The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) Act--Texas Radiation Control Act, Health and Safety Code, Chapter 401.

(3) Adult--An individual 18 or more years of age.

(4) Agency--The Department of State Health Services.

(5) Agreement State--Any state with which the United States Nuclear Regulatory Commission (NRC) has entered into an effective agreement under §274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(6) As low as is reasonably achievable (ALARA)--Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this chapter as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and radiation machines in the public interest.

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

(8) Certificate of registration--A form of permission given by the agency to an applicant who has met the requirements for registration or mammography system certification set out in the Texas Radiation Control Act (Act) and this chapter.

(9) Certification of mammography systems (state certification)--A form of permission given by the agency to an applicant who has met the requirements for mammography system certification set out in the Act and this chapter.

(10) Chiropractor--An individual licensed by the Texas Board of Chiropractic Examiners.

(11) Collective dose--The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

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

(13) Deep dose equivalent (DDE), that applies to external whole body exposure--The dose equivalent (DE) at a tissue depth of 1 centimeter (cm) (1,000 milligrams per square centimeter (mg/cm^2)).

(14) Dentist--An individual licensed by the Texas State Board of Dental Examiners.

(15) Dose--For external exposure to x-ray radiation from radiation machines, a generic term that means absorbed dose, DE, or total effective dose equivalent. For purposes of this chapter, "radiation dose" is an equivalent term.

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

(17) Dose limits--The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this chapter, "limits" is an equivalent term.

(18) Dosimetry processor--A person that processes and evaluates personnel monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(19) Embryo/fetus--The developing human organism from conception until the time of birth.

(20) Entrance or access point--Any opening through which an individual or extremity of an individual could gain access to radiation areas or to radiation machines. This includes portals of sufficient size to permit human access, irrespective of their intended use.

(21) Exposure--The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The International System of Units (SI) unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this chapter, this term is used as a noun.

(22) Exposure rate (air kerma rate)--The exposure per unit of time.

(23) External dose--That portion of the DE received from any source of radiation outside the body.

(24) Extremity--Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(25) Gray (Gy)--The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

(26) High radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving a DE in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(27) Human use--For exposure to x-ray radiation from radiation machines, the external administration of radiation to human beings for healing arts purposes or research and/or development specifically authorized by the agency.

(28) Individual--Any human being.

(29) Individual monitoring--The assessment of DE to an individual by the use of:

(A) individual monitoring devices; or

(B) survey data.

(30) Individual monitoring devices--Devices designed to be worn by a single individual for the assessment of DE. For purposes of this chapter, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices include, but are not limited to, film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers (pocket dosimeters), and electronic personal dosimeters.

(31) Inspection--An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Act and rules, orders, requirements, and conditions of the agency.

(32) Ionizing radiation--Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(33) Lens dose equivalent (LDE)--The external DE to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm^2).

(34) License--A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Act and this chapter.

(35) Licensed material--Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(36) Licensee--Any person who is licensed by the agency in accordance with the Act and this chapter.

(37) Licensing state--Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc.

(38) Lost or missing radiation machine(s)--A radiation machine(s) whose location is unknown.

(39) Machine-produced radiation--A stimulated emission of radiation from a manufactured product or device or component part of a manufactured product or device that has an electronic circuit that during operation can generate or emit a physical field of radiation.

(40) Manufacture--To fabricate or mechanically produce.

(41) Member of the public--Any individual, except when that individual is receiving an occupational dose.

(42) Minimal threat radiation machines--Those radiation machines capable of generating or emitting fields of radiation that, during the operation of which:

(A) no deliberate exposure of an individual occurs;

(B) the radiation is not emitted in an open beam configuration; and

(C) no physical injury to an individual has occurred and is known by the agency.

(43) Minor--An individual less than 18 years of age.

(44) Monitoring--The measurement of radiation and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(45) Occupational dose--The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to sources of radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, from voluntary participation in medical research programs, or as a member of the public.

(46) Particle accelerator--Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and designed to discharge the resultant particulate or other associated radiation at energies usually in excess of 1 MeV.

(47) Person--Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than the NRC, and other than federal government agencies licensed or exempted by the NRC.

(48) Personnel monitoring equipment--(See definition for individual monitoring devices.)

(49) Physician--An individual licensed by the Texas Medical Board.

(50) Podiatrist--An individual licensed by the Texas State Board of Podiatric Medical Examiners.

(51) Public dose--The dose received by a member of the public from exposure to sources of radiation released by a licensee, or to any other source of radiation under the control of a licensee/registrant. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter, or from voluntary participation in medical research programs.

(52) Quarter--A period of time equal to one-fourth of the year observed by the registrant, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(53) Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 gray).

(54) Radiation--One or more of the following:

(A) gamma and x-ray; alpha and beta particles and other atomic or nuclear particles or rays;

(B) radiation emitted to energy density levels that could reasonably cause bodily harm from an electronic device; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(55) Radiation area--Any area, accessible to individuals, in which radiation levels could result in an individual receiving a DE in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 cm from the radiation machine or from any surface that the radiation penetrates.

(56) Radiation machine--Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(57) Radiation safety officer (RSO)--An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who must be specifically authorized on a certificate of registration, and who is the primary contact with the agency.

(58) Registrant--Any person issued a certificate of registration by the agency in accordance with the Act and this chapter.

(59) Regulation--(See definition for rule.)

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

(61) Remote inspection--An examination by the agency of information submitted by the registrant on a form provided by the agency.

(62) Research and development--Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

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

(64) Roentgen (R)--The special unit of exposure. One roentgen (R) equals 2.58 x 10^{-4} C/kg of air. (See definition for exposure.)

(65) Rule (as defined in the Government Code, Chapters 2001 and 2002, as amended)--Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(66) Shallow dose equivalent (H_s) (that applies to the external exposure of the skin of the whole body or the skin of an extremity)--The dose equivalent at a tissue depth of 0.007 cm (7 mg/cm^2). For purposes of this chapter, the acronym SDE has the same meaning as the term shallow dose equivalent.

(67) SI--The abbreviation for the International System of Units.

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

(69) Site boundary--That line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.

(70) Source of radiation--Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(71) Special units--The conventional units historically used by registrants, for example, rad (absorbed dose), and rem (DE).

(72) Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, disposal, and/or presence of sources of radiation. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of equipment, measurements of levels of radiation present, and evaluation of administrative and/or engineered controls.

(73) Termination--A release by the agency of the obligations and authorizations of the registrant under the terms of the certificate of registration. It does not relieve a person of duties and responsibilities imposed by law.

(74) Texas Regulations for Control of Radiation (TRCR)--All sections of Title 25 Texas Administrative Code (TAC), Chapter 289.

(75) Total effective dose equivalent (TEDE)--For external exposures only to x-ray radiation from radiation machines, the TEDE is equal to the DDE. If an individual receives an occupational dose from both radiation machines and radioactive materials, the TEDE is the sum of the DDE for external exposures and the committed effective dose equivalent for internal exposures as defined in §289.201(b) of this title.

(76) Unrestricted area (uncontrolled area)--An area, access to which is neither limited nor controlled by the registrant. For purposes of this chapter, "uncontrolled area" is an equivalent term.

(77) Very high radiation area--An area, accessible to individuals, in which radiation levels from sources of radiation external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter (m) from a radiation machine or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of DE, Sv and rem.

(78) Veterinarian--An individual licensed by the Texas Board of Veterinary Medical Examiners.

(79) Week--Seven consecutive days starting on Sunday.

(80) Whole body--For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(81) Worker--An individual engaged in work under a certificate of registration issued by the agency and controlled by a registrant, but does not include the registrant.

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

(d) Exemptions. The agency may, upon application therefor or upon its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this chapter if the agency determines that the exemption is not prohibited by law and will not result in a significant risk to public health and safety and the environment. In determining such exemptions, the agency will consider:

(1) state of technology;

(2) economic considerations in relation to benefits to the public health and safety; and

(3) other societal, socioeconomic, or public health and safety considerations.

(e) Prohibited uses.

(1) A hand-held fluoroscopic screen shall not be used unless accepted for certification by the United States Food and Drug Administration (FDA), Center for Devices and Radiological Health.

(2) A shoe-fitting fluoroscopic device shall not be used.

(f) Additional requirements. The agency may, by rule, order, or condition of certificate of registration, impose upon any registrant such requirements in addition to those established in this chapter as it deems appropriate or necessary to minimize danger to public health and safety or property or the environment.

(g) Violations. A court injunction or agency order may be issued prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be subject to civil and/or administrative penalties. Such person may also be guilty of a misdemeanor and upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(h) Impounding. Radiation machines shall be subject to impounding in accordance with §401.068 of the Act and §289.205 of this title (relating to Hearing and Enforcement Procedures).

(i) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be addressed to the Radiation Control Program, Department of State Health Services, P.O. Box 149347, Mail Code 1987, Austin, Texas, 78714-9347. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

(2) Documents transmitted to the agency will be deemed submitted on the date of the postmark, telegram, telefacsimile, or electronic media transmission.

(j) Interpretations. Except as specifically authorized by the agency in writing, no interpretation of the meaning of this chapter by any officer or employee of the agency other than a written legal interpretation by the agency, will be considered binding upon the agency.

(k) Mean quality factors and absorbed dose equivalencies.

(1) As used in this chapter, the quality factors for converting absorbed dose to DE are shown in the following table:

MEAN QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-Energy protons	10	0.1

* Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(2) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in paragraph (1) of this subsection, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of this section, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use
the fluence rate per unit DE or the appropriate Q value from the following table to convert a measured tissue dose in rad (gray) to DE in rem (Sv).

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MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor** (Q)	Fluence per Unit Dose Equivalent* (neutrons $cm^{-2}rem^{-1)}$	Fluence per Unit Dose Equivalent* (neutrons $cm^{-2}Sv^{-1)}$
(thermal)	2.5×10^{-8}	2	980×10^{6}	980×10^{8}
	1.0×10^{-7}	2	980×10^{6}	980×10^{8}
	1.0×10^{-6}	2	810×10^{6}	810×10^{8}
	1.0×10^{-5}	2	810×10^{6}	810×10^{8}
	1.0×10^{-4}	2	840×10^{6}	840×10^{8}
	1.0×10^{-3}	2	980×10^{6}	980×10^{8}
	1.0×10^{-2}	2.5	$1{,}010 \times 10^{6}$	$1{,}010 \times 10^{8}$
	1.0×10^{-1}	7.5	170×10^{6}	170×10^{8}
	5.0×10^{-1}	11	39×10^{6}	39×10^{8}
	1.0	11	27×10^{6}	27×10^{8}
	2.5	9	29×10^{6}	29×10^{8}
	5.0	8	23×10^{6}	23×10^{8}
	7.0	7	24×10^{6}	24×10^{8}
	10	6.5	24×10^{6}	24×10^{8}
	14	7.5	17×10^{6}	17×10^{8}
	20	8	16×10^{6}	16×10^{8}
	40	7	14×10^{6}	14×10^{8}
	60	5.5	16×10^{6}	16×10^{8}
	1.0×10^{2}	4	20×10^{6}	20×10^{8}
	2.0×10^{2}	3.5	19×10^{6}	19×10^{8}
	3.0×10^{2}	3.5	16×10^{6}	16×10^{8}
	4.0×10^{2}	3.5	14×10^{6}	14×10^{8}

*Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

**Value of quality factor (Q) at the point where the DE is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

(l) As low as reasonably achievable (ALARA). The registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are ALARA.

(m) Occupational dose limits.

(1) The registrant shall control the occupational dose to individuals to the following dose limits.

(A) An annual limit shall be the TEDE being equal to 5 rems (0.05 Sv).

(B) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities shall be:

(i) an LDE of 15 rems (0.15 Sv); and

(ii) an SDE of 50 rems (0.5 Sv) to the skin of the whole body, or to the skin of any extremity.

(C) The annual limits for a minor shall be 10% of the annual occupational dose limits specified in subparagraphs (A) and (B) of this paragraph.

(D) If a woman declares her pregnancy, the registrant shall ensure that the DE to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). If a woman chooses not to declare pregnancy, the occupational dose limits specified in paragraph (1)(A) and (B) of this subsection are applicable to the woman.

(i) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate (air kerma rate) to a declared pregnant woman so as to satisfy the limit in paragraph (1) of this subsection. The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any 1 month.

(ii) If by the time the woman declares pregnancy to the registrant, the DE to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the registrant shall be deemed to be in compliance with paragraph (1) of this subsection, if the additional DE to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(iii) The DE to an embryo/fetus shall be taken as the DE that is most representative of the DE to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(iv) If multiple measurements have been made, assignment of the DDE for the declared pregnant woman from the individual monitoring device that is most representative of the DE to the embryo/fetus shall be the DE to the embryo/fetus. Assignment of the highest DDE for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative DDE for the region of the embryo/fetus.

(v) If multiple measurements have not been made, assignment of the highest DDE for the declared pregnant woman shall be the DE to the embryo/fetus.

(2) The assigned DDE shall be for the portion of the body receiving the highest exposure. The assigned SDE shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

(3) When a protective apron is worn while working with fluoroscopic equipment used for clinical diagnostic or research purposes, the effective dose equivalent (EDE) for external radiation shall be determined as follows.

(A) When only 1 individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported DDE shall be the EDE for external radiation; or

(B) When only 1 individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25% of the limit specified in paragraph (1) of this subsection, the reported DDE value multiplied by 0.3 shall be the EDE for external radiation; or

(C) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck (collar), the EDE for external radiation shall be assigned the value of the sum of the DDE reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the DDE reported for the individual monitoring device located at the neck (collar) outside the protective apron multiplied by 0.04.

(4) The EDE determined by paragraph (3) of this subsection shall be recorded as part of an individual's dose record and will contribute to that individual's annual TEDE.

(5) The DDE, LDE, and SDE may be assessed from surveys or radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(6) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received from radiation machines or radioactive materials while employed by any other person. See subsection (r)(4) of this section.

(n) Conditions requiring individual monitoring of occupational dose.

(1) Each registrant shall monitor exposures from radiation machines at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum, each registrant shall monitor occupational exposure to radiation from radiation machines and shall supply and require the use of individual monitoring devices by:

(A) adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the limits in subsection (m)(1) of this section;

(B) minors likely to receive, in 1 year from sources of radiation external to the body, a DDE in excess of 0.1 rem (1 mSv), an LDE in excess of 0.15 rem (1.5 mSv), or an SDE to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(C) declared pregnant women likely to receive during the entire pregnancy, from sources of radiation external to the body, a DDE in excess of 0.1 rem (1 mSv); and

(D) individuals entering a high or very high radiation area.

(2) Notwithstanding the requirements of paragraph (1)(A) of this subsection, no personnel monitoring shall be required for personnel operating only minimal threat radiation machines as specified in subsection (ll)(3) of this section.

(o) Dose limits for individual members of the public.

(1) Each registrant shall conduct operations so that:

(A) the TEDE to individual members of the public from exposure to radiation from radiation machines does not exceed 0.5 rem (5 mSv) in a year, exclusive of the dose contribution from background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs; and

(B) the dose in any unrestricted area from registered external sources does not exceed 0.002 rem (0.02 mSv) in any 1 hour.

(2) If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(3) The agency may impose additional restrictions on radiation levels in unrestricted areas in order to restrict the collective dose.

(4) The registrant shall ensure that in facilities utilizing both radiation producing machines and radioactive materials, the TEDE to an individual member of the public shall not exceed 0.1 rem (1 mSv) in 1 year.

(p) Compliance with dose limits for individual members of the public.

(1) The registrant shall make or cause to be made surveys of radiation levels in unrestricted areas to demonstrate compliance with the dose limits for individual members of the public as required in subsection (o) of this section.

(2) A registrant shall show compliance with the annual dose limit in subsection (o) of this section by demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit.

(3) Registrants exempt from individual monitoring requirements in accordance with subsection (n)(2) of this section are exempt from the requirements of paragraphs (1) and (2) of this subsection.

(q) Location and use of individual monitoring devices.

(1) Each registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subsection (n)(l) of this section wear and use individual monitoring devices as follows.

(A) An individual monitoring device shall be assigned to and worn by only one individual.

(B) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(C) If an additional individual monitoring device is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, in accordance with subsection (n)(1)(C) of this section, it shall be located at the waist under any protective apron being worn by the woman.

(D) An individual monitoring device used for monitoring the LDE, to demonstrate compliance with subsection (m)(1)(B)(i) of this section, shall be located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.

(E) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subsection (m)(1)(B)(ii) of this section, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device, to the extent practicable, shall be oriented to measure the highest dose to the extremity being monitored.

(2) Each registrant shall ensure that individual monitoring devices are returned to the dosimetry processor for proper processing.

(3) Each registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(r) Determination of occupational dose for the current year.

(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring in accordance with subsection (n) of this section, the registrant shall determine the occupational radiation dose received during the current year. Occupational dose includes doses received from exposure to registered/licensed or unregistered/unlicensed sources of radiation as defined in subsection (c) of this section**.**

(2) In complying with the requirements of paragraph (1) of this subsection, a registrant may:

(A) accept, as a record of the occupational dose that the individual received during the current year, RC Form 231-3 from prior or other current employers, or other clear and legible record, of all information required on that form and indicating any periods of time for which data are not available; or

(B) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's prior or other current employer(s) for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; or

(C) obtain reports of the individual's DE from prior or other current employer(s) for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, or letter. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(3) The registrant shall record the exposure data for the current year, as required by paragraph (1) of this subsection, on RC Form 231-3, or other clear and legible record, of all the information required on RC Form 231-3.

(4) If the registrant is unable to obtain a complete record of an individual's current occupational dose while employed by any other registrant or licensee, the registrant shall assume in establishing administrative controls in accordance with subsection (m)(6) of this section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 millisieverts (mSv)) for each quarter; or 416 millirems (mrem) (4.16 mSv) for each month for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) If an individual has incomplete (for example, a lost or damaged personnel monitoring device) current occupational dose data for the current year and that individual is employed solely by the registrant during the current year, the registrant shall:

(A) assume that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter;

(B) assume that the allowable dose limit for the individual is reduced by 416 mrem (4.16 mSv) for each month; or

(C) assess an occupational dose for the individual during the period of missing data using surveys, radiation measurements, or other comparable data for the purpose of demonstrating compliance with the occupational dose limits.

(6) Administrative controls established in accordance with paragraph (4) of this subsection shall be documented and maintained for inspection by the agency. Occupational dose assessments made in accordance with paragraph (5) of this subsection and records of data used to make the assessment shall be maintained for inspection by the agency. The registrant shall retain the records in accordance with subsection (ll)(6) of this section.

(s) General surveys and monitoring.

(1) Each registrant shall make, or cause to be made, surveys that:

(A) are necessary for the registrant to comply with this section; and

(B) are necessary under the circumstances to evaluate:

(i) the magnitude and extent of radiation levels; and

(ii) the potential radiological hazards.

(2) The registrant shall ensure that instruments and equipment used for qualitative and quantitative radiation measurements, for example, dose rate, are operable and calibrated:

(A) by a person licensed or registered by the agency, another agreement state, a licensing state, or the NRC to perform such service;

(B) at intervals not to exceed 12 months unless a different time interval is specified in another section of this chapter;

(C) after each instrument or equipment repair;

(D) for the types of radiation used and at energies appropriate for use; and

(E) at an accuracy within 20% of the true radiation level.

(3) All individual monitoring devices, except for direct and indirect reading pocket dosimeters, electronic personal dosimeters, and those individual monitoring devices used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with subsection (m) of this section, with other applicable provisions of this chapter, shall be processed and evaluated by a dosimetry processor:

(A) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(B) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(t) Control of access to high radiation areas.

(1) The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(A) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a DDE of 0.1 rem (1 mSv) in one hour at 30 cm from the source of radiation from any surface that the radiation penetrates;

(B) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(C) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(2) In place of the controls required by paragraph (1) of this subsection for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) The registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

(4) The registrant shall establish the controls required by paragraphs (1) and (3) of this subsection in a way that does not prevent individuals from leaving a high radiation area.

(5) The registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a high radiation area as described in this subsection if the registrant has met all the specific requirements for access and control specified in other applicable sections of this chapter, such as §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts), §289.229 of this title (relating to Radiation Safety for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices), and §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(u) Control of access to very high radiation areas.

(1) In addition to the requirements in subsection (t) of this section, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 m from a radiation machine or any surface through which the radiation penetrates at this level.

(2) The registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a very high radiation area as described in paragraph (1) of this subsection if the registrant has met all the specific requirements for access and control specified in other applicable sections of this chapter, such as §289.227 of this title, §289.229 of this title, and §289.255 of this title.

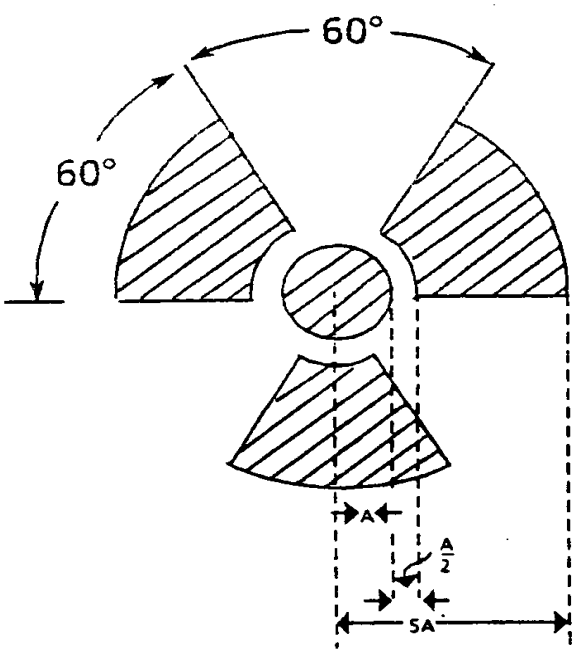
(3) The entry control devices required by paragraphs (1) and (2) of this subsection shall be established in such a way that no individual will be prevented from leaving the area.

(v) Security and control of radiation machines.

(1) The registrant shall secure radiation machines from unauthorized removal.

(2) The registrant shall use devices and/or administrative procedures to prevent unauthorized use of radiation machines.

(w) Caution signs. Unless otherwise authorized by the agency, the standard radiation symbol prescribed shall use the colors magenta, or purple, or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:



(1) the cross-hatched area of the symbol is to be magenta, purple, or black; and

(2) the background of the symbol is to be yellow.

(x) Posting requirements.

(1) The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(2) The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(3) The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." If the very high radiation area involves medical treatment of patients, the registrant may omit the word "GRAVE" from the sign or signs.

(y) Exceptions to posting requirements. A registrant is not required to post caution signs in areas or rooms containing radiation machines for periods of less than 8 hours, if each of the following conditions is met:

(1) the radiation machines are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation in excess of the limits established in this section; and

(2) the area or room is subject to the registrant's control.

(z) Labeling radiation machines. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the control unit.

(aa) Open records.

(1) Subject to the limitations provided in the Texas Public Information Act, Government Code, Chapter 552, all information and data collected, assembled, or maintained by the agency are public records open to inspection and copying during regular office hours.

(2) Any person who submits written information or data to the agency and requests that the information be considered confidential, privileged, or otherwise not available to the public under the Texas Public Information Act, shall justify such request in writing, including statutes and cases where applicable, addressed to the agency.

(A) Documents containing information that is claimed to fall within an exception to the Texas Public Information Act shall be marked to indicate that fact. Markings shall be placed on the document on origination or submission.

(i) The words "NOT AN OPEN RECORD" shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.

(ii) The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

"INFORMATION FALLING WITHIN EXCEPTION OF THE TEXAS PUBLIC INFORMATION ACT, GOVERNMENT CODE, CHAPTER 552 ---- CONFIDENTIAL

This document contains information submitted to the Department of State Health Services, Radiation Control by

_____
(Name of Company)(Name of Submitter)

which is claimed to fall within the following exception to the Texas Public Information Act, Government Code, Chapter 552, Subchapter C _____
(Appropriate Subsection)

WITHHOLD FROM PUBLIC DISCLOSURE

_____
(Signature and Title)(Office)(Date)"

(B) The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application.

(C) Failure to comply with any of the procedures described in subparagraphs (A) and (B) of this paragraph may result in all information in the agency file being disclosed upon an open records request.

(3) The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The agency will determine whether or not there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it does not fall within an exception.

(4) Requests for information.

(A) All requests for open records information must be in writing and refer to documents currently in possession of the agency.

(B) The agency will ascertain whether the information may be released or whether it falls within an exception to the Texas Public Information Act.

(i) The agency may take a reasonable period of time to determine whether information falls within one of the exceptions to the Texas Public Information Act.

(ii) If the information is determined to be public, it will be presented for inspection and/or copies of documents will be furnished within a reasonable period of time. A fee will be charged to recover agency costs for copies.

(C) Original copies of public records may not be removed from the agency. Under no circumstances shall material be removed from existing records.

(bb) General provisions for records.

(1) All records required by this chapter shall be accurate and factual. These records shall be maintained by the registrant in accordance with subsection (ll)(6) of this section. Additional record requirements are specified elsewhere in this chapter.

(2) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(3) Each registrant shall use the SI units gray, sievert, and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

(4) The registrant shall make a clear distinction among the quantities entered on the records required by this section, such as TEDE, SDE, LDE, or DDE.

(5) Records required in accordance with subsections (cc)-(ee) of this section shall include the date and the identification of individual(s) making the record, and, as applicable, a unique identification of survey instrument(s) used, and an exact description of the location of the survey.

(6) Copies of records required in accordance with subsections (cc)-(ee) of this section, and by certificate of registration conditions that are relevant to operations at an additional authorized use/storage site shall be maintained at that site in addition to the main site specified on a certificate of registration in accordance with subsection (ll)(6) of this section.

(cc) Records of surveys.

(1) Each registrant shall make and maintain records showing the results of surveys and calibrations required by subsection (s) of this section. The registrant shall retain these records in accordance with subsection (ll)(6) of this section.

(2) The registrant shall retain the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual DEs in accordance with subsection (ll)(6) of this section.

(dd) Records of individual monitoring results.

(1) Each registrant shall make and maintain records in accordance with subsection (r) of this section of the doses received by all individuals for whom monitoring was required in accordance with subsection (n) of this section, and records of doses received during accidents, and emergency conditions. Assessments of DE and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(A) the DDE to the whole body, LDE, SDE to the skin of the whole body, and SDE to the skin of any extremities; and

(B) the data used to make occupational dose assessments in accordance with subsection (r)(5) of this section.

(2) The registrant shall make entries of the records specified in paragraph (1) of this subsection at intervals not to exceed 1 year and within 90 days of the end of the year.

(3) The registrant shall maintain the records specified in paragraph (1) of this subsection on RC Form 231-3, in accordance with the instructions for RC Form 231-3, or in clear and legible records containing all the information required by RC Form 231-3.

(4) The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(5) The registrant shall retain each required form or record required by this subsection and records used in preparing RC Form 231-3 or equivalent in accordance with subsection (ll)(6) of this section.

(ee) Records of dose to individual members of the public.

(1) Each registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See subsections (o) and (p) of this section.

(2) The registrant shall retain the records required by paragraph (1) of this subsection in accordance with subsection (ll)(6) of this section.

(ff) Form of records.

(1) Each record required by this chapter shall be legible throughout the specified retention period.

(2) The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

(3) The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.

(4) Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.

(5) The registrant shall maintain adequate safeguards against tampering with and loss of records.

(gg) Reports of stolen, lost, or missing radiation machines.

(1) Each registrant shall report to the agency by telephone a stolen, lost, or missing radiation machine immediately after its occurrence becomes known to the registrant.

(2) Each registrant required to make a report in accordance with paragraph (1) of this subsection shall, within 30 days after making the telephone report, make a written report to the agency that includes the following information:

(A) a description of the radiation machine involved, including, the manufacturer, model and serial number;

(B) a description of the circumstances under which the loss or theft occurred;

(C) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible TEDE to persons in unrestricted areas;

(D) actions that have been taken, or will be taken, to recover the radiation machine; and

(E) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of radiation machines.

(3) Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

(4) The registrant shall prepare any report filed with the agency in accordance with this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(hh) Notification of incidents.

(1) Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual, except a patient administered radiation for the purpose of medical diagnosis or therapy, to receive:

(A) a TEDE of 25 rems (0.25 Sv) or more;

(B) an LDE of 75 rems (0.75 Sv) or more; or

(C) an SDE to the skin of the whole body or to the skin of the extremities of 250 rads (2.5 grays) or more.

(2) Each registrant shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a radiation machine possessed by the registrant that may have caused, or threatens to cause an individual to receive, in a period of 24 hours:

(A) a TEDE exceeding 5 rems (0.05 Sv);

(B) an LDE exceeding 15 rems (0.15 Sv); or

(C) an SDE to the skin of the whole body or to the skin of the extremities exceeding 50 rems (0.5 Sv).

(3) Registrants shall make the initial notification reports required by paragraphs (1) and (2) of this subsection by telephone to the agency and shall confirm the initial notification report within 24 hours by telegram, mailgram, or facsimile to the agency.

(4) The registrant shall prepare each report filed with the agency in accordance with this section so that names of individuals who have received exposure to radiation are stated in a separate and detachable portion of the report.

(ii) Reports of exposures and radiation levels exceeding the limits.

(1) In addition to the notification required by subsection (hh) of this section, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(A) incidents for which notification is required by subsection (hh) of this section;

(B) doses in excess of any of the following:

(i) the occupational dose limits for adults in subsection (m)(1)(A) and (B) of this section;

(ii) the occupational dose limits for a minor in subsection (m)(1)(C) of this section;

(iii) the limits for an embryo/fetus of a declared pregnant woman in subsection (m)(1)(D) of this section;

(iv) the limits for an individual member of the public in subsection (o) of this section; or

(v) any applicable limit in the registration;

(C) levels of radiation in:

(i) a restricted area in excess of applicable limits in the certificate of registration; or

(ii) an unrestricted area in excess of 10 times the applicable limit set forth in this section or in the registration, whether or not involving exposure of any individual in excess of the limits in subsection (o) of this section.

(2) Each report required by paragraph (1) of this subsection shall describe the extent of exposure of individuals to radiation, including, as appropriate:

(A) estimates of each individual's dose;

(B) the levels of radiation involved;

(C) the cause of the elevated exposures, dose rates; and

(D) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated registration conditions.

(3) Each report filed in accordance with paragraph (1) of this subsection shall include for each individual exposed: the name, social security number, and date of birth. With respect to the limit for the embryo/fetus in subsection (m)(1)(D) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(4) All registrants who make reports in accordance with paragraph (1) of this subsection shall submit the report in writing to the agency.

(jj) Notifications and reports to individuals.

(1) Requirements for notification and reports to individuals of exposure to radiation are specified in §289.203 of this title (relating to Notices, Instructions and Reports to Workers; Inspections).

(2) When a registrant is required in accordance with subsection (ii) of this section to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation, the registrant shall also notify the individual and provide a copy of the report submitted to the agency, to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of §289.203 of this title.

(kk) Inspections.

(1) The agency may enter public or private property at reasonable times to determine whether, in a matter under the agency's jurisdiction, there is compliance with the Act, the agency's rules, certificate of registration conditions, and orders issued by the agency.

(2) Each registrant shall afford the agency, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(3) Each registrant shall make available to the agency for inspection, upon reasonable notice, records made and maintained in accordance with this chapter.

(4) Inspection of radiation machines and services.

(A) Routine inspections by agency personnel will be made no more frequently than the intervals specified in subsection (ll)(2) of this section. Registrants having certificates of registration authorizing multiple uses will be inspected at the most frequent interval specified for the uses authorized.

(B) Notwithstanding the inspection intervals specified in this section, the agency may inspect registrants more frequently due to:

(i) the persistence or severity of violations found during an inspection;

(ii) investigation of an incident or complaint concerning the facility;

(iii) a request for an inspection by a worker(s) in accordance with §289.203 of this title;

(iv) any change in a facility or equipment that might cause a significant increase in radiation output or hazard; or

(v) a mutual agreement between the agency and registrant.

(C) On-site routine inspections and remote inspections may be alternated as determined by the agency.

(D) For remote inspection of radiation machines, each registrant shall respond to a request from the agency for a remote inspection by performing the following:

(i) completing the remote inspection forms in accordance with the instructions included with the forms; and

(ii) returning to the agency the completed remote inspection forms with documentation of the most recent equipment performance evaluation performed in accordance with §289.227(o) of this title and an inventory in accordance with §289.226(m)(1)(B) of this title, by the deadline indicated on the form.

(E) The agency will conduct inspections of radiation machines or lasers in a manner designed to cause as little disruption of a healing arts practice as is practicable.

(5) A person who inspects medical radiation machines or lasers will have training in the design and uses of the machines and will receive training specified in subsection (ll)(4) and/or (5) of this section.

(6) Each registrant shall perform, upon instructions from the agency, or shall permit the agency to perform such reasonable surveys as the agency deems appropriate or necessary including, but not limited to, surveys of:

(A) radiation machines;

(B) facilities where radiation machines are used or stored;

(C) radiation detection and monitoring instruments; and

(D) other equipment and devices used in connection with utilization or storage of radiation machines.

(ll) Appendices.

(1) Definitions of machine types and types of use. For the purposes of this section, the listed machine types and types of use have the following meanings:

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(A) CT - computerized tomography machines used for medical purposes;

(B) fluoroscopy - fluoroscopic machines used for medical purposes;

(C) accelerators, simulators other therapeutic machines, and electronic brachytherapy devices, used for medical purposes;

(D) radiographic only - facilities possessing and using only radiographic machines for medical purposes, including but not limited to, tomography, chiropractic machines, and bone densitometers;

(E) podiatric radiographic only - facilities possessing and using only radiographic machines for podiatry. This category may also include bone densitometers;

(F) minimal threat only - facilities possessing and using only machines defined as minimal threat machines;

(G) industrial radiography only - facilities possessing and using radiographic machines for industrial radiography, including accelerators. This category includes machines used at permanent and temporary job sites;

(H) other industrial - facilities possessing and using radiation machines for other industrial purposes (non-human use), including diffraction, hand-held light intensifying imaging devices, flash radiography, accelerators, CT, and fluoroscopy;

(I) services - persons providing the services listed in §289.226(b)(10) of this title;

(J) laser (human use/research/academic) - lasers used for medical and/or research or academic purposes, including veterinary use; and

(K) laser other (industrial/entertainment/services) - lasers used for industrial purposes, for demonstration/sales, and for stationary/mobile entertainment light shows. This category also includes facilities that provide calibration/repair services for lasers and that provide lasers to facilities for short periods of time.

(2) Inspection intervals for registrants.

Machine Type/Type of Use	Years Between Inspections
CT	2 years
Fluoroscopy	2 years
Accelerators, Simulators, and Other Therapeutic Radiation Machines	2 years
Radiographic Only	3 years
Podiatric Radiographic Only	4 years
Minimal Threat	5 years
Industrial Radiography	1 year
Other Industrial	5 years
Services	5 years
Laser (Human Use/Research/Academic)	As deemed necessary by the agency
Other Laser	As deemed necessary by the agency
Mammography	1 year

NOTE: The inspection intervals specified above were based upon the average number of health-related violations per inspection by category, as determined from compliance history data. These intervals will be reviewed at least every 2 years, and appropriate adjustments will be made.

(3) Minimal threat radiation machines. Minimal threat radiation machines include, but are not limited to, the following:

(A) x-ray fluorescence (machine);

(B) x-ray gauges;

(C) particle size analyzer (x-ray);

(D) electron beam welding;

(E) ion implantation devices;

(F) cathodoluminescence devices;

(G) package x-ray; and

(H) certified cabinet x-ray.

(4) Training for agency inspectors of radiation machines for human use.

(A) Objectives. Training of agency individuals performing inspections of radiation machines for human use will be conducted by the agency. Upon completion of training, the inspector will be able to:

(i) select and operate the necessary testing equipment used to perform an inspection of radiation machines;

(ii) utilize radiation protection principles;

(iii) operate radiation detection instruments;

(iv) define basic regulatory terminology;

(v) apply this section regarding radiation machines;

(vi) perform routine agency inspections of radiation machines;

(vii) complete agency inspection documentation;

(viii) demonstrate knowledge of agency ethics, professional, and technical policies; and

(ix) successfully achieve the objectives in this subparagraph.

(B) Initial training program.

(i) Initial training will be conducted during a six-month period.

(ii) All training evaluation instruments will be developed by the agency.

(iii) Instruments to be used in determining a proficiency level are as follows:

(I) evaluation of each inspector's training needs prior to initial training;

(II) evaluation of knowledge obtained and verification of tasks performed by each inspector subsequent to training received by the agency; and

(III) evaluation of each inspector's task performance by the agency.

(C) Continuing education.

(i) The agency inspector of radiation machines for human use will accumulate 24 hours of continuing education regarding radiation machines for human use, at intervals not to exceed 24 months. These hours of continuing education may be acquired as follows:

(I) documented continuing education earned in an agency-accepted training format; and

(II) agency staff meetings.

(ii) Failure to obtain 24 hours of continuing education within each 24-month interval may result in a reassessment by the agency of an agency inspector's proficiency level.

(iii) After the initial training period, each inspector of radiation machines for human use will be evaluated by the agency, at intervals not to exceed 12 months.

(D) Agency proficiency standards. The agency proficiency standards for agency inspectors of radiation machines for human use are as follows.

(i) Level I. The agency inspector has not successfully achieved the objectives in subparagraph (A) of this paragraph after the initial training period. Additional training is required. Unsupervised inspections will not be performed.

(ii) Level II. The agency inspector has partially achieved the objectives in subparagraph (A) of this paragraph, but has not achieved the objective in subparagraph (A)(ix) of this paragraph after the initial training period. Additional training is required. Unsupervised inspections are not permitted for the type of radiation machines for human use for which the objectives of subparagraph (A)(ix) of this paragraph have not been achieved. Unsupervised inspections may be performed for the type of radiation machines for human use for which the objectives in subparagraph (A)(ix) of this paragraph have been successfully achieved.

(iii) Level III. The agency inspector has successfully achieved the objectives in subparagraph (A) of this paragraph. Supervision is not required for routine inspections.

(5) Training for agency inspectors of lasers. Initial training will include an introduction to the requirements in this chapter and inspection forms. Inspections of 2 medical and 2 entertainment lasers, conducted by an inspector having completed the requirements of this paragraph, shall be observed before unsupervised inspection of lasers is permitted.

(6) Time requirements for record keeping. The following are time requirements for record keeping.

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Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(r)(6)	Occupational dose assessments and administrative controls	Until termination of registration
(bb)(6)	Records at Additional Authorized Use/Storage Locations	While site is authorized on registration
(cc)(1)	Routine Surveys, Instrument Calibration	3 years
(cc)(2)	Surveys, Measurements, Calculations Used for Dose Determination	Until termination of registration
(dd)(1)-(3)	Individual Monitoring Results; RC Form 231-3	Update annually; Maintain until termination of registration
(dd)(4)	Embryo/Fetus Dose	Until termination of registration
(dd)(5)	Records Used to Prepare RC Form, 231-3	3 years
(ee)	Dose to Individual Members of the Public	Until termination of registration

(7) Occupational exposure form. The following, RC Form 231-3, is to be used to document occupational exposure record for a monitoring period.

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PAGE _____ OF _____

RC Form 231-3
December 2011

Department of State Health Services/Radiation Control

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

10A. RADIONUCLIDE	10B. CLASS	10C. MODE	10D. INTAKE IN μCi

DOSES (in rem)

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 RC FORM 231-3

(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 §289.202(ggg)(2)(F) 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. 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.

20. Signature of the person designated to represent the licensee or registrant.

21. Enter the date this form was prepared.