

DEPARTMENT OF HEALTH

Repeal of Chapter 11-40 and Adoption of
Chapter 11-45, Hawaii Administrative rules

[11/12/99]

1. Chapter 40 of Title 11, Hawaii Administrative Rules, Entitled "Radiation Protection" is repealed.
2. Chapter 45 of Title 11, Hawaii Administrative Rules, Entitled "Radiation Control," is adopted.

TITLE 11
HAWAII ADMINISTRATIVE RULES
DEPARTMENT OF HEALTH

CHAPTER 40

Repealed

§§11-40-1 to 11-40-19 Repealed [11/12/99]

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 45

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SUBCHAPTER 1

GENERAL PROVISIONS

§11-45-1 Purpose and scope. This chapter sets minimum standards for all persons and facilities who receive, possess, use, transfer, own, or acquire any source of radiation, all persons who install and service sources of radiation, and all persons who provide radiation services. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-2 Definitions. As used in this chapter:

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

"Accelerator-produced material" means any material made radioactive by a particle accelerator.

"Accessible surface" means the external surface of the enclosure or housing of an x-ray system component provided by the manufacturer.

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

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

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

produced, prepared, received, used, or stored.

"Adult" means an individual eighteen or more years of age.

"Air kerma" (K) means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

- (1) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I, of subchapter 4, or
- (2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or twelve DAC-hours.

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

"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.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of five rems (0.05 sievert) or a committed dose equivalent of fifty rems (0.5 sievert) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B of subchapter 4.

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

"Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

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

in relation to utilization of nuclear energy and licensed sources of radiation in the public interest.

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

"Attenuation block" means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions twenty centimeters by twenty centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"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. (Includes devices such as phototimers and ion chambers.)

"Background radiation" means radiation from cosmic sources; naturally-occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the department.

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

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

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

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to one disintegration or transformation per second (s^{-1}).

"Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

"Byproduct material" means:

- (1) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and
- (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"C-Arm x-ray system" means an x-ray system in which the

image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in subchapter 4 of these rules.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

"Calendar quarter" means not less than twelve consecutive weeks nor more than fourteen consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee shall change the method observed by him of determining calendar quarters for purposes of this chapter except at the beginning of a calendar year.

"Calibration" means the determination of:

- (1) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or
- (2) The strength of a source of radiation relative to a standard.

"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.

"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.

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

"Certified cabinet x-ray system" means an x-ray system which has been certified in accordance with 21 C.F.R. ?1010.2 as being manufactured and assembled pursuant to the provisions of 21 C.F.R. ?1020.40.

"Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, Radiation Control for Health and Safety Act of 1968.

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

"C.F.R." means Code of Federal Regulations.

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

"Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than ten days, for Class W, Weeks, from ten to one hundred days, and for Class Y, Years, of greater than one hundred days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

"Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.

"Collective dose" means 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.

"Collimator" means a device used to limit the size, shape, and direction of the primary radiation beam.

"Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the fifty-year period following the intake.

"Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

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

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

$$CS = \frac{\mu_x - \mu_w}{(CTN)_x - (CTN)_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

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

"Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

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

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors.

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

"Curie" (Ci) means a unit of quantity of radioactivity. One curie is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

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

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy.

"Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of one centimeter (one-thousand milligrams per square centimeter).

"Department" means the department of health.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of two thousand hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for two thousand hours in a year.

DAC values are given in Table I, Column 3, of Appendix B of subchapter 4.

"Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take two thousand DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 sievert).

"Detector" (See "Radiation detector").

"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 pharmaceutical, dosage, and route of administration.

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

"Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

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

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

"Director" means the director of the department of health,

State of Hawaii, or a duly authorized agent.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

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

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

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

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

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

"Dosimetry processor" means person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Effective dose equivalent" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).

"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").

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

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Existing equipment" means therapy systems subject to subchapter 14 which were manufactured on or before January 1, 1985.

"Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

"Exposure" means, when used as a verb, being exposed to ionizing radiation or to radioactive material. When used as a noun, "exposure" means the quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " dm " are completely stopped in air. The special unit of exposure is the roentgen (R). One roentgen is equal to 2.58×10^{-4} coulombs per kilogram of air.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

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

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (three hundred milligrams per centimeter squared).

"Facility" means the location at which one or more devices or sources are installed and/or located within a building, office, vehicle, or under one roof.

"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 a safety or warning device.

"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.

"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.

"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 fifty 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.

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

"Fissile material" means any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium-238, plutonium-239, plutonium-241, uranium-233, and uranium-235. Neither natural nor depleted uranium is fissile material.

"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.

"Focal spot (actual)" means the area on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

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

"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.

"Giga-" (G) means one billion times when used in conjunction with a specified unit.

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

"Gray" (Gy) means the SI unit of absorbed dose. One gray is

equal to an absorbed dose of one joule per kilogram (one hundred rads).

"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.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 C.F.R. Part 261.

"Healing arts" means the medical, dental, chiropractic, podiatric, and veterinary professions.

"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.

"High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (one millisievert) in one hour at thirty centimeters from any source of radiation or from any surface that the radiation penetrates. For purposes of these rules, rooms or areas in which diagnostic x-ray systems are used for healing arts purposes are not considered high radiation areas.

"HRS" means Hawaii Revised Statutes.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"HVL" See "Half-value layer".

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

"Image receptor" means any device, such as a fluorescent screen 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.

"Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

- (1) Dose equivalent by the use of individual monitoring devices or by the use of survey data; or
- (2) Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, individual monitoring equipment and personnel monitoring equipment are equivalent terms.

Examples of individual monitoring devices are film badges,

thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

"Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

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

"Inspection" means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements, and conditions of the department.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

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

"Ionizing radiation" means any radiation consisting of charged particles having sufficient kinetic energy to produce ionization by collision, or uncharged particles which can liberate directly ionizing particles or can initiate a nuclear transformation, or a mixture of both charged and uncharged particles.

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

"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.

"Kilo-" (k) means one thousand times when used in conjunction with a specified unit.

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

"kV" means kilovolts.

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

"kWs" means kilowatt second.

"Landfill" means a disposal facility or part of a facility at which solid waste is permanently placed in or on land and which is not a landspreading facility.

"Landspreading facility" means a facility that applies sludges or other solid wastes onto or incorporates solid waste into the soil surface at greater than vegetative utilization and soil conditioner and/or immobilization rates.

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

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

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

"Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in

measuring leakage radiation. They are defined as follows:

- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs, i.e., ten milliampere seconds, or the minimum obtainable from the unit, whichever is larger.
- (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
- (3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"License" means a written authorization issued by the department in accordance with the rules adopted by the department, when used without reference to the U.S. Nuclear Regulatory Commission, agreement state, or other state.

"Licensee" means any person who is issued a license by the department and is legally obligated to have a license with the department pursuant to these rules.

"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.

"Limits" (See "Dose limits").

"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: Percent line-voltage regulation = $100 (V_n - V_l) / V_l$ where V_n = No-load line potential and V_l = Load line potential.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, 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.

"Lost or missing licensed material" means licensed material whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"mA" means milliampere.

"mAs" means milliampere second.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or

small industrial programs. Type A and B quantities are defined in 10 C.F.R. §71.4.

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

"Mega-" (M) means a million times when used in conjunction with a specified unit.

"Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

"Micro-" (μ) means one-millionth of when used in conjunction with a specified unit.

"Milli-" (m) means one-thousandth of when used in conjunction with a specified unit.

"Minor" means an individual less than eighteen years of age.

"Misadministration" means the administration of:

- (1) External beam radiation therapy involving the wrong patient, wrong treatment modality, or wrong treatment site; when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose; when the calculated weekly administered dose is thirty percent greater than the weekly prescribed dose; or when the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose;
- (2) A therapeutic radiopharmaceutical dosage involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration, or when the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage;
- (3) A gamma stereotactic radiosurgery radiation dose involving the wrong patient or wrong treatment site, or when the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;
- (4) A teletherapy radiation dose involving the wrong patient, wrong mode of treatment, or wrong treatment site, or when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose, or when the calculated weekly administered dose is thirty percent greater than the weekly prescribed dose, or when the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose;
- (5) A brachytherapy radiation dose involving the wrong patient, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site), or involving a sealed source that is

leaking, or when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or when the calculated administered dose to the treatment site differs from the prescribed dose by more than twenty percent of the prescribed dose;

- (6) A diagnostic radiopharmaceutical dosage, both involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs by more than twenty percent of the prescribed dosage, and when the dose to the patient exceeds five rems (fifty millisieverts) effective dose equivalent or fifty rems (five hundred millisieverts) dose equivalent to any individual organ.

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

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

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, radiation monitoring and radiation protection monitoring are equivalent terms.

"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.

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

"Nano-" (n) means one-billionth of when used in conjunction with a specified unit.

"NARM" means any naturally-occurring and/or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides.

"New equipment" means systems subject to subchapter 14 which were manufactured after January 1, 1985.

"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:

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

where:

CS = Contrast scale

μ_w = Linear attenuation coefficient of water.

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

"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.

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, a "deterministic effect" is an equivalent term.

"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 licensee, and data recording procedures, which are related to radiation safety.

"Normal treatment distance" means:

- (1) 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; and
- (2) 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.

"Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, or other person. Occupational dose does not include dose received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

"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.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt.

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

"PBL" (See "Positive Beam Limitation").

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

"Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed.

"Person" means any individual, partnership, firm, association, public or private corporation, trust estate or any other legal entity.

"Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee

while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Personnel monitoring equipment" (See "Individual monitoring devices").

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

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

"Pico-" (p) means one-trillionth of when used in conjunction with a specified unit.

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

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

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

"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.

"Positive beam limitation" means the automatic or semi-automatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustment.

"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) The total dose and dose per fraction as documented in the written directive for external beam radiotherapy which is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique; or
- (2) The total dose as documented in the written directive for gamma stereotactic radiosurgery; or
- (3) The total dose and dose per fraction as documented in the written directive for teletherapy; or
- (4) Either the total source strength and exposure time, or the total dose, as documented in the written directive for brachytherapy.

"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.

"Primary protective barrier" See "Protective barrier".

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

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

- (1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.
- (2) "Secondary protective barrier" means the material which attenuates stray radiation.

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

"Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

"Qualified health physicist" means a physicist licensed to provide health physics services.

"Qualified medical physicist" means a physicist licensed to provide medical physics services.

"Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately thirteen 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.

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

"Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

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

"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.

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

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to

be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay" (See "Bioassay").

"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.

"Radiographer" means any individual in industrial radiography who performs or personally supervises industrial radiographic operations, or any individual in the healing arts who practices radiography on human patients as specified in chapter 11-44.

"Radiographer instructor" means any radiographer who has been authorized by the department to provide on-the-job training to radiographer trainees, relative to industrial radiography.

"Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction, relative to industrial radiography.

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

"Radiographic personnel" means any radiographer, radiographer instructor, or radiographer trainee, relative to industrial radiography.

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

"Recordable event" means the administration of:

- (1) An external beam radiation therapy dose when the calculated weekly administered dose is fifteen percent greater than the weekly prescribed dose;
- (2) A radiopharmaceutical or radiation without a written directive where a written directive is required;
- (3) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
- (4) A therapeutic radiopharmaceutical dosage when the administered dosage differs from the prescribed dosage by more than ten percent of the prescribed dosage;
- (5) A teletherapy radiation dose when the calculated weekly administered dose is fifteen percent greater than the weekly prescribed dose; or
- (6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.

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

"Reference man" means a hypothetical aggregation of human physical and physiological characteristics determined by

international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

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

"Regulations of the U.S. Department of Transportation" means the regulations in 49 C.F.R. Parts 100-189.

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

"Research and development" means:

- (1) Theoretical analysis, exploration, or experimentation;
or
- (2) 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. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

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

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

"Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

"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.

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

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

"Scan time" means the period of time between the beginning

and end of x-ray transmission data accumulation for a single scan.

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

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

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

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

"Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (seven milligrams per centimeter squared) averaged over an area of one square centimeter.

"Shielded-room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in subchapter 4 of these rules.

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SI" means an abbreviation of the International System of Units.

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

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

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

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

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

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

"Source material" means:

- (1) Uranium or thorium, or any combination thereof, in any physical or chemical form; or
- (2) Ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing radiation.

"Special form radioactive material" means radioactive

material which satisfies the following conditions:

- (1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
- (2) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and
- (3) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed before July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, shall meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

- (1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
- (2) Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding three hundred fifty grams of contained U-235; uranium-233 in quantities not exceeding two hundred grams; plutonium in quantities not exceeding two hundred grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175(\text{grams contained U-235})}{350} + \frac{50(\text{grams U-233})}{200} + \frac{50(\text{grams Pu})}{200} = 1$$

"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.

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

"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.

"SSD" means the distance between the source and the skin entrance plane of the patient.

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

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

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, probabilistic effect is an equivalent term.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

"Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure an x-ray system when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device.

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

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

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

"Technique factors" means the following conditions of operations:

- (1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- (2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
- (3) 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;
- (4) 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
- (5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current

and exposure time in mAs.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed on the license.

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

"Test" means the process of verifying compliance with an applicable provisions of this chapter.

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

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

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

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

"Transport index" means the dimensionless number, rounded up to the first decimal place, 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 the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

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

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

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

"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.

"Uncontrolled area" means any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

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

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

"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.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five hundred rads (five grays) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates. (At very high doses received at high dose rates, units of absorbed dose, rad and gray, are appropriate, rather than units of dose equivalent, rem and sievert.)

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

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

"Waste" means those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (a) by the U.S. Nuclear Regulatory Commission.

"Waste handling licensees" mean persons licensed to receive and store radioactive wastes before disposal.

"Week" means seven consecutive days starting on Sunday.

"Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS	
Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

^b For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure shall be approved on a case-by-case basis until such time as specific guidance is issued.

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

"Worker" means an individual engaged in work licensed and controlled by a licensee, but does not include the licensee.

"Working level" (WL) means any combination of short-lived radon daughters in one liter of air that shall result in the ultimate emission of 1.3×10^5 mega electron volts of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

"Working level month" (WLM) means an exposure to one working level for one hundred seventy hours -- two thousand working hours per year divided by twelve months per year is approximately equal to one hundred seventy hours per month.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user before the administration of a radiopharmaceutical or radiation, except as specified in (6) containing the following information:

- (1) For external beam radiotherapy, total dose, dose per fraction, treatment site and overall treatment period; or
- (2) For a therapeutic administration of a radiopharmaceutical; the radiopharmaceutical, dosage, and route of administration; or
- (3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or
- (4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or
- (5) For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or
- (6) For all other brachytherapy, before implantation: the radionuclide, number of sources, and source strengths; and after implantation but before completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

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

"X-ray equipment" means an x-ray system, subsystem, or

component thereof. Types of x-ray equipment are as follows:

- (1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
- (2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.
- (3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

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

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

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

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

"Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee may change the starting date of the year used to determine compliance provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-3 Exemptions. (a) Sources of radiation licensed by the U.S. Nuclear Regulatory Commission are exempt from the requirements of this chapter to the extent they are regulated by the U.S. Nuclear Regulatory Commission.

(b) Nothing in this chapter shall be construed to limit the kind and amount of radiation that may be intentionally applied to a person for diagnostic or therapeutic purposes by, or under the direction of, persons licensed as physicians, dentists, chiropractors, podiatrists, or veterinarians in the State provided their sources of radiation are licensed in accordance with subchapter 2 and conform with the applicable provisions of this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-4 Inspections. (a) The department shall inspect and examine facilities with sources of radiation in order to

determine compliance with this chapter. The frequency of inspections shall be determined by the director.

(b) If such inspection indicates that the facility is not in compliance with this chapter, the owner, operator, or user shall be so notified in writing, with specification of any deficiencies.

(c) Persons conducting inspections relative to this chapter shall have been trained in health physics and radiation protection, the performance testing of radiation machines, and the operation of instruments utilized for radiation detection and measurement, performance standards testing of radiation machines, and quality control measures. Persons who have completed training shall be certified as competent by the director. The department shall determine the extent of training. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

Historical Note: §11-45-4 is based substantially upon §11-40-15. [Eff 11/5/81]

§11-45-5 Proceedings before director. (a) When the director has grounds to believe that anyone has violated any provision of these rules or of any order of the director, the director may notify the alleged violator or violators of the alleged violation order and may require that the alleged violator appear before the director at a time and place specified in the notice, and answer the allegations. The notice and order shall comply with the chapter 91, HRS, procedures for contested cases.

(b) The director may issue an order for immediate action to protect the public health from an imminent and substantial danger. The director shall provide an opportunity for a hearing within twenty-four hours after service of the order. After a hearing pursuant to this subsection, the director may affirm, modify, or rescind the order as appropriate. The director may institute a civil action in any court of appropriate jurisdiction for the enforcement of any order issued pursuant to this subsection. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-20, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-20, 321-71)

§11-45-6 General requirements. (a) Each licensee shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified in these rules.

(b) Each licensee shall afford the department at all reasonable times entrance to private or public property for the purpose of inspecting and investigating conditions relative to sources of radiation, physically examining sources of radiation, the premises, and the facilities wherein such sources of radiation are used or stored.

(c) Each licensee shall make available to the department inspection records maintained pursuant to these rules. Copies of

such records shall be submitted to the department upon request.

(d) Each licensee shall perform upon instructions from the department, or shall utilize a qualified medical physicist, or shall permit the department to perform, such reasonable tests as the department deems appropriate or necessary including, but not limited to, tests of:

- (1) Sources of radiation;
- (2) Facilities wherein sources of radiation are used or stored;
- (3) Radiation detection and monitoring instruments; and
- (4) Other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

(e) Upon receipt of an inspection report rendered by the department, each licensee shall complete corrective action to meet the requirements of this chapter in the time period specified by the department. If additional time is necessary to complete corrective action, a written request shall be submitted to the department for review and determination before the date specified for completion of corrective action. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-7 Additional requirements. The department may impose upon any licensee or person such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-8 Reserved.

§11-45-9 Reserved.

§11-45-10 Reserved.

§11-45-11 Prohibited uses. (a) The following sources of radiation shall not be used:

- (1) A hand-held fluoroscopic screen using x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Department of Health and Human Services.
- (2) A direct view fluoroscopic unit without image intensification.
- (3) A shoe-fitting fluoroscopic device.
- (4) Ionizing radiation from sources of radiation for demonstration purposes which violate the exposure limitations and the as-low-as-is-reasonably-achievable (ALARA) principle specified in subchapter 4.

- (5) Except for sources of radiation exempted from a license, sources of radiation which have no license. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-12 Reserved.

§11-45-13 Units of exposure and dose. (a) As used in these rules, the unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

- (b) As used in these rules, the units of dose are:
- (1) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule per kilogram (one hundred rads).
 - (2) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of one hundred erg per gram or 0.01 joule per kilogram (0.01 gray).
 - (3) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (one rem = 0.01 sievert).
 - (4) Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (one sievert = one hundred rems).

(c) As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Appendix A of this subchapter.

(d) 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 subsection (c), one rem (0.01 sievert) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of twenty five million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from Appendix B of this subchapter to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

(e) The exhibits at the end of chapter 11-45 entitled "Appendix A of Subchapter 1, Quality Factors and Absorbed Dose Equivalencies (2/2/93)" and "Appendix B of Subchapter 1, Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons (2/2/93)" are made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-14 Units of radioactivity. For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time:

- (1) One becquerel (Bq) = one disintegration or transformation per second (s^{-1}).
- (2) One curie (Ci) = 3.7×10^{10} disintegrations or transformations per second = 3.7×10^{10} becquerel (Bq) = 2.22×10^{12} disintegrations or transformations per minute. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-15 Penalties and injunctions. Any person who violates any provisions of this chapter is subject to the penalties pursuant to §321-18, HRS, the remedies pursuant to §321-20, HRS, and injunctions pursuant to §603-23, HRS. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

Historical Note: §11-45-15 is based substantially upon §11-40-18. [Eff 11/5/81]

§11-45-16 Severability. If any provisions of this chapter, or its application to any person or circumstances, is held invalid, the application of such provision to other persons or circumstances, and the remainder of this chapter, shall not be affected thereby. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

Historical Note: §11-45-16 is based substantially upon §11-40-19. [Eff 11/5/81]

SUBCHAPTER 2

License

§11-45-17 Purpose and scope. (a) This subchapter establishes requirements for the licensing of sources of radiation, the licensing of persons providing radiation services, and the licensing of persons transporting or delivering radioactive material to a carrier for transport.

(b) In addition to the requirements of this subchapter, all licensees are subject to the applicable provisions of other subchapters of this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-18 Exemptions. (a) The following radiation machines are exempt from the requirements of this subchapter:

- (1) Electronic equipment that produces radiation

incidental to its operation for other purposes is exempt from the license and notification requirements of this subchapter, provided that the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem (five microsieverts) per hour at five centimeters from any accessible surface of such equipment;

- (2) Radiation machines while in transit or storage incident thereto; and
- (3) Domestic television receivers;
- (b) The following source material is exempt from the requirements of this subchapter:
 - (1) Any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution, or alloy;
 - (2) Unrefined and unprocessed ore containing source material;
 - (3) Any quantities of thorium contained in:
 - (A) Incandescent gas mantles;
 - (B) Vacuum tubes;
 - (C) Welding rods;
 - (D) Electric lamps for illuminating purposes provided that each lamp does not contain more than fifty milligrams of thorium;
 - (E) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
 - (F) Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; and
 - (G) Personnel neutron dosimeters, provided that each dosimeter does not contain more than fifty milligrams of thorium;
 - (4) Source material contained in the following products:
 - (A) Glazed ceramic tableware, provided that the glaze contains not more than twenty percent by weight source material;
 - (B) Glassware containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;
 - (C) Glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; and
 - (D) Piezoelectric ceramic containing not more than two percent by weight source material;
 - (5) Photographic film, negatives, and prints containing

- uranium or thorium;
- (6) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;
 - (7) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:
 - (A) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 C.F.R. Part 40;
 - (B) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";
 - (C) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; and
 - (D) This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;
 - (8) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:
 - (A) The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and
 - (B) The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one eighth inch (3.2 millimeters);
 - (9) Thorium contained in finished optical lenses, provided that each lens does not contain more than thirty percent by weight of thorium, and that this exemption shall not be deemed to authorize either:
 - (A) The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or
 - (B) The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;
 - (10) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcuries of uranium; and

- (11) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
 - (A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
 - (B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.
- (12) Source material licensed by the U.S. Nuclear Regulatory Commission.
- (c) The following radioactive material other than source material is exempt from the requirements of this subchapter:
 - (1) Products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this subchapter;
 - (2) Radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Appendix B of this subchapter;
 - (3) Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:
 - (A) Twenty-five millicuries (nine hundred twenty-five megabecquerels) of tritium per timepiece;
 - (B) Five millicuries (one hundred eighty-five megabecquerels) of tritium per hand;
 - (C) Fifteen millicuries (five hundred fifty-five megabecquerels) of tritium per dial (bezels when used shall be considered as part of the dial);
 - (D) One hundred microcuries (3.7 megabecquerels) of promethium-147 per watch or two hundred microcuries (7.4 megabecquerels) of promethium-147 per any other timepiece;
 - (E) Twenty microcuries (0.74 megabecquerels) of promethium-147 per watch hand or forty microcuries (1.48 megabecquerels) of promethium-147 per other timepiece hand;
 - (F) Sixty microcuries (2.22 megabecquerels) of promethium-147 per watch dial or one hundred twenty microcuries (4.44 megabecquerels) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);
 - (G) The radiation dose rate from hands and dials containing promethium-147 shall not exceed, when measured through fifty milligrams per square centimeter of absorber;
 - (H) For wrist watches, 0.1 millirad (one microgray) per hour at ten centimeters from any surface;
 - (I) For pocket watches, 0.1 millirad (one microgray) per hour at one centimeter from any surface;
 - (J) For any other timepiece, 0.2 millirad (two microgray) per hour at ten centimeters from any surface; and
 - (K) One microcurie (thirty-seven kilobecquerels) of

- radium-226 per timepiece in timepieces acquired before the effective date of this chapter;
- (4) Lock illuminators containing not more than fifteen millicuries (five hundred fifty-five megabecquerels) of tritium or not more than two millicuries (seventy-four megabecquerels) of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 shall not exceed one millirad (ten microgray) per hour at one centimeter from any surface when measured through fifty milligrams per square centimeter of absorber;
 - (5) Precision balances containing not more than one millicurie (thirty-seven megabecquerels) of tritium per balance or not more than 0.5 millicurie (18.5 megabecquerels) of tritium per balance part;
 - (6) Automobile shift quadrants containing not more than twenty-five millicuries (nine hundred twenty-five megabecquerels) of tritium;
 - (7) Marine compasses containing not more than seven hundred fifty millicuries (27.8 gigabecquerels) of tritium gas and other marine navigational instruments containing not more than two hundred fifty millicuries (9.25 gigabecquerels) of tritium gas;
 - (8) Thermostat dials and pointers containing not more than twenty-five millicuries (nine hundred twenty-five megabecquerels) of tritium per thermostat;
 - (9) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:
 - (A) One hundred fifty millicuries (5.55 gigabecquerels) of tritium per microwave receiver protector tube or ten millicuries (three hundred seventy megabecquerels) of tritium per any other electron tube;
 - (B) One microcurie (thirty-seven kilobecquerels) of cobalt-60;
 - (C) Five microcuries (one hundred eighty-five kilobecquerels) of nickel-63;
 - (D) Thirty microcuries (1.11 megabecquerels) of krypton-85;
 - (E) Five microcuries (one hundred eighty-five kilobecquerels) of cesium-137; and
 - (F) Thirty microcuries (1.11 megabecquerels) of promethium-147;

And provided further, that the radiation dose rate from each electron tube containing radioactive material shall not exceed one millirad (ten microgray) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber;
 - (10) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive

material, provided that:

- (A) Each source contains no more than one exempt quantity set forth in Appendix B of this subchapter; and
 - (B) Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this subchapter, provided that the sum of such fractions shall not exceed unity; and
 - (C) 0.05 microcuries (1.85 kilobecquerels) of americium-241;
- (11) Spark gap irradiators containing not more than one microcuries (thirty-seven kilobecquerels) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour;
- (12) Self-luminous products containing radioactive material:
- (A) Tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 C.F.R. §32.22, which authorizes the transfer of the product to persons who are exempt from regulatory requirements; and
 - (B) Articles containing less than 0.1 microcuries (3.7 kilobecquerels) of radium-226 which were acquired before the effective date of this chapter;
- (13) Radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 C.F.R. §32.26, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements;
- (14) Synthetic plastic resins containing scandium-46 which are designed for sand consolidation.
- (15) Radioactive material other than source material licensed by the U.S. Nuclear Regulatory Commission.
- (d) The following persons are exempt from the requirements of this subchapter:
- (1) Common and contract carriers, freight forwarders, and warehousemen which are subject to the requirements of the U.S. Department of Transportation in 49 C.F.R. Parts 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual),

Section 124.3 incorporated by reference, 39 C.F.R. §111.11 (1974), and the U.S. Postal Service are exempt from the requirements of this subchapter to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto.

- (2) Any person who delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcuries per gram (seventy-four becquerels/gram), or a package containing no more than a Type A quantity of radioactive material which contains no fissile radioactive material.

(e) The exhibits at the end of chapter 11-45 entitled "Appendix A of Subchapter 2, Exempt Concentrations (2/2/93)" and "Appendix B of Subchapter 2, Exempt Quantities (2/2/93)", are made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-19 Reserved.

§11-45-20 Reserved.

§11-45-21 Reserved.

§11-45-22 Application for license. (a) All persons purchasing or acquiring any radiation machine, which is not exempt pursuant to section 11-45-18 after the effective date of these rules, shall apply for a license with the department at least sixty days before purchasing, acquiring, or operating any radiation machine.

(b) All persons purchasing or acquiring any radioactive material, which is not exempt pursuant to section 11-45-18 after the effective date of these rules, shall apply for a license with the department at least sixty days before purchasing or acquiring, storing, manufacturing, using, or handling any radioactive material.

(c) Any person who is engaged in the business of selling, leasing, installing, or offering to install radiation machines, engaged in the business of furnishing or offering to furnish radiation machine servicing or services, engaged in the business of furnishing radiation services for radioactive materials, engaged in the business of providing health physics services, or engaged in the business of providing medical physics services in this State shall apply for a license of such services with the department at least sixty days before furnishing or offering to furnish any such services.

(d) Any person, other than those who are exempt under section 11-45-18, who is engaged in transporting or delivering radioactive material to a carrier for transport shall apply for a

license with the department at least sixty days before furnishing such services.

(e) Application for a license shall be completed on forms furnished by the department and shall contain all the information required by the form and accompanying instructions. Information includes:

- (1) Applicant identification;
- (2) Type of facility or service;
- (3) Purpose of source of radiation use;
- (4) Location of radiation facility or service;
- (5) Listing of each radiation machine according to the manufacturer's name, model number, serial number, and date of manufacture of the control assembly;
- (6) Listing of radioactive materials and maximum activity;
- (7) Current curriculum vitae and copies of board certification for applicants of health physics services or medical physics services.
- (8) Identification of the radiation machine installer; and
- (9) Such other information deemed as the director may request.

(f) The director shall not act upon or consider any incomplete application for a license. An application shall be deemed complete only when all required and requested information, including the application form, have been submitted.

(g) Every application shall be signed by the applicant and shall constitute an acknowledgment and agreement that the applicant shall comply with all the conditions of the license and this chapter.

(h) The director may require the submission of additional information after the application has been submitted, and may ensure that, if an application is incomplete or otherwise deficient, processing of the application shall not be completed until such time as the applicant has submitted all required information or otherwise corrected the deficiency.

(i) The failure of the director to act on a completed application within sixty days of the receipt of such application, shall be deemed a grant of such application; provided that the applicant acts consistently with the application process.

(j) The application for a license shall be accompanied by a non-refundable, initial license fee per facility payable to the department. The initial license fee schedule according to type of facility or services is as follows:

- (1) Medical x-ray facility with eight or more x-ray units - \$150.
- (2) Medical x-ray facility with more than four but less than eight x-ray units - \$100.
- (3) Medical x-ray facility with four or less x-ray units - \$50.
- (4) Chiropractic x-ray facility - \$50.
- (5) Dental x-ray facility with more than four x-ray units - \$50.
- (6) Dental x-ray facility with four or less x-ray units - \$30.
- (7) Podiatry x-ray facility - \$30.

- (8) Veterinary x-ray facility - \$30.
- (9) Radiation therapy facility - \$100.
- (10) Medical radionuclide facility - \$100.
- (11) Industrial radiography - \$50
- (12) All other radiation facilities - \$30.
- (13) Radiation services - \$30.
- (k) The license fee for an entity with more than one type facility or services shall be the fee for the type of facility or services with the highest dollar value. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-11.5, 321-27, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-11.5, 321-27, 321-71)

§11-45-23 Issuance of license. (a) Upon determination that an applicant meets the requirements of the rules, the department shall issue a license.

(b) All persons with sources of radiation registered with the department before the effective date of these rules shall be issued a license after payment of the appropriate license fee unless the use and/or the source of radiation is prohibited by section 11-45-11. The department shall determine the duration and expiration date of the initial license to establish the beginning of the biennial period.

(c) All persons approved by the department as qualified experts under chapter 11-40 before the effective date of these rules shall be issued a license after payment of the appropriate license fee. The department shall determine the duration and expiration date of the initial license to establish the beginning of the biennial period.

(d) The department may incorporate in the license at the time of issuance or thereafter by appropriate notification, rule, or order, such additional requirements and conditions as it deems appropriate or necessary.

(e) No person shall conduct activities with sources of radiation or provide radiation services specified in section 11-45-22 without a license.

(f) Each license shall expire on the date specified by the department biennially.

(g) The original license shall be posted in a location which is visible to individuals utilizing the facility. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-24 Renewal of license. (a) All licensees shall renew their license biennially before the expiration date by submitting a renewal application on a form furnished by the department and a renewal license fee according to the initial fee schedule in section 11-45-22.

(b) Notices to renew licenses shall be mailed biennially to licensees at the addresses recorded by the department. Failure to receive the notice shall not be a valid reason for not renewing licenses.

(c) A renewal application shall contain all the

information required by the form and accompanying instructions.

This includes:

- (1) Licensee identification;
- (2) Change in name, type, purpose, or location of facility or service;
- (3) Current listing of each radiation machine according to the manufacturer's name, model number, serial number, and date of manufacture of the control assembly;
- (4) Current listing of radioactive materials and maximum activity;
- (5) Current curriculum vitae and copies of new board certification for health physicists and medical physicists; and
- (6) Such other information deemed as the director may request.

(d) The director shall not act upon or consider any incomplete renewal application for a license. An application shall be deemed complete only when all required and requested information, including application form, have been submitted.

(e) Every renewal application shall be signed by the licensee and shall constitute an acknowledgment and agreement that the licensee shall comply with all the conditions of the license and this chapter.

(f) The director may require the submission of additional information after the renewal application has been submitted, and may ensure that, if an application is incomplete or otherwise deficient, processing of the application shall not be completed until such time as the licensee has submitted all required information or otherwise corrected the deficiency.

(g) The failure of the director to act on a completed renewal application within sixty days of the receipt of such application, shall be deemed a grant of such application; provided that the licensee acts consistently with the application process.

(h) Renewal fees received by mail shall be considered as paid when due if the envelope bears the postmark of the expiration date or earlier.

(i) Any license which is not renewed shall be declared defunct.

(j) The licensee shall meet all requirements pursuant to this chapter before renewal of a license. At the discretion of the director, renewal of license may be allowed if corrective actions are acceptable to the director. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-11.5, 321-27, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-11.5, 321-27, 321-71)

§11-45-25 Report of changes. The licensee shall notify the department in writing of any change which would render the information contained in the license no longer accurate.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-26 Approval not implied. No person, in any advertisement, shall refer to the fact that a facility with sources of radiation is licensed, and no person shall state or imply that any activity under such license has been approved by the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71).

§11-45-27 Assembly and transfer. (a) No radiation machines shall be assembled or installed in a facility which does not have a current license.

(b) No source of radiation shall be transferred to a facility which does not have a current license.

(c) No person shall manufacture, sell, lease, transfer, lend, assemble, or install one or more components of radiation machines or the supplies used in connection with such machines without having a current license. Radiation machines and supplies when properly placed in operation and used shall meet the requirements of this chapter.

(d) Any person who sells, leases, transfers, lends, disposes, assembles, or installs one or more components of radiation machines in this State shall notify the department within fifteen days of:

- (1) The name and address of persons who have received these machines;
- (2) The manufacturer, model, and serial number of the control assembly of each radiation machine transferred; and
- (3) The date of transfer of one or more radiation machine components.

(e) The following items are exempt from the requirements specified in subsection (d):

- (1) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;
- (2) Certified accessory components that have been identified as such to the U.S. Department of Health and Human Services;
- (3) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the x-ray system was reported; or
- (4) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

"Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation"

The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified by subsection (d).

(f) In the case of diagnostic x-ray systems which contain one or more certified components, a copy of the assembler's report prepared in compliance with requirements of the federal diagnostic x-ray standard, 21 C.F.R. §1020.30(d), shall be submitted to the department within fifteen days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-28 Reserved.

§11-45-29 Reserved.

§11-45-30 Out-of-state source of radiation. (a) Before any source of radiation currently licensed by another state or the U.S. Nuclear Regulatory Commission is brought into the State, for any temporary use, the person proposing to bring such source into the State shall give written notice to the department at least seven working days before such source is brought into the State. The notice shall include:

- (1) The type of source of radiation;
 - (2) The nature, duration, and scope of use;
 - (3) The exact location(s) where the source of radiation is to be used, stored, and secured; and
 - (4) Copy of a license issued by the U.S. Nuclear Regulatory Commission, or copy of a license issued by other states for the source of radiation.
- (b) The person referred to in subsection (a) shall:
- (1) Comply with all applicable rules; and
 - (2) Supply the department with such other information as the department may reasonably request.
- [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-31 Prohibitions. No radiation facility licensee shall allow any person in the business of providing radiation machine installation or radiation services to furnish such services to their sources of radiation or to a facility that does not have a valid license issued by the department. This does not

include persons who provide radiation machine installation or radiation services for their own facility.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 3

SHIELDING EVALUATION AND AREA RADIATION SURVEY

§11-45-32 Purpose and scope. This subchapter establishes requirements for shielding of facilities with sources of radiation. This subchapter applies to all licensees and persons who intend to obtain sources of radiation.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-33 Shielding evaluation. (a) Before construction, the construction plans of all new facilities, or modifications of existing facilities, utilizing sources of radiation shall be submitted to the department for review and approval. These plans shall show, as a minimum, the following:

- (1) Normal location of the source of radiation;
- (2) General direction(s) of the useful beam for x-ray devices;
- (3) Locations of any windows and doors;
- (4) If the source of radiation is an x-ray device, the location of the operator's booth or position and the location of the control assembly;
- (5) Structural composition, dimensions, and thickness of all walls, doors, partitions, floor, and ceiling of room(s);
- (6) Dimensions and thickness of lead (in inches, millimeters, or nominal weight in pounds for a one square foot section) specified for walls, doors, partitions, floors, or ceiling of room(s);
- (7) Dimensions of the room(s);
- (8) Type of occupancy of all adjacent rooms and areas inclusive of space above and below the room(s) with sources of radiation; and
- (9) If there is an exterior wall, the distance to the closest area(s) where it is likely that individuals may be present.

(b) The licensee or person intending to establish a facility or operation with sources of radiation shall utilize the services of a qualified medical physicist to determine the shielding requirements of the new facility or modification of an existing facility. A written shielding evaluation report by the qualified medical physicist shall be submitted with the architectural and electrical plans to the department as specified in subsection (a). The evaluation report shall include, but not limited to:

- (1) The anticipated workload or exposure from the source

- of radiation; and
- (2) All basic assumptions used in the development of the shielding specifications.
 - (3) All other relevant shielding specifications.
 - (c) The shielding specifications on the construction plan shall be equal or greater than the shielding specifications identified on the qualified medical physicist's shielding evaluation report.
 - (d) The approval of radiation shielding by the department shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate a change in spatial relationship in the radiation facility or conditions which may be contrary to the requirements in subchapter 4.
 - (e) A shielding evaluation before construction is optional for the following:
 - (1) Dental facilities;
 - (2) Podiatric facilities; or
 - (3) Facilities determined by the department.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-34 Area radiation survey. (a) An area radiation survey of a new facility or modification to an existing facility shall be conducted by, or under the direction of, a qualified medical physicist within six months after the beginning of its operation to determine compliance with subchapter 4.

(b) The licensee shall forward a report of the area radiation survey to the department within thirty days after the completion of the survey.

(c) A subsequent area radiation survey of the facility shall be conducted if the following occur:

- (1) Changes in the number of sources of radiation; or
- (2) Changes in the spatial relationship of sources of radiation, relative to walls, partitions, doors, floors, ceilings; or
- (3) Changes in workload or utilization of the source of radiation; or
- (4) Conditions which may be contrary to subchapter 4.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-35 Reserved.

SUBCHAPTER 4

STANDARDS FOR PROTECTION AGAINST RADIATION

§11-45-36 Purpose and scope. This subchapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses issued by the

department. These standards are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee 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 subchapter. However, nothing in this subchapter shall be construed as limiting actions that may be necessary to protect health and safety. The limits in this subchapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-37 Exemptions. Sources of radiation licensed by the U.S. Nuclear Regulatory Commission are exempt from the requirements of this subchapter to the extent they are regulated by the U.S. Nuclear Regulatory Commission. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-38 Implementation. (a) Any existing license condition that is more restrictive than subchapter 4 remains in force until there is an amendment or renewal of the license.

(b) If a license condition exempts a licensee from a provision of subchapter 4 in effect on or before effective date of these rules, it also exempts the licensee from the corresponding provision of this subchapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-39 Radiation protection programs. (a) Each licensee shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this subchapter and acceptable to the department.

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The department shall specify the minimum requirements for the radiation protection program according to sources of radiation and type of radiation activity and facility.

(d) The licensee shall, at least annually, review the radiation protection program content and implementation.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-40 Occupational dose limits for adults. (a) The licensee shall control the occupational dose to individual adults,

except for planned special exposures, to the following dose limits:

- (1) An annual limit, which is the more restrictive of:
 - (A) The total effective dose equivalent being equal to five rems (0.05 sievert); or
 - (B) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to fifty rems (0.50 sievert).
 - (2) The annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - (A) An eye dose equivalent of fifteen rems (0.15 sievert), and
 - (B) A shallow dose equivalent of fifty rems (0.50 sievert) to the skin or to any extremity.
- (b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime.
- (c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:.
- (1) The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.
 - (2) Reserved.
 - (d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits.
 - (e) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to ten milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.
 - (f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.
 - (g) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-41 Compliance with requirements for summation of external and internal doses. (a) If the licensee is required to monitor pursuant to section 11-45-54(a) and (b), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only pursuant to section 11-45-54(a) or only pursuant to section 11-45-54(b), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subsections (b), (c), and (d). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(b) If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

- (1) The sum of the fractions of the inhalation ALI for each radionuclide, or
- (2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by two thousand, or
- (3) The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten percent of the maximum weighted value of H_{50} , that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

(c) If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-42 Determination of external dose from airborne radioactive material. (a) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

(b) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose

equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(c) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-43 Determination of internal exposure. (a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under section 11-45-54, take suitable and timely measurements of:

- (1) Concentrations of radioactive materials in air in work areas; or
- (2) Quantities of radionuclides in the body; or
- (3) Quantities of radionuclides excreted from the body; or
- (4) Combinations of these measurements.

(b) Unless respiratory protective equipment is used, as provided in section 11-45-60, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

- (1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and
- (2) Upon prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and
- (3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in subsection (a)(2) or (a)(3), the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by sections 11-45-89 and 11-45-90. This delay licenses the licensee to make additional measurements basic to the

assessments.

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

- (1) The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or
- (2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

- (1) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in section 11-45-40 and in complying with the monitoring requirements in section 11-45-54(b), and
- (2) The concentration of any radionuclide disregarded is less than ten percent of its DAC, and
- (3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed thirty percent.

(h) When determining the committed effective dose equivalent, the following information may be considered:

- (1) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of two thousand DAC-hours, results in a committed effective dose equivalent of five rems (0.05 sievert) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
- (2) For an ALI and the associated DAC determined by the nonstochastic organ dose limit of fifty rems (0.50 sievert), the intake of radionuclides that would result in a committed effective dose equivalent of five rems (0.05 sievert), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee shall also demonstrate that the limit in section 11-45-40(a)(1)(B) is met.

(i) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-44 Determination of prior occupational dose. (a)

For each individual who may enter the licensee's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to section 11-45-54, the licensee shall:

- (1) Determine the occupational radiation dose received during the current year; and
 - (2) Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (b) Before permitting an individual to participate in a planned special exposure, the licensee shall determine:
- (1) The internal and external doses from all previous planned special exposures; and
 - (2) All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.
- (c) In complying with the requirements of subsection (a), a licensee may:
- (1) 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 most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
 - (2) Accept, as the record of lifetime cumulative radiation dose, an up-to-date department form, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee; and
 - (3) Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee, by telephone, telegram, facsimile, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
- (d) The licensee shall record the exposure history, as required by subsection (a), on a form provided by the department, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the department form. For any period in which the licensee does not obtain a report, the licensee shall place a notation on the department form indicating the periods of time for which data are not available. Licensees are not required to reevaluate the separate external dose equivalents and internal

committed dose equivalents or intakes of radionuclides assessed before the effective date of these rules. Further, occupational exposure histories obtained and recorded on the department form before the effective date of these rules, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(e) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume:

- (1) In establishing administrative controls under section 11-45-40(f). for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 millisieverts) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
- (2) That the individual is not available for planned special exposures.

(f) The licensee shall retain records until the department terminates each pertinent license requiring this record.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-45 Planned special exposures. A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in section 11-45-40 provided that each of the following conditions is satisfied:

- (1) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.
- (2) The licensee, and employer if the employer is not the licensee, specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- (3) Before a planned special exposure, the licensee ensures that each individual involved is:
 - (A) Informed of the purpose of the planned operation; and
 - (B) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 - (C) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- (4) Before permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by section 11-45-44(b) during the lifetime of the individual for each individual involved.

- (5) Subject to section 11-45-40(b), the licensee shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 - (A) The numerical values of any of the dose limits in section 11-45-40(a) in any year; and
 - (B) Five times the annual dose limits in section 11-45-40(a) during the individual's lifetime.
- (6) The licensee maintains records of the conduct of a planned special exposure in accordance with section 11-45-82 and submits a written report in accordance with section 11-45-91.
- (7) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to section 11-45-40(a), but shall be included in evaluations required by paragraphs (4) and (5).
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-46 Occupational dose limits for minors. The annual occupational dose limits for minors are ten percent of the annual occupational dose limits specified for adult workers in section 11-45-40. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-47 Dose to an embryo/fetus. (a) The licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (five millisieverts).

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subsection (a).

(c) The dose to an embryo/fetus shall be taken as the sum of:

- (1) The deep dose equivalent to the declared pregnant woman; and
- (2) The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If by the time the woman declares pregnancy to the licensee, the dose to the embryo/fetus has exceeded 0.45 rem (4.5 millisieverts), the licensee shall be deemed to be in compliance with subsection (a). if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.50 millisieverts) during the remainder of the pregnancy. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-48 Dose limits for individual members of the public.

- (a) Each licensee shall conduct operations so that:
- (1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (one millisieverts) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with section 11-45-72 (Retrofit shall not be required for locations within facilities where only radiation machines existed before the effective date of these rules and met the previous requirements of 0.5 rem (five millisieverts) in a year), and
 - (2) The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 millisieverts) in any one hour.
- (b) If the licensee allows members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.
- (c) A licensee may apply for prior department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (five millisieverts). This application shall include the following information:
- (1) Demonstration of the need for and the expected duration of operations in excess of the limit in subsection (a); and
 - (2) The licensee's program to assess and control dose within the 0.5 rem (five millisieverts) annual limit; and
 - (3) The procedures to be followed to maintain the dose ALARA.
- (d) In addition to the requirements of subchapter 4, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 C.F.R. Part 190 shall comply with those standards.
- (e) The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-49 Compliance with dose limits for individual members of the public. (a) The licensee shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in section 11-45-48.

(b) A licensee shall show compliance with the annual dose limit in section 11-45-48 by:

- (1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or
- (2) Demonstrating that:
 - (A) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and
 - (B) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 millisieverts) in an hour and 0.05 rem (0.50 millisieverts) in a year.

(c) Upon approval from the department, the licensee may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

(d) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-50 Reserved.

§11-45-51 Reserved.

§11-45-52 Testing for leakage or contamination of sealed sources. (a) Each sealed source with a half-life greater than thirty days and in any form other than gas, shall be tested for leakage or contamination before initial use and, unless otherwise authorized by the department, at intervals not to exceed six months, except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months. If, at any other time, there is reason to suspect that a sealed source might have been damaged or might be leaking, it shall be tested for leakage before further use. In the absence of a certificate from a transferor indicating that a test for leakage has been made within six months before the transfer, the sealed source shall not be put into use until tested and the results received.

- (1) Tests for leakage for all sealed sources, except those manufactured to contain radium, shall be capable of

detecting the presence of 0.005 microcuries (one hundred eighty-five becquerels) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate.

- (2) The test for leakage for sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 0.001 microcuries (thirty-seven becquerels) of radon-222 in a twenty-four hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.
- (3) Test samples shall also be taken from the interior surfaces of the container in which sealed sources of radium are stored. This test shall be capable of detecting the presence of 0.005 microcuries (one hundred eighty-five becquerels) of a radium daughter which has a half-life greater than four days.
- (4) Notwithstanding the periodic test for leakage required, any sealed source is exempt from such tests for leakage when the sealed source contains one hundred microcuries (3.7 megabecquerels) or less of beta or gamma emitting material or ten microcuries (three hundred seventy becquerels) or less of alpha emitting material.

(b) Tests for leakage or contamination shall be performed by persons specifically authorized by the department to perform such services.

(c) The following shall be considered evidence that the sealed source is leaking:

- (1) The presence of 0.005 microcuries (one hundred eighty-five becquerels) or more of removable contamination on any test sample. If the test of a sealed source, other than radium, reveals the presence of 0.005 microcuries (one hundred eighty-five becquerels) or more of removable contamination, the licensee shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, and cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with subchapter 4.
- (2) Leakage of 0.001 microcuries (thirty-seven becquerels) of radon-222 per twenty-four hours for sealed sources manufactured to contain radium. If the test of a sealed source manufactured to contain radium reveals the presence of removable contamination resulting from the decay of 0.005 microcuries (one hundred eighty-five becquerels) or more of radium-226, the licensee shall immediately withdraw the sealed source from use, take action to prevent the spread of contamination, cause the sealed source to be decontaminated and repaired or to be disposed of in accordance with

subchapter 4.

(d) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the department for three years.

(e) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to section 11-45-96. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-53 Surveys and monitoring. (a) Radiation surveys shall be conducted in all areas in the vicinity of sources of radiation by, or under the direction of, a qualified medical physicist.

(b) Instruments and equipment used for quantitative radiation measurements shall be calibrated at least annually.

(c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees to comply with section 11-45-40, with other applicable provisions of this chapter, or with conditions specified in a license shall be processed and evaluated by a dosimetry processor:

- (1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
- (2) 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.

(d) The licensee shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-54 Conditions requiring individual monitoring of external and internal occupational dose. (a) Each licensee shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

- (1) Adults likely to receive, in one year from sources external to the body, a dose in excess of ten percent of the limits in section 11-45-40(a); and
- (2) Minors and declared pregnant women likely to receive, in one year from sources external to the body, a dose in excess of ten percent of any of the applicable limits in sections 11-45-46 and 11-45-47; and
- (3) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor, to determine compliance with section 11-45-43, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

- (1) Adults likely to receive, in one year, an intake in excess of ten percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
 - (2) Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.05 rem (0.50 millisievert).
- (c) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-55 Control of access to high radiation areas. (a) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

- (1) 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 deep dose equivalent of 0.1 rem (one millisievert) in one hour at thirty centimeters from the source of radiation from any surface that the radiation penetrates; or
 - (2) 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
 - (3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.
- (b) In place of the controls required by subsection (a) for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.
- (c) The licensee may apply to the department for approval of alternative methods for controlling access to high radiation areas.
- (d) The licensee shall establish the controls required by subsections (a) and (c) in a way that does not prevent individuals from leaving a high radiation area.
- (e) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:
- (1) The packages do not remain in the area longer than three days; and
 - (2) The dose rate at one meter from the external surface of any package does not exceed 0.01 rem (0.1 millisievert) per hour.

(f) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this subchapter and to operate within the ALARA provisions of the licensee's radiation protection program.

(g) The licensee is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this section if the licensee has met all the specific requirements for access and control specified in other applicable subchapters. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-56 Control of access to very high radiation areas.

(a) In addition to the requirements in section 11-45-55, the licensee shall institute additional 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 five hundred rads (five grays) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(b) The licensee is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subsection (a) if the licensee has met all the specific requirements for access and control specified in other applicable subchapters. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-57 Control of access to very high radiation areas -- irradiators.

(a) This section applies to licensees with sources of radiation in non-self-shielded irradiators, and does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create a radiation level of five hundred rads (five grays) or more in one hour at one meter in an area that is accessible to any individual.

(b) Each area in which there may exist radiation levels in excess of five hundred rads (five grays) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

- (1) Each entrance or access point shall be equipped with entry control devices which:
 - (A) Function automatically to prevent any individual

- from inadvertently entering a very high radiation area; and
- (B) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (one millisievert) in one hour; and
 - (C) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (one millisievert) in one hour.
- (2) Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by paragraph (1):
- (A) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (one millisievert) in one hour; and
 - (B) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
- (3) The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the source's shielded storage container:
- (A) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (one millisievert) in one hour; and
 - (B) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.
- (4) When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- (5) Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of paragraphs (3) and (4).

- (6) Each area shall be equipped with devices that shall automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which shall be installed in the area and which can prevent the source of radiation from being put into operation.
- (7) Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel before each use of the source of radiation.
- (8) Each area shall be checked by a radiation measurement to ensure that, before the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (one millisievert) in one hour.
- (9) The entry control devices required in paragraph (1) shall have been tested for proper functioning.
 - (A) Testing shall be conducted before initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and
 - (B) Testing shall be conducted before resumption of operation of the source of radiation after any unintentional interruption; and
 - (C) The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
- (10) The licensee shall not conduct operations, other those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.
- (11) Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.
 - (c) Licensees of sources of radiation within the purview of subsection (b) which shall be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of subsection (b), such as those for the automatic control of radiation levels, may apply to the department for approval of alternative safety

measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in subsection (b). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(d) The entry control devices required by subsections (b) and (c) shall be established in such a way that no individual shall be prevented from leaving the area. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-58 Use of process or other engineering controls.

The licensee shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-59 Use of other controls. When it is not

practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (1) Control of access; or
- (2) Limitation of exposure times; or
- (3) Use of respiratory protection equipment; or
- (4) Other controls. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-60 Use of individual respiratory protection

equipment. (a) If the licensee uses respiratory protection equipment to limit intakes pursuant to section 11-45-59:

- (1) Except as provided in paragraph (2), the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.
- (2) If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, and has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment,

including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

- (3) The licensee shall implement and maintain a respiratory protection program that includes:
 - (A) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and
 - (B) Surveys and bioassays, as appropriate, to evaluate actual intakes; and
 - (C) Testing of respirators for operability immediately before each use; and
 - (D) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately before each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
 - (E) Determination by a physician before initial fitting of respirators, and at least every twelve months thereafter, that the individual user is physically able to use the respiratory protection equipment.
- (4) The licensee shall issue a written policy statement on respirator usage covering:
 - (A) The use of process or other engineering controls, instead of respirators; and
 - (B) The routine, nonroutine, and emergency use of respirators; and
 - (C) The length of periods of respirator use and relief from respirator use.
- (5) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
- (6) The licensee shall use equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
 - (b) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to section 11-45-59, provided that the following conditions, in addition to those in subsection (a), are satisfied:
 - (1) The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak

concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in section 11-45-59 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

- (2) The licensee shall obtain authorization from the department before assigning respiratory protection factors in excess of those specified in Appendix A. The department may authorize a licensee to use higher protection factors on receipt of an application that:
- (A) Describes the situation for which a need exists for higher protection factors, and
 - (B) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(c) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(d) The licensee shall notify the department in writing at least thirty days before the date that respiratory protection equipment is first used pursuant to either subsection (a) or (b).

(e) The exhibit at the end of chapter 11-45 entitled, "Appendix A of Subchapter 4, Protection Factors for Respirators (2/2/93)", is made a part of this section.

(f) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-61 Security of stored sources of radiation. The licensee shall secure from unauthorized removal or access licensed

sources of radiation that are stored in controlled or unrestricted areas. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-62 Control of sources of radiation not in storage.

(a) The licensee shall control and maintain constant surveillance of licensed radioactive material that is in a controlled or unrestricted area and that is not in storage or in a patient.

(b) The licensee shall maintain control of licensed radiation machines that are in a controlled or unrestricted area and that are not in storage. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-63 Caution signs. (a) Unless otherwise authorized by the department, the radiation symbol is the three-bladed design specified in Appendix D.

(b) Notwithstanding the requirements of subsection (a), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) In addition to the contents of signs and labels prescribed in this subchapter, the licensee shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(d) The exhibit at the end of chapter 11-45 entitled, "Appendix D of Subchapter 4, Radiation Symbol (8/19/98)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-64 Posting requirements. (a) The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) The licensee 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."

(c) The licensee 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."

(d) The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(f) The exhibit at the end of chapter 11-45 entitled, "Appendix C of Subchapter 4, Quantities of Material Requiring Labeling (2/2/93)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-65 Exceptions to posting requirements. (a) A licensee is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

- (1) The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this subchapter; and
 - (2) The area or room is subject to the licensee's control.
- (b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to this section provided that the patient could be released from confinement pursuant to subchapter 7.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at thirty centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 millisieverts) per hour.

(d) A room or area is not required to be posted with a caution sign because of the presence of a diagnostic x-ray system used solely for healing arts purposes. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-66 Labeling containers and radiation machines. (a) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to license individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee shall, before removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) Each licensee shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-67 Exemptions to labeling requirements. (a) A licensee is not required to label:

- (1) Containers holding licensed material in quantities less than the quantities listed in Appendix C; or
- (2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or
- (3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this subchapter; or
- (4) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation, or
- (5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
- (6) Installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.

(b) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage (2/2/93)", is made a part of this section and is available from the department.

(c) The exhibit at the end of chapter 11-45 entitled, "Appendix C of Subchapter 4, Quantities of Material Requiring Labeling (2/2/93)", is made a part of this section.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-68 Reserved.

§11-45-69 Reserved.

§11-45-70 Waste disposal. (a) A licensee shall dispose of licensed radioactive material only:

- (1) By transfer to an authorized recipient as provided in section 11-45-75; or
- (2) By decay in storage; or
- (3) By release in effluents within the limits in section

11-45-48; or

- (4) As authorized in this subchapter.
- (b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
 - (1) Treatment before disposal; or
 - (2) Treatment or disposal by incineration; or
 - (3) Decay in storage; or
 - (4) Storage until transferred to a disposal facility authorized to receive the waste.
- (c) Disposal of licensed radioactive material other than that specified in subsections (a) and (b) shall be prohibited. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-71 Method for obtaining approval of proposed disposal procedures. A licensee may apply to the department for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

- (1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and
- (2) An analysis and evaluation of pertinent information on the nature of the environment; and
- (3) The nature and location of other potentially affected facilities; and
- (4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this subchapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-72 Disposal by release into sanitary sewerage. (a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

- (1) The material is readily soluble, or is readily dispersible biological material, in water; and
- (2) The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and
- (3) If more than one radionuclide is released, the following conditions shall also be satisfied:
 - (A) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide

- listed in Table III of Appendix B; and
- (B) The sum of the fractions for each radionuclide required by subparagraph (A) does not exceed unity; and
- (4) The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed one curie (thirty seven gigabecquerels) of all other radioactive materials combined.
- (b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subsection (a).
- (c) Appendix B to Part D of the Conference of Radiation Control Program Directors, Inc. Suggested State Regulations for Control of Radiation, Volume I, December 1995 Edition, entitled, "Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage", is made a part of this section and is available from the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-73 Treatment or disposal by incineration. A licensee may treat or dispose of licensed material by incineration only as specifically approved by the department pursuant to section 11-45-71. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-74 Reserved.

§11-45-75 Transfer for disposal and manifests. The transfer of low-level radioactive waste intended for disposal at a low-level radioactive waste disposal facility, shipment manifests, and certification of the waste generator, shall meet the requirements of the Northwest Interstate Compact on Low-Level Radioactive Waste Management. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-76 Compliance with environmental and health protection regulations. Nothing in subchapter 4 relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of pursuant to subchapter 4. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-77 Units and quantities on records. (a) Each licensee shall use the SI units becquerel, gray, sievert and

coulomb per kilogram, or the special units: curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this subchapter.

(b) The licensee shall make a clear distinction among the quantities entered on the records required by this subchapter such as, total effective dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-78 Records of radiation protection programs. (a) Each licensee shall maintain records of the radiation protection program, including:

- (1) The provisions of the program; and
- (2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraphs (1) and (2) for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-79 Records of surveys. (a) Each licensee shall maintain records showing the results of surveys and calibrations required by section 11-45-53. The licensee shall retain these records for inspection by the department for three years.

(b) The licensee shall retain each of the following records for inspection by the department for three years:

- (1) Records of 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 dose equivalents; and
- (2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and
- (3) Records showing the results of air sampling, surveys, and bioassays required pursuant to section 11-45-60(a)(3)(A) and (B); and
- (4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-80 Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources shall be kept in units of becquerel or curies and maintained for inspection by the department for three years.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)

(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-81 Records of prior occupational dose. (a) The licensee shall retain the records of prior occupational dose and exposure history as specified in section 11-45-44 for inspection by the department for three years.

(b) Upon termination of the license, the licensee shall permanently store records. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-82 Records of planned special exposures. (a) For each use of the provisions of section 11-45-45 for planned special exposures, the licensee shall maintain records that describe:

- (1) The exceptional circumstances requiring the use of a planned special exposure; and
- (2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and
- (3) What actions were necessary; and
- (4) Why the actions were necessary; and
- (5) What precautions were taken to assure that doses were maintained ALARA; and
- (6) What individual and collective doses were expected to result; and
- (7) The doses actually received in the planned special exposure.

(b) The licensee shall retain records for inspection by the department for three years.

(c) Upon termination of the license, the licensee shall permanently store records. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-83 Records of individual monitoring results. (a) Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 11-45-54, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this chapter need not be changed. These records shall include, when applicable:

- (1) The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and
- (2) The estimated intake or body burden of radionuclides; and
- (3) The committed effective dose equivalent assigned to the intake or body burden of radionuclides; and
- (4) The specific information used to calculate the committed effective dose equivalent pursuant to section 11-45-43(c).; and
- (5) The total effective dose equivalent when required by

section 11-45-41; and

(6) The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) The licensee shall make entries of the records specified in subsection (a) at least annually.

(c) The licensee shall maintain the records specified in subsection (a).

(d) The licensee 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.

(e) The licensee shall retain each required form or record for inspection by the department for three years.

(f) Upon termination of the license, the licensee shall permanently store records. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-84 Records of dose to individual members of the public. (a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public.

(b) The licensee shall retain the records required by subsection (a) for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-85 Records of waste disposal. (a) Each licensee shall maintain records of the disposal of licensed materials made pursuant to sections 11-45-71, 11-45-72, and 11-45-73.

(b) The licensee shall retain the records required by this section for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-86 Records of testing entry control devices for very high radiation areas. (a) Each licensee shall maintain records of tests made pursuant to section 11-45-57(b)(9). on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.

(b) The licensee shall retain the records required by subsection (a). [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-87 Form of records. Each record required by this subchapter shall be legible. 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 or the record may

also be stored in electronic media with the capability for producing legible, accurate, and complete records. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-88 Reports of stolen, or lost, or missing sources of radiation. (a) Each licensee shall report to the department by telephone as follows:

- (1) Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing radioactive material in an aggregate quantity equal to or greater than one thousand times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or
- (2) Within thirty days after its occurrence becomes known to the licensee, lost, stolen, or missing radioactive material in an aggregate quantity greater than ten times the quantity specified in Appendix C that is still missing.
- (3) Immediately after its occurrence becomes known to the licensee, a stolen, lost, or missing radiation machine.

(b) Each licensee required to make a report pursuant to subsection (a) shall, within thirty days after making the telephone report, make a written report to the department setting forth the following information:

- (1) A description of the source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;
 - (2) A description of the circumstances under which the loss or theft occurred; and
 - (3) A statement of disposition, or probable disposition, of the source of radiation involved; and
 - (4) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
 - (5) Actions that have been taken, or shall be taken, to recover the source of radiation; and
 - (6) Procedures or measures that have been, or shall be, adopted to ensure against a recurrence of the loss or theft of sources of radiation.
- (c) Subsequent to filing the written report, the licensee shall also report additional substantive information on the loss or theft within thirty days after the licensee learns of such information.
- (d) The licensee shall prepare any report filed with the

department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(e) The exhibit at the end of this chapter entitled, "Appendix C of Subchapter 4, Quantities of Materials Requiring Labelling 2/2/93", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-89 Notification of incidents. (a) Notwithstanding other requirements for notification, each licensee shall immediately report each event involving a source of radiation possessed by the licensee that may have caused or threatens to cause any of the following conditions:

- (1) An individual to receive:
 - (A) A total effective dose equivalent of twenty-five rems (0.25 sievert) or more; or
 - (B) An eye dose equivalent of seventy-five rems (0.75 sievert) or more; or
 - (C) A shallow dose equivalent to the skin or extremities of two hundred fifty rads (2.5 grays) or more; or
- (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake five times the occupational ALI.

(b) Each licensee shall, within twenty-four hours of discovery of the event, report each event involving loss of control of licensed source of radiation possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

- (1) An individual to receive, in a period of twenty-four hours:
 - (A) A total effective dose equivalent exceeding five rems (0.05 sievert); or
 - (B) An eye dose equivalent exceeding fifteen rems (0.15 sievert); or
 - (C) A shallow dose equivalent to the skin or extremities exceeding fifty rems (0.5 sievert); or
- (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four hours, the individual could have received an intake in excess of one occupational ALI.

(c) The licensee shall prepare each report filed with the department pursuant to this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(d) Licensees shall make the reports required by subsections (a) and (b) by telephone, telegram, mailgram, or facsimile to the department.

(e) The provisions of this section do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to section 11-45-91. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-90 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits. (a)

In addition to the notification required by section 11-45-89, each licensee shall submit a written report within thirty days after learning of any of the following occurrences:

- (1) Incidents for which notification is required by section 11-45-89; or
 - (2) Doses in excess of any of the following:
 - (A) The occupational dose limits for adults in section 11-45-40; or
 - (B) The occupational dose limits for a minor in section 11-45-46; or
 - (C) The limits for an embryo/fetus of a declared pregnant woman in section 11-45-47; or
 - (D) The limits for an individual member of the public in section 11-45-48; or
 - (E) Any applicable limit in the license; or
 - (3) Levels of radiation or concentrations of radioactive material in:
 - (A) A restricted area in excess of applicable limits in the license; or
 - (B) An unrestricted area in excess of ten times the applicable limit set forth in this subchapter or in the license, whether or not involving exposure of any individual in excess of the limits in section 11-45-48; or
 - (4) For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 C.F.R. Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.
- (b) Contents of reports.
- (1) Each report required by subsection (a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
 - (A) Estimates of each individual's dose; and
 - (B) The levels of radiation and concentrations of radioactive material involved; and
 - (C) The cause of the elevated exposures, dose rates, or concentrations; and
 - (D) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to subsection (a) shall include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus in section 11-45-47, 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.

(c) All licensees who make reports pursuant to subsection (a) shall submit the report in writing to the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-91 Reports of planned special exposures. The licensee shall submit a written report to the department within thirty days following any planned special exposure conducted in accordance with section 11-45-45, informing the department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by section 11-45-82. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-92 Reserved.

§11-45-93 Reserved.

§11-45-94 Reserved.

§11-45-95 Notifications and reports to individuals. (a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in subchapter 10.

(b) When a licensee is required pursuant to section 11-45-90 to report to the department any exposure of an individual to radiation or radioactive material, the licensee shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the department, and shall comply with the provisions of subchapter 10. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-96 Reports of leaking or contaminated sealed sources. If the test for leakage or contamination indicates a sealed source is leaking or contaminated, a report of the test shall be filed within five days with the department describing the equipment involved, the test results and the corrective action taken. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-97 Vacating premises. Each licensee shall, no less than thirty days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the licensee shall decontaminate the premises in such a manner as the department may specify.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 5

INDUSTRIAL RADIOGRAPHIC OPERATIONS

§11-45-98 Purpose and scope. This subchapter establishes requirements for the use of sources of radiation for industrial radiography. The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements in this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-99 Exemptions. (a) Sources of radiation licensed by the U.S. Nuclear Regulatory Commission are exempt from the requirements of this subchapter to the extent the sources are regulated by the U.S. Nuclear Regulatory Commission.

(b) Industrial uses of portable light-intensified imaging devices are exempt from the requirements in this part.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-100 Storage precautions. X-ray systems shall be physically secured to prevent tampering or removal by unauthorized personnel. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-101 Radiation survey instruments. (a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this subchapter and subchapter 4. Instrumentation required by this section shall have a range such that two milliroentgens (5.16×10^{-7} coulombs per kilogram) per hour through one roentgen (2.58×10^{-4} coulombs per kilogram) per hour can be measured.

- (b) Each radiation survey instrument shall be calibrated:
- (1) At energies appropriate for use and at intervals not to exceed three months and after each instrument servicing;
 - (2) Such that accuracy within plus or minus twenty percent can be demonstrated; and

- (3) At two points located approximately one-third and two-thirds of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments.

(c) Records of these calibrations shall be maintained after the calibration date for inspection by the department for three years.

(d) Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-102 Utilization logs. Each licensee shall maintain current logs which shall be kept available for inspection by the department for three years, showing for each x-ray system the following information:

- (1) A unique identification, such as a serial number, of each x-ray system;
- (2) The identity of the radiographer to whom assigned;
- (3) Locations where used and dates of use; and
- (4) The date(s) each x-ray system is removed from storage and returned to storage. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-103 Inspection and maintenance. (a) Each licensee shall ensure that checks are made for obvious defects in x-ray systems before use each day.

(b) Each licensee shall conduct a program of at least quarterly inspection and maintenance of x-ray systems to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the department for three years.

(c) If any inspection reveals damage to components critical to radiation safety, the x-ray system shall be removed from service and labeled as defective until repairs have been made.

(d) Inspections of x-ray systems utilized for non-destructive testing shall be conducted by, or under the supervision of, a qualified medical physicist. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-104 Permanent radiographic installations. Permanent radiographic installations having high radiation area entrance controls of the type described in subchapter 4 shall also meet the

following requirements:

- (1) Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation during exposure.
- (2) The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-105 Reserved.

§11-45-106 Training and testing of radiographic personnel.

- (a) No licensee shall permit any individual to act as a radiographer trainee unless such individual has received copies of, instructions in, and has demonstrated an understanding of:
 - (1) The subjects outlined in Appendix A of this subchapter;
 - (2) This subchapter and subchapter 4;
 - (3) The appropriate license; and
 - (4) The licensee's operating and emergency procedures.
- (b) No licensee shall permit any individual to act as a radiographer, as defined in this part, until such individual:
 - (1) Has met the requirements of subsection (a);
 - (2) Has provided the department with documentation showing completion of at least thirty days of on-the-job training by a radiographer instructor as a radiographer trainee following completion of the requirements of subsection (a);
 - (3) Has demonstrated competence in the use of x-ray systems, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments; and
 - (4) Has demonstrated an understanding of the instructions in subsection (a) by successful completion of a written test and a field examination on the subjects covered.
- (c) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the licensee for inspection by the department for three years following termination of employment.
- (d) Each licensee shall conduct an internal audit program to ensure that the department's license conditions or licensee's

operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the department for three years.

(e) The exhibit at the end of chapter 11-45 entitled, "Appendix A of Subchapter 5, Subjects for Instruction of Radiographer Trainees (2/2/93)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-107 Operating and emergency procedures. The licensee's operating and emergency procedures shall include instructions in at least the following:

- (1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in subchapter 4;
 - (2) Methods and occasions for conducting radiation surveys;
 - (3) Methods for controlling access to radiographic areas;
 - (4) Methods and occasions for locking and securing x-ray systems;
 - (5) Personnel monitoring and the use of personnel monitoring equipment, including steps that shall be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;
 - (6) Notification procedures in the event of an accident;
 - (7) Maintenance of records; and
 - (8) The inspection and maintenance of x-ray systems.
- [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-108 Personnel monitoring control. (a) The licensee shall not permit any individual to act as a radiographer or as a radiographer trainee unless, at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD). Pocket dosimeters shall have a range from zero to two hundred milliroentgens (5.16×10^{-5} coulombs per kilogram) and shall be recharged daily or at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded at least once daily.

(c) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus thirty percent of the true radiation exposure. Records of this check shall be maintained for inspection by the department for three years.

(d) Each alarm ratemeter shall:

- (1) Be checked to ensure that the alarm functions properly

- (sounds) before use at the start of each shift;
- (2) Be set to give an alarm signal at a preset dose rate of five hundred milliroentgens per hour;
- (3) Require special means to change the preset alarm function; and
- (4) Be calibrated at periods not to exceed one year for correct response to radiation. Acceptable ratemeters shall alarm within plus or minus twenty percent of the true radiation dose rate. Records of these calibrations shall be maintained for inspection by the department for three years.

(e) If an individual's pocket dosimeter is inoperable or discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be processed immediately. The individual shall not return to work with x-ray systems until a determination of the radiation exposure has been made.

(f) Reports received from the film badge or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the department for three years.

(g) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-109 Security. During each radiographic operation, the radiographer, radiographer instructor or radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in subchapter 1, except:

- (1) Where the high radiation area is equipped with a control device or alarm system as described in subchapter 4, or
 - (2) Where the high radiation area is locked to protect against unauthorized or accidental entry.
- [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-110 Posting. Areas in which radiography is being performed shall be conspicuously posted as required by subchapter 4. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-111 Radiation surveys and survey records. (a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation is available and used at each site where radiographic exposures are made.

(b) A physical radiation survey shall be made after each radiographic exposure to determine that the machine is "off".

(c) A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that x-ray system is not operational. The area at and surrounding the collimator of the x-ray system shall be surveyed.

(d) Records shall be kept for the required surveys. Such records shall be maintained for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-112 Documents and records required at temporary jobsites. Each licensee conducting industrial radiography at a temporary jobsite shall have the following records available at that site for inspection by the department for three years:

- (1) Copy of license;
- (2) Operating and emergency procedures;
- (3) Chapter 11-45;
- (4) Survey records pursuant to subchapter 5 and area survey records pursuant to subchapter 4 for the period of operation at the site;
- (5) Daily pocket dosimeter records for the period of operation at the site; and
- (6) The latest instrument calibration records for survey instruments in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-113 Specific requirements for radiographic personnel performing industrial radiography. (a) At a jobsite, the following shall be supplied by the licensee:

- (1) At least one operable, calibrated survey instrument;
- (2) A current whole body personnel monitor (TLD or film badge) for each individual;
- (3) An operable, calibrated pocket dosimeter with a range of zero to two hundred milliroentgens (5.16×10^{-5} coulombs per kilogram) for each worker; and
- (4) The appropriate barrier ropes and signs.

(b) Industrial radiographic operations shall not be performed if any of the items in subsection (a) are not available at the jobsite or are inoperable.

(c) Each licensee shall provide a minimum of two radiographic personnel when x-ray systems are used at temporary jobsites. If one of the personnel is a radiographer trainee, the other shall be a radiographer instructor.

(d) No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.

(e) No individual shall act as a radiographer instructor unless such individual:

- (1) Has met the requirements of subchapter 5;

- (2) Has one year of documented experience as a radiographer; and
- (3) Has been named as a radiographer instructor on the license issued by the department.

(f) During an inspection by the department, the department inspector may terminate an operation if any of the items in subsection (a) are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-114 Special requirements and exemptions for cabinet radiography. (a) Systems for cabinet radiography designed to allow admittance of individuals shall:

- (1) Comply with all applicable requirements of this subchapter and subchapter 4. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this subchapter and 21 C.F.R. §1020.40.
- (2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements of this subchapter. Records of these evaluations shall be maintained for inspection by the department for three years.

(b) Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this subchapter except that:

- (1) Operating personnel shall be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results shall be maintained for inspection by the department for three years.
- (2) No licensee shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with paragraph (1) shall be maintained for inspection by the department for three years.
- (3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with section 11-45-104.
- (4) The licensee shall perform an evaluation, at intervals not to exceed one year, to determine conformance with subchapter 4. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 C.F.R. §1020.40. Records of these evaluations shall be maintained for inspection by the department for three years.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 C.F.R. §1020.40 unless prior approval has been

granted by the department pursuant to subchapter 1.
 [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS
 §§321-1, 321-11(21), 321-71)

SUBCHAPTER 6

X-RAYS IN THE HEALING ARTS

§11-45-115 Purpose and scope. This subchapter establishes requirements for use of x-ray equipment in the healing arts. The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements of this chapter.
 [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS
 §§321-1, 321-11(21), 321-71)

§11-45-116 General requirements. (a) The licensee shall be responsible for directing the operation of the x-ray system(s) under the licensee's administrative control. The licensee or the licensee's agent shall assure that the requirements of this subchapter are met in the operation of the x-ray system(s).

- (1) An x-ray system which does not meet the provisions of this subchapter shall not be operated for diagnostic purposes if so directed by the department.
- (2) Individuals who will be operating x-ray systems shall be adequately instructed on the operating procedures and be competent in the safe use of the equipment.
- (3) Individuals practicing radiologic technology shall be licensed under chapter 11-44.
- (4) 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:
 - (A) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
 - (B) Type and size of the film or screen-film combination to be used;
 - (C) Type and focal distance of the grid to be used, if any;
 - (D) Source-image receptor distance to be used (except for dental intraoral radiography);
 - (E) Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and
 - (F) For mammography, indication of kilovoltage peak/target/filter combination.
- (5) The licensee of a facility shall establish and make available to x-ray operators written safety procedures, including patient holding and 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.

- (6) Except for human patients who cannot be moved out of the room, only the staff, ancillary personnel, or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - (A) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material or otherwise authorized by a qualified medical physicist.
 - (B) The x-ray operator, other staff, ancillary personnel and other persons required for the medical procedure 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 material, unless otherwise authorized by a qualified medical physicist.
 - (C) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material, or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor, unless otherwise authorized by a qualified medical physicist.
- (7) Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human 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.
- (8) 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:
 - (A) Exposure of an individual for training, demonstration, or other non-healing arts purposes; and
 - (B) Reserved.
- (9) When a patient or film requires auxiliary support during a radiation exposure:
 - (A) Mechanical holding devices shall be used. The written safety procedures, required by paragraph (5), shall list individual projections where holding devices cannot be utilized;
 - (B) Written safety procedures, as required by paragraph (5), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 - (C) The human holder shall be instructed in personal

- radiation safety and protected as required by paragraph (6);
- (D) No individual shall be used routinely to hold film or human patients;
 - (E) In those cases where an individual 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; or
 - (F) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection for all personnel who are involved with x-ray operations and who are otherwise not shielded.
- (10) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
- (A) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of standard film packets for intraoral use in dental radiography.
 - (B) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 - (C) 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.
 - (D) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:
 - (i) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray; and
 - (ii) If of the focused type, be of the proper focal distance for the SID's being used.
- (11) All individuals who are associated with the operation of an x-ray system are subject to the requirements of subchapter 4.
- (12) Reserved.
- (13) The licensee shall maintain the following information for each x-ray system for inspection by the department:
- (A) Model and serial numbers of all major components, and user's manuals for those components;
 - (B) Tube rating charts and cooling curves;
 - (C) Records of surveys, calibrations, maintenance,

- and modifications performed on the x-ray system(s);
- (D) Copy of all correspondence with this department regarding that x-ray system.
- (14) Each facility shall maintain either an x-ray log containing the name of the patient, the type of x-ray examination, the date of the x-ray examination, the name of the referring practitioner, and the name of the individual who performed the x-ray examination (facilities subject to chapter 11-44), or a patient record specifying the type of x-ray examination and the date of the x-ray examination. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
- (b) Each installation using a radiographic x-ray system and using analog image receptors (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:
- (1) Manually developed film:
- (A) Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
- (B) The temperature of solutions in the tanks shall be maintained within the range of sixty degrees Fahrenheit to eighty degrees Fahrenheit (sixteen degrees Celsius to twenty-seven degrees Celsius). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with Appendix A of this subchapter.
- (C) Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.
- (2) Automatic processors and other closed processing systems:
- (A) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed according to Appendix B of this subchapter.
- (B) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.
- (3) Processing deviations from the requirements of paragraph (1) shall be documented by the licensee in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).
- (c) Other requirements:
- (1) Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall

incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

- (2) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1.0 to 2.0 when processed shall not have a fog density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.
- (3) Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.
- (4) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
- (5) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
- (6) Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.
- (7) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(d) The exhibits at the end of chapter 11-45 entitled, "Appendix A of Subchapter 6, Time-Temperature Chart (2/2/93)" and "Appendix B of Subchapter 6, Temperature-Immersion Chart (2/2/93)", are made a part of this section.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-117 All diagnostic x-ray systems. (a) 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."

(b) 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.

(c) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed one hundred milliroentgens (25.8

microcoulombs per kilogram) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters with no linear dimension greater than twenty centimeters.

(d) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two milliroentgens (0.516 microcoulombs per kilogram) in one hour at five 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 one hundred square centimeters with no linear dimension greater than twenty centimeters.

(e) Beam quality:

- (1) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the appropriate value specified in Appendix C of this subchapter under "specified dental systems," for any dental system designed for use with intraoral image receptors and manufactured after December 1, 1980; and under "other x-ray systems," for all other x-ray systems subject to this section. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Appendix C, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.
- (2) For capacitor energy storage equipment, compliance with the requirements of paragraph (1) shall be determined with the maximum quantity of charge per exposure. This shall be deemed to have been met if an milliamperes-second of ten has been used.
- (3) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.
- (4) For x-ray systems which have variable kilovoltage peak and variable filtration for the useful beam, a device shall link the kilovolts peak selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the half-value layer required by paragraph (1) is in the useful beam for the given kilovolts peak which has been selected.

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

(g) The tube housing assembly supports shall be adjusted such that the tube housing assembly shall remain stable during an exposure unless tube housing movement is a designed function of

the x-ray system.

- (h) Technique indicators:
 - (1) 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 before the exposure shall be indicated.
 - (2) The requirement of paragraph (1) 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.
- (i) Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the federal x-ray equipment performance standard, 21 C.F.R. Part 1020, shall be maintained in compliance with applicable requirements of that standard and this subchapter.
- (j) All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.
- (k) The exhibit at the end of chapter 11-45 entitled, "Appendix C of Subchapter 6, Half-Value Layer (7/25/96)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-118 Fluoroscopic x-ray systems. (a) All fluoroscopic x-ray systems shall be image intensified or used in conjunction with a digital imaging system.

- (b) The useful beam shall be limited as follows:
 - (1) Primary barrier:
 - (A) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-image receptor distance; and
 - (B) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.
 - (2) Fluoroscopic beam limitation:
 - (A) For certified fluoroscopic systems with or without a spot film device, 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 three percent of the source-image receptor distance. The sum of the excess length and the excess width shall be no greater than four percent of the source-image receptor distance.
 - (B) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum

- source-image receptor distance available but at no less than twenty centimeters table top to the film plane distance.
- (C) For uncertified fluoroscopic systems without a spot film device, the requirements of subparagraph (A) apply.
 - (D) Other requirements for fluoroscopic beam limitation:
 - (i) 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 source-image receptor distance and/or a visible area of greater than three hundred square centimeters shall be provided with means for stepless adjustment of the x-ray field;
 - (ii) All equipment with a fixed source-image receptor distance and a visible area of three hundred 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 one hundred twenty-five square centimeters or less;
 - (iii) If provided, stepless adjustment shall, at the greatest source-image receptor distance, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;
 - (iv) 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
 - (v) For rectangular x-ray fields used with circular image reception, 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.
 - (E) Spot-film devices which are certified components shall meet the following additional requirements:
 - (i) 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 except when the

- x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, 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;
- (ii) 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 source-image receptor distance shall be equal to, or less than, five centimeters by five centimeters;
 - (iii) 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 two percent of the source-image receptor distance; and
 - (iv) 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.
- (F) If a means exists to override any of the automatic x-ray field size adjustments required in subparagraph (E), that means:
- (i) Shall be designed for use only in the event of system failure;
 - (ii) Shall incorporate a signal visible at the fluoroscopist's position which shall indicate whenever the automatic field size adjustment is overridden; and
 - (iii) Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(c) 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.

- (d) Entrance exposure rate allowable limits:
 - (1) Fluoroscopic equipment which is provided with

automatic exposure rate control shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of ten roentgens (2.58 millicoulombs per kilogram) per minute at the point where the center of the useful beam enters the patient, except:

- (A) During recording of fluoroscopic images, or
 - (B) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of five roentgens (1.29 millicoulombs per kilogram) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. 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. A continuous signal audible to the fluoroscopist shall indicate that high level control is being employed.
- (2) Fluoroscopic equipment which is not provided with automatic exposure rate control (manual mode) shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of five roentgens (1.29 millicoulombs per kilogram) per minute at the point where the center of the useful beam enters the patient, except:
- (A) During recording of fluoroscopic images, or
 - (B) When an optional high level control is activated. 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. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (3) Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of ten roentgens (2.58 millicoulombs per kilogram) per minute in either mode at the point where the center of the useful beam enters the patient, except:
- (A) During recording of fluoroscopic images; or
 - (B) When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of five roentgens (1.29 millicoulombs per kilogram) per minute at the point where the center of the useful beam enters

- the patient, unless the high level control is activated. 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. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (4) Any fluoroscopic equipment manufactured after May 19, 1995 which can exceed five roentgens (1.29 millicoulombs per kilogram) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be ten roentgens (2.58 millicoulombs per kilogram) per minute with an upper limit of twenty roentgens (5.16 millicoulombs per kilogram) per minute when high level control is activated.
- (5) Compliance with the requirements of this subsection shall be determined as follows:
- (A) If the source is below the x-ray table, the exposure rate shall be measured one centimeter above the tabletop or cradle.
 - (B) If the source is above the x-ray table, the exposure rate shall be measured at thirty centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - (C) For a C-arm type of fluoroscope, the exposure rate shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty centimeters from the input surface of the fluoroscopic imaging assembly.
 - (D) For a lateral type fluoroscope, the exposure rate shall be measured at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the x-ray table.
- (6) Periodic measurement of entrance exposure rate shall be performed as follows:
- (A) Such measurements shall be made by, or under the supervision of, a qualified medical physicist at least annually or after any maintenance of the system which might affect the exposure rate.
 - (B) 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 section 11-45-116

- (a)(13)(C). The measurement results shall be stated in roentgens (coulombs per kilogram) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results.
- (C) Conditions of periodic measurement of maximum entrance exposure rate are as follows:
- (i) The measurement shall be made under the conditions that satisfy the requirements of this subsection;
 - (ii) The kilovolts peak and milliamperes shall be typical of clinical use of the x-ray system;
 - (iii) The x-ray system(s) that incorporates automatic exposure rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and/or kilovoltage typical of the use of the x-ray system; and
- (e) Barrier transmitted radiation rate limits:
- (1) 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 two milliroentgens (0.516 microcoulombs per kilogram) per hour at ten 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.
 - (2) Measuring compliance of barrier transmission.
 - (A) 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 one hundred square centimeters with no linear dimension greater than twenty centimeters.
 - (B) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty centimeters above the tabletop.
 - (C) If the source is above the tabletop and the source-image receptor distance 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 thirty centimeters.
 - (D) Movable grids and compression devices shall be removed from the useful beam during the measurement.

- (f) During fluoroscopy and cinefluorography the tube potential and tube current shall be continuously indicated.
- (g) The source-to-skin distance shall not be less than:
- (1) Thirty-eight centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974,;
 - (2) A distance of 35.5 centimeters on stationary fluoroscopic systems manufactured before August 1, 1974;
 - (3) Thirty centimeters on all mobile and portable fluoroscopes; and
 - (4) Twenty centimeters for all image-intensified fluoroscopes used for specific surgical application.
- (h) Fluoroscopic timer:
- (1) 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 five minutes without resetting.
 - (2) 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.
- (i) Control of scattered radiation:
- (1) 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.
 - (2) 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:
 - (A) Is at least one hundred twenty centimeters from the center of the useful beam; or
 - (B) 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.
- (j) Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of section 11-45-119 when operating in the spot film mode.
- (k) Radiation therapy simulation systems shall be exempt from all the requirements of subsections (b), (d), (e), and (h) provided that:
- (1) 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

- (2) Systems which do not meet the requirements of subsection (h) 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.

- (1) All newly-assembled, installed, or reassembled fluoroscopic x-ray systems shall be evaluated by, or under the supervision of, a qualified medical physicist before use on human patients unless otherwise authorized by the director.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-119 Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography systems. (a) The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, (e.g., projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

- (1) General purpose stationary, mobile, and portable x-ray systems, including veterinary systems installed after the effective date of this chapter:
 - (A) Means shall be provided for independent stepless adjustment of the size of the x-ray field. Each dimension of the minimum field size at an source-image receptor distance of one hundred centimeters shall be equal to or less than five centimeters.
 - (B) 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 two 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.
- (2) In addition to the requirements of paragraph (1), all stationary general purpose x-ray systems shall meet the following requirements:
 - (A) 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 two percent of the source-image receptor distance, and to indicate the source-image receptor distance to within two percent;
 - (B) The beam-limiting device shall indicate numerically the field size in the plane of the

- image receptor to which it is adjusted; and
- (C) Indication of field size dimensions and source-image receptor distances 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 two percent of the source-image receptor distances when the beam axis is indicated to be perpendicular to the plane of the image receptor.
- (3) Radiographic equipment designed for only one image receptor size at a fixed source-image receptor distances 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 two percent of the source-image receptor distance, 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.
- (4) Radiographic systems other than those designated in paragraphs (1), (2), and (3), and veterinary systems installed before the effective date of this chapter:
- (A) 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 two percent of the source-image receptor distance when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- (B) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the source-image receptor distance, 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. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.
- (C) The requirements of subparagraphs (A) and (B) may be met with a system that meets the requirements for a general purpose x-ray system as specified in paragraph (1) or, when alignment means are also provided, may be met with either:
- (i) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for

- which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and source-image receptor distance for which it is designed; or
- (ii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and source-image receptor distance for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and source-image receptor distance for which each aperture is designed and shall indicate which aperture is in position for use.
- (b) Radiation exposure control:
- (1) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.
 - (2) 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. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
 - (A) When manual exposure control is provided, an x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for:
 - (i) Exposure of one-half second or less; and
 - (ii) During serial radiography when means shall be provided to permit completion of any single exposure of the series in progress.
 - (B) When an automatic exposure control is provided:
 - (i) Indication shall be made on the control panel when this mode of operation is selected;
 - (ii) If the x-ray tube potential is equal to or greater than fifty-one kilovolts peak, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
 - (iii) The minimum exposure time for all equipment other than that specified in clause (ii) shall be equal to or less than one-sixtieth second or a time interval required to deliver five milliamperes-

- seconds, whichever is greater;
- (iv) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than sixty kilowatt-seconds per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than six hundred milliamperes-seconds per exposure, except that when the x-ray tube potential is less than fifty-one kilovolts peak, the product of x-ray tube current and exposure time shall be limited to not more than two thousand milliamperes-seconds per exposure; and
 - (v) A visible signal shall indicate when an exposure has been terminated at the limits required by clause (iv), and manual resetting shall be required before further automatically timed exposures can be made.
- (3) Means shall be provided for visual indication of x-ray production 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.
- (4) With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time (Tmax) and the minimum exposure time (Tmin) shall be less than or equal to ten percent of the average exposure time (T), when four timer tests are performed:
- $$(T_{\max} - T_{\min}) \leq 0.1T$$
- (5) The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.
- (6) Operator protection, except veterinary systems:
- (A) Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.
 - (B) Mobile and portable x-ray systems which are:
 - (i) Used continuously for greater than one week in the same location, i.e., a room or suite shall be considered as stationary systems under subparagraph (A).
 - (ii) Used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet (two meters) high for operator protection during exposures, or means shall be provided to allow the operator to be at least twelve feet (3.7 meters) from the tube housing assembly during the exposure.

- (7) Operators of all stationary, mobile or portable x-ray systems used for veterinary work shall be provided with a 6.5 foot (two meters) high protective barrier for operator protection during exposures, or a means to allow the operator to be at least twelve feet (3.7 meters) from the tube housing assembly during exposures, or a protective apron and protective gloves.

(c) All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than thirty centimeters, except for veterinary systems.

(d) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the difference between the maximum exposure (E_{max}) and the minimum exposure (E_{min}) shall be less than or equal to ten percent of the average exposure (E):

$$(E_{max} - E_{min}) \leq 0.1E$$

(e) 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 two milliroentgens (0.516 microcoulombs per kilogram) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(f) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value.

(g) Linearity, uncertified x-ray systems only: The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty percent to one hundred percent of the maximum rated.

- (1) Equipment having independent selection of x-ray tube current: The average ratios of exposure to the indicated milliamperere seconds product (mR/mAs (or C/kg/mAs)) obtained at any two tube current settings shall not differ by more than 0.10 times their sum:

$$[X1 - X2] \leq 0.10(X1 + X2)$$

where X1 and X2 are the average mR/mAs (or C/kg/mAs) values obtained at any two tube current settings.

- (2) Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector: The average ratios of exposure to the indicated milliamperere seconds product (mR/mAs (or C/kg/mAs)) obtained at any

two mAs selector settings shall not differ by more than 0.10 times their sum:

$$[X1 - X2] \leq 0.10(X1 + X2)$$

where X1 and X2 are the average mR/mAs (or C/kg/mAs) values obtained at any two mAs selector settings.

- (3) Determination of compliance shall be based on four exposures, of no less than 0.05 seconds each, taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(h) 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).

- (1) Linearity: When the equipment 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 forty to one hundred percent of the maximum rated.
- (A) For equipment having independent selection of x-ray tube current, the average ratios of exposure to the indicated milliampere seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$[X1 - X2] \leq 0.10(X1 + X2)$$

where X1 and X2 are the average mR/mAs (C/kg/mAs) values obtained at each of two consecutive tube current settings or at two settings differing by no more than a factor of two where the tube current selection is continuous.

- (B) For equipment having selection of x-ray tube current-exposure time product manufactured after May 3, 1994, the average ratios of exposure to the indicated milliampere seconds product obtained at any two consecutive milliampere seconds selector settings shall not differ by more than 0.10 times their sum:

$$[X1 - X2] \leq 0.10(X1 + X2)$$

where X1 and X2 are the average mR/mAs (C/kg/mAs) values obtained at each of two

- consecutive milliamperere seconds selector settings or at two settings differing by no more than a factor of two where the milliamperere seconds selector provides continuous selection.
- (2) Beam limitation for stationary and mobile general purpose x-ray systems:
- (A) There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an source-image receptor distance of one hundred centimeters shall be equal to or less than five centimeters by five centimeters.
 - (B) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than one hundred sixty lux or fifteen footcandles at one hundred centimeters or at the maximum source-image receptor distance, 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 manufactured on and after May 27, 1980, are exempt from this requirement.
 - (C) The edge of the light field at one hundred centimeters or at the maximum source-image receptor distance, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three 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 one millimeter in diameter.
- (3) Beam limitation for portable x-ray systems shall meet the beam limitation requirements of paragraphs (1) and (2).
- (4) 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 C.F.R. §1020.30(c) shall have manual collimation for field limitation and alignment.
- (5) If positive beam limitation is installed on stationary, general purpose x-ray systems after the effective date of these rules, the following requirements shall be met:

- (A) Positive beam limitation shall prevent the production of x-rays when:
- (i) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by subparagraph (E), from the corresponding image receptor dimensions by more than three percent of the source-image receptor distance; or
 - (ii) The sum of the length and width differences as stated in clause (i) without regard to sign exceeds four percent of the source-image receptor distance.
 - (iii) The beam limiting device is at an source-image receptor distance for which positive beam limitation is not designed for sizing.
- (B) If a means of overriding the positive beam limitation system exists, that means shall be designed for use only in the event of positive beam limitation system failure or if the system is being serviced.
- (C) 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,
- (i) Shall require that a key be utilized to defeat the positive beam limitation;
 - (ii) Shall require that the key remain in place during the entire time the positive beam limitation system is overridden; and
 - (iii) Shall require that the key or key switch be clearly and durably labeled as follows:

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- (D) Compliance with subparagraph (A) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor.
- (E) 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 source-image receptor distance of one hundred centimeters shall be equal to or less than five centimeters by five centimeters.
- (F) Positive beam limitation 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 subparagraph (B), then any change of image receptor size or source-image receptor distance shall cause the automatic return.

- (6) Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

- (i) A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-120 Intraoral dental radiographic systems. (a) 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 eighteen centimeters.

- (b) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that the x-ray field at the minimum source-to-skin distance shall be containable in a circle having a diameter of no more than seven centimeters.

- (c) Radiation exposure control for certified and non-certified systems:

- (1) Exposure initiation:
 - (A) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and
 - (B) 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.
 - (2) Exposure termination:
 - (A) 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.
 - (B) An x-ray exposure 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 second or less.
 - (C) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
 - (3) Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
 - (4) With a timer setting of 0.5 seconds or less, the

difference between the maximum exposure time (T_{max}) and the minimum exposure time (T_{min}) shall be less than or equal to ten percent of the average exposure time (T), when four timing tests are performed:

$$(T_{max} - T_{min}) \leq 0.10T$$

- (5) Exposure control location and operator protection:
- (A) Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and
 - (B) Mobile and portable x-ray systems which are:
 - (i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subparagraph (A);
 - (ii) Used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet (two meters) high for operator protection, or means to allow the operator to be at least twelve feet (3.7 meters) from the tube housing assembly while making exposures.

(d) The coefficient of variation for exposure reproducibility shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made within a period of one hour at identical technique factors, the difference between the maximum exposure value (E_{max}) and the minimum exposure value (E_{min}) shall be less than or equal to ten percent of the average exposure:

$$(E_{max} - E_{min}) \leq 0.10E$$

(e) When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty to one hundred percent of the maximum rating, the average ratios of exposure to the indicated milliampere seconds product obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X1 - X2) \leq 0.10(X1 + X2)$$

where $X1$ and $X2$ are the average mR/mAs (C/kg/mAs) values obtained at each of two consecutive tube current settings.

(f) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed ten percent of the indicated value.

(g) Dental x-ray machines with a nominal fixed kilovolts peak of less than fifty kilovolts peak shall not be used to make diagnostic dental radiographs of humans.

- (h) Administrative controls:

- (1) Patient and film holding devices shall be used when appropriate.
- (2) The tube housing and the position indicating device shall not be hand-held during an exposure.
- (3) 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 subsection (b).
- (4) Dental fluoroscopy without image intensification shall not be used. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-121 Computed tomography x-ray systems. (a)

General requirements:

- (1) 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 scan time to no more than one hundred ten percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
- (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means required by paragraph (1).
- (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under computed tomography x-ray system control, of greater than one-half second duration.
- (4) 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.
- (5) 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.
- (6) If a device using a light source is used to satisfy paragraphs (4) and (5), 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 five hundred lux.
- (7) The computed tomography x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
- (8) Each emergency button or switch shall be clearly labeled as to its function.
- (9) The computed tomography x-ray system shall be designed such that the computed tomography conditions of

operation to be used during a scan or a scan sequence shall be indicated before 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 computed tomography conditions of operation shall be visible from any position from which scan initiation is possible.

- (10) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by section 11-45-117 (c).
- (11) The angular position where the maximum surface computed tomography dose index occurs shall be identified to allow for reproducible positioning of a computed tomography dosimetry phantom.
- (12) Additional requirements applicable to computed tomography x-ray systems containing a gantry manufactured after September 3, 1985:
 - (A) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.
 - (B) 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 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.
 - (C) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from zero to one hundred kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or thirty 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.
 - (D) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the computerized tomography conditions of operation before the initiation of another scan.
- (b) Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- (c) Viewing systems:
 - (1) 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.

- (2) 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.
- (d) Surveys:
 - (1) All computed tomography x-ray systems installed after the effective date of these rules and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified medical physicist before use on human patients unless otherwise authorized by the director. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - (2) A written report of the survey shall be available for inspection by the department for three years.
- (e) Radiation calibrations:
 - (1) Calibration of the radiation output of the computed tomography x-ray system shall be performed by, or under the direction of, a qualified medical physicist who is physically present at the facility during such calibration.
 - (2) Calibration of a computed tomography x-ray system shall be performed at intervals specified by a qualified medical physicist and after any change or replacement of components which, in the opinion of the qualified medical physicist, could cause a change in the radiation output.
 - (3) Calibration of the radiation output of a computed tomography 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.
 - (4) Computed tomography dosimetry phantom(s) shall be used in determining the radiation output of a computed tomography x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:
 - (A) Computed tomography 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 fourteen centimeters in length and shall have diameters of 32.0 centimeters for testing computed tomography 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.
 - (B) Computed tomography 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.
- (C) 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.
 - (D) All dose measurements shall be performed with the computed tomography dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.
- (5) Calibration shall be required for each type of head, body, or whole-body scan performed at the facility.
 - (6) Calibration shall include the center multiple scan average dose and the surface multiple scan average dose.
 - (7) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the department for three years.
- (f) Spot checks shall be conducted:
 - (1) Procedures shall be in writing and shall have been developed by a qualified medical physicist.
 - (2) Procedures shall incorporate the use of a computed tomography dosimetry 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 computed tomography number for water or other reference material.
 - (3) Spot checks shall be included in the calibration required by subsection (e) and at time intervals and under system conditions specified by a qualified medical physicist.
 - (4) Spot checks shall include acquisition of images obtained with the computed tomography dosimetry phantom(s) using the same processing mode and computed tomography conditions of operation as are used to perform calibrations required by subsection (e). The images shall be retained, until a new calibration is performed, in two forms as follows:
 - (A) Photographic copies of the images obtained from the image display device; and
 - (B) Images stored in digital form on a storage medium compatible with the computed tomography x-ray system.
 - (5) Written records of the spot checks shall be maintained for inspection by the department for three years.
- (g) Operating procedures:
 - (1) The computed tomography x-ray system shall be operated by an individual who has been specifically trained in its operation and licensed under chapter 11-44.

- (2) Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:
 - (A) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;
 - (B) Instructions on the use of the computed tomography 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;
 - (C) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
 - (D) A current technique chart available at the control panel which specifies for each routine examination the computed tomography conditions of operation and the number of scans per examination.
- (3) If the calibration or spot check of the computed tomography x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified medical physicist, use of the computed tomography x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified medical physicist. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-122 Bone densitometry systems. (a) Only systems certified by the U.S. Department of Health and Human Services shall be utilized for healing arts purposes.

(b) System performance shall be maintained in accordance with all performance standards specified by the U.S. Department of Health and Human Services.

(c) Operators of bone densitometry systems shall be licensed under chapter 11-44. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-123 Reserved.

§11-45-124 Reserved.

§11-45-125 Mammography x-ray systems and facilities. (a) Only x-ray systems, pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900, shall be used for screening and diagnostic mammography.

(b) A facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900.

(c) A facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image, and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900.

(d) A facility without a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900 shall electronically disconnect diagnostic mammography x-ray systems from the power source.

(e) Each mammography facility shall maintain accurate records of mammography services performed at the facility with at least the following information:

- (1) Patient's name;
- (2) Referring physician's name;
- (3) Mammography examination date;
- (4) Type of mammography examination; and
- (5) Name of radiologic technologist who performed the mammography examination.

(f) No individual or facility shall obstruct, prevent, or deny a holder of a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900 from acquiring data, information, or statistics on outcome required by Public Law 102-539. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 7

USE OF RADIONUCLIDES IN THE HEALING ARTS

§11-45-126 Purpose and scope. This subchapter establishes requirements for the receipt, possession, production, preparation, compounding, use, and transfer of radionuclides in the healing arts. The requirements of this subchapter are in addition to, and not in substitution for, other requirements in this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-127 Exemptions. Radionuclides licensed by the U.S. Nuclear Regulatory Commission are exempt from the requirements of this subchapter to the extent they are regulated by the U.S. Nuclear Regulatory Commission. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-128 Notifications. A licensee shall notify the department in writing within thirty days when an authorized user, radiation safety officer, or qualified medical physicist, permanently discontinues performance of duties.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-129 ALARA program. (a) 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.

(b) To satisfy the requirement of subsection (a):

- (1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this subchapter or the radiation safety committee; or
- (2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

(c) The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, 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 individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(d) The licensee shall retain a current written description of the ALARA program which shall include:

- (1) A commitment by management to keep occupational doses as low as reasonably achievable;
- (2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;
- (3) Personnel exposure investigational levels as established in accordance with section 11-45-131(c)(8) that, when exceeded, shall initiate an investigation by the radiation safety officer of the cause of the exposure; and
- (4) Personnel exposure investigational levels that, when exceeded, shall 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.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11,

321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-130 Radiation safety officer. (a) 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.

- (b) The radiation safety officer shall:
- (1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;
 - (2) Implement written policy and procedures for:
 - (A) Authorizing the purchase of radioactive material;
 - (B) Receiving and opening packages of radioactive material;
 - (C) Storing radioactive material;
 - (D) Keeping an inventory record of radioactive material;
 - (E) Using radioactive material safely;
 - (F) Taking emergency action if control of radioactive material is lost;
 - (G) Performing periodic radiation surveys;
 - (H) Performing checks and calibrations of survey instruments and other safety equipment;
 - (I) Disposing of radioactive material;
 - (J) Training personnel who work in or frequent areas where radioactive material is used or stored; and
 - (K) Keeping a copy of all records and reports required by this chapter; and
 - (3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management before submittal to the department for action; or
 - (4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-131 Radiation safety committee. (a) Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

- (b) The committee shall meet the following administrative requirements:
- (1) Membership shall 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.

- (2) The committee shall meet at least once each calendar quarter.
- (3) 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.
- (4) The minutes of each radiation safety committee meeting shall include:
 - (A) Date of the meeting;
 - (B) Members present;
 - (C) Members absent;
 - (D) Summary of deliberations and discussions;
 - (E) Recommended actions and the numerical results of all ballots; and
 - (F) Document any reviews required in section 11-45-129(c) and subsection (c).
- (5) The committee shall provide each member with a copy of the meeting minutes, and retain one copy.

(c) To oversee the use of licensed material, the committee shall:

- (1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
- (2) Review, on the basis of safety and with regard to the training and experience standards of this part, and approve or disapprove any individual who is to be listed as an authorized user, the radiation safety officer, or qualified medical physicist before submitting an application for a license or request for amendment or renewal;
- (3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
- (4) 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 before submittal to the department for license action;
- (5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;
- (6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;
- (7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

- (8) Establish a table of investigational levels for occupational dose that, when exceeded, shall initiate investigations and considerations of action by the radiation safety officer. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-132 Statement of authorities and responsibilities.

- (a) A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:
- (1) Identify radiation safety problems;
 - (2) Initiate, recommend, or provide solutions; and
 - (3) Verify implementation of corrective actions.
- (b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-133 Supervision. (a) A licensee who allows the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

- (1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;
 - (2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;
 - (3) Require an authorized user to be immediately available to communicate with the supervised individual; and
 - (4) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients.
- (b) The supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material shall:
- (1) Follow the instructions of the supervising authorized user;
 - (2) Follow the written radiation safety procedures established by the licensee;
 - (3) Follow the procedures established by the radiation safety officer; and
 - (4) Comply with this chapter and the license conditions with respect to the use of radioactive material. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-134 Visiting authorized user. (a) A licensee may permit any visiting authorized user to use radioactive materials for medical use for sixty days each year if:

- (1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and
- (2) Only those procedures for which the visiting authorized user is specifically authorized are performed by that individual.

(b) A licensee shall retain copies of the records specified in subsection (a). [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-135 Mobile nuclear medicine service administrative requirements. (a) The mobile nuclear medicine service shall be licensed if the service receives, uses, or possesses radioactive material. The client of the mobile nuclear medicine service shall be licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

(b) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. If the client is licensed, the letter shall document procedures for notification, receipt, storage, and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.

(c) A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license. Radioactive material delivered to the client's address of use shall be received in conformance with the client's license.

(d) A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management or nursing staff in charge of the patient or the nursing unit, who is on site at the time that radiopharmaceuticals are being administered. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-136 Procedures for human administrations. (a) Each licensee shall establish and maintain a written program to provide assurance that radioactive material or radiation therefrom is administered to humans as directed by the authorized user. The program shall include procedures for:

- (1) Preparing written directives for the administration of radiation, however, a written directive is not required when an authorized user personally assays and administers a dosage provided the pertinent facts are documented as otherwise required;
- (2) Verifying by more than one method the identity of the individual to be administered radiation or radioactive

- material;
- (3) Updating the diagnostic clinical procedures manual;
 - (4) Verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with respective written directives;
 - (5) Assuring that administration of radiation is carried out as specified in the written directive or the diagnostic clinical procedures manual;
 - (6) Identifying and evaluating unintended deviations from the written directive or diagnostic clinical procedures manual including taking appropriate action for recordable events and misadministrations;
- (b) Each licensee shall evaluate and respond to misadministrations in accordance with section 11-45-137.
- (c) Each licensee shall evaluate and respond to recordable events within thirty days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking appropriate action to prevent recurrence.
- (d) Each licensee shall conduct an annual evaluation of the human administration program including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that radioactive material and the radiation therefrom is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.
- (e) Each licensee shall retain, in auditable form:
- (1) Each written directive;
 - (2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required;
 - (3) A record of each annual review of the program including the evaluations and findings of the review;
 - (4) A record of each recordable event, the relevant facts, and any corrective actions taken.
- (f) Individuals practicing nuclear medicine technology shall be licensed under chapter 11-44. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-137 Records, notifications, and reports of misadministrations. (a) The following actions shall be taken for a misadministration by the licensee:

- (1) The licensee shall notify the department by telephone no later than twenty-four hours after discovery of the misadministration.
- (2) The licensee shall submit a written report to the department within fifteen days after discovery of the misadministration. The written report shall include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to

prevent recurrence; whether the licensee notified the patient; or the patient's responsible relative or guardian, and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient.

- (3) The licensee shall notify the referring physician and also notify the patient of the misadministration not later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that he or she shall inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within twenty-four hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.
- (4) If the patient was notified, the licensee shall also furnish, within fifteen days after discovery of the misadministration, a written report to the patient by sending either:
 - (A) A copy of the report that was submitted to the department, or
 - (B) A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the department can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration. The record shall contain the names of all individuals involved including the prescribing physician, allied health personnel, the patient, and the patient's referring physician, the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in subsections (a) and (b) shall affect any rights or duties of licensees, and physicians in relation to each other, patients, or patient's responsible relatives or guardians.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-138 Suppliers. A licensee shall use for medical use only:

- (1) Radioactive material manufactured, produced, labeled,

- prepared, compounded, packaged, and distributed pursuant to these rules or the equivalent regulations of an agreement state or the U.S. Nuclear Regulatory Commission; and
- (2) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services.
 - (3) Radiopharmaceuticals compounded from a prescription in accordance with chapter 16-95.
 - (4) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of an agreement state or the U.S. Nuclear Regulatory Commission. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-139 Quality control of diagnostic equipment. Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers and procedures which have been approved by the department. The licensee shall conduct quality control procedures in accordance with written procedures. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-140 Possession, use, calibration, and check of dose calibrators. (a) 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. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the licensee shall use an alternative method. Any alternative method for the use of a dose calibrator shall be approved by the department. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

(b) Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute:

- (1) 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 section, the check shall be done on a frequently used setting with a sealed source of not less than fifty microcuries (1.85 megabecquerels) with energies representative of the radionuclides in clinical use at the facility;
- (2) Test each dose calibrator for accuracy upon

installation and at intervals not to exceed twelve months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within five percent of the stated activity, with minimum activity of fifty microcuries (1.85 megabecquerels) and energies representative of the radionuclides in clinical use at the facility;

- (3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between ten microcuries (three hundred seventy kilobecquerels) and the highest dosage that shall be assayed; and
- (4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it shall be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten percent if the dosage is greater than ten microcuries (three hundred seventy kilobecquerels) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.

(d) A licensee shall also perform checks and tests required by subsection (b) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each check and test required by this section. The records required by subsection (b) shall include:

- (1) For subsection (b)(1), 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;
- (2) For subsection (b)(2), 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 individual who performed the test;
- (3) For subsection (b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the radiation safety officer; and
- (4) For subsection (b)(4), 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 individual who performed the test.

(f) A licensee shall use dose calibrator reference and calibration sources traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-141 Calibration and check of survey instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with this part have been calibrated before first use, annually, and following repair.

(b) To satisfy the requirements of subsection (a), the licensee shall:

- (1) Calibrate all required scale readings up to one thousand millirems (ten millisieverts) per hour with a radiation source;
- (2) For each scale that shall be calibrated, calibrate two readings separated by at least fifty percent of scale rating; and
- (3) 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.

(c) To satisfy the requirements of subsection (b), the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than twenty percent, and shall conspicuously attach a correction chart or graph to the instrument.

(d) A licensee shall check each survey instrument for proper operation with the dedicated check source before each use.

The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in subsection(a). The record shall include:

- (1) A description of the calibration procedure; and
- (2) 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.

(f) To meet the requirements of subsections (a), (b), and (c), the licensee may obtain the services of individuals licensed to perform calibrations of survey instruments. Records of calibrations which contain information required by subsection (e) shall be maintained by the licensee. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-142 Assay of radiopharmaceutical dosages. (a) An assay shall be conducted, before medical use, of the activity of each radiopharmaceutical dosage that contains more than ten microcuries (three hundred seventy kilobecquerels) of a photon-emitting radionuclide;

(b) Radiopharmaceuticals emitting alpha and/or beta radiations as the radiation of principal interest shall be obtained:

- (1) In unit dose form, calibrated by the supplier for individual patients; and
- (2) From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit doses have a calibration traceable to a national standard.

(c) The licensee shall retain a record of the assays or calibrations required by subsections (a) and (b). To satisfy this requirement, the record shall contain the:

- (1) Radiopharmaceutical, or the radionuclide administered;
- (2) Patient's name, and identification number if one has been assigned;
- (3) Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;
- (4) Date and time of the assay or calibration and the date and time of the administration; and
- (5) Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)

(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-143 Authorization for calibration and reference sources. A licensee for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

- (1) Sealed sources manufactured and distributed by persons specifically licensed pursuant to these rules or provisions of the U.S. Nuclear Regulatory Commission, and that do not exceed fifteen millicuries (five hundred fifty-five megabecquerels) each;
- (2) Any radioactive material with a half-life of one hundred days or less in individual amounts not to exceed fifteen millicuries (five hundred fifty-five megabecquerels); and
- (3) Any radioactive material with a half-life greater than one hundred days in individual amounts not to exceed two hundred microcuries (7.4 megabecquerels) each.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)

(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-144 Possession of sealed sources and brachytherapy sources. (a) 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 department and shall maintain the

instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

- (1) The source is tested 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
- (2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the department, another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

(c) To satisfy the leak test requirements of subsection (b), the licensee shall assure that:

- (1) Leak tests are capable of detecting the presence of 0.005 microcuries (one hundred eighty-five becquerels) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 0.001 microcuries (thirty-seven becquerels) per twenty-four hours;
- (2) 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
- (3) Test samples are taken when the source is in the "off" position.

(d) A licensee shall retain leak test records. 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 microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the individual who performed the test.

(e) If the leak test reveals the presence of 0.005 microcuries (one hundred eighty-five becquerels) or more of removable contamination, the licensee shall:

- (1) Immediately withdraw the sealed source from use and store, repair, or dispose of it in accordance with the requirements of subchapter 4; and
- (2) File a report with the department within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

(f) A licensee need not perform a leak test on the following sources:

- (1) Sources containing only radioactive material with a half-life of less than thirty days;
- (2) Sources containing only radioactive material as a gas;
- (3) Sources containing one hundred microcuries (3.7 megabecquerels) or less of beta- or photon-emitting material or ten microcuries (three hundred seventy kilobecquerels) or less of alpha-emitting material; and

- (4) 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.

(g) 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. 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 individual who performed the inventory.

(h) 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 units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in subsection (h). 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 millirem (millisieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the individual who performed the survey. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-145 Syringe shields. (a) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(b) 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. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-146 Syringe labels. Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield as to contents or intended patient. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-147 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. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-148 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. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-149 Surveys for contamination and ambient radiation dose rate. (a) 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.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by subsections (a) and (b) so as to be able to measure dose rates as low as 0.1 millirem (one microsievert) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by subsections (a) 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.

(e) A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by subsection (e) so as to be able to detect contamination on each wipe sample of two thousand disintegrations per minute (33.3 becquerels).

(g) A licensee shall establish removable contamination action levels for the surveys required by subsection (e) and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by subsections (a), (b), and (e). The record shall 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 millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per one hundred 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.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-150 Release of patients containing radiopharmaceuticals or permanent implants. A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical or administered a permanent implant until the dose rate from the patient at the time of

release shall not result in a total effective dose equivalent exceeding five hundred millirems (five millisieverts) to any other individual during complete decay of the radionuclide.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-151 Mobile nuclear medicine service technical requirements. A licensee providing mobile nuclear medicine service shall:

- (1) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;
- (2) Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- (3) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;
- (4) In addition to complying with sections 11-45-140 and 11-45-141, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;
- (5) Carry a survey meter calibrated in accordance with section 11-45-141 in each vehicle that is being used to transport radioactive material, and, before leaving a client area 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;
- (6) Retain a record of each survey. The record shall 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 millirem (millisieverts) 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;
- (7) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the department for compliance with airborne release standards; and
- (8) Remove all radioactive material from the mobile vehicle and monitor the vehicle for contamination at the end of each day of use. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-152 Storage of volatiles and gases. (a) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multidose container in a properly functioning fume hood. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-153 Decay-in-storage. (a) A licensee shall hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the waste disposal requirements of subchapter 4 if the licensee:

- (1) Holds radioactive material for decay a minimum of ten half-lives;
- (2) 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;
- (3) Removes or obliterates all radiation labels; and
- (4) 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.

(b) For radioactive material disposed in accordance with subsection (a), the licensee shall retain a record of each disposal. The record shall 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 dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-154 Reserved.

§11-45-155 Specific requirements for the use of radiopharmaceuticals for uptake, dilution, or excretion studies.

(a) A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion;

- (1) Which has been granted acceptance or approval by the U.S. Department of Health and Human Services; or
- (2) Which is prepared and compounded in accordance with chapter 16-95.

(b) A licensee authorized to use radioactive material for uptake, dilution, excretion, imaging, and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 microsievert) per hour to fifty millirems (five hundred microsieverts) per hour. The instrument shall be operable and calibrated in accordance with section 11-45-140.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-156 Specific requirements for the use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies. (a) A licensee may use any radioactive material in a non-gaseous or non-aerosol diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a non-gaseous or non-aerosol radiopharmaceutical containing radioactive material:

- (1) Which has been granted acceptance or approval by the U.S. Department of Health and Human Services; or
- (2) Which has been prepared and compounded in accordance with chapter 16-95.
- (3) A licensee shall elute generators.
 - (b) Radionuclide contaminants.
 - (1) A licensee shall not administer a radiopharmaceutical containing:
 - (A) Reserved.
 - (B) More than 0.02 microcurie (0.02 kilobecquerel) of strontium-82 per millicurie (megabecquerel) of rubidium-82 chloride injection;
 - (C) More than 0.2 microcurie (0.2 kilobecquerel) of strontium-85 per millicurie (megabecquerel) of rubidium-82 chloride injection.
 - (2) A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in paragraph (1).
 - (3) A licensee who shall measure radionuclide contaminant concentration shall retain a record of each measurement. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in millicuries (megabecquerels), the measured activity of contaminant expressed in microcuries (kilobecquerels), the ratio of the measures expressed in microcuries (kilobecquerels) of contaminant per millicurie (megabecquerel), the date of the test, and the initials of the individual who performed the test.
 - (4) A licensee shall report immediately to the department each occurrence of radionuclide contaminant concentration exceeding the limits specified in paragraph (1).
- (c) Control of aerosols and gases.
 - (1) A licensee who administers radioactive aerosols or gases shall do so with a system that shall keep airborne concentrations within the limits prescribed in subchapter 4.
 - (2) The system shall provide collection and decay or disposal of the aerosol or gas in a shielded

container.

- (3) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- (4) 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 in subchapter 4. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.
- (5) A licensee shall post the time calculated in paragraph (4) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.
- (6) 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.
- (7) A copy of the calculations required in paragraph (4) shall be recorded and retained for the duration of the license.

(d) 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 0.1 millirem (one microsievert) per hour to fifty millirems (five hundred microsieverts) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The instruments shall be operable and calibrated in accordance with section 11-45-141.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-157 Specific requirements for the use of radiopharmaceuticals for therapy. (a) A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use:

- (1) Which has been granted acceptance or approval by the U.S. Department of Health and Human Services; or
- (2) Which has been prepared and compounded in accordance with chapter 16-95.
- (b) Safety instruction.
 - (1) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.
 - (2) To satisfy paragraph (1), the instruction shall describe the licensee's procedures for:
 - (A) Patient control;

- (B) Visitor control;
 - (C) Contamination control;
 - (D) Waste control;
 - (E) Notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency; and
 - (F) Training for workers.
- (3) A licensee shall keep a record of individuals receiving instruction required by paragraph (1), 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 department for three years.
- (c) Safety precautions.
- (1) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with section 11-45-150, a licensee shall:
- (A) Provide a private room with a private sanitary facility;
 - (B) Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;
 - (C) Authorize visits by individuals under eighteen years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;
 - (D) 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 subchapter 4 and retain 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 millirems (microsieverts) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
 - (E) Either monitor material and items removed from the patient'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, or handle these materials and items as radioactive waste;
 - (F) Instruct the patient and, if practical, the patient's family, orally and in writing concerning radiation safety precautions that shall help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;

- (G) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room shall not be reassigned until removable contamination is less than two hundred disintegrations per minute (3.33 becquerels) per one hundred square centimeters.
- (2) For each non-hospitalized patient receiving radiopharmaceutical therapy, the licensee shall instruct the patient and, if practical, the patient's family, orally and in writing concerning radiation safety precautions that shall help to keep radiation doses to the household members and the public as low as reasonably achievable.
- (3) A licensee shall notify the radiation safety officer or the authorized user immediately if the patient expires or has a medical emergency.
- (d) 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 0.1 millirem (one microsievert) per hour to fifty millirems (five hundred microsieverts) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The instruments shall be operable and calibrated in accordance with section 11-45-141. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-158 Specific requirements for the use of sealed sources for diagnosis. 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 0.1 millirem (one microsievert) per hour to fifty millirems (five hundred microsieverts) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The instrument shall be operable and calibrated in accordance with section 11-45-141. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-159 Specific requirements for the use of sources for brachytherapy. (a) A licensee shall use radioactive sources in accordance with the manufacturer's radiation safety and handling instructions.

(b) Safety instruction.

(1) The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training

- shall be provided at intervals not to exceed one year.
- (2) To satisfy paragraph (1), the instruction shall describe:
 - (A) Size and appearance of the brachytherapy sources;
 - (B) Safe handling and shielding instructions in case of a dislodged source;
 - (C) Procedures for patient control;
 - (D) Procedures for visitor control;
 - (E) Procedures for notification of the radiation safety officer or authorized user if the patient expires or has a medical emergency; and
 - (F) Training for workers.
 - (3) A licensee shall maintain a record of individuals receiving instruction required by paragraph (1), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.
 - (c) Safety precautions.
 - (1) For each patient receiving implant therapy a licensee shall:
 - (A) Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in subchapter 4 at a distance of one meter from the implant;
 - (B) Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;
 - (C) Authorize visits by individuals under eighteen years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;
 - (D) 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 subchapter 4 and retain 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 millirems (microsieverts) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and
 - (E) Provide the patient with radiation safety guidance that shall help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.
 - (2) A licensee shall notify the radiation safety officer

- or authorized user immediately if the patient expires or has a medical emergency.
- (d) Brachytherapy sources inventory.
 - (1) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.
 - (2) A licensee shall make a record of brachytherapy source utilization which includes:
 - (A) The names of the individuals permitted to handle the sources;
 - (B) The number and activity of sources removed from storage, the room number of use and patient'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
 - (C) The number and activity of sources returned to storage, the room number of use and patient'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.
 - (3) Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
 - (4) A licensee shall maintain records required in paragraphs (2) and (3).
 - (e) Release of patients treated with temporary implants.
 - (1) Immediately after removing the last temporary implant source from a patient, the licensee shall perform a radiation survey of the patient 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 treated by temporary implant until all sources have been removed.
 - (2) A licensee shall maintain a record of patient surveys which demonstrate compliance with paragraph (1). Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed in millirems (microsieverts) per hour and measured within one meter from the patient, and the initials of the individual who made the survey.
 - (f) A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over a range 0.1 millirem (one microsievert) per hour to fifty millirems (five

hundred microsieverts) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The instruments shall be operable and calibrated in accordance with section 11-45-141. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-160 Reserved.

§11-45-161 Reserved.

§11-45-162 Reserved.

§11-45-163 Reserved.

§11-45-164 Reserved.

§11-45-165 Training for radiation safety officer. An individual fulfilling the responsibilities of the radiation safety officer shall:

- (1) Be certified by the:
 - (A) American Board of Health Physics in Comprehensive Health Physics; or
 - (B) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or
 - (C) American Board of Nuclear Medicine; or
 - (D) American Board of Science in Nuclear Medicine; or
 - (E) Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or
 - (F) American Board of Medical Physics in Radiation Oncology Physics; or
 - (G) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or
- (2) Have had two hundred hours of classroom and laboratory training covering:
 - (A) Radiation physics and instrumentation;
 - (B) Radiation protection;
 - (C) Mathematics pertaining to the use and measurement of radioactivity;
 - (D) Radiation biology; and
 - (E) Radiopharmaceutical chemistry; and
 - (F) Have had one year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on a department

license, agreement state, licensing state, or a U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

- (3) Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-166 Training for experienced radiation safety officer. An individual identified as a radiation safety officer on a license, or a U.S. Nuclear Regulatory Commission license on the effective date of this chapter who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of section 11-45-165. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-167 Training for uptake, dilution, or excretion studies. Except as provided in sections 11-45-169 and 11-45-170, the licensee shall require the authorized user of a radiopharmaceutical listed in section 11-45-155 to be a physician who:

- (1) Is certified in:
- (A) Nuclear medicine by the American Board of Nuclear Medicine; or
 - (B) Diagnostic radiology by the American Board of Radiology; or
 - (C) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - (D) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
 - (E) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (2) 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. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-168 Training for imaging and localization studies. Except as provided in sections 11-45-169 and 11-45-170, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in section 11-45-156 to be a physician who:

- (1) Is certified in:
- (A) Nuclear medicine by the American Board of

- Nuclear Medicine; or
 - (B) Diagnostic radiology by the American Board of Radiology; or
 - (C) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - (D) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or
 - (E) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
- (2) 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.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-169 Training for experienced authorized users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an agreement state license, or U.S. Nuclear Regulatory Commission license on the effective date of this chapter who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of sections 11-45-165 and 11-45-171. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-170 Physician training in a three-month program. A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of sections 11-45-167 or 11-45-168. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-171 Recentness of training. The training and experience specified in sections 11-45-165 through 11-45-168 shall have been obtained within the five years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 8

ANALYTICAL X-RAY EQUIPMENT

§11-45-172 Purpose and scope. This subchapter provides requirements for analytical x-ray equipment (x-ray diffraction and

fluorescence analysis). The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements in this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-173 Exemptions. Equipment utilizing sources of radiation licensed by the U.S. Nuclear Regulatory Commission are exempt from the requirements of this subchapter to the extent they are regulated by the U.S. Nuclear Regulatory Commission. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-174 Equipment requirements. (a) A safety 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 licensee may apply to the department for an exemption from the requirement of a safety device. Such application shall include:

- (1) A description of the various safety devices that have been evaluated;
- (2) The reason each of these devices cannot be used; and
- (3) A description of the alternative methods that shall be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area shall be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of:

- (1) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or
- (2) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

- (1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or
- (2) 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.

(d) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these rules, warning devices shall have fail-safe characteristics.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which shall prevent casual opening.

(f) All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and

the words:

- (1) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and
- (2) "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
- (3) "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with subchapter 4 if the radiation source is a radionuclide.

(g) On open-beam configurations installed after the effective date of these rules, 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.

(h) Each radiation source housing shall be subject to the following requirements:

- (1) 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; and
- (2) 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 five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 millisievert) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(i) Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 microsieverts) in one hour. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-175 Area requirements. (a) 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 subchapter 4. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Radiation surveys, as required by subchapter 4, of all analytical x-ray systems sufficient to show compliance with subsection (a) shall be performed:

- (1) Upon installation of the equipment, and at least once every twelve months thereafter;
- (2) Following any change in the initial arrangement, number, or type of local components in the system;
- (3) Following any maintenance requiring the disassembly or removal of a local component in the system;

- (4) 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;
- (5) Any time a visual inspection of the local components in the system reveals an abnormal condition; and
- (6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in subchapter 4.

(c) Radiation survey measurements shall not be required if a licensee can demonstrate compliance with subchapter 4 to the satisfaction of the department.

(d) 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 subchapter 4. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-176 Operating requirements. (a) 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.

(b) 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.

(c) Except as specified in subsection (b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and shall remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures licensed by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-177 Personnel requirements. (a) 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:

- (1) Identification of radiation hazards associated with the use of the equipment;
 - (2) Significance of the various radiation warning, 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;
 - (3) Proper operating procedures for the equipment;
 - (4) Recognition of symptoms of an acute localized exposure; and
 - (5) Proper procedures for reporting an actual or suspected exposure.
- (b) Finger or wrist dosimetric devices shall be provided to and shall be used by:
- (1) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
 - (2) 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.
- (c) Reported dose values shall not be used for the purpose of determining compliance with subchapter 4 unless evaluated by a qualified health or medical physicist. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 9

PARTICLE ACCELERATORS

§11-45-178 Purpose and scope. (a) This subchapter establishes requirements for the non-healing arts use of particle accelerators. The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements in this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-179 General requirements. (a) The licensee shall be qualified by reason of training and experience to use the accelerator in such a manner as to minimize danger to public health and safety or property.

(b) The licensee's equipment, facilities, and operating and emergency procedures shall be adequate to protect health and minimize danger to public health and safety or property.

(c) The licensee shall appoint a radiation safety officer.

(d) The licensee and the licensee's staff shall have experience in the use of particle accelerators and training for application to its intended uses.

(e) The licensee shall establish a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the department.

(f) The licensee shall have a training program for operators of particle accelerators. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-180 Reserved.

§11-45-181 Limitations. (a) No licensee shall permit an individual to act as an operator of a particle accelerator until such individual:

- (1) Has been instructed in radiation safety and has demonstrated an understanding thereof;
- (2) Has received copies of and instruction in this subchapter and the applicable requirements of this chapter, pertinent license conditions and the licensee's operating and emergency procedures, and shall have demonstrated understanding thereof; and
- (3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which shall be employed.

(b) 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.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-182 Shielding and safety design requirements. (a) A qualified health or medical physicist shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with subchapter 4. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-183 Particle accelerator controls and interlock systems. (a) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the accelerator under conditions of barrier penetration.

(c) Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

(d) All safety interlocks shall be designed so that any

defect or component failure in the safety interlock system prevents operation of the accelerator.

(e) 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.

(f) 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.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-184 Warning devices. (a) Each location designated as 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.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for fifteen seconds before the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with subchapter 4. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-185 Operating procedures. (a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the department for three years.

(d) Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the department and shall be available to the operator at each accelerator facility.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

- (1) Authorized by the radiation safety committee or radiation safety officer;
- (2) Recorded in a permanent log and a notice posted at the accelerator control console; and
- (3) Terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-186 Radiation monitoring requirements. (a) 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.

(b) A radiation protection survey shall be performed and documented by a qualified health or medical physicist when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(d) All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

(g) All surveys shall be made in accordance with the written procedures established by a qualified health or medical physicist or the radiation safety officer.

(h) Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-187 Ventilation systems. (a) Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced shall not be exposed to airborne radioactive material in excess of those limits specified in subchapter 4.

(b) A licensee shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area, except as authorized by subchapter 4. Concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as low as is reasonably achievable.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

Subchapter 10

NOTICES, INSTRUCTIONS, REPORTS, AND INSPECTIONS

§11-45-188 Purpose and scope. This subchapter establishes requirements for notices, instructions, and reports by licensees to individuals engaged in activities under a license and options available to such individuals in connection with department inspections of licensees to ascertain compliance with this chapter. This subchapter applies to all persons who receive, possess, use, own, or transfer sources of radiation licensed pursuant to subchapter 2. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-189 Posting of notices to workers. (a) Each licensee shall post current copies of the following documents:

- (1) This subchapter and subchapter 4;
- (2) License and documents incorporated into the license by reference and amendments thereto;
- (3) The operating procedures applicable to activities under the license; and
- (4) Any violation involving radiological working conditions, or order issued pursuant to this chapter, and any response from the licensee.

(b) If posting of a document specified in subsection (a) is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

(c) Department form "Notice to Employees" shall be posted by each licensee as required by this subchapter.

(d) Department documents posted pursuant to subsection (a) shall be posted within five working days after receipt of the documents from the department; the licensee's response, if any, shall be posted within five working days after dispatch from the licensee. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license 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. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-190 Instructions to workers. (a) All individuals likely to receive an occupational dose:

- (1) Shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;
- (2) Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in

precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

- (3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of this chapter for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;
- (4) Shall be instructed of their responsibility to report promptly to the licensee any condition which may constitute, lead to, or cause a violation of this chapter, or cause unnecessary exposure to radiation or radioactive material;
- (5) Shall be 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
- (6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to section 11-45-191.

(b) The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-191 Notifications and reports to individuals. (a) 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 this section. The information reported shall include data and results obtained pursuant to this chapter, orders, or license conditions, as shown in records maintained by the licensee pursuant to section 11-45-83. Each notification and report shall:

- (1) Be in writing;
- (2) Include appropriate identifying data such as the name of the licensee, the name of the individual, and the individual's identification number, preferably social security number;
- (3) Include the individual's exposure information; and
- (4) Contain the following statement:
"This report is furnished to you under the provisions of chapter 45. You should preserve this report for further reference."

(b) Each licensee shall advise each worker annually of the worker's dose as shown in records maintained by the licensee pursuant to section 11-45-83.

(c) Each licensee shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee. The report shall include the dose record for each year the worker was required to be monitored pursuant to section 11-45-54. Such report shall be furnished within thirty days from date the request

was made, or within thirty days after the dose of the individual has been determined by the licensee, 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 in which the worker participated during this period.

(d) When a licensee is required pursuant to section 11-45-90 to report to the department any exposure of an individual to sources of radiation, the licensee shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.

(e) At the request of a worker who is terminating employment with the licensee in work involving exposure to radiation or radioactive material, during the current year, each licensee 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 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.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-192 Presence of representatives of licensees and workers during inspection. (a) Each licensee shall afford to the department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to this chapter.

(b) During an inspection, department inspectors may consult privately with workers as specified in section 11-45-193.

The licensee may accompany department inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during department inspections, the licensee 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.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee and shall have received instructions as specified in section 11-45-190.

(e) Different representatives of licensees 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.

(f) With the approval of the licensee and the workers' representative, an individual who is not routinely engaged in work under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany department inspectors during the

inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-193 Consultation with workers during inspections.

(a) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of this chapter to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) 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 this chapter, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's control. Any such notice in writing shall comply with the requirements of section 11-45-194.

(c) The provisions of subsection (b) shall not be interpreted as authorization to disregard instructions pursuant to section 11-45-190. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-194 Requests by workers for inspections. (a) Any worker or representative of workers believing that a violation of this chapter, or license conditions exists or has occurred in work under a license with regard to radiological working conditions in which the worker is engaged may request an inspection by giving the alleged violation to the department. 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 by the department no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's 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 department.

(b) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in subsection (a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(c) No licensee, or contractor or subcontractor of a

licensee 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 this chapter or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this subchapter.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-195 Inspections not warranted; informal review. (a)

If the department determines, with respect to a complaint under section 11-45-194, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the department. The department shall provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the department. The department shall provide the complainant with a copy of such statement by certified mail.

(b) Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant shall be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the department shall affirm, modify, or reverse the determination and furnish the complainant and the licensee a written notification of the decision and the reason thereof.

(c) If the department determines that an inspection is not warranted because the requirements of section 11-45-194(a) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of section 11-45-194(a). [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-196 Reserved.

§11-45-197 Reserved.

§11-44-198 Reserved.

§11-44-199 Reserved.

SUBCHAPTER 11

HEALTH PHYSICS SERVICES AND MEDICAL PHYSICS SERVICES

§11-45-200 Purpose and scope. This subchapter establishes requirements for health physics services and medical physics services and the use of these services for radiation facilities. The requirements of this subchapter apply to all persons who provide health physics services or medical physics services and to all licensees requiring these services. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-201 General requirements. (a) All persons licensed for health physics services shall have at least one qualified health physicist certified by the American Board of Health Physics in the appropriate fields or specialties in which services are provided.

(b) All persons licensed for medical physics services shall have at least one qualified medical physicist with qualifications in the appropriate fields or specialties in which services are provided.

(c) Qualified medical physicists shall be:

- (1) Medical physicists certified in an appropriate field or specialty by The American Board of Radiology; or The American Board of Medical Physics; or The American Board of Science in Nuclear Medicine; or The Canadian College of Physicists in Medicine; or
- (2) Within six months after the effective date of these rules, medical physicists who are not certified in an appropriate specialty by one of the boards specified in paragraph (1) but have the following formal education, training, and experience:

(A) Master or doctorate degree in a physical science or engineering with not less than thirty semester hours or equivalent in college level physics and/or radiation science with at least one year of full time work experience in an appropriate field under the supervision of a qualified medical physicist who meets the requirements specified in paragraph (1); and one year of training in an appropriate field in medical physics; or

(B) Bachelor degree in a physical science or engineering with at least five years of full time work experience in an appropriate field under the supervision of a qualified medical physicist who meets the requirements specified in paragraph (1); and one year of training in an appropriate field in medical physics.

(d) Qualified medical physicists for mammography shall be medical physicists who are certified by the American Board of

Radiology or the American Board of Medical Physics, and who meet the requirements specified by the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900.

(e) All surveys, audits, reports, and other work performed by a health physics service or medical physics service for licensed facilities shall be reviewed and signed by a qualified health physicist or a qualified medical physicist, respectively. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-44-202 Records. (a) All health physics services or medical physics services shall have records of services provided to licensed facilities with sources of radiation.

(b) Records shall be maintained for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-44-203 Use of medical physics services. (a) In addition to specifications requiring the use of a qualified medical physicist pursuant to this chapter, medical physics services shall be utilized by licensees who provide the following services:

- (1) Mammography;
- (2) Diagnostic and therapeutic use of radioactive materials;
- (3) Therapeutic use of sources of radiation; or
- (4) Fluoroscopy.

(b) To assure radiation protection and quality control pursuant to this chapter, licensees providing services specified in subsection (a) shall have surveys physically conducted at least annually by, or under the direction of, a qualified medical physicist.

(c) Records of surveys shall be maintained by the licensee for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-44-204 Reserved.

SUBCHAPTER 12

TRANSPORTATION OF RADIOACTIVE MATERIAL

§11-45-205 Purpose and scope. This subchapter establishes requirements for transportation of radioactive material and applies to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-206 General requirements. (a) Each licensee who transports radioactive material outside of the confines of the licensee's premises or other place of use, or who delivers radioactive material to a carrier for transport, shall:

- (1) Comply with the regulations of the U.S. Department of Transportation; and
- (2) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

(b) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed radioactive material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 13

WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

§11-45-207 Purpose and scope. This subchapter establishes requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements of this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-208 Exemptions. Sources of radiation licensed by U.S. Nuclear Regulatory Commission are exempt from the requirements of this subchapter to the extent they are regulated by the U.S. Nuclear Regulatory Commission. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-209 Prohibition. No licensee shall perform wireline service operations with a sealed source(s) unless, before commencement of the operation, the licensee has a written agreement with the well-operator, well-owner, drilling contractor, or land owner that:

- (1) In the event a sealed source is lodged downhole, a reasonable effort at recovery shall be made; and
- (2) In the event a decision is made to abandon the sealed source downhole, the requirements of section 11-45-231(c) shall be met. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-210 Limits on levels of radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of subchapter 12 and the dose limitation requirements of subchapter 4 are met.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-211 Storage precautions. (a) Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which shall minimize danger from explosion or fire.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-212 Transport precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-213 Radiation survey instruments. (a) The licensee shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this subchapter and subchapter 4. Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs per kilogram) per hour through at least fifty milliroentgens (12.9 microcoulombs per kilogram) per hour. Survey instruments acquired before the effective date of this chapter and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs per kilogram) per hour through at least twenty milliroentgens (5.16 microcoulombs per kilogram) per hour also satisfies this requirement five years after the effective date of this chapter.

(b) Each radiation survey instrument shall be calibrated:

- (1) At intervals not to exceed six months and after each instrument servicing;
- (2) For linear scale instruments, at two points located approximately one-third and two-thirds 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 appropriate points; and
- (3) So that accuracy within twenty percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained at the facility for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-214 Leak testing of sealed sources. (a) 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 or becquerels and maintained for inspection by the department for three years.

(b) Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the department. 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 to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (one hundred eighty-five becquerels) of radioactive material on the test sample.

(c) Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made before 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.

(d) If the test reveals the presence of 0.005 microcurie (one hundred eighty-five becquerels) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with this chapter. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the department within five days of receiving the test results.

(e) The following sources are exempt from the periodic leak test requirements of subsections (a) through (d):

- (1) Sources of radioactive material with a half-life of thirty days or less;
- (2) Sealed sources of radioactive material in gaseous form;
- (3) Sources of beta- or gamma-emitting radioactive material with an activity of one hundred microcuries (3.7 megabecquerels) or less; and
- (4) Sources of alpha-emitting radioactive material with an activity of ten microcuries (0.370 megabecquerels) or less. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-215 Quarterly inventory. Each licensee shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for inspection by the department for three years and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-216 Utilization records. Each licensee shall maintain current records, which shall be kept available for inspection by the department for three years, showing the following information for each source of radiation:

- (1) Make, model number, and a serial number, or a description of each source of radiation used;
 - (2) The identity of the well-logging supervisor or field unit to whom assigned;
 - (3) Locations where used and dates of use; and
 - (4) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.
- [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-217 Design, performance, and certification criteria for sealed sources used in downhole operations. (a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured one year after the effective date of this chapter shall be certified by the manufacturer, or other testing organization acceptable to the department, to meet the following minimum criteria:

- (1) Be of doubly encapsulated construction;
- (2) Contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and
- (3) Has been individually pressure tested to at least 24,656 pounds per square inch absolute (one hundred seventy MN/m²) without failure.

(b) For sealed sources, except those containing radioactive material in gaseous form, acquired one year after the effective date of this chapter, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of subsection (a), the sealed source shall not be put into use until such determinations and testing have been performed.

(c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations two years after the effective date of this chapter shall be certified by the manufacturer, or other testing organization acceptable to the department, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N43.6, "Classification of Sealed Radioactive Sources," formerly N542, ANSI/NBS 126.

(d) Certification documents shall be maintained for inspection by the department for three years. If the source is abandoned downhole, the certification documents shall be maintained until the department authorizes disposition.

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-218 Labeling. (a) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER (OR CAUTION)
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER (OR CAUTION)
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES [OR NAME OF COMPANY]

[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-219 Inspection and maintenance. (a) Each licensee shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for inspection by the department for three years.

(b) If any inspection conducted pursuant to subsection (a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(c) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the department.

(d) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the department. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-220 Reserved.

§11-45-221 Training requirements. (a) No licensee shall permit any individual to act as a logging supervisor as defined in this chapter until such individual has:

(1) Received, in a course recognized by the department,

instruction in the subjects outlined in Appendix A of this subchapter and demonstrated an understanding thereof;

- (2) Read and received instruction in the requirements contained in this subchapter and the applicable requirements of this chapter, license conditions, and the licensee's operating and emergency procedures, and demonstrated an understanding thereof; and
 - (3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which shall be used on the job.
- (b) No licensee shall permit any individual to assist in the handling of sources of radiation until such individual has:
- (1) Read or received instruction in the licensee's operating and emergency procedures and demonstrated an understanding thereof; and
 - (2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which shall be used on the job.
- (c) The licensee shall maintain employee training records for inspection by the department for three years.
- (d) The exhibit at the end of chapter 11-45 entitled, "Appendix A of Subchapter 13, Subjects to be Included in Training Courses for Logging Supervisors (2/2/93)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-222 Operating and emergency procedures. The licensee's operating and emergency procedures shall include instructions in at least the following:

- (1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in subchapter 4;
- (2) Methods and occasions for conducting radiation surveys;
- (3) Methods and occasions for locking and securing sources of radiation;
- (4) Personnel monitoring and the use of personnel monitoring equipment;
- (5) Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;
- (6) Minimizing exposure of individuals in the event of an accident;
- (7) Procedure for notifying proper personnel in the event of an accident;
- (8) Maintenance of records;
- (9) Use, inspection and maintenance of source holders, logging tools, source handling tools, storage

- containers, transport containers, and injection tools;
- (10) Procedure to be followed in the event a sealed source is lodged downhole;
 - (11) Procedures to be used for picking up, receiving, and opening packages containing radioactive material;
 - (12) For the use of tracers, decontamination of the environment, equipment, and personnel;
 - (13) Maintenance of records generated by logging personnel at temporary jobsites;
 - (14) Notifying proper persons in the event of an accident; and
 - (15) Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by section 11-45-213. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-223 Personnel monitoring. (a) No licensee shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD shall be promptly processed.

(b) Personnel monitoring records shall be maintained for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-224 Security. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-225 Handling tools. The licensee shall provide and require the use of tools that shall assure remote handling of sealed sources other than low-activity calibration sources. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-226 Subsurface tracer studies. (a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or

inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-227 Particle accelerators. No licensee 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 so controlled or shielded that the requirements of subchapter 4, as applicable, are met. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-228 Radiation surveys. (a) Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

(b) Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation. These surveys shall include measurements of radiation levels before and after the operation.

(e) Records required pursuant to subsections (a) through (d) shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the department for three years. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-229 Documents and records required at field stations. Each licensee shall maintain, for inspection by the department, the following documents and records for the specific devices and sources used at the field station:

- (1) License;
- (2) Operating and emergency procedures;
- (3) Chapter 11-45;
- (4) Records of the latest survey instrument calibrations pursuant to section 11-45-213;
- (5) Records of the latest leak test results pursuant to section 11-45-214;
- (6) Records of quarterly inventories required pursuant to section 11-45-215;

- (7) Utilization records required pursuant to section 11-45-216;
- (8) Records of inspection and maintenance required pursuant to section 11-45-219;
- (9) Survey records required pursuant to section 11-45-228; and
- (10) Training records required pursuant to section 11-45-221. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-230 Documents and records required at temporary jobsites. Each licensee conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the department:

- (1) Operating and emergency procedures;
- (2) Survey records required pursuant to section 11-45-228 for the period of operation at the site;
- (3) Evidence of current calibration for the radiation survey instruments in use at the site;
- (4) Copy of license; and
- (5) Shipping papers for the transportation of radioactive material. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-231 Notification of incidents, abandonment, and lost sources. (a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of subchapter 4.

- (b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
 - (1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
 - (2) Notify the department immediately by telephone and subsequently, within thirty days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.
- (c) When it becomes apparent that efforts to recover the radioactive source shall not be successful, the licensee shall
 - (1) Advise the well-operator of an appropriate method of abandonment, which shall include:
 - (A) The immobilization and sealing in place of the radioactive source with a cement plug,
 - (B) The setting of a whipstock or other deflection

- device, and
- (C) The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by subsection (d);
- (2) Notify the department by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and
- (3) File a written report with the department within thirty days of the abandonment. The licensee shall send a copy of the report to the agency who issued permits or otherwise approved of the drilling operation. The report shall contain the following information:
 - (A) Date of occurrence;
 - (B) A description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;
 - (C) Surface location and identification of the well;
 - (D) Results of efforts to immobilize and seal the source in place;
 - (E) A brief description of the attempted recovery effort;
 - (F) Depth of the source;
 - (G) Depth of the top of the cement plug;
 - (H) Depth of the well;
 - (I) Any other information, such as a warning statement, contained on the permanent identification plaque; and
 - (J) The names of state agencies receiving a copy of this report.
- (d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:
 - (1) Be constructed of long-lasting material, such as stainless steel or monel; and
 - (2) Contain the following information engraved on its face:
 - (A) The word "CAUTION";
 - (B) The radiation symbol without the conventional color requirement;
 - (C) The date of abandonment;
 - (D) The name of the well-operator or well-owner;
 - (E) The well name and well identification number(s) or other designation;
 - (F) The sealed source(s) by radionuclide and activity;
 - (G) The source depth and the depth to the top of the plug; and
 - (H) An appropriate warning, depending on the specific circumstances of each abandonment.
- (e) The licensee shall immediately notify the department by telephone and subsequently by confirming letter if the licensee

knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

SUBCHAPTER 14

THERAPEUTIC RADIATION MACHINES

§11-45-232 Purpose and scope. This subchapter establishes requirements for the use of therapeutic radiation machines. The requirements of this subchapter are in addition to, and not in substitution for, other applicable requirements of this chapter. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-233 General administrative requirements for facilities using therapeutic radiation machines. (a) The licensee shall be responsible for directing the operation of the therapeutic radiation machine. The licensee or the licensee's agent shall ensure that the requirements of this subchapter are met in the operation of the therapeutic radiation machine(s).

(b) A therapeutic radiation machine which does not meet the provisions of this subchapter shall not be used for irradiation of patients.

(c) The licensee for any therapeutic radiation machine subject to section 11-45-236 or section 11-45-238 shall require the authorized user to be a physician who:

- (1) Is certified in:
 - (A) Radiology or therapeutic radiology by the American Board of Radiology; or
 - (B) Radiation oncology by the American Osteopathic Board of Radiology; or
 - (C) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - (D) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- (2) Is in the active practice of therapeutic radiology, and has completed two hundred hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred hours of supervised work experience, and a minimum of three years of supervised clinical experience.
 - (A) To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;

- (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology.
- (B) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
- (i) Review of the full calibration measurements and periodic quality assurance checks;
 - (ii) Preparing treatment plans and calculating treatment times;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a external beam radiation therapy unit or console; and
 - (v) Checking and using radiation survey meters.
- (C) To satisfy the requirement for a period of supervised clinical experience, training shall include 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. The supervised clinical experience shall include:
- (i) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
 - (ii) Selecting proper dose and how it is to be administered;
 - (iii) Calculating the external beam radiation therapy 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
 - (iv) Post-administration follow-up and review of case histories.
- (3) Notwithstanding the requirements of subparagraphs (A) and (B), the licensee for any therapeutic radiation machine less than five hundred kilovolts may also submit the training of the prospective authorized user physician for department review on a case-by-case basis.

(4) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the department.

(d) The licensee for any photon therapy systems (five hundred kilovolts and above) and electron therapy systems (five hundred kilo electron volts and above) shall utilize the services of a qualified medical physicist in radiation therapy.

(e) Individuals operating a therapeutic radiation machine and practicing radiation therapy technology shall be licensed under chapter 11-44.

(f) Written safety procedures shall be developed by a qualified medical physicist and shall be available at the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

(g) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts facility. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

(h) Notwithstanding the provisions of subsection (c), a licensee may permit any physician to act as a visiting authorized user for up to sixty days per calendar year under the following conditions:

- (1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and
- (2) The visiting authorized user meets the requirements established for authorized user(s) in subsection (c).

(i) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's quality management program.

(j) The licensee shall maintain the following information in a separate file or package for each therapeutic radiation machine:

- (1) Report of acceptance testing;
- (2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this subchapter, as well as the name(s) of person(s) who performed such activities;
- (3) Records of major maintenance and/or modifications performed on the therapeutic radiation machine after the effective date of this chapter, as well as the name(s) of person(s) who performed such services;
- (4) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-234 General technical requirements for facilities using therapeutic radiation machines. (a) Protection surveys.

- (1) The licensee shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with this subchapter. The radiation protection survey shall be performed by, or under the direction of, a qualified medical physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:
 - (A) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in subchapter 4; and
 - (B) Radiation levels in unrestricted areas do not exceed the limits specified in subchapter 4.
- (2) In addition to the requirements of paragraph (1), a radiation protection survey shall also be performed before any subsequent medical use and:
 - (A) After making any change in the treatment room shielding;
 - (B) After making any change in the location of the therapeutic radiation machine within the treatment room;
 - (C) After relocating the therapeutic radiation machine; or
 - (D) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.
- (3) The survey record shall indicate all instances where the facility, in the opinion of the qualified medical physicist, is in violation of applicable chapters. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) 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 individual responsible for conducting the survey;
- (4) If the results of the surveys required by subsection (a) indicate any radiation levels in excess of the respective limit specified in paragraph (1), the licensee shall lock the control in the "OFF" position and not use the unit;
 - (A) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the

therapeutic radiation machine shielding, or the treatment room shielding; or

- (B) Until the licensee has received a specific exemption from the department.

(b) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by subchapter 4, before beginning the treatment program the licensee shall:

- (1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with subchapter 4;
- (2) Perform the survey required by subsection (a); and
- (3) Include in the report required by subsection (d), the results of the initial survey, a description of the modification made to comply with paragraph (1), and the results of the second survey.

(c) Dosimetry equipment.

- (1) The licensee shall have a calibrated dosimetry system available for use. The system shall have been calibrated for Cobalt-60 by the National Institute of Standards and Technology or by an American Association of Physicists in Medicine Accredited Dosimetry Calibration Laboratory. The calibration shall have been performed within the previous twenty-four months and after any servicing that may have affected system calibration;
- (2) The licensee shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (1). This comparison shall have been performed within the previous twelve months (six months if the dosimetry system is an ionization chamber) and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in paragraph (1);
- (3) The licensee shall maintain a record of each dosimetry system 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 paragraphs (1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision of, a qualified medical physicist.

(d) The licensee for any therapeutic radiation machine subject to section 11-45-236 or section 11-45-238 shall furnish a copy of the records required in subsections (a) and (b) to the department within thirty days following completion of the action

that initiated the record requirement. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-235 Quality management program. (a) Each applicant or licensee subject to section 11-45-236 or section 11-45-238 shall establish and maintain a written quality management program to provide high confidence that radiation shall be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

- (1) Before administration, a written directive is prepared for any external beam radiation therapy dose;
 - (A) Notwithstanding this paragraph, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user before the administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;
 - (B) Notwithstanding this paragraph, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within forty-eight hours of the oral revision;
 - (C) Notwithstanding this paragraph, if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within twenty-four hours of the oral directive.
 - (2) Before the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;
 - (3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;
 - (4) Each administration is in accordance with the written directive; and
 - (5) Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
- (c) Development of quality management program.

- (1) Each application for a license subject to section 11-45-236 or section 11-45-238 shall develop a quality management program as part of the application required by subchapter 2. The licensee shall implement the program upon issuance of a license by the department;
- (2) Each existing licensee subject to sections 11-45-236 and 11-45-238 shall, within thirty days of the effective date of this chapter, submit to the department a written certification that a quality management program has been implemented.
- (d) As a part of the quality management program, the licensee shall:
 - (1) Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;
 - (2) Conducted these reviews at intervals not to exceed twelve months;
 - (3) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of subsection (b); and
 - (4) Maintain records of each review, including the evaluations and findings of the review.
- (e) The licensee shall evaluate and respond, within thirty days after discovery of the recordable event, to each recordable event by:
 - (1) Assembling the relevant facts including the cause;
 - (2) Identifying what, if any, corrective action is required to prevent recurrence; and
 - (3) Retaining a record, in an auditable form, of the relevant facts and what corrective action, if any, was taken.
- (f) The licensee shall retain:
 - (1) Each written directive; and
 - (2) A record of each administered radiation dose, in an auditable form.
- (g) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.
- (h) The licensee shall evaluate each misadministration and shall take the following actions in response to a misadministration:
 - (1) Notify the department by telephone no later than the next calendar day after discovery of the misadministration;
 - (2) Submit a written report to the department within fifteen days after discovery of the misadministration. The written report shall include: the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to

prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient or the patient's responsible relative or guardian (this person shall subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

- (3) Notify the referring physician and also notify the patient of the misadministration no later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that he/she shall inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within twenty-four hours, the licensee shall notify the patient as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;
- (4) Retain a record of each misadministration. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and
- (5) If the patient was notified, furnish, within fifteen days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the department, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the department can be obtained from the licensee;
 - (i) Aside from the notification requirement, nothing in subsection (h) affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-236 Therapeutic radiation machines of less than five hundred kilovolts.

- (a) When the x-ray tube is operated at its maximum rated

tube current for the maximum kilovolts, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

- (1) Five to fifty kilovolt systems: The leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one hundred millirad (one milligray) in any one hour.
 - (2) Greater than fifty and less than five hundred kilovolt systems: The leakage air kerma rate measured at a distance of one meter from the source in any direction shall not exceed one rad (one centigray) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed thirty rad (thirty centigray) per hour.
- (b) Permanent beam limiting devices: Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.
- (c) Adjustable or removable beam limiting devices:
- (1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;
 - (2) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.
- (d) The filter system shall be so designed that:
- (1) Filters can not be accidentally displaced at any possible tube orientation;
 - (2) For equipment installed after the effective date of this chapter, an interlock system prevents irradiation if the proper filter is not in place;
 - (3) The air kerma rate escaping from the filter slot shall not exceed one rad (one centigray) per hour at one meter under any operating conditions; and
 - (4) Each filter shall be marked as to its material of construction and its thickness.
- (e) Tube immobilization:
- (1) The x-ray tube shall be so mounted that it can not accidentally turn or slide with respect to the housing aperture; and
 - (2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.
- (f) The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.
- (g) Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at one hundred kilovolts, which can be positioned over the entire useful beam exit port during periods

when the beam is not in use.

(h) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

- (1) 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;
- (2) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" 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;
- (3) The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
- (4) The timer shall permit accurate pre-setting and determination of exposure times as short as one second;
- (5) The timer shall not permit an exposure if set at zero;
- (6) The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
- (7) Timer shall be accurate to within one percent of the selected value or one second, whichever is greater.

(i) The control panel, in addition to the displays required by other provisions in this section, shall have:

- (1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
- (2) An indication of whether x-rays are being produced;
- (3) Means for indicating x-ray tube potential and current;
- (4) The means for terminating an exposure at any time;
- (5) A locking device which shall prevent unauthorized use of the therapeutic radiation machine; and
- (6) For therapeutic radiation machines manufactured after the effective date of this chapter, a positive display of specific filter(s) in the beam.

(j) When a control panel may energize more than one x-ray tube:

- (1) It shall be possible to activate only one x-ray tube at any time;
- (2) There shall be an indication at the control panel identifying which x-ray tube is activated; and
- (3) There shall be an indication at the tube housing assembly when that tube is energized.

(k) Target-to-skin distance (TSD): There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(1) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray

"ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(m) Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(n) Facility design requirements for therapeutic radiation machines capable of operating in the range fifty kilovolts to five hundred kilovolts: In addition to shielding adequate to meet requirements of section 11-45-241, the treatment room shall meet the following design requirements:

- (1) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;
- (2) Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(o) Treatment rooms which contain a therapeutic radiation machine capable of operating above one hundred fifty kilovolts shall meet the following additional requirements:

- (1) All protective barriers shall be fixed except for entrance doors or beam interceptors;
- (2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
- (3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall 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; and
- (4) When any door referred to in paragraph (3) is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one hundred millirad (one milligray) per hour.

(p) Full calibration measurements:

- (1) Full calibration of a therapeutic radiation machine subject to section 11-45-236 shall be performed by, or under the direct supervision of, a qualified medical physicist:

(A) Before the first medical use following

- installation or reinstallation of the therapeutic radiation machine;
- (B) At intervals not exceeding one year; and
- (C) Before medical use under the following conditions:
 - (i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and
 - (ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
- (D) Notwithstanding the requirements of subparagraph (C):
 - (i) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - (ii) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in clause (i).
- (2) To satisfy the requirement of paragraph (1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).
- (3) The 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 therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the qualified medical physicist responsible for performing the calibration.
- (q) Periodic quality assurance checks:
 - (1) Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to this section, which are capable of operation at greater than fifty kilovolts.
 - (2) To satisfy the requirement of paragraph (1), quality assurance checks shall meet the following requirements:
 - (A) The licensee shall perform quality assurance

- checks in accordance with written procedures established by the qualified medical physicist; and
- (B) The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subsection (p). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subsection (p), shall be stated.
- (3) The cause for a parameter exceeding a tolerance set by the qualified medical physicist shall be investigated and corrected before the system is used for patient irradiation;
- (4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the qualified medical physicist's quality assurance check procedures, the system shall be recalibrated as required in subsection (p);
- (5) The licensee shall use the dosimetry system described in section 11-45-234(c)(2) to make the quality assurance check required in paragraph (2);
- (6) The licensee shall have the qualified medical physicist review and sign the results of each radiation output quality assurance check at intervals not to exceed one month;
- (7) Therapeutic radiation machines subject to this section shall have safety quality assurance checks of each external beam radiation therapy facility performed at intervals not to exceed one month;
- (8) To satisfy the requirement of paragraph (7), safety quality assurance checks shall ensure proper operation of:
- (A) Electrical interlocks at each external beam radiation therapy room entrance;
 - (B) Proper operation of the "BEAM-ON" and termination switches;
 - (C) Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
 - (D) Viewing systems;
 - (E) Electrically operated treatment room doors from inside and outside the treatment room;
- (9) The licensee shall promptly repair any system identified in paragraph (8) that is not operating properly.
- (10) The licensee shall maintain a record of each quality assurance check required by paragraphs (1) and (7) for three years. The record shall include the date of the

quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

- (r) Operating procedures:
- (1) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subsections (p) and (q) have been met;
- (2) Therapeutic radiation machines shall not be left unattended unless it is secured pursuant to subsection (i);
- (3) When a patient shall be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
- (4) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed fifty kilovolts. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at one hundred kilovolts;
- (5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and
- (6) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above one hundred fifty kilovolts. At energies less than or equal to one hundred fifty kilovolts, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of subchapter 4.

(s) Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The survey instrument(s) shall be operable and calibrated in accordance with section 11-45-240. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-237 Reserved.

§11-45-238 Therapeutic radiation machines - photon therapy systems (five hundred kilovolts and above) and electron therapy

systems (five hundred kilo electron volts and above). (a) Each facility location authorized to use a therapeutic radiation machine in accordance with this section shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one millirem (ten microsieverts) per hour to one thousand millirems (ten millisieverts) per hour. The survey instrument(s) shall be operable and calibrated in accordance with section 11-45-240.

(b) Leakage radiation outside the maximum useful beam in photon and electron modes:

- (1) The absorbed dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;
- (2) Except for the area defined in paragraph (1), the absorbed dose rate in water (excluding that from neutrons) at one meter from the electron path between the source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate in water on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;
- (3) The neutron absorbed dose rate outside the useful beam shall be kept as low as practicable. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area not exceeding eight hundred square centimeters; and
- (4) For each therapeutic radiation machine, the licensee shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (1) through (3) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection.

(c) Leakage radiation through beam limiting devices:

- (1) Photon radiation: All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeters

- by ten centimeters radiation field;
- (2) Electron radiation: All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:
 - (A) A maximum of two percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
 - (B) A maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.
 - (3) Measurement of leakage radiation:
 - (A) Photon radiation: Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters;
 - (B) Electron radiation: Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.
 - (4) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.
 - (d) Filters/wedges:
 - (1) Each filter and/or wedge which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is damaged, the wedge transmission factor shall be redetermined;
 - (2) If the absorbed dose rate information required by subsection (a) 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;

- (3) For equipment manufactured after the effective date of this chapter which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:
 - (A) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
 - (B) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - (C) A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
 - (D) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

(e) For equipment manufactured after the effective date of this chapter, the licensee shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1.

(f) All therapeutic radiation machines subject to this section shall be provided with beam monitoring devices. The sensors for this device shall be fixed in the useful beam during treatment to indicate the air kerma rate or dose rate.

- (1) Equipment manufactured after the effective date of this chapter shall be provided with at least two independently powered integrating dose meters. Alternatively, a common power supply may be used if the production of radiation is terminated upon failure of any common element.
- (2) Equipment manufactured on or before the effective date of this chapter shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;
- (3) The detector and the system into which that detector is incorporated shall meet the following requirements:
 - (A) Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
 - (B) Each detector shall form part of a beam monitoring system from which readings in dose monitor units the absorbed dose at a reference

- point in the treatment volume can be calculated;
- (C) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and
- (D) For equipment manufactured after the effective date of this chapter, the design of the beam monitoring systems shall ensure that the:
 - (i) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and
 - (ii) Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.
- (E) Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of this chapter, each display shall:
 - (i) Maintain a reading until intentionally reset;
 - (ii) Have only one scale and no electrical or mechanical scale multiplying factors;
 - (iii) Utilize a design such that increasing dose is displayed by increasing numbers; and
 - (iv) In the event of power failure, the beam monitoring information required in clause (iii) displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty minute period of time.
- (g) Beam symmetry:
 - (1) Bent-beam linear accelerators subject to this section shall be provided with auxiliary device(s) to monitor beam symmetry;
 - (2) The device(s) referenced in paragraph (1) shall be able to detect field asymmetry greater than ten percent; and
 - (3) The device(s) referenced in paragraph (1) shall be configured to terminate irradiation if the specifications in paragraph (2) cannot be maintained.
- (h) Selection and display of dose monitor units:
 - (1) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;
 - (2) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;
 - (3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and
 - (4) For equipment manufactured after the effective date of this chapter, after termination of irradiation, it shall be necessary for the operator to reset the pre-

selected dose monitor units before irradiation can be initiated.

(i) For equipment manufactured after the effective date of this chapter, a system shall be provided from which readings the air kerma rate or absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in subsection (f) may form part of this system. In addition:

- (1) The dose monitor unit dose rate shall be displayed at the treatment control panel;
- (2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation shall be terminated shall be a record maintained by the licensee;
- (3) For equipment manufactured after the effective date of this chapter, if the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four hundred rads (four grays); and
- (4) For each therapeutic radiation machine, the licensee shall determine, or obtain from the manufacturer, the maximum value(s) specified in paragraphs (2) and (3) for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection.

(j) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy:

- (1) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;
- (2) If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen percent or forty dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and
- (3) For equipment manufactured after the effective date of this chapter, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(k) It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to

termination condition at any time from the operator's position at the treatment control panel.

(1) If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(m) A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

- (1) 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;
- (2) The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" 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;
- (3) For equipment manufactured after the effective date of this chapter, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary for the operator to reset the pre-set time selector;
- (4) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(n) Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

- (1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
- (2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;
- (3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;
- (4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain a verification film, when electron applicators are fitted;
- (5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
- (6) 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.

(o) Equipment capable of generating radiation beams of different energies shall meet the following requirements:

- (1) Irradiation shall not be possible until a selection of

- energy has been made at the treatment control panel;
- (2) The measured energy value selected shall be displayed (megavolts for photons and mega electron volts for electrons) at the treatment control panel before and during irradiation; and
 - (3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
- (p) Therapeutic radiation machines capable of both stationary beam radiation therapy and rotational arc radiation therapy shall meet the following requirements:
- (1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;
 - (2) The mode of operation shall be displayed at the treatment control panel;
 - (3) An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
 - (4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
 - (5) Rotational arc radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement for equipment manufactured after the effective date of this chapter:
 - (A) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any fifteen degrees of arc differs by more than twenty percent from the selected value;
 - (B) Where gantry angle terminates the irradiation in rotational arc radiation therapy, the dose monitor units shall differ by less than five percent from the value calculated from the absorbed dose per unit angle and total angle relationship;
 - (C) An interlock shall be provided to prevent the gantry moving more than five degrees beyond the selected angular limits during rotational arc radiation therapy;
 - (D) An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise rotational arc radiation therapy.
 - (6) Where the beam monitor system terminates the irradiation in rotational arc radiation therapy, the termination of irradiation shall be as required by subsection (j); and
 - (7) For equipment manufactured after the effective date of

this chapter, an interlock system shall be provided to terminate irradiation if movement of the gantry:

- (A) Occurs during stationary beam radiation therapy; or
- (B) Stops during rotational arc radiation therapy unless such stoppage is a pre-planned function.

(q) Facility design requirements for therapeutic radiation machines operating above five hundred kilovolts: In addition to shielding adequate to meet requirements of section 11-45-241, the following design requirements are made:

- (1) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;
- (2) In addition to other requirements specified in this subchapter, the control panel shall also:
 - (A) Be located outside the treatment room;
 - (B) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
 - (C) Provide an indication of whether radiation is being produced; and
 - (D) Include an access control (locking) device which shall prevent unauthorized use of the therapeutic radiation machine;
- (3) Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;
- (4) Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;
- (5) Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which shall indicate when the useful beam is "ON" and when it is "OFF";
- (6) Interlocks shall be provided such that all entrance doors shall 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;
- (7) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with subchapter 4, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the

- useful beam is directed at the designated barrier(s);
- (8) At least one "scram button" or other emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subsection (k). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;
 - (9) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and
 - (10) Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten megavolts before machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.
- (r) Qualified medical physicist support:
- (1) The services of a qualified medical physicist shall be utilized in facilities having therapeutic radiation machines with energies of five hundred kilovolts and above. The qualified medical physicist shall be responsible for:
 - (A) Full calibration(s) required by subsection (t) and protection surveys required by section 11-45-234(a);
 - (B) Supervision and review of dosimetry;
 - (C) Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
 - (D) Quality assurance, including quality assurance check review required by subsections (u) and (v);
 - (E) Consultation with the authorized user in treatment planning, as needed; and
 - (F) Perform calculations/assessments regarding misadministrations.
 - (2) If the qualified medical physicist is not a full-time employee of the licensee, the operating procedures required by subsection (s) shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.
- (s) Operating procedures:
- (1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;
 - (2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of

- section 11-45-234(a), subsections (t) and (u) have been met;
- (3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
 - (4) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and
 - (5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
- (t) Full calibration measurements:
- (1) Full calibration of a therapeutic radiation machine subject to this section shall be performed by, or under the direct supervision of, a qualified medical physicist:
 - (A) Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
 - (B) At intervals not exceeding one year; and
 - (C) Before medical use under the following conditions:
 - (i) Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and
 - (ii) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
 - (D) Notwithstanding the requirements of subparagraph (C):
 - (i) Full calibration of therapeutic radiation machines with multi-energy and/or multi-mode capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - (ii) If the repair, replacement or modification does not affect all modes and/or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in clause (i).
 - (2) To satisfy the requirement of paragraph (1), full calibration shall include all measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";
 - (3) The licensee shall use the dosimetry system described in section 11-45-234(c) to measure the radiation

- output for one set of exposure conditions. The remaining radiation measurements required in paragraph (2) may then be made using a dosimetry system that indicates relative dose rates; and
- (4) The 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 the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the qualified medical physicist responsible for performing the calibration.
 - (u) Periodic quality assurance checks:
 - (1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to this section at intervals not to exceed one week;
 - (2) To satisfy the requirement of paragraph (1), quality assurance checks shall include determination of all parameters for periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";
 - (3) The licensee shall use a dosimetry system which has been inter-compared within the previous six months with the dosimetry system described in section 11-45-234(c)(1) to make the periodic quality assurance checks required in paragraph (2);
 - (4) The licensee shall perform periodic quality assurance checks required by paragraph (1) in accordance with procedures established by the qualified medical physicist;
 - (5) The licensee shall review the results of each periodic radiation output check according to the following procedures:
 - (A) The authorized user and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable range. The therapeutic radiation machine shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable range;
 - (B) If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or qualified medical physicist within three treatment days; and
 - (C) The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.
 - (6) Therapeutic radiation machines subject to this section shall have safety quality assurance checks performed

- at intervals not to exceed one week;
- (7) To satisfy the requirement of paragraph (6), safety quality assurance checks shall ensure proper operation of:
 - (A) Electrical interlocks at each external beam radiation therapy room entrance;
 - (B) Proper operation of the "BEAM-ON", interrupt and termination switches;
 - (C) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
 - (D) Viewing systems;
 - (E) Electrically operated treatment room door(s) from inside and outside the treatment room;
 - (F) At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.
 - (8) The licensee shall promptly repair any system identified in paragraph (7) that is not operating properly; and
 - (9) The licensee shall maintain a record of each quality assurance check required by paragraphs (1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.
[Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71)
(Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-239 Reserved.

§11-45-240 Calibration and check of survey instruments.

- (a) The licensee shall ensure that the survey instruments used to show compliance with this subchapter have been calibrated before first use, at intervals not to exceed twelve months, and following repair.
 - (b) To satisfy the requirements of subsection (a), the licensee shall:
 - (1) Calibrate all required scale readings up to one thousand millirems (ten millisieverts) per hour with an appropriate radiation source;
 - (2) Calibrate at least two points on each scale to be

calibrated. These points should be at approximately one-third and two-thirds of scale rating.

- (c) To satisfy the requirements of subsection (b), the licensee shall:
- (1) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent; and
 - (2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent if a correction factor or graph is conspicuously attached to the instrument.
- (d) The licensee shall retain a record of each calibration required in subsection (a). The record shall include:
- (1) A description of the calibration procedure; and
 - (2) 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.
- (e) The licensee may obtain the services of individuals licensed to perform calibrations of survey instruments. Records of calibrations which contain information required by subsection (d) shall be maintained by the licensee. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

§11-45-241 Shielding and safety design requirements. (a) Each therapeutic radiation machine subject to sections 11-45-236 and 11-45-238 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with subchapter 4.

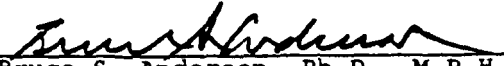
(b) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for department approval before actual installation of the therapeutic radiation machine. The minimum facility design information that shall be submitted is contained in Appendix A to subchapter 14.

(c) The exhibit at the end of chapter 45 entitled "Appendix A of Subchapter 14, Information on Radiation Shielding Required for Plan Reviews (2/2/93)", is made a part of this section. [Eff 11/12/99] (Auth: HRS §§321-10, 321-11, 321-71) (Imp: HRS §§321-1, 321-11(21), 321-71)

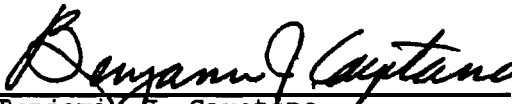
DEPARTMENT OF HEALTH

Chapter 11-40, Hawaii Administrative Rules, was repeal and chapter 11-45, Hawaii Administrative Rules on the Summary Page dated NOV 12 1999, was adopted on NOV 12 1999, following public hearings held on September 8, 1999 in Kailua-Kona, Hawaii, September 9, 1999 in Hilo, Hawaii, September 14, 1999 in Wailuku, Hawaii, September 15, 1999 in Honolulu, Hawaii, and September 16, 1999 in Lihue, Hawaii, after public notice was given in the Hawaii State & County Public Notices on August 2, 1999.

The repeal of chapter 11-40 and the adoption of chapter 11-45 shall take effect ten days after filing with the Office of the Lieutenant Governor.


Bruce S. Anderson, Ph.D., M.P.H.
Director of Health

APPROVED:

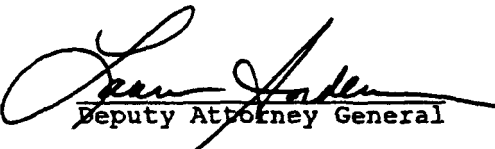

Benjamin J. Cayetano
Governor
State of Hawaii

Dated: 11/1/99

NOV 02 1999

Filed

APPROVED AS TO FORM:


Deputy Attorney General

99 NOV -2 P 1:59

LIEUTENANT GOVERNOR'S
OFFICE

Appendix A of Subchapter 1

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES (2/2/93)

Quality Factor TYPE OF RADIATION	Absorbed Dose (Q)	Equal to a Unit Dose Equivalent ^a
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

^aAbsorbed dose in rad equal to one rem or the absorbed dose in gray equal to one Sv.

Appendix B of Subchapter 1

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE
EQUIVALENT FOR MONOENERGETIC NEUTRONS (2/2/93)

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons ₁ cm ⁻² rem ⁻¹)	Fluence per Unit Dose Equivalent ^b (neutrons ₁ cm ⁻² Sv ⁻¹)
(thermal)	2.5 x 10 ⁻⁸	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻⁷	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻⁶	2	810 x 10 ⁶	810 x 10 ⁸
	1 x 10 ⁻⁵	2	810 x 10 ⁶	810 x 10 ⁸
	1 x 10 ⁻⁴	2	840 x 10 ⁶	840 x 10 ⁸
	1 x 10 ⁻³	2	980 x 10 ⁶	980 x 10 ⁸
	1 x 10 ⁻²	2.5	1010 x 10 ⁶	1010 x 10 ⁸
	1 x 10 ⁻¹	7.5	170 x 10 ⁶	170 x 10 ⁸
	5 x 10 ⁻¹	11	39 x 10 ⁶	39 x 10 ⁸
	1	11	27 x 10 ⁶	27 x 10 ⁸
	2.5	9	29 x 10 ⁶	29 x 10 ⁸
	5	8	23 x 10 ⁶	23 x 10 ⁸
	7	7	24 x 10 ⁶	24 x 10 ⁸
	10	6.5	24 x 10 ⁶	24 x 10 ⁸
	14	7.5	17 x 10 ⁶	17 x 10 ⁸
	20	8	16 x 10 ⁶	16 x 10 ⁸
	40	7	14 x 10 ⁶	14 x 10 ⁸
	60	5.5	16 x 10 ⁶	16 x 10 ⁸
	1 x 10 ²	4	20 x 10 ⁶	20 x 10 ⁸
	2 x 10 ²	3.5	19 x 10 ⁶	19 x 10 ⁸
	3 x 10 ²	3.5	16 x 10 ⁶	16 x 10 ⁸
	4 x 10 ²	3.5	14 x 10 ⁶	14 x 10 ⁸

^aValue of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

^bMonoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

Appendix A of Subchapter 2
EXEMPT CONCENTRATIONS (2/2/93)

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
	Ca-45		9×10^{-5}
Calcium (20)	Ca-47		5×10^{-4}
	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
	Cs-131		2×10^{-2}
Cesium (55)	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
	Cl-38	9×10^{-7}	4×10^{-3}
Chlorine (17)	Cr-51		2×10^{-2}
Chromium (24)	Co-57		5×10^{-3}
Cobalt (27)	Co-58		1×10^{-3}
	Co-60		5×10^{-4}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

Element (atomic number)	Radionuclide	Column I	Column II
		Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152(9.2 h)		6×10^{-4}
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-4}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1</u> /	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2</u> /
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}
	Hg-203		2×10^{-4}
Molybdenum (42)	Mo-99		2×10^{-4}
Neodymium (60)	Nd-147		6×10^{-3}
	Nd-149		3×10^{-3}
Nickel (28)	Ni-65		1×10^{-3}
Niobium (Columbium) (41)	Nb-95		1×10^{-3}
	Nb-97		9×10^{-4}
	Os-185		7×10^{-4}
Osmium (76)	Os-191m		3×10^{-3}
	Os-191		2×10^{-3}
	Os-193		6×10^{-4}
	Pd-103		3×10^{-3}
Palladium (46)	Pd-109		9×10^{-4}
	P-32		2×10^{-4}
Phosphorus (15)	Pt-191		1×10^{-3}
Platinum (78)	Pt-193m		1×10^{-2}
	Pt-197m		1×10^{-2}
	Pt-197		1×10^{-3}
	K-42		3×10^{-3}
Potassium (19)	Pr-142		3×10^{-4}
Praseodymium (59)	Pr-143		5×10^{-4}
	Pm-147		2×10^{-3}
Promethium (61)	Pm-149		4×10^{-4}
	Re-183		6×10^{-3}
Rhenium (75)	Re-186		9×10^{-4}
	Re-188		6×10^{-4}
	Rh-103m		1×10^{-1}
Rhodium (45)	Rh-105		1×10^{-3}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Rubidium (37)	Rb-86		7×10^{-4}
Ruthenium (44)	Ru-97		4×10^{-3}
	Ru-103		8×10^{-4}
	Ru-105		1×10^{-3}
	Ru-106		1×10^{-4}
	Sm-153		8×10^{-4}
Samarium (62)	Sm-153		8×10^{-4}
	Scandium (21)	Sc-46	4×10^{-4}
		Sc-47	9×10^{-4}
	Sc-48	3×10^{-4}	
Selenium (34)	Se-75		3×10^{-3}
Silicon (14)	Si-31		9×10^{-3}
Silver (47)	Ag-105		1×10^{-3}
	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-3}
	Na-24		2×10^{-3}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
	S-35	9×10^{-8}	6×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
	Te-125m		2×10^{-3}
Tellurium (52)	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
	Tb-160		4×10^{-4}
Terbium (65)	Tb-160		4×10^{-3}
	Thallium (81)	Tl-200	
Tl-201			3×10^{-3}
Tl-202			1×10^{-3}
Tl-204			1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
	Tm-171		5×10^{-3}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

Element (atomic number)	Radionuclide	Column I Gas concentration $\mu\text{Ci/ml}$ <u>1/</u>	Column II Liquid and solid concentration $\mu\text{Ci/ml}$ <u>2/</u>
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten (Wolfram) (74)	W-181		4×10^{-3}
	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
	Y-93		3×10^{-3}
Zinc (30)	Zn-65		1×10^{-4}
	Zn-69m		7×10^{-4}
	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta- and/or gamma-emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

1/ Values are given in Column I only for those materials normally used as gases.

2/ $\mu\text{Ci/g}$ for solids.

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Appendix A, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: Where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Appendix A for the specific radionuclide when not in combination. The sum of such ratios may not exceed "1".

Example:
$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} \leq 1$$

Note 3: To convert $\mu\text{Ci/ml}$ to SI units of megabecquerels per liter multiply the above values by 37.

Example: Zirconium (40) Zr-97 ($2 \times 10^{-4} \mu\text{Ci/ml}$ multiplied by 37 is equivalent to $74 \times 10^{-4} \text{ MBq/l}$)

Appendix B of Subchapter 2

EXEMPT QUANTITIES (2/2/93)

Radioactive Material	Micro- curies
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1
Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152)9.2h	100
Europium-152 (Eu 152)13 yr	1
Europium-154 (Eu 154)	1

Radioactive Material	Micro- curies
Europium-155 (Eu 155)	10
Fluorine-18 (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	10
Germanium-71 (Ge 71)	100
Gold-195 (Au 195)	10
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.1
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100

Radioactive Material	Micro- curies
Nickel-63 (Ni 63)	10
Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10

Radioactive Material	Micro- curies
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10

<u>Radioactive Material</u>	<u>Micro- curies</u>
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

Note 1: For purposes of C.25(f)(5)(ii) where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and 1,000 times the amount in Appendix B for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed 1.

Example:

$$\frac{\text{Amt. of Radionuclide A possessed}}{\text{1000 x Appendix B quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{\text{1000 x Appendix B quantity for Radionuclide B}} \leq 1$$

Note 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 μCi multiplied by 37 is equivalent to 370 kBq).

Appendix A of Subchapter 4
 PROTECTION FACTORS FOR RESPIRATORS¹ (2/2/93)

Description ²	Protection Factors ⁴		National Institute for Occupational Safety and Administration	Tested & Certified Equipment National Institute for Occupational Safety and Administration tests for permissibility
	Modes ³	Particu- lates		
I. AIR-PURIFYING RESPIRATORS⁶				
Facepiece, half-mask ⁷	NP	10		30 CFR 11, Subpart K.
Facepiece, full	NP	50		
Facepiece, half-mask full, or hood	PP	1000		
II. ATMOSPHERE-SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	CF		1000	
Facepiece, half-mask	D		5	
Facepiece, full	CF		2000	
Facepiece, full	D		5	30 CFR 11, Subpart J.
Facepiece, full	PD		2000 ⁸	
Hood	CF			
Suit	CF		⁹	10
2. Self-contained breathing apparatus (SCBA)				
Facepiece, full	D		50	
Facepiece, full	PD		10,000 ¹¹	30 CFR 11, Subpart H.
Facepiece, full	RD		50 ¹²	
Facepiece, full	RP		5,000	
III. COMBINATION RESPIRATORS				
Any combination of air-purifying and atmosphere-supplying respirators		Protection factor for type and mode of operation as listed above		30 CFR 11, Sec. 11.63(b).

See next page for footnotes.

FOOTNOTES

1. For use in the selection of respiratory protective equipment to be used only where the contaminants have been identified and the concentrations, or possible concentrations, are known.
2. Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. Hoods and suits are excepted.
3. The mode symbols are defined as follows:
 - CF = continuous flow
 - D = demand
 - NP = negative pressure, that is, negative phase during inhalation
 - PD = pressure demand, that is, always positive pressure
 - PP = positive pressure
 - RD = demand, recirculating or closed circuit
 - RP = pressure demand, recirculating or closed circuit
4. a. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment, usually inside the facepiece, under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:
$$\text{Concentration inhaled} = \frac{\text{Ambient airborne concentration}}{\text{Protection factor}}$$
- b. The protection factors apply:
 - (i) Only for individuals trained in using respirators and wearing properly fitted respirators that are used and maintained under supervision in a well-planned respiratory protective program.
 - (ii) For air-purifying respirators only when high efficiency particulate filters, above 99.97% removal efficiency by thermally generated 0.3 μm dioctyl phthalate (DOP) test or equivalent, are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.
 - (iii) No adjustment is to be made for the use of sorbents against radioactive material in the form of gases or vapors.
 - (iv) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration certification described in 30 CFR 11. Oxygen and air shall not be used in the same apparatus.

5. Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor for respiratory protective equipment is 5, the effective protection factor for tritium is about 1.4; with protection factors of 10, the effective factor for tritium oxide is about 1.7; and with protection factors of 100 or more, the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote 9 concerning supplied-air suits.
6. Canisters and cartridges shall not be used beyond service-life limitations.
7. Under-chin type only. This type of respirator is not satisfactory for use where it might be possible, such as, if an accident or emergency were to occur, for the ambient airborne concentrations to reach instantaneous values greater than 10 times the pertinent values in Table I, Column 3 of Appendix B of Subchapter 4. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.
8.
 - a. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000 may be utilized for tested-and-certified supplied-air hoods when a minimum air flow of 6 cubic feet per minute (0.17 m³/min) is maintained and calibrated air line pressure gauges or flow measuring devices are used. A protection factor of up to 2000 may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than 6 cubic feet per minute (0.17 m³/min) and calibrated air line pressure gauges or flow measuring devices are used.
 - b. The design of the supplied-air hood or helmet, with a minimum flow of 6 cubic feet per minute (0.17 m³/min) of air, may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres. See footnote 9.
9. Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used.

10. No approval schedules are currently available for this equipment. Equipment is to be evaluated by testing or on the basis of reliable test information.
11. This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption, must be taken into account in such circumstances.
12. Quantitative fit testing shall be performed on each individual, and no more than 0.02% leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer.

Note 1: Protection factors for respirators approved by the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health, according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radioactive hazards. The selection and use of respirators for such circumstances should take into account applicable approvals of the U.S. Bureau of Mines and the National Institute for Occupational Safety and Health.

Note 2: Radioactive contaminants, for which the concentration values in Table I, Column 3 of Appendix B of Subchapter 4 are based on internal dose due to inhalation, may present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

Appendix C of Subchapter 4

QUANTITIES¹ OF MATERIAL REQUIRING LABELING (2/2/93)

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-11	1,000	Manganese-51	1,000
Carbon-14	1,000	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62m	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000
Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82m	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-92	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Niobium-88	1,000	Palladium-101	1,000
Niobium-89m (66 min)	1,000	Palladium-103	100
Niobium-89 (122 min)	1,000	Palladium-107	10
Niobium-90	100	Palladium-109	100
Niobium-93m	10	Silver-102	1,000
Niobium-94	1	Silver-103	1,000
Niobium-95m	100	Silver-104m	1,000
Niobium-95	100	Silver-104	1,000
Niobium-96	100	Silver-105	100
Niobium-97	1,000	Silver-106m	100
Niobium-98	1,000	Silver-106	1,000
Molybdenum-90	100	Silver-108m	1
Molybdenum-93m	100	Silver-110m	10
Molybdenum-93	10	Silver-111	100
Molybdenum-99	100	Silver-112	100
Molybdenum-101	1,000	Silver-115	1,000
Technetium-93m	1,000	Cadmium-104	1,000
Technetium-93	1,000	Cadmium-107	1,000
Technetium-94m	1,000	Cadmium-109	1
Technetium-94	1,000	Cadmium-113m	0.1
Technetium-96m	1,000	Cadmium-113	100
Technetium-96	100	Cadmium-115m	10
Technetium-97m	100	Cadmium-115	100
Technetium-97	1,000	Cadmium-117m	1,000
Technetium-98	10	Cadmium-117	1,000
Technetium-99m	1,000	Indium-109	1,000
Technetium-99	100	Indium-110m (69.1m)	1,000
Technetium-101	1,000	Indium-110 (4.9h)	1,000
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000
Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120 (16m)	1,000	Iodine-131	1
Antimony-120 (5.76d)	100	Iodine-132m	100
Antimony-122	100	Iodine-132	100
Antimony-124m	1,000	Iodine-133	10
Antimony-124	10	Iodine-134	1,000
Antimony-125	100	Iodine-135	100
Antimony-126m	1,000	Xenon-120	1,000
Antimony-126	100	Xenon-121	1,000
Antimony-127	100	Xenon-122	1,000
Antimony-128 (10.4m)	1,000	Xenon-123	1,000
Antimony-128 (9.01h)	100	Xenon-125	1,000
Antimony-129	100	Xenon-127	1,000
Antimony-130	1,000	Xenon-129m	1,000
Antimony-131	1,000	Xenon-131m	1,000
Tellurium-116	1,000	Xenon-133m	1,000
Tellurium-121m	10	Xenon-133	1,000
Tellurium-121	100	Xenon-135m	1,000
Tellurium-123m	10	Xenon-135	1,000
Tellurium-123	100	Xenon-138	1,000
Tellurium-125m	10	Cesium-125	1,000
Tellurium-127m	10	Cesium-127	1,000
Tellurium-127	1,000	Cesium-129	1,000
Tellurium-129m	10	Cesium-130	1,000
Tellurium-129	1,000	Cesium-131	1,000
Tellurium-131m	10	Cesium-132	100
Tellurium-131	100	Cesium-134m	1,000
Tellurium-132	10	Cesium-134	10
Tellurium-133m	100	Cesium-135m	1,000
		Cesium-135	100
		Cesium-136	10
		Cesium-137	10
		Cesium-138	1,000

* To convert FCI to kBq, multiply the FCI value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-144	10
Barium-131	100	Promethium-145	10
Barium-133m	100	Promethium-146	1
Barium-133	100	Promethium-147	10
Barium-135m	100	Promethium-148m	10
Barium-139	1,000	Promethium-148	10
Barium-140	100	Promethium-149	100
Barium-141	1,000	Promethium-150	1,000
Barium-142	1,000	Promethium-151	100
Lanthanum-131	1,000	Samarium-141m	1,000
Lanthanum-132	100	Samarium-141	1,000
Lanthanum-135	1,000	Samarium-142	1,000
Lanthanum-137	10	Samarium-145	100
Lanthanum-138	100	Samarium-146	1
Lanthanum-140	100	Samarium-147	100
Lanthanum-141	100	Samarium-151	10
Lanthanum-142	1,000	Samarium-153	100
Lanthanum-143	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150	
Cerium-144	1	(12.62h)	100
Praseodymium-136	1,000	Europium-150	
Praseodymium-137	1,000	(34.2y)	1
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m (5.0h)	1,000	Lutetium-169	100
Terbium-156m (24.4h)	1,000	Lutetium-170	100
Terbium-156	100	Lutetium-171	100
Terbium-157	10	Lutetium-172	100
Terbium-158	1	Lutetium-173	10
Terbium-160	10	Lutetium-174m	10
Terbium-161	100	Lutetium-174	10
Dysprosium-155	1,000	Lutetium-176m	1,000
Dysprosium-157	1,000	Lutetium-176	100
Dysprosium-159	100	Lutetium-177m	10
Dysprosium-165	1,000	Lutetium-177	100
Dysprosium-166	100	Lutetium-178m	1,000
Holmium-155	1,000	Lutetium-178	1,000
Holmium-157	1,000	Lutetium-179	1,000
Holmium-159	1,000	Hafnium-170	100
Holmium-161	1,000	Hafnium-172	1
Holmium-162m	1,000	Hafnium-173	1,000
Holmium-162	1,000	Hafnium-175	100
Holmium-164m	1,000	Hafnium-177m	1,000
Holmium-164	1,000	Hafnium-178m	0.1
Holmium-166m	1	Hafnium-179m	10
Holmium-166	100	Hafnium-180m	1,000
Holmium-167	1,000	Hafnium-181	10
Erbium-161	1,000	Hafnium-182m	1,000
Erbium-165	1,000	Hafnium-182	0.1
Erbium-169	100	Hafnium-183	1,000
Erbium-171	100	Hafnium-184	100
Erbium-172	100	Tantalum-172	1,000
Thulium-162	1,000	Tantalum-173	1,000
Thulium-166	100	Tantalum-174	1,000
Thulium-167	100	Tantalum-175	1,000
Thulium-170	10	Tantalum-176	100
Thulium-171	10	Tantalum-177	1,000
Thulium-172	100	Tantalum-178	1,000
Thulium-173	100	Tantalum-179	100
Thulium-175	1,000	Tantalum-180m	1,000
		Tantalum-180	100
		Tantalum-182m	1,000

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	
Tungsten-176	1,000	(1.4m)	10
Tungsten-177	1,000	Iridium-192	
Tungsten-178	1,000	(73.8d)	1
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182		Platinum-193m	100
(12.7h)	1,000	Platinum-193	1,000
Rhenium-182		Platinum-195m	100
(64.0h)	100	Platinum-197m	1,000
Rhenium-184m	10	Platinum-197	100
Rhenium-184	100	Platinum-199	1,000
Rhenium-186m	10	Platinum-200	100
Rhenium-186	100	Gold-193	1,000
Rhenium-187	1,000	Gold-194	100
Rhenium-188m	1,000	Gold-195	10
Rhenium-188	100	Gold-198m	100
Rhenium-189	100	Gold-198	100
Osmium-180	1,000	Gold-199	100
Osmium-181	1,000	Gold-200m	100
Osmium-182	100	Gold-200	1,000
Osmium-185	100	Gold-201	1,000
Osmium-189m	1,000	Mercury-193m	100
Osmium-191m	1,000	Mercury-193	1,000
Osmium-191	100	Mercury-194	1
Osmium-193	100	Mercury-195m	100
Osmium-194	1	Mercury-195	1,000
Iridium-182	1,000	Mercury-197m	100
Iridium-184	1,000	Mercury-197	1,000
Iridium-185	1,000	Mercury-199m	1,000
Iridium-186	100	Mercury-203	100
Iridium-187	1,000		

* To convert FCI to kBq, multiply the FCI value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-201	1,000	Actinium-224	1
Thallium-200	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100
Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-211	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236	
Francium-222	100	(1.15E+5)	0.001

* To convert FCI to kBq, multiply the FCI value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
Neptunium-236 (22.5h)	1	Curium-242	0.01
Neptunium-237	0.001	Curium-243	0.001
Neptunium-238	10	Curium-244	0.001
Neptunium-239	100	Curium-245	0.001
Neptunium-240	1,000	Curium-246	0.001
Plutonium-234	10	Curium-247	0.001
Plutonium-235	1,000	Curium-248	0.001
Plutonium-236	0.001	Curium-249	1,000
Plutonium-237	100	Berkelium-245	100
Plutonium-238	0.001	Berkelium-246	100
Plutonium-239	0.001	Berkelium-247	0.001
Plutonium-240	0.001	Berkelium-249	0.1
Plutonium-241	0.01	Berkelium-250	10
Plutonium-242	0.001	Californium-244	100
Plutonium-243	1,000	Californium-246	1
Plutonium-244	0.001	Californium-248	0.01
Plutonium-245	100	Californium-249	0.001
Americium-237	1,000	Californium-250	0.001
Americium-238	100	Californium-251	0.001
Americium-239	1,000	Californium-252	0.001
Americium-240	100	Californium-253	0.1
Americium-241	0.001	Californium-254	0.001
Americium-242m	0.001	Einsteinium-250	100
Americium-242	10	Einsteinium-251	100
Americium-243	0.001	Einsteinium-253	0.1
Americium-244m	100	Einsteinium-254m	1
Americium-244	10	Einsteinium-254	0.01
Americium-245	1,000	Fermium-252	1
Americium-246m	1,000	Fermium-253	1
Americium-246	1,000	Fermium-254	10
Curium-238	100	Fermium-255	1
Curium-240	0.1	Fermium-257	0.01
Curium-241	1	Mendelevium-257	10
		Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha- emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

* To convert FCi to kBq, multiply the FCi value by 37.

Radionuclide	Quantity (FCi)*	Radionuclide	Quantity (FCi)*
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NOTE: Where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

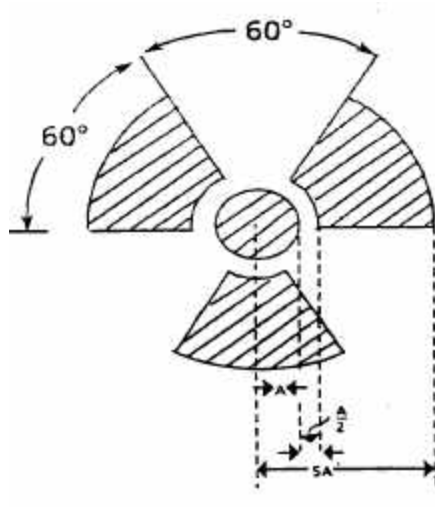
¹The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to Subchapter 4, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 FCi). Values of 3.7 MBq (100 FCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 FCi), to take into account their low specific activity.

* To convert FCi to kBq, multiply the FCi value by 37.

Appendix D of Subchapter 4

RADIATION SYMBOL (8/19/98)

Cross-hatched area is magenta, or purple, or black. The background is yellow.



Appendix A of Subchapter 5

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER TRAINEES (2/2/93)

Training to qualify individuals as radiographer trainees shall be presented on a formal basis and shall include the following subjects:

- I. Fundamentals of Radiation Safety
 - A. Characteristics of radiation
 - B. Units of radiation dose and quantity of radioactivity
 - C. Significance of radiation dose
 - 1. Radiation protection standards
 - 2. Biological effects of radiation
 - 3. Case histories of radiography accidents
 - D. Levels of radiation from sources of radiation
 - E. Methods of controlling radiation dose
 - 1. Working time
 - 2. Working distances
 - 3. Shielding
- II. Radiation Detection Instrumentation to be Used
 - A. Use of radiation survey instruments
 - 1. Operation
 - 2. Calibration
 - 3. Limitations
 - B. Survey techniques
 - C. Use of personnel monitoring equipment
 - 1. Film badges
 - 2. Thermoluminescent dosimeters (TLD)
 - 3. Pocket dosimeters
 - 4. Alarm ratemeter
- III. The Requirements of Pertinent Federal and State Regulations
- IV. The Registrant's Written Operating and Emergency Procedures
- V. Radiographic Equipment to be Used
 - A. Remote handling equipment
 - B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed)
 - C. Storage and transport containers, source changers
 - D. Operation and control of x-ray equipment
 - E. Collimators

Appendix A of Subchapter 6

TIME-TEMPERATURE CHART (2/2/93)

Thermometer Reading (degrees)		Minimum Developing Time (minutes)
C	F	
26.7	80	2
26.1	79	2
25.6	78	2 1/2
25.0	77	2 1/2
24.4	76	3
23.9	75	3
23.3	74	3 1/2
22.8	73	3 1/2
22.2	72	4
21.7	71	4
21.1	70	4 1/2
20.6	69	4 1/2
20.0	68	5
19.4	67	5 1/2
18.9	66	5 1/2
18.3	65	6
17.8	64	6 1/2
17.2	63	7
16.7	62	8
16.1	61	8 1/2
15.6	60	9 1/2

Appendix B of Subchapter 6

TEMPERATURE-IMMERSION CHART (2/2/93)

Developer Temperature		Minimum Immersion Time*
EC	EF	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

*Immersion time only, no crossover time included.

Appendix C of Subchapter

HALF-VALUE LAYER (7/25/96)

Design Operating Range	<u>X-Ray Tube Voltage</u> (kilovolt peak)	<u>Minimum Half-Value Layer</u> (millimeters of aluminum)	
	Measured Potential (kVp)	Dental Intraoral Manufactured Before 8/1/74 & On or After 12/1/80	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

Appendix A of Subchapter 13

SUBJECTS TO BE INCLUDED IN TRAINING COURSES
FOR LOGGING SUPERVISORS (2/2/93)

- I. Fundamentals of Radiation Safety
 - A. Characteristics of radiation
 - B. Units of radiation dose and quantity of radioactivity
 - C. Significance of radiation dose
 - 1. Radiation protection standards
 - 2. Biological effects of radiation dose
 - D. Levels of radiation from sources of radiation
 - E. Methods of minimizing radiation dose
 - 1. Working time
 - 2. Working distances
 - 3. Shielding
 - F. Radiation safety practices including prevention of contamination and methods of decontamination
- II. Radiation Detection Instrumentation to be Used
 - A. Use of radiation survey instruments
 - 1. Operation
 - 2. Calibration
 - 3. Limitations
 - B. Survey techniques
 - C. Use of personnel monitoring equipment
- III. Equipment to be Used
 - A. Handling equipment
 - B. Sources of radiation
 - C. Storage and control of equipment
 - D. Operation and control of equipment
- IV. The Requirements of Pertinent Federal and State Regulations
- V. The Licensee's Written Operating and Emergency Procedures
- VI. The Licensee's Recordkeeping Procedures

Appendix A of Subchapter 14

INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS (2/2/93)

I. ALL THERAPEUTIC RADIATION MACHINES

- A. Basic facility information including: name, telephone number and department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address including room number of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).
- B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.
- C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. THERAPEUTIC RADIATION MACHINES UP TO ONE HUNDRED FIFTY kV
(PHOTONS ONLY)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to one hundred fifty kV shall submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.
- B. Maximum design workload for the facility including total weekly radiation output, expressed in gray (rad) or air kerma at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.
- C. A facility blueprint/drawing indicating: scale 0.25 inch = one foot is typical; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with subchapter 4.
- D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
- E. 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.
- F. At least one example calculation which shows the methodology used to determine the amount of shielding

required for each physical condition (ie: primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

- (1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.
- (2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

III. THERAPEUTIC RADIATION MACHINES OVER ONE HUNDRED FIFTY KV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of one hundred fifty kV and/or electrons and/or protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (ie: photon, electron).
The source to isocenter distances shall be specified.
- B. Maximum design workload for the facility including total weekly radiation output expressed in gray (rad) at one meter, total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.
- C. Facility blueprint/drawing including both floor plan and elevation views indicating relative orientation of the therapeutic radiation machine, scale 0.25 inch = one foot is typical, type(s), thickness and minimum density of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.
- D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
- E. 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.
- F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (ie., room may be designed for six MV unit although only a four MV unit is currently proposed, work-load, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.
- G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (ie., primary and secondary/leakage barriers, restricted and

unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

- (1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.
- (2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above ten MV shall submit shielding plans which contain, as a minimum, the following additional information:

- A. The structural composition, thickness, minimum density and location of all neutron shielding material.
- B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.
- C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (ie., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.
 - (1) If commercial software is used to generate shielding requirements, please also identify the software used and the version/ revision date.
 - (2) If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.
- D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. REFERENCES

- A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).
- B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).
- C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).