From: Black, Traci L (DOH)
To: Henderson, Pamela; Schneider, Kathleen
Cc: Halvorson, Clark R (DOH); Austin, Michelle (DOH)
Subject: RATS ID 2007-3
Date: Thursday, August 02, 2012 2:46:53 PM
Attachments: 2007-3 WA Response.pdf

August 2, 2012

Pamela Henderson, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

SUBJECT: RATS ID 2007-3

Dear Ms. Henderson:

Attached is a copy of the final revisions to the Washington Radiological Health Rules for RATS ID 2007-3, Requirements for expanded definition of byproduct material.

RATS ID	Title	State Rules and Sections
2007-3	Requirements for expanded definition of byproduct material	WAC 246-220-010 WAC 246-249-090 WAC

246-249-010

WAC 246-233-020

WAC 246-235-100

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please contact me at 360.236.3259 or Michelle Austin, Rules Coordinator, at 360.236.3250 or e-mail Michelle.austin@doh.wa.gov.

Sincerely,

Traci Black

Section Manager

Washington State Office of Radiation Protection

Attached: PDF 2007-3 WA Response

WA Reference	NRC Section	NRC's Comment	WA's Comment
WAC 246-220-010	20.1003 2007-3	**Definition: Waste** Washington needs to revise the second sentence of the definition of "waste" in WAC 246-220-010 to "For the purposes of this definition, low- level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material **as defined in paragraphs (b), (c), and (d) of the definition of By-product material** in this section. Washington needs to make the above change to WAC 246-220-010 in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003 definitions Waste.	We corrected this. See page 14 of the PDF.
WAC 246-249-090 (2)	20.2006 (e)	**Transfer for disposal and manifests** Washington needs to insert the phrase "WAC 246-249-010 (2) (c) and (d)" after "Any licensee shipping by- product as defined in" in WAC 246-249-090 (2) (c). Washington needs to make the above change to WAC 246-249-090 in order to meet the Compatibility Category B designation assigned to 10 CFR 20.2006(e).	We corrected this. See page 16 of the PDF.
WAC 246-249-010 (13)	61.2	**Definition: Low Level Radioactive Waste** In WAC 246-249-010(13), Washington had adopted a definition for low-level radioactive waste as a separate definition. This definition is in conflict with the second sentence of the definition of Waste in WAC 246-249-010(31) and WAC 246-250-010(24). Washington should delete this definition, because it creates conflicts with the portion of the definition of "Waste" that redefines low-level radioactive waste after the passage of the Energy Policy Act of 2005. Washington needs to make the above change to WAC 246-249-010(13) in order to meet the Compatibility Category B designation assigned to 10 CFR 61.2 definition Waste.	We deleted the definition low-level radioactive waste.

WA Reference	NRC Section	NRC's Comment	WA's Comment
WAC 246-233-020	31.5	**Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere** Washington omitted in WAC 246-233-020(3)(k)(i) information for radium-226 corresponding to 10 CFR 31.5(c)(13)(i). Washington needs to include the phrase "3.7 megabecquerels (0.1 millicuries) of radium-226" in this sentence. Washington needs to revise the reference in section 246-233-020 (3)(k)(i) to paragraph (k)(ii) instead of paragraph (k)(i). Washington needs to make the above changes to WAC 246-233-020 in order to meet the Compatibility Category B designation assigned to 10 CFR 31.5.	We corrected this. See page 25 of the PDF.
WAC 246-235-100	32.72	**Manufacture, preparation, or transfer for commercial use of radioactive drugs containing byproduct material for medical use under part 35** Washington omitted in WAC 246-235-100 the equivalent text from 10 CFR 32.72 (a)(2)(iv) and (a)(2)(v). In WAC 246-235-100(1)(b)(i) Washington omits the reference to 21 CFR 207.20(a). Washington needs to make the above changes to WAC 246-235-100 in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.	We corrected this. See page 27 of the PDF.

WAC 246-220-010
Definitions.

As used in chapters 246-220 through 246-254 WAC, these terms have the definitions set forth below. Additional definitions used only in a certain chapter will be found in that chapter.

(1) **"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.

(2) **"Accelerator produced material"** means any material made radioactive by exposing it in a particle accelerator.

(3) **"Act"** means Nuclear energy and radiation, chapter 70.98 RCW.

(4) **"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).

(5) **"Adult"** means an individual eighteen or more years of age.

(6) **"Agreement state"** means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

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

(8) **"Airborne radioactivity area"** means a room, enclosure, or operating area in which airborne radioactive material exists in concentrations (a) in excess of the derived air concentration (DAC) specified in WAC 246-221-290, Appendix A, or (b) to the 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.

(9) **"Air purifying respirator"** means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(10) **"Alert"** means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

(11) **"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 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in WAC 246-221-290.

(12) **"Assigned protection factor"** (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(13) **"Atmosphere-supplying respirator"** means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

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

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

(16) **"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 regulations,

"radiobioassay" is an equivalent term.

(17) **"By-product material"** means:

(a) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(b) 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 solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "by-product material" within this definition;

(c)(i) Any discrete source of radium 226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that:

(A) Has been made radioactive by use of a particular accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(d) Any discrete source of naturally occurring radioactive material, other than source material, that:

(i) The commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency determines would pose a threat similar to the threat posed by a discrete source of radium 226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use for in a commercial, medical, or research activity.

(18) **"Calendar quarter"** means at least twelve but no more than fourteen consecutive weeks. The first calendar quarter of each year begins in January and subsequent calendar quarters shall be arranged so 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. A licensee or registrant may not change the method of determining calendar quarters for purposes of these regulations.

(19) **"Calibration"** means the determination of (a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (b) the strength of a source of radiation relative to a standard.

(20) **"C.F.R."** means Code of Federal Regulations.

(21) **"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 regulations, "lung class" and "inhalation class" are equivalent terms. For "class of waste" see WAC 246-249-040.

(22) **"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.

(23) **"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.

(24) **"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 ($H_{E,50} = S_{gr}; w_T, H_{T,50}$).

(25) **"Consortium"** means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for

noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

(26) **"Constraint"** or dose constraint means a value above which specified licensee actions are required.

(27) **"Controlled area."** See "Restricted area."

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

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

(30) **"Deep dose equivalent"** (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(31) **"Demand respirator"** means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(32) **"Department"** means the Washington state department of health, which has been designated as the state radiation control agency under chapter 70.98 RCW.

(33) **"Depleted uranium"** means the source material uranium in which the isotope Uranium-235 is less than 0.711 percent by weight of the total uranium present. Depleted uranium does not include special nuclear material.

(34) **"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 regulations, 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 WAC 246-221-290.

(35) **"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 or registrant may take two thousand DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(36) **"Discrete source"** means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

(37) **"Disposable respirator"** means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

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

(39) **"Dose commitment"** means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed fifty years.

(40) **"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.

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

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

(43) **"dpm"** means disintegrations per minute. See also "curie."

(44) **"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 ($H_E = S_{gr}; w_T H_T$).

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

(46) **"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, without respect to their intended use.

(47) **"Exposure"** means (a) being exposed to ionizing radiation or to radioactive material, or (b) the quotient of &Dgr;Q by &Dgr;m where "&Dgr;Q" 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 "&Dgr;m" are completely stopped in air. The special unit of exposure is the roentgen (R) and the SI equivalent is the coulomb per kilogram. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

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

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

(50) **"Extremity"** means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

(51) **"Filtering facepiece"** (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(52) **"Fit factor"** means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(53) **"Fit test"** means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(54) **"Former United States Atomic Energy Commission (AEC) or United States Nuclear Regulatory Commission (NRC) licensed facilities"** means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

(55) **"Generally applicable environmental radiation standards"** means standards issued by the United States Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(56) **"Gray"** (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rad).

(57) **"Healing arts"** means the disciplines of medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.

(58) **"Helmet"** means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(59) **"High radiation area"** means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates. For purposes of these regulations, rooms or areas in which diagnostic X-ray systems are used for healing arts purposes are not considered high radiation areas.

(60) **"Hood"** means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(61) **"Human use"** means the intentional internal or external administration of radiation or radioactive material to human beings.

(62) **"Immediate"** or **"immediately"** means as soon as possible but no later than four hours after the initiating condition.

(63) **"IND"** means investigatory new drug for which an exemption has been claimed under the United States Food, Drug and Cosmetic Act (Title 21 C.F.R.).

(64) **"Individual"** means any human being.

(65) **"Individual monitoring"** means the assessment of:

(a) Dose equivalent (i) by the use of individual monitoring devices or (ii) by the use of survey data; or

(b) Committed effective dose equivalent (i) by bioassay or (ii) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

(66) **"Individual monitoring devices"** (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent e.g., as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

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

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

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

(70) **"Irretrievable source"** means any sealed source containing licensed material which is pulled off or not connected to the wireline downhole and for which all reasonable effort at recovery, as determined by the department, has been expended.

(71) **"Lens dose equivalent"** (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm^2).

(72) **"License"** means a license issued by the department.

(73) **"Licensed material"** means radioactive material received, possessed, used, transferred, or disposed under a general or specific license issued by the department.

(74) **"Licensee"** means any person who is licensed by the department under these rules and the act.

(75) **"Licensing state"** means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

(76) **"Loose-fitting facepiece"** means a respiratory inlet covering that is designed to form a partial seal with the face.

(77) **"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.

(78) **"Member of the public"** means an individual except when the individual is receiving an occupational dose.

(79) **"Minor"** means an individual less than eighteen years of age.

(80) **"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 regulations, radiation monitoring and radiation protection monitoring are

equivalent terms.

(81) **"NARM"** means any naturally occurring or accelerator-produced radioactive material. It does not include by-product, source, or special nuclear material. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc. (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

(82) **"Nationally tracked source"** means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in WAC 246-221-236. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

(83) **"Natural radioactivity"** means radioactivity of naturally occurring nuclides.

(84) **"NDA"** means a new drug application which has been submitted to the United States Food and Drug Administration.

(85) **"Negative pressure respirator"** (tight-fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(86) **"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.

(87) **"Nuclear Regulatory Commission"** (NRC) means the United States Nuclear Regulatory Commission or its duly authorized representatives.

(88) **"Occupational dose"** means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received: From background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under chapter 246-240 WAC, from voluntary participation in medical research programs, or as a member of the public.

(89) **"Ore refineries"** means all processors of a radioactive material ore.

(90) **"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 1 MeV. For purposes of this definition, "accelerator" is an equivalent term.

(91) **"Permittee"** means a person who has applied for, and received, a valid site use permit for use of the low-level waste disposal facility at Hanford, Washington.

(92) **"Person"** means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, but shall not include federal government agencies.

(93) **"Personal supervision"** means supervision where the supervisor is physically present at the facility and in sufficient proximity that contact can be maintained and immediate assistance given as required.

(94) **"Personnel monitoring equipment."** See individual monitoring devices.

(95) **"PET"** means positron emission tomography.

(96) **"Pharmacist"** means an individual licensed by this state to compound and dispense drugs, and poisons.

(97) **"Physician"** means a medical doctor or doctor of osteopathy licensed by this state to prescribe and dispense drugs in the practice of medicine.

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

(99) **"Positive pressure respirator"** means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(100) **"Powered air-purifying respirator"** (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(101) **"Practitioner"** means an individual licensed by the state in the practice of a healing art (i.e., physician, dentist, podiatrist, chiropractor, etc.).

(102) **"Pressure demand respirator"** means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(103) **"Public dose"** means the dose received by a member of the public from exposure to sources of radiation under the licensee's or registrant's control or to radiation or radioactive material released by the licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under chapter 246-240 WAC, or from voluntary participation in medical research programs.

(104) **"Qualified expert"** means an individual who has demonstrated to the satisfaction of the department he/she has the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. The department reserves the right to recognize the qualifications of an individual in specific areas of radiation protection.

(105) **"Qualitative fit test"** (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(106) **"Quality factor"** (Q) means the modifying factor, listed in Tables I and II, that is used to derive dose equivalent from absorbed dose.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose 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

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 Sv.

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

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE

EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(thermal) 2.5×10^{-8}	2	980×10^6	980×10^8
1×10^{-7}	2	980×10^6	980×10^8
1×10^{-6}	2	810×10^6	810×10^8
1×10^{-5}	2	810×10^6	810×10^8
1×10^{-4}	2	840×10^6	840×10^8
1×10^{-3}	2	980×10^6	980×10^8
1×10^{-2}	2.5	1010×10^6	1010×10^8
1×10^{-1}	7.5	170×10^6	170×10^8
5×10^{-1}	11	39×10^6	39×10^8
1	11	27×10^6	27×10^8
2.5	9	29×10^6	29×10^8
5	8	23×10^6	23×10^8
7	7	24×10^6	24×10^8

10	6.5	24×10^6	24×10^8
14	7.5	17×10^6	17×10^8
20	8	16×10^6	16×10^8
40	7	14×10^6	14×10^8
60	5.5	16×10^6	16×10^8
1×10^2	4	20×10^6	20×10^8
2×10^2	3.5	19×10^6	19×10^8
3×10^2	3.5	16×10^6	16×10^8
4×10^2	3.5	14×10^6	14×10^8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

(107) **"Quantitative fit test"** (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(108) **"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.

(109) **"Rad"** means the special unit of absorbed dose. One rad equals one-hundredth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray).

(110) **"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 regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include magnetic fields or nonionizing radiation, like radiowaves or microwaves, visible, infrared, or ultraviolet light.

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

(112) **"Radiation machine"** means any device capable of producing ionizing radiation except those devices with radioactive materials as the only source of radiation.

(113) **"Radiation safety officer"** means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned that responsibility by the licensee or registrant.

(114) **"Radiation source."** See "Source of radiation."

(115) **"Radioactive material"** means any material (solid, liquid, or gas) which emits radiation spontaneously.

(116) **"Radioactive waste"** means any radioactive material which is no longer of use and intended for disposal or treatment for the purposes of disposal.

(117) **"Radioactivity"** means the transformation of unstable atomic nuclei by the emission of radiation.

(118) **"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.

(119) **"Registrable item"** means any radiation machine except those exempted by RCW 70.98.180 or exempted by the department under the authority of RCW 70.98.080.

(120) **"Registrant"** means any person who is registered by the department or is legally obligated to register with the department in accordance with these rules and the act.

(121) **"Registration"** means registration with the department in accordance with the regulations adopted by the department.

(122) **"Regulations of the United States Department of Transportation"** means the regulations in 49 C.F.R. Parts 170-189, 14 C.F.R. Part 103, and 46 C.F.R. Part 146.

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

(124) **"Research and development"** means: (a) Theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

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

(126) **"Restricted area"** means any area to which access is limited by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive material. "Restricted area" does not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

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

(128) **"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 or registrant.

(129) **"Sealed source"** means any radioactive material that is encased in a capsule designed to prevent leakage or the escape of the radioactive material.

(130) **"Self-contained breathing apparatus"** (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(131) **"Shallow dose equivalent"** (H_s), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

(132) **"SI"** means an abbreviation of the International System of Units.

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

(134) **"Site area emergency"** means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

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

(136) **"Source container"** means a device in which radioactive material is transported or stored.

(137) **"Source material"** means: (a) Uranium or thorium, or any combination thereof, in any physical or chemical form, or (b) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

(138) **"Source material milling"** means the extraction or concentration of uranium or thorium from any ore processing primarily for its source material content.

(139) **"Source of radiation"** means any radioactive material, or any device or equipment emitting or capable of producing ionizing radiation.

(140) **"Special nuclear material"** means:

(a) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the United States Nuclear Regulatory Commission, under 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

(b) Any material artificially enriched in any of the foregoing, but does not include source material.

(141) **"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 the ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

(142) **"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 regulations, probabilistic effect is an equivalent term.

(143) **"Supplied-air respirator"** (SAR) or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

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

(145) **"Test"** means (a) the process of verifying compliance with an applicable regulation, or (b) a method for determining the characteristics or condition of sources of radiation or components thereof.

(146) **"These rules"** mean all parts of the rules for radiation protection of the state of Washington.

(147) **"Tight-fitting facepiece"** means a respiratory inlet covering that forms a complete seal with the face.

(148) **"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.

(149) **"Total organ dose equivalent"** (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ or tissue receiving the highest dose.

(150) **"United States Department of Energy"** means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the United States Atomic Energy Commission, its chairman, members, officers and components and transferred to the United States Energy Research and Development Administration and to the administrator thereof under sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814 effective January 19, 1975) and retransferred to the Secretary of Energy under section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

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

(152) **"Unrestricted area"** (uncontrolled area) means any area which is not a restricted area. Areas where the external dose exceeds 2 mrem in any one hour or where the public dose, taking into account occupancy factors, will exceed 100 mrem total effective dose equivalent in any one year must be restricted.

(153) **"User seal check"** (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(154) **"Very high radiation area"** means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates.

(155) **"Waste"** means those low-level radioactive wastes containing source, special nuclear or by-product material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material as defined in subsection (b), (c), and (d) of the definition of by-product material in this section.

(156) **"Waste handling licensees"** mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

(157) **"Week"** means seven consecutive days starting on Sunday.

(158) **"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 form 0.06 for each of 5 "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 will be approved on a case-by-case basis until such time as specific guidance is issued.

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

(160) **"Worker"** means an individual engaged in activities under a license or registration issued by the department and controlled by a licensee or registrant but does not include the licensee or registrant. Where the licensee or registrant is an individual rather than one of the other legal entities defined under "person," the radiation exposure limits for the worker also apply to the individual who is the licensee or registrant. If students of age eighteen years or older are subjected routinely to work involving radiation, then the students are considered to be workers. Individuals of less than eighteen years of age shall meet the requirements of WAC 246-221-050.

(161) **"Working level"** (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV 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.

(162) **"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.

(163) **"Year"** means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 11-03-020, § 246-220-010, filed 1/7/11, effective 2/7/11; 09-06-003, § 246-220-010, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 06-05-019, § 246-220-010, filed 2/6/06, effective 3/9/06; 04-23-093, § 246-220-010, filed 11/17/04, effective 12/18/04; 01-05-110, § 246-220-010, filed 2/21/01, effective 3/24/01; 00-08-013, § 246-220-010, filed 3/24/00, effective 4/24/00; 99-15-105, § 246-220-010, filed 7/21/99, effective 8/21/99; 98-13-037, § 246-220-010, filed 6/8/98, effective 7/9/98; 95-01-108, § 246-220-010, filed 12/21/94, effective 1/21/95; 94-01-073, § 246-220-010, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-220-010, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-220-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-12-050, filed 12/11/86; 83-19-050 (Order 2026), § 402-12-050, filed 9/16/83. Statutory Authority: Chapter 70.121 RCW. 81-16-031 (Order 1683), § 402-12-050, filed 7/28/81. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-12-050, filed 12/8/80; Order 1095, § 402-12-050, filed 2/6/76; Order 708, § 402-12-050, filed 8/24/72; Order 1, § 402-12-050, filed 7/2/71; Order 1, § 402-12-050, filed 1/8/69; Rules (part), filed 10/26/66.]

WAC 246-249-090
Transfer for disposal and manifests.

The requirements of this section are designed to control transfers of radioactive waste by any waste generator, waste collector, or waste processor licensee who ships radioactive waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility; establish a manifest tracking system; and supplement existing requirements concerning transfers and recordkeeping for those wastes.

(1) Effective March 1, 1998, each shipment of radioactive waste intended for disposal at a licensed land disposal facility in the state of Washington must be accompanied by a uniform low-level radioactive waste shipment manifest.

(2) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this section.

(a) Each shipment manifest must include a certification by the waste generator as specified in this section.

(b) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in this section.

(c) Any licensee shipping by-product material as defined in subsection (2)(c) and (d) of this section intended for ultimate disposal at a land disposal facility licensed under chapter 246-250 WAC must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with this section.

(d) When recording information on shipment manifests, information must be recorded in the International System of Units (SI) or in SI and units of curie, rad, rem, including multiples and subdivisions.

(3) A waste generator, collector, or processor who transports, or offers for transportation, radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by the department to comply with the manifesting requirements of this section when they ship:

(a) Radioactive waste for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) Radioactive waste that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this section may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

This section includes information requirements of the U.S. Department of Transportation, as codified in 49 C.F.R. Part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 C.F.R. Parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this section.

(4) Information requirements.

(a) General information.

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

(i) The name, facility address, and telephone number of the licensee shipping the waste;

(ii) An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

(iii) The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

(b) Shipment information.

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

(i) The date of the waste shipment;

(ii) The total number of packages/disposal containers;

(iii) The total disposal volume and disposal weight in the shipment;

(iv) The total radionuclide activity in the shipment;

(v) The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

(vi) The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(c) Disposal container and waste information.

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(i) An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(ii) A physical description of the disposal container, including the manufacturer and model of any high integrity container;

(iii) The volume displaced by the disposal container;

(iv) The gross weight of the disposal container, including the waste;

(v) For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(vi) A physical and chemical description of the waste;

(vii) The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(viii) The approximate volume of waste within a container;

(ix) The sorbing, stabilization, or solidification media, if any, and the identity of the solidification or stabilization media vendor and brand name;

(x) The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(xi) The total radioactivity within each container; and

(xii) For wastes consigned to a disposal facility, the classification of the waste under this chapter. The shipper must identify the waste if it does not meet the structural stability requirements in this chapter.

(d) Uncontainerized waste information.

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(i) The approximate volume and weight of the waste;

(ii) A physical and chemical description of the waste;

(iii) If the chelating agent exceeds 0.1% by weight, the total weight percentage of chelating agent plus the identity of the principal chelating agent;

(iv) For waste consigned to a disposal facility, the classification of the waste under this chapter. The shipper must identify the waste if it does not meet the structural stability requirements in this chapter;

(v) The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(vi) For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(e) Multigenerator disposal container information.

This subsection applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the radioactive waste resulting from a processor's activities may be attributable to one or more "generators," including "waste generators." It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.)

(i) For homogeneous mixtures of waste, such as incinerator ash, provide waste description applicable to the mixture and the volume of the waste attributed to each generator.

(ii) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(A) The volume of waste within the disposal container;

(B) A physical and chemical description of the waste, including the stabilization or solidification agent, if any;

(C) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(D) The sorbing, solidification, or stabilization media, if any, and the identity of the stabilization media vendor and brand name, if the media is claimed to meet stability requirements in WAC 246-249-050(2); and

(E) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

(5) Certification.

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation, the U.S. Nuclear Regulatory Commission, and the department. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

(6) Control and tracking.

(a) Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in (a)(i) through (ix) of this subsection. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of (a)(iv) through (ix) of this section. A licensee shall:

(i) Prepare all wastes so that the waste is classified according to WAC 246-249-040 and meets the waste

characteristics requirements in WAC 246-249-050;

(ii) Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste, in accordance with WAC 246-249-040;

(iii) Conduct a quality assurance program to assure compliance with WAC 246-249-040 and 246-249-050 (the program must include management evaluation of audits);

(iv) Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this section;

(v) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either receipt of the manifest precedes the waste shipment or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both methods is also acceptable;

(vi) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in (a)(v) of this subsection;

(vii) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(viii) Retain a copy of, or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations; and

(ix) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with (e) of this subsection.

(b) Any waste collector licensee who handles only prepackaged waste shall:

(i) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(ii) Prepare a new manifest to reflect consolidated shipments that meet the requirements of this section. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

(iii) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either receipt of the manifest precedes the waste shipment, or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both methods is also acceptable;

(iv) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in (b)(iii) of this subsection;

(v) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(vi) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations;

(vii) For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with this section; and

(viii) Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

(c) Any licensed waste processor who treats or repackages waste shall:

(i) Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

(ii) Prepare a new manifest that meets the requirements of this section. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in

subsection (4)(e) of this section;

(iii) Prepare all wastes so that the waste is classified according to WAC 246-249-040 and meets the waste characteristics requirements in WAC 246-249-050;

(iv) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with WAC 246-249-040 and 246-249-060;

(v) Conduct a quality assurance program to assure compliance with WAC 246-249-040 and 246-249-050 (the program shall include management evaluation of audits);

(vi) Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either receipt of the manifest precedes the waste shipment, or the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both methods is also acceptable;

(vii) Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in (c)(vi) of this subsection;

(viii) Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

(ix) Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by these regulations;

(x) For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with (e) of this subsection; and

(xi) Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

(d) The land disposal facility operator shall:

(i) Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

(ii) Maintain copies of all completed manifests and electronically store the information required by WAC 246-250-600(8) until the license is terminated; and

(iii) Notify the shipper and the department when any shipment, or part of a shipment, has not arrived within sixty days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

(e) If the shipper does not receive acknowledgment from the land disposal facility operator for any shipment or part of a shipment within the times set in this section, the shipper must:

(i) Investigate if the shipper has not received notification or receipt within twenty days after transfer; and

(ii) Trace the shipment or part of shipment and report the investigation to the department. Each licensee who conducts a trace investigation shall file a written report with the department within two weeks of completion of the investigation.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 11-03-020, § 246-249-090, filed 1/7/11, effective 2/7/11. Statutory Authority: RCW 70.98.050. 05-21-128, 05-23-113 and 06-01-105, § 246-249-090, filed 10/19/05, 11/18/05 and 12/21/05, effective 8/15/06. Statutory Authority: RCW 70.98.050 and 70.98.080. 98-09-117, § 246-249-090, filed 4/22/98, effective 5/23/98; 97-02-014, § 246-249-090, filed 12/20/96, effective 1/20/97; 91-16-109 (Order 187), § 246-249-090, filed 8/7/91, effective 9/7/91.]

WAC 246-249-010
Definitions.

As used in this chapter, the following definitions apply:

(1) "Broker" means a person who performs one or more of the following functions for a radioactive waste generator:

(a) Arranges for transportation of the radioactive waste;

(b) Collects and/or consolidates shipments of radioactive waste (waste collector);

(c) Processes radioactive waste in some manner, not including carriers whose sole function is to transport radioactive waste (waste processor).

(2) "By-product material" means:

(a) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(b) 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 solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute by-product material within this definition;

(c)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that:

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(d) Any discrete source of naturally occurring radioactive material, other than source material, that:

(i) The Nuclear Regulatory Commission, in consultation with the administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

(3) "Chelating agent" means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

(4) "Chemical description" means a description of the principal chemical characteristics of a radioactive waste.

(5) "Computer-readable medium" means the regulatory agency's computer can transfer the information from the medium into its memory.

(6) "Consignee" means the designated receiver of the shipment of radioactive waste.

(7) "Decontamination facility" means a facility operating under a commission or agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this section, is not considered to be a consignee for radioactive waste shipments.

(8) "Disposal container" means a container principally used to confine radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

(9) "EPA identification number" means the number assigned by the EPA administrator under 40 C.F.R. Part 263.

(10) "Generator" means any entity including a licensee operating under a commission or agreement state license who:

(a) Is a waste generator as defined in this part; or

(b) Is the entity or licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

(11) "High integrity container (HIC)" means a container commonly designed to meet the structural stability requirements of this chapter, and to meet department of transportation Type A package requirements.

(12) "Land disposal facility" means the land, buildings, and equipment which are intended to be used for the disposal of radioactive wastes. For the purposes of this chapter, a land disposal facility does not include a geologic repository.

(13) "Motor vehicle" means any vehicle, truck, tractor, semi-trailer, or trailer (or any permitted combination of these), driven by mechanical power and used upon the highways to carry property.

(14) "Motor common carrier" means a person holding itself out to the general public to provide motor vehicle transportation for compensation over regular or irregular routes, or both.

(15) "Motor contract carrier" means a person other than a common carrier providing motor vehicle transportation of property for compensation under continuing agreements with one or more persons.

(16) "Motor private carrier" means a person, other than a motor carrier, transporting property by motor vehicle when the person is the owner, lessee, or bailee of the property being transported; and the property is being transported for sale, lease, rent, or bailment, or to further a commercial enterprise.

(17) "Motor carrier" means a motor common carrier and a motor contract carrier.

(18) "Naturally occurring and accelerator produced material" (NARM) means any radioactive material of natural or accelerator origin; but does not include by-product, source or special nuclear material. Diffuse NARM is low activity NARM that has less than 2 nCi/g of 226-Ra.

(19) "NRC Forms 540, 540A, 541, 541A, 542, and 542A" are official NRC Forms referenced in this section. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

(20) "Package" means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

(21) "Physical description" means the items on NRC Form 541 that describe a radioactive waste.

(22) "Radioactive waste" means either or both low-level radioactive waste and naturally occurring and accelerator produced radioactive material.

(23) "Residual waste" means radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

(24) "Rollover volume" means the difference, in a calendar year, between the volume of NARM disposed at the disposal site and the site volume limit set forth under WAC 246-249-080(4).

(25) "Shipper" means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

(26) "Shipment" means the total radioactive waste material transported in one motor vehicle.

(27) "Shipping paper" means NRC Form 540 and, if required, NRC Form 540A which includes the information

required by DOT in 49 C.F.R. Part 172.

(28) "Transuranic waste" means material contaminated with elements that have an atomic number greater than 92.

(29) "Uniform Low-Level Radioactive Waste Manifest or uniform manifest" means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

(30) "Waste" means those low-level radioactive wastes containing source, special nuclear, or by-product material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or by-product material as defined in WAC 246-249-010 (2)(b), (c), and (d).

(31) "Waste collector" means an entity, operating under a commission or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

(32) "Waste description" means the physical, chemical and radiological description of a radioactive waste as called for on NRC Form 541.

(33) "Waste generator" means an entity, operating under a commission or agreement state license, who:

(a) Possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use; and

(b) Transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal.

A licensee performing processing or decontamination services may be a "waste generator" if the transfer of radioactive waste from its facility is defined as "residual waste."

(34) "Waste processor" means an entity, operating under a commission or agreement state license, whose principal purpose is to process, repackage, or otherwise treat radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

(35) "Waste type" means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified or stabilized in a specifically defined media).

[Statutory Authority: RCW 70.98.050 and 70.98.080. 11-03-020, § 246-249-010, filed 1/7/11, effective 2/7/11. Statutory Authority: RCW 70.98.050. 05-21-128, 05-23-113 and 06-01-105, § 246-249-010, filed 10/19/05, 11/18/05 and 12/21/05, effective 8/15/06. Statutory Authority: RCW 70.98.050 and 70.98.080. 98-09-117, § 246-249-010, filed 4/22/98, effective 5/23/98; 91-16-109 (Order 187), § 246-249-010, filed 8/7/91, effective 9/7/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-249-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-62-020, filed 12/11/86.]

WAC 246-233-020
General license — Certain measuring, gauging or controlling devices.
(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of subsections (2), (3), and (4) of this section, radioactive material excluding special nuclear material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in subsection (1) of this section applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued by the department pursuant to WAC 246-235-093 or in accordance with the Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution or transfer of devices to persons generally licensed by the United States Nuclear Regulatory Commission, an agreement state or licensing state**. The devices shall have been received from one of the specific licensees described in this subsection or through a transfer made under subsection (3)(h) of this section.

**Note: Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in Section 179.21 of 21 C.F.R. Part 179.

(3) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in subsection (1) of this section:

(a) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(b) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material; and

(ii) Devices containing only tritium or not more than 3.7 megabecquerels (100 microcuries) of other beta and/or gamma emitting material or 370 kilobecquerels (10 microcuries) of alpha emitting material need not be tested for any purpose. Devices held in storage in the original shipping container prior to initial installation need not be tested until immediately prior to use;

(c) Shall assure that the tests required by (b) of this subsection and other testing, installing, servicing, and removing from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels; or

(ii) By a person holding a specific license from the department or from the United States Nuclear Regulatory Commission or from any agreement state or from a licensing state to perform such activities;

(d) Shall maintain records showing compliance with the requirements of (b) and (c) of this subsection. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installing, servicing, and removing from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by (b) of this subsection shall be maintained for three years after the next required leak test is performed or the sealed source is transferred or disposed. Records of tests of the on/off mechanism and indicator required by (b) of this subsection shall be maintained for three years after the next required test of the on/off mechanism and indicator is performed or the sealed source is transferred or disposed. Records of other testing, installation, servicing, and removal from installation required by (c) of this subsection shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed;

(e) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 185 becquerels (0.005 microcuries) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the department, the United

States Nuclear Regulatory Commission, or from an agreement state or a licensing state to repair such devices, or disposed by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within thirty days, furnish to the department a written report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerels (0.005 microcuries) or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use (see WAC 246-246-020);

(f) Shall not abandon the device containing radioactive material;

(g) Except as provided in (h) of this subsection, shall transfer or dispose the device containing radioactive material only by transfer to a person holding a specific license of the department, the United States Nuclear Regulatory Commission, or an agreement state, or a licensing state whose specific license authorizes the person to receive the device and within thirty days after transfer of a device to a specific licensee shall furnish to the department a report containing identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number; the name, address, and license number of the person receiving the device, and the date of transfer. Prior written approval from the department is required before transferring the device to any other specific licensee not specifically identified in this subsection;

(h) Shall transfer the device to another general licensee only:

(i) Where the device remains in use at a particular location. In such case, the transferor shall give the transferee a copy of this section, a copy of WAC 246-221-240, 246-221-250, 246-232-050, and 246-232-060, and any safety documents identified in the label of the device and within thirty days of the transfer, report to the department the manufacturer's (or transferor's) name, model number, and serial number of device transferred, the transferee's name and mailing address for the location of use, and the name, title, and phone number of the responsible individual identified by the transferee in accordance with (j) of this subsection to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;

(i) Shall comply with the provisions of WAC 246-221-240 and 246-221-250 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of chapters 246-221 and 246-222 WAC;

(j) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(k)(i) Shall register, in accordance with (k)(ii) and (iii) of this subsection, devices containing at least 370 megabecquerels (10 millicuries) of Cesium-137, 3.7 megabecquerels (0.1 millicuries) of Strontium-90, 37 megabecquerels (1 millicurie) of Cobalt-60, or 37 megabecquerels (1 millicurie) of Americium-241, 3.7 megabecquerels (0.1 millicurie) of Radium-226, or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under (k)(iii)(D) of this subsection, represents a separate general licensee and requires a separate registration and fee;

(ii) If in possession of a device meeting the criteria of (k)(i) of this subsection, shall register these devices annually with the department and shall pay the fee required by WAC 246-254-090. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the department. The registration information must be submitted to the department within thirty days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of (k)(i) of this subsection is subject to the bankruptcy notification requirement in WAC 246-232-050;

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the department:

(A) Name and mailing address of the general licensee;

(B) Information about each device: The manufacturer (or initial transferor), model number, serial number, the radionuclide and activity (as indicated on the label);

(C) Name, title, and telephone number of the responsible person designated as a representative of the general

licensee under (j) of this subsection;

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage;

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information;

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license;

(iv) Persons generally licensed by the U.S. Nuclear Regulatory Commission, or an agreement state with respect to devices meeting the criteria in (k)(i) of this subsection are not subject to registration requirements if the devices are used in areas subject to Washington state jurisdiction for a period less than one hundred eighty days in any calendar year. The department will not request registration information from such licensees;

(l) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the department within thirty days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage;

(m) Shall not hold devices that are not in use for longer than two years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by (b) of this subsection need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in subsection (1) of this section does not authorize the manufacture, import or export of devices containing radioactive material.

(5) The general license provided in this subsection is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-100, 246-221-240, 246-221-250, 246-232-050, 246-232-060, 246-232-070, 246-232-080, and 246-232-090.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-233-020, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 04-04-055, § 246-233-020, filed 1/30/04, effective 3/1/04; 98-13-037, § 246-233-020, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-233-020, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-233-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-21-050, filed 12/11/86; 83-19-050 (Order 2026), § 402-21-050, filed 9/16/83. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-21-050, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-21-050, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-040.]

WAC 246-235-100

Manufacture, production, preparation, and/or transfer of radiopharmaceuticals for medical use.

(1) An application for a specific license to manufacture, produce, prepare, and/or transfer for distribution radiopharmaceuticals containing radioactive material for use by persons licensed under chapter 246-240 WAC for medical use in humans will be approved if:

(a) The applicant satisfies the general requirements specified in WAC 246-235-020;

(b) The applicant submits evidence that the applicant is:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer, preparer, propagator, compounder or processor of a drug under 21 C.F.R. 207.20(a); or

(ii) Licensed as a nuclear pharmacy by the state board of pharmacy;

(iii) Registered or licensed as a radiopharmaceutical production facility or nuclear pharmacy with the U.S. Nuclear Regulatory Commission or a state agency;

(iv) Operating as a nuclear pharmacy within a federal medical institution; or

(v) A positron emission tomography drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide, chemical and physical form, maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and

(d) The applicant satisfies the following labeling requirements:

(i) Those specified by the state board of pharmacy in WAC 246-903-020 for both commercial and noncommercial distribution;

(ii) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "caution-radioactive material" or "danger-radioactive material," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than one hundred days, the time may be omitted;

(iii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "caution-radioactive material" or "danger-radioactive material" and an identifier that allows the syringe, vial, or other container to be correlated with the information on the transport radiation shield label; and

(iv) For a drug manufacturer, the labels required by this subsection are in addition to the labeling required by the Food and Drug Administration (FDA) and may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(2) A medical facility or an educational institution, may produce positron emission tomography or other approved accelerator-produced radioactive drugs, for noncommercial transfer to licensees within their consortium, as defined in WAC 246-220-010 and 246-235-010, if they have a valid Washington radioactive materials license and are authorized for medical use under chapter 246-240 WAC or an equivalent agreement state or U.S. Nuclear Regulatory Commission license; and

(a) Request authorization to produce accelerator-produced radionuclides at a radionuclide production facility within their consortium to prepare approved radioactive drugs for use only by licensees within that consortium. The applicant must have a current state radioactive materials license or evidence of an existing license issued by U.S. Nuclear Regulatory Commission or another agreement state.

(b) The applicant must be qualified to produce radioactive drugs for medical use by meeting the criteria in subsections (1) and (3) of this section.

(c) Identification of individual(s) authorized to prepare radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in subsection (3) of this section.

(d) Labeling information identified in subsection (1)(d) of this section is applied to any radiopharmaceuticals or radioactive materials to be noncommercially transferred to members of its consortium.

(3) A nuclear pharmacy licensee:

(a) May prepare radiopharmaceuticals for medical use provided the radiopharmaceutical is prepared by or under the supervision of an authorized nuclear pharmacist.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in WAC 246-240-010;

(ii) This individual meets the state board of pharmacy requirements in WAC 246-903-030, Nuclear pharmacists, and the requirements of WAC 246-240-081 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with (d) of this subsection.

(c) The actions authorized in (a) and (b) of this subsection are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist as an authorized nuclear pharmacist if:

(i) The individual was identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the department, the U.S. NRC, or an agreement state; or

(ii) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at any other pharmacies as of December 1, 2008.

(e) Shall provide to the department a copy of each individual's letter of notification from the state board of pharmacy recognizing the individual as a nuclear pharmacist, within thirty days of the date the licensee allows the individual to work as an authorized nuclear pharmacist under (b), (c) or (d) of this subsection.

(3) A manufacturer or nuclear pharmacy licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals, prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) A licensee preparing radiopharmaceuticals from generators; (e.g., molybdenum-99/technetium-99m or rubidium-82 from strontium-82/rubidium-82) shall test generator eluates for breakthrough or contamination of the parent isotope, in accordance with WAC 246-240-160. The licensee shall record the results of each test and retain each record for three years after the record is made.

(5) Nothing in this section relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radiopharmaceuticals.

[Statutory Authority: RCW 70.98.050 and 70.98.080. 09-06-003, § 246-235-100, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. 07-14-131, § 246-235-100, filed 7/3/07, effective 8/3/07; 06-05-019, § 246-235-100, filed 2/6/06, effective 3/9/06; 98-13-037, § 246-235-100, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-235-100, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-235-100, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-22-110, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-110, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-076.]