To: Bollin

From: "Frazee, Terry" <tcf0303@doh.wa.gov>
To: TWFN_DO.twf1_po(PHL)
Date: Wed, May 26, 1999 7:16 PM
Subject: RATS update #2

This refers to your letter of May 18, 1998 from Lohaus to Frazee stating that the draft regulations reviewed at that time would meet the compatibility and health and safety categories if adopted without significant change. In accordance with SA-201 final rules are to be submitted to NRC; identified with any changes made between the proposed and the final; be in electronic form whenever possible; with an accompanying statement as to whether the Agreement State believes its regulations satisfy the compatibility and health and safety component designations. It also asks that we identify the date by which the State needs comments from NRC.

The draft regulations submitted to you in our letter of April 30, 1998 were adopted with NO changes from draft to final. Therefore an additional paper submittal is not warranted as no subsequent changes were made. These rules have an effective date of July 9, 1998. For an electronic form (and independent verification of action taken on these rules) please visit the state of Washington's Coder Reviser web site and download any rules of interest. The files obtained in this manner are compatible with Microsoft's Word 97. Hopefully, your versions of WordPerfect will be as good.

We need to check this out and send another letter

These rules were adopted under an exception rule process requiring that they be adopted "without material change" from the federal rules. Therefore, we certainly believe that these rules fully satisfy the compatibility and health and safety designations as denoted in SA-200. We need comments from NRC before the IMPEP review scheduled for the end of August 1999.

Here are specific notations related to the affected RATS IDs:

1992-1 (QMP & Misadministration) -- the deficiency noted in the December 27, 1994 letter from Lohaus to Frazee relating to WAC 246-240-015 was fixed during this rulemaking. Please be sure to enter your final review date for this RATS ID.

Nad to ck - 5/18/98 OK

1995-1 (Preparation, Commercial Distribution, Medical Use) -- No change from draft; please send final review letter; enter date in RATS

5/18/98

1995-2 (Frequency of medical exam) -- No change from draft; please send final review letter; enter date in RATS

5/18/98

1995-7 (Medical Administration) -- Enter draft reviewed date of 5/18/98; no change from draft; please send final review letter; enter final review date in RATS

5/18/98

1997-3 (Patient Release) -- No change from draft; please send final review letter; enter date in RATS

5/18/98

If there are any questions or if you need either a hardcopy or a

different electronic version, please let me know.

Thanks!

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This message from: Terry Frazee tcf0303@doh.wa.gov

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Also, visit our Home Page at
--> http://www.doh.wa.gov/ehp/rp

CC: ARL_DO.ARL_PO(MLM1,MRS),TWFN_DO.twf1_po(DMS4)

WAC 246-221-117
Use of individual respiratory protection equipment.

(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to WAC 246-221-113:
(a) The licensee shall use only respiratory protection equipment that is:
(i) Tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration; or
(ii) Approved by the department on the basis of the licensee's submittal of an application for authorized use of other respiratory protection equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
(b) The licensee shall implement and maintain a respiratory protection program that includes:
(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and
(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes; and
(iii) Testing of respirators for operability immediately prior to each use; and
(iv) Written procedures regarding selection, fitting, issuance, maintenance, cleaning, repair, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
(v) Determination by a physician prior to initial fitting of respirators, and either every twelve months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.
(c) The licensee shall issue a written policy statement on respirator usage covering:
(i) The use of process or other engineering controls, instead of respirators; and
(ii) The routine, nonroutine, and emergency use of respirators; and
(iii) The length of periods of respirator use and relief from respirator use.
(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
(e) The licensee shall use equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
(2) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection

equipment used to limit intakes pursuant to WAC 246-221-113, provided that the following conditions, in addition to those in subsection (1) of this section, are satisfied:

(a) The licensee selects respiratory protection equipment that provides a protection factor, specified in WAC 246-221-285, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in WAC 246-221-290, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in WAC 246-221-113 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

(b) The licensee shall obtain authorization from the department before assigning respiratory protection factors in excess of those specified in WAC 246-221-285. The department may authorize a licensee to use higher protection factors on receipt of an application that:

(i) Describes the situation for which a need exists for higher protection factors, and

(ii) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

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

(4) Unless already authorized by license condition, the licensee shall notify the department in writing at least thirty days before the date that respiratory protection equipment is first used pursuant to either subsection (1) or (2) of this section.

[Statutory Authority: RCW 70.98.050. 98-13-034, § 246-221-117, filed 6/8/98, effective 7/9/98; 94-01-073, § 246-221-117, filed 12/9/93, effective 1/9/94.]

WAC 246-220-010
Definitions.

As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

(1) "A_1" means the maximum activity of special form radioactive material permitted to be transported in a Type A package. "A_2" means the maximum activity of normal form radioactive material permitted to be transported in a Type A package. A_1 and A_2 values are assigned to individual radionuclides and are tabulated in WAC 246-220-110, Appendix A. Methods of calculating values are also given.

(2) "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.

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

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

(5) "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).

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

(7) "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).

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

(9) "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 such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or twelve DAC-hours.

(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) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including

global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the department.

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

(14) "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.

(15) "Byproduct 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 utilizing special nuclear material, and (b) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

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

(17) "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.

(18) "CFR" means Code of Federal Regulations.

(19) "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.

(20) "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.

(21) "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.

(22) "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 ($H_{E,50}$= &Sgr; $w_T, H_{T,50}$).

(23) "Controlled area." See "Restricted area."

(24) "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).

(25) "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy, and her estimated date of conception.

(26) "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).

(27) "Department" means the department of health, division of radiation protection, which has been designated as the state radiation control agency.

(28) "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.

(29) "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.

(30) "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).

(31) "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 regulations, "radiation dose" is an equivalent term.

(32) "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.

(33) "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.

(34) "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.

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

delivered to the monitoring devices.
(36) "dpm" means disintegrations per minute. See also "curie."
(37) "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= &Sgr; $w_T H_T$).
(38) "Embryo/fetus" means the developing human organism from conception until the time of birth.
(39) "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.
(40) "Exposure" means (a), when used as a verb, being exposed to ionizing radiation or to radioactive material, or (b), when used as a noun, 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 x 10^{-4} coulomb per kilogram of air.
(41) "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.
(42) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
(43) "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.
(44) "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).
(45) "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.
(46) "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.
(47) "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rad).
(48) "Healing arts" means the disciplines of medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.
(49) "High radiation area" means any area, accessible to individuals, in which radiation levels 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 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.
(50) "Highway route controlled quantity" means a quantity of radioactive material in a single package which exceeds:
(a) 3,000 times the A_1 or A_2 quantity as appropriate; or
(b) 30,000 curies, whichever is less.
(51) "Human use" means the intentional internal or external administration of radiation or radioactive material to human beings.
(52) "Immediate" or "immediately" means as soon as possible but no later than four hours after the initiating condition.
(53) "IND" means investigatory new drug for which an exemption has been claimed under the United States Food, Drug and Cosmetic Act (Title 21 CFR).
(54) "Individual" means any human being.
(55) "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.
(56) "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these regulations, individual monitoring equipment, personnel monitoring device, personnel dosimeter, and dosimeter are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.
(57) "Inspection" means an official examination or observation by the department including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the department.
(58) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
(59) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.
(60) "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.
(61) "License" means a license issued by the department in accordance with the regulations adopted by the department.
(62) "Licensed material" means radioactive material received, possessed, used, transferred, or disposed under a general or specific license issued by the department.
(63) "Licensee" means any person who is licensed by the department in accordance with these regulations and the act.
(64) "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.
(65) "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.
(66) "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.
(67) "Member of the public" means an individual except when the individual is receiving an occupational dose.
(68) "Minor" means an individual less than eighteen years of age.
(69) "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.
(70) "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.
(71) "Natural radioactivity" means radioactivity of naturally occurring nuclides.
(72) "NDA" means a new drug application which has been submitted to the United States Food and Drug Administration.
(73) "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 regulations, a "deterministic effect" is an equivalent term.
(74) "Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as "special form radioactive material."
(75) "Nuclear Regulatory Commission" (NRC) means the United States Nuclear Regulatory Commission or its duly authorized representatives.
(76) "Nuclear waste" as used in WAC 246-232-090(5) means any quantity of source or byproduct material, (not including radiography sources being returned to the manufacturer) required to be in Type B packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site. Nuclear waste, as used in these regulations, is a special classification of radioactive waste.
(77) "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 pursuant to chapters 246-239 and 246-240 WAC, from voluntary participation in medical research programs, or as a member of the public.

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

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

(80) "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.

(81) "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.

(82) "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.

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

(84) "Personnel monitoring equipment." See individual monitoring devices.

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

(86) "Physician" means an individual licensed by this state to prescribe and dispense drugs in the practice of medicine.

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

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

(89) "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 pursuant to chapters 246-239 and 246-240 WAC, or from voluntary participation in medical research programs.

(90) "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.

(91) "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.

(92) "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.

(93) "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).

(94) "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, such as radiowaves or microwaves, visible,

infrared, or ultraviolet light.
(95) "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.
(96) "Radiation machine" means any device capable of producing ionizing radiation except those devices with radioactive materials as the only source of radiation.
(97) "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.
(98) "Radiation source." See "Source of radiation."
(99) "Radioactive material" means any material (solid, liquid, or gas) which emits radiation spontaneously.
(100) "Radioactive waste" means any radioactive material which is no longer of use and intended for disposal or treatment for the purposes of disposal.
(101) "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
(102) "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.
(103) "Registrable item" means any radiation machine except those exempted by RCW 70.98.180 or exempted by the department pursuant to the authority of RCW 70.98.080.
(104) "Registrant" means any person who is registered by the department or is legally obligated to register with the department in accordance with these regulations and the act.
(105) "Registration" means registration with the department in accordance with the regulations adopted by the department.
(106) "Regulations of the United States Department of Transportation" means the regulations in 49 CFR Parts 170-189, 14 CFR Part 103, and 46 CFR Part 146.
(107) "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).
(108) "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.
(109) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.
(110) "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" shall 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.

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

(112) "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.

(113) "Sealed source" means any device containing radioactive material to be used as a source of radiation which has been constructed in such a manner as to prevent the escape of any radioactive material.

(114) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

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

(116) "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).

(117) "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.

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

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

(120) "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.

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

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

(123) "Special form radioactive material" means radioactive material which satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can only be opened by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

(c) It satisfies the test requirements specified by the United States Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the United States Nuclear Regulatory Commission

requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

(124) "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, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

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

(125) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding three hundred fifty grams of contained U-235; Uranium-233 in quantities not exceeding two hundred grams; Plutonium in quantities not exceeding two hundred grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

(126) "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.

(127) "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, such evaluation includes, but is not limited to, tests, physical examinations, calculations and measurements of levels of radiation or concentration of radioactive material present.

(128) "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.

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

(130) "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.
(131) "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.
(132) "Type A packaging" means packaging designed in accordance with 49 CFR 173.411 and 173.412 to retain its integral containment and shielding under normal conditions of transport as demonstrated by tests described in 49 CFR 173.465 or 173.466 as appropriate. The contents are limited to A_1 or A_2 quantities. The package does not require competent authority approval.
(133) "Type A quantity" means a quantity of radioactive material less than or equal to the A_1 or A_2 value for a single radionuclide, or for which the sum of the fractions does not exceed unity for a mixture of radionuclides.
(134) "Type B packaging" means packaging approved by the United States Nuclear Regulatory Commission for the transport of quantities of radioactivity in excess of A_1 or A_2. It is defined in detail in 10 CFR 71.4.
(135) "Type B quantity" means a quantity of radioactive material in excess of a Type A quantity. It requires Type B packaging for transportation.
(136) "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 pursuant to 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 pursuant to 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).
(137) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.
(138) "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.
(139) "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates.
(140) "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

(141) "Week" means seven consecutive days starting on Sunday.
(142) "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.

(143) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.
(144) "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.
(145) "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.
(146) "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.
(147) "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. 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 246-221-130
Exceptions from posting and labeling requirements.

(1) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 30 centimeters from the surface of the source container or housing does not exceed 0.05 mSv (five millirem) per hour.
(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs because of the presence of patients containing radioactive material provided that the patient could be released from licensee control pursuant to chapters 246-239 and 246-240 WAC.
(3) Caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than eight hours provided that:
(a) The material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in this part; and
(b) Such area or room is subject to the licensee's or registrant's control.
(4) A room or other area is not required to be posted with a caution sign because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the United States Department of Transportation.
(5) A room or area is not required to be posted with a caution sign because of the presence of a diagnostic x-ray system used solely for healing arts purposes.
(6) The interior of a teletherapy room is not required to be posted with caution signs provided such posting is conspicuously placed at the entrance(s) to the rooms.
(7) A licensee is not required to label:
(a) Containers holding licensed material in quantities less than the quantities listed in WAC 246-221-300; or
(b) Containers holding licensed material in concentrations less than those specified in WAC 246-221-290, Table III; or
(c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by this chapter; or
(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the United States Department of Transportation; or
(e) Containers such as those located in water-filled canals, storage vaults, or hot cells, that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, provided the contents are identified to these individuals by a readily available written record. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
(f) Installed manufacturing or process equipment, such as chemical process equipment, piping, and tanks.
(8) Each licensee, prior to removal or disposal of empty

uncontaminated containers to unrestricted areas, shall remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

[Stacutory Authority: RCW 70.98.050. 98-13-037, § 246-221-130, filed 6/8/98, effective 7/9/98; 94-01-073, § 246-221-130, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-221-130, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-221-130, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 83-19-050 (Order 2026), § 402-24-095, filed 9/16/83. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-24-095, filed 12/8/80; Order 1095, § 402-24-095, filed 2/6/76.]

WAC 246-221-001
Purpose and scope.

(1) This chapter establishes standards for protection against radiation hazards. Except as otherwise specifically provided, this chapter applies to all licensees or registrants. The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter.
(2) The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released pursuant to chapters 246-239 and 246-240 WAC, or to voluntary participation in medical research programs.
(3) Nothing in this chapter shall be interpreted as limiting actions that may be necessary to protect health and safety in an emergency.
(4) The definitions contained in WAC 246-220-010 also apply to this chapter. WAC 246-220-007, Statement of philosophy, is directly applicable to this chapter.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-221-001, filed 6/8/98, effective 7/9/98; 94-01-073, § 246-221-001, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-221-001, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-221-001, filed 12/27/90, effective 1/31/91; Order 1095, § 402-24-010, filed 2/6/76; Order 1, § 402-24-010, filed 1/8/69; Rules (part), filed 10/26/66.]

WAC 246-221-060
Dose limits for individual members of the public.

(1) Each licensee or registrant shall conduct operations so that:
(a) The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released pursuant to chapters 246-239 and 246-240 WAC, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with WAC 246-221-190; and
(b) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released pursuant to chapters 246-239 and 246-240 WAC, does not exceed 0.02 mSv (0.002 rem) in any one hour.
(2) If the licensee or registrant permits members of the public to have access to restricted areas, they shall be escorted and the limits for members of the public continue to apply to those individuals.
(3) Notwithstanding subsection (1) of this section, a licensee or registrant may continue to operate a facility constructed and put into operation prior to January 1, 1994, where the annual dose limit for an individual member of the public is more than 1 mSv (0.1 rem) and less than 5 mSv (0.5 rem) total effective dose equivalent, provided:
(a) The facility's approved operating conditions for each radiation source remain the same. Any increase in the following operating conditions shall require reevaluation and/or modification of the facility shielding applicable to the source of radiation to meet the 1 mSv (0.1 rem) total effective dose equivalent limit for individual members of the public: size of the radiation source, workload, or occupancy factors associated with the source of radiation; and
(b) Any change in the permanent shielding of the facility due to remodeling, repair or replacement shall require the facility to meet the 1 mSv (0.1 rem) total effective dose equivalent limit for individual members of the public for areas affected by that portion of the shielding.
(4) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-221-060, filed 6/8/98, effective 7/9/98; 94-01-073, § 246-221-060, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-221-060, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-221-060, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-24-040, filed 12/11/86. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-24-040, filed 12/8/80; Order 1095, § 402-24-040, filed 2/6/76; Order 1, § 402-24-040, filed 1/8/69; Rules (part), filed 10/26/66.]

WAC 246-235-080
Special requirements for issuance of certain specific licenses for radioactive material.

(1) *Human use of radioactive material in institutions.* In addition to the requirements set forth in WAC 246-235-020 a specific license for human use of radioactive material in institutions will be issued if:
(a) The applicant has appointed a radiation safety committee to coordinate the use of radioactive material throughout that institution and to maintain surveillance over the institution's radiation safety program. Membership of the committee should include a specialist (where applicable a physician) from each department where radioactive material is used, a representative of the institution's management, a representative of the nursing staff, and a person trained in radiation safety. The radiation safety committee shall meet at least quarterly. Minutes shall be taken and maintained for two years for inspection by the department;
(b) The applicant possesses adequate facilities for the clinical care of patients. The applicant is advised that construction of new radioisotope facilities and modification of existing facilities must also comply with the requirements of WAC 246-318-660 of the construction review section of the department;
(c) The physician(s) designated on the application as the individual user(s) has (or have) substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
(d) If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.
(2) *Licensing of individual physicians for human use of radioactive material.* In addition to the requirements set forth in WAC 246-235-020 a specific license for the human use of radioactive material will be issued to an individual physician if:
(a) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable;
(b) The applicant has extensive experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients;
(c) The application is for use in the applicant's practice in an office outside a medical institution; and
(d) The department will approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution only if:
(i) The use of radioactive material is limited to the:
(A) Administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
(B) Performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;
(C) Performance of in vitro diagnostic studies; or
(D) Calibration and quality control checks of radioactive assay

instrumentation, radiation safety instrumentation and diagnostic instrumentation;
(ii) The physician brings the radioactive material with him or her and removes the radioactive material when he or she departs. (The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient); and
(iii) The medical institution does not hold a radioactive material license issued pursuant to the provisions of subsection (1) of this section.
(3) *Specific licenses for certain groups of medical uses of radioactive material.*
(a) Subject to the provisions of (b), (c) and (d) of this subsection an application for a specific license pursuant to subsection (1), (2) or (4) of this section, or for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of WAC 246-235-120, Schedule A, will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:
(i) The applicant satisfies the requirements of subsection (1), (2) or (4) of this section;
(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;
(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;
(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups, specifically:
(A) For Groups I through V, applicant must possess and use a calibrated and operable low-range survey instrument with a thin window (less than 7 mg/cm^2) capable of detecting radiation levels of 0.05 milliroentgen per hour up to at least 20 milliroentgens per hour;
(B) For Groups III, V, and VI, applicant must possess a calibrated and operable high-range survey instrument capable of detecting radiation levels up to at least one Roentgen per hour;
(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.
(b) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in (a) of this subsection and WAC 246-235-120, Schedule A, is subject to the following conditions:
(i) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 246-235-100, a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess or use generators or reagent kits containing radioactive material unless manufactured, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 246-235-100, a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.
(iii) For Group VI, no licensee or registrant shall receive, possess or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the department pursuant to WAC 246-235-102, a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.
(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions which are approved by the department, the United States Nuclear Regulatory Commission, an agreement state or a licensing state and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit.
(c) Any licensee who is licensed pursuant to (a) of this subsection for one or more of the medical use groups in WAC 246-235-120, Schedule A, also is authorized, subject to the provisions of (c) and (d) of this subsection to receive, possess and use for calibration and reference standards:
(i) Any radioactive material authorized for use under Group I, Group II, or Group III of WAC 246--235-120, Schedule A, with a half-life not longer than one hundred days, in amounts not to exceed 15 millicuries total;
(ii) Any radioactive material authorized for use under Group I, Group II, or Group III of WAC 246-235-120, Schedule A, with half-life greater than one hundred days in amounts not to exceed 200 microcuries total;
(iii) Technetium-99m in amounts not to exceed 50 millicuries;
(iv) Any radioactive material excluding Radium-226, in amounts not to exceed fifteen millicuries per sealed source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the department pursuant to WAC 246-235-102, a specific license issued by the United States Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.
(d) Leak tests.
(i) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to (c) of this subsection shall cause each sealed source containing radioactive material, other than Hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate

from a transferor indicating that a test has been made within six months prior to the transfer, the sealed sources shall not be used until tested: *Provided, however,* That no leak tests are required when:
(A) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material;
(B) The sealed source is stored and is not being used: *Provided,* That a physical inventory of the source and wipe surveys of the storage area or storage container are conducted.
(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the department.
(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with chapters 246-235 and 246-221 WAC. A report shall be filed within five days of the test with the department describing the equipment involved, the test results, and the corrective action taken.
(e) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to (c)(iv) of this subsection shall:
(i) Follow the radiation safety and handling instructions approved by the department, the United States Nuclear Regulatory Commission, an agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and
(ii) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include at a minimum the quantities and kinds of radioactive material, location of sources, name of person performing the inventory, and the date of the inventory.
(4) *Human use of sealed sources.* In addition to the requirements set forth in WAC 246-235-020, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:
(a) Has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training; and
(b) Is a physician.
(5) *Use of sealed sources in industrial radiography.* In addition to the requirements set forth in WAC 246-235-020, a specific license for use of sealed sources in industrial radiography will be issued if:
(a) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the department a schedule or description of such program which specifies the:

(i) Initial training;
(ii) Periodic training;
(iii) On-the-job training;
(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with department regulations and licensing requirements, and the operating and emergency procedures of the applicant; and
(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;
(b) The applicant submits to the department and complies with satisfactory written operating and emergency procedures (described in WAC 246-243-140);
(c) The applicant will have a quarterly internal inspection system, to assure that license provisions, regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants. Records of this management control program shall be maintained for two years;
(d) The applicant submits to the department a description of the applicant's overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;
(e) The applicant who desires to conduct leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the department a description of such procedures including:
(i) Instrumentation to be used;
(ii) Method of performing tests, e.g., points on equipment to be smeared and method of taking smear; and
(iii) Pertinent experience of the person who will perform the tests;
(f) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.
(6) *Environmentally significant licensing actions.* In addition to the requirements set forth in WAC 246-235-020, a specific license for any activity within the licensing authority of the department which the department determines will significantly affect the radiological quality of the human environment, including those specified in WAC 197-11-845(1) and 246-03-030 (1)(a)(ii) (i.e., licenses to operate low level waste burial facilities or licenses to operate or expand beyond the design capacity, mineral processing facilities or their tailings areas, whose products, or byproducts, have concentrations of naturally occurring radioactive material in excess of exempt concentrations as specified in WAC 246-232-130, Schedule C), will be issued if the following conditions are met:
(a) Environmental impact statement.
(i) The application for a license or license amendment (other than administrative amendments) is accompanied or preceded by a final environmental impact statement or final declaration of nonsignificance completed in accordance with the State Environmental Policy Act (SEPA) procedures and guidelines specified in chapters 197-11 and 246-03 WAC.
For any uranium or thorium mill in operation on or before the effective date of this regulation for which an environmental impact

statement has not been prepared previously, an application for license renewal must be accompanied or preceded by a final environmental impact statement or final declaration of nonsignificance completed in accordance with SEPA guidelines.

Note: No construction shall be commenced until the license has been issued or unless an emergency exemption from SEPA requirements is granted in accordance with WAC 197-11-880. For the purposes of this subsection, the term "commencement of construction" means any clearing of land, excavation or other substantial action related to a proposed activity for specific licensing that would adversely affect the natural environment of a site; this term does not include changes desirable for the temporary use of the land for public recreational use, limited borings to determine site characteristics as necessary for environmental assessment, or other preconstruction monitoring to establish background information related to suitability of a site or to the protection of environmental values. In the case where an exemption is granted, the applicant shall assume all financial risk for construction activity; waive any claim of entitlement to the issuance of a license based solely upon the grant of the exemption or the commencement of construction pursuant thereto; and furnish, if the circumstances warrant and the department so requires, a financial surety arrangement to insure the protection of the public health, safety and the environment in the event of abandonment, default, or inability of the license applicant to meet the requirements of the act or these regulations.

(ii) In addition to the information required in chapter 197-11 WAC, the following additional areas shall be addressed in the final environmental impact statement:
(A) Alternative sites to those chosen by the applicant shall include all alternative sites, whether or not those sites are under the control or ownership of the applicant.
(B) Long term impacts shall include, but not be limited to, decommissioning, decontamination, reclamation impacts and material management associated with the proposed activities.
(C) Environmental reviews, dose assessments, ecology, construction effects on biota, impact on the environment from the use of chemicals, and socioeconomic effects shall be addressed.
(D) Alternative disposal sites and techniques for disposal shall be evaluated to determine if a site or technique is clearly superior.
(b) For uranium or thorium milling operations, a bond made payable to the department of health or other acceptable government agency, and in an amount specified by the department, shall be posted to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements for reclamation and disposal of tailings and for decommissioning the site. The bond, or a copy thereof when the bond is made payable to another government agency, shall be received by the department prior to issuance of the license, or prior to license renewal for mills in operation on or before the effective date of this regulation. Other acceptable surety arrangements in addition to surety bonding include cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit or combinations of the foregoing. The amount and mechanism of the surety arrangement may be reviewed by the department preceding each license renewal and adjustments may be required of the licensee prior to such renewal.
(c) The owner of the proposed uranium or thorium mill and tailings site(s) agrees to transfer or revert to the appropriate state or federal agency upon termination of the license, all lands, buildings and grounds, and any interest therein, necessary to fulfill the purposes of this subsection, except where the lands are held in trust for, or are owned by any Indian tribe. For any uranium or thorium mill in operation on or before the effective date of this regulation, such an agreement will be required prior to license renewal.
(d) For all uranium and thorium milling operations, the owner or operator shall arrange to pay to the department or its designee a fee

in accordance with WAC 246-254-150 for a special security fund for the further maintenance, surveillance or care which may be required after a licensee has ceased to operate.
A minimum fund of two hundred fifty thousand dollars shall be provided by the licensee payable to the state. If a shortfall exists between the amount of money in the special security fund and the two hundred fifty thousand dollars minimum amount, a surety bond, or other acceptable surety instrument as defined above shall be arranged.
(e) The application for a license includes a description of an appropriate program for effluent monitoring, environmental monitoring and data reporting. Such description shall encompass locations, frequency, and types of sampling, analytical plans and procedures, minimum detection levels, sampling equipment and quality assurance programs.
(f) All licensees or registrants required to meet the additional requirements set forth in this subsection shall establish environmental monitoring programs adequate to determine the impact of their activity on the natural environment around the site of their environmentally significant activity. The established environmental and effluent monitoring program shall address all environmentally significant radionuclide releases and external radiation sources caused or threatened to be caused by the licensee's activities.
(i) Effluent and environmental monitoring results shall include the following minimum information as pertinent:
(A) Information as to flow rates, total volume of effluent, peak concentration, concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;
(B) A description of the properties of the effluents, including:
(I) Chemical composition;
(II) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas aerosol for air effluents;
(III) The hydrogen ion concentrations (pH) of liquid effluents; and
(IV) The size range of particulates in effluent released into air;
(C) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river stream a description of water uses downstream from the point of release of the effluent.
(D) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:
(I) In air at any point of human occupancy; or
(II) In water at points of use downstream from the point of release of the effluent;
(E) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent;
(F) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release;
(G) A written description of sampling techniques and sample analysis methods;
(H) A written description of how all calculated results were obtained

from sample analysis data. This explanation shall include example calculations and estimates of the precision and sensitivity of monitoring results;

(I) A written description of the licensee's quality control program including specification of control samples and standard samples used.

(ii) The licensee shall submit in writing to the department within sixty days after January 1 and July 1 of each year, reports specifying the quantities of each of the principle radionuclides released to unrestricted areas in liquid and in gaseous effluent during the previous six months of operations. This data shall be reported in a manner that will permit the department to confirm the potential annual radiation doses to the public. All data from the radiological and nonradiological environmental monitoring program will also be submitted for the same time period and frequency as specified above. The data shall be reported in a manner which will allow the department to confirm the potential annual radiation doses to the public.

(g) For land disposal of radioactive material, the provisions of chapter 246-250 WAC must also be met.

(h) For operation of mineral processing facilities, the provisions of chapter 246-252 WAC must also be met.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-235-080, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-235-080, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-235-080, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-22-070, filed 12/11/86; 83-19-050 (Order 2026), § 402-22-070, filed 9/16/83. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-22-070, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073 (Order 1459), § 402-22-070, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-070.]

WAC 246-235-100
Manufacture, preparation, or commercial transfer of radiopharmaceuticals for medical use.

(1) An application for a specific license to manufacture and, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to WAC 246-235-080 (1), (2), or (3) for medical use in humans will be approved if:
(a) The applicant satisfies the general requirements specified in WAC 246-235-020 of this part;
(b) The applicant submits evidence that:
(i) The applicant is registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer; or
(ii) The applicant is licensed as a nuclear pharmacy by the state board of pharmacy;
(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 labeling requirements specified by the state board of pharmacy in WAC 246-903-020. 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 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 this individual meets the state board of pharmacy requirements in WAC 246-903-030, Nuclear pharmacists.
(c) 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, no later than thirty days after the date the licensee allows the individual to work as an authorized nuclear pharmacist pursuant to (b) 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) 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. 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.]

WAC 246-235-120

Schedule A groups of medical uses of radioactive material (ref. WAC 246-235-080(3) and 246-235-100(9)).

(1) *Group I.* Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies.

(a) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for this group of medical uses, or an individual under the supervision of either as permitted by statute.

(b) The provisions of (a) of this subsection notwithstanding, no radioactive material in gaseous form or for use as an aerosol is permitted by this subsection except as specifically authorized in a license.

(2) *Group II.* Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies.

(a) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for this group of medical uses, or an individual under the supervision of either as permitted by statute;

(b) The provisions of (a) of this subsection notwithstanding, no radioactive material in gaseous form or for use as an aerosol is permitted by this subsection except as specifically authorized by a license or subsection (3)(b) of this section.

(3) *Group III.* Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for diagnostic imaging and localization studies.

(a) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for this group of medical uses, or an individual under the supervision of either as permitted by statute.

(b) The provisions of (a) of this subsection notwithstanding, no generator or reagent kit is authorized for preparation of any gaseous form or aerosol of a radioactive material, except Technetium-99m as sodium pentetate as an aerosol for pulmonary function studies when used only with an approved and shielded delivery system, and disposed in accordance with applicable requirements, or as specifically authorized in a license.

(4) *Group IV.* Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.

(a) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;
(b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;
(c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;
(d) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for this group of medical uses, or an individual under the supervision of either as permitted by statute.
(5) *Group V.* Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety.
(a) Gold-198 as colloid for intracavitary treatment of malignant effusions;
(b) Iodine-131 as iodide for treatment of thyroid carcinoma;
(c) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for this group of medical uses, or an individual under the supervision of either as permitted by statute.
(6) *Group VI.* Use of sources and devices containing radioactive material for certain medical uses.
(a) Americium-241 as a sealed source in a device for bone mineral analysis;
(b) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
(c) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
(d) Gold-198 as seeds for interstitial treatment of cancer;
(e) Iodine-125 as a sealed source in a device for bone mineral analysis;
(f) Gadolinium-153 as a sealed source in a device for bone mineral analysis;
(g) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
(h) Strontium-90 sealed in an applicator for treatment of superficial eye conditions; and
(i) Iodine-125 as seeds for interstitial treatment of cancer.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-235-120, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-235-120, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-235-120, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-22-200, filed 12/11/86. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-22-200, filed 12/8/80. Statutory Authority: RCW 70.98.080. 79-12-073

[Order 1459), § 402-22-200, filed 11/30/79, effective 1/1/80. Formerly WAC 402-20-260.]

WAC 246-239-010
Definitions.

(1) "Authorized nuclear pharmacist" means a pharmacist who is identified as an authorized nuclear pharmacist on a department license that authorizes the use of radioactive material in the practice of nuclear pharmacy.
(2) "Authorized user" means a physician who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission or agreement state license that authorizes the medical use of radioactive material.
(3) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.
(4) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.
(5) "Nuclear medicine" means the intentional internal or external administration of unsealed radioactive material to human beings.
(6) "Nuclear medicine technologist" means any individual who performs nuclear medical procedures under the supervision of a physician licensed pursuant to chapter 246-235 WAC.
(7) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:
(a) In a written directive; or
(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.
(8) "Radiopharmaceutical misadministration" means the administration of:
(a) A radiopharmaceutical dosage greater than 30 microcuries of sodium iodide I-125 or I-131:
(i) Involving the wrong individual or wrong radiopharmaceutical; or
(ii) When both the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage, and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries;
(b) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
(i) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
(ii) When the administered dosage differs from the prescribed dosage by more than twenty percent of the prescribed dosage;
(c) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of sodium iodide I-125 or I-131, both:
(i) Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
(ii) When the dose to the individual exceeds 5 rems effective dose

equivalent or 50 rems dose equivalent to any individual organ.
(9) "Recordable event" means the administration of:
(a) A radiopharmaceutical without a written directive where a written directive is required;
(b) A radiopharmaceutical where a written directive is required without daily recording of each administered radiopharmaceutical dosage in the appropriate record;
(c) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:
(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and
(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;
(d) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage.
(10) "Training" means instruction or experience acquired under the direct supervision of a physician, a certified/registered nuclear medicine technologist, and/or a qualified expert who has the necessary knowledge and training to advise personnel on radiation protection.
(11) "Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical, containing the following information:
(a) For any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131: The dosage;
(b) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: The radiopharmaceutical, dosage, and route of administration.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-239-010, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 92-06-008 (Order 245), § 246-239-010, filed 2/21/92, effective 3/23/92; 91-15-112 (Order 184), § 246-239-010, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-239-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 83-19-050 (Order 2026), § 402-34-030, filed 9/16/83.]

WAC 246-239-022
Policy and procedures for radiopharmaceutical administration.

(1) Each licensee shall establish and maintain a written program to provide assurance that radioactive material or radiation from radioactive material will be administered as directed by the authorized user ordering the administration. The program must include written policies and procedures to meet the following specific objectives:
(a) That, prior to administration, a written directive is prepared for:
(i) Any administration of quantities greater than 30 microcuries of sodium iodide I-131; or
(ii) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-131. A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided the revision is dated and signed by the authorized user prior to the administration of the radiopharmaceutical or radiobiologic dosage. If a delay would jeopardize the patient's health, and the authorized user is not personally assaying and administering the dose, an oral directive or revision to an existing written directive will be acceptable, provided the oral revision is documented immediately in the patient's chart or record, and the revised written directive is signed by the authorized user within forty-eight hours of the oral revision;

Note: A written directive is not required when an authorized user personally assays and administers a dosage provided the pertinent facts are documented as otherwise required.

(b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;
(c) That each administration is in accordance with the written directive; and
(d) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
(2) The licensee shall:
(a) Develop procedures for and conduct a review of the radiopharmaceutical administration program including, since the last review, an evaluation of:
(i) A representative sample of patient and human research subject administrations;
(ii) All recordable events; and
(iii) All misadministrations to verify compliance with all aspects of the radiopharmaceutical administration program; these reviews shall be conducted at intervals no greater than twelve months;
(b) Evaluate each of these reviews to determine the effectiveness of the radiopharmaceutical administration program and, if required, make modifications to meet the objectives of subsection (1) of this section; and
(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.
(3) The licensee shall evaluate and respond, within thirty days after discovery of the recordable event, to each recordable event by:

(a) Assembling the relevant facts including the cause;
(b) Identifying what, if any, corrective action is required to prevent recurrence; and
(c) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.
(4) The licensee shall retain:
(a) Each written directive (provided, however, that such written directive is not required if the dose is both personally assayed and administered by the authorized user); and
(b) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in subsection (1)(a) of this section, in an auditable form, for three years after the date of administration.
(5) The licensee may make modifications to the program to increase the program's efficiency provided the program's effectiveness is not decreased.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-239-022, filed 6/8/98, effective 7/9/98; 94-06-017, § 246-239-022, filed 2/22/94, effective 3/25/94.]

WAC 246-239-025
Notifications, records, and reports of radiopharmaceutical misadministrations.

(1) The licensee shall notify the department by telephone at (206) 682-5327 no later than the next calendar day after the discovery of a radiopharmaceutical misadministration.
(2) The licensee also shall notify the referring physician and the individual receiving the radiopharmaceutical misadministration (or the individual's responsible relative or guardian) of the radiopharmaceutical misadministration not later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that the physician will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or individual receiving the radiopharmaceutical misadministration cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the radiopharmaceutical misadministration, because of any delay in notification.
(3) The licensee shall submit a written report to the department within fifteen days after discovery of the radiopharmaceutical misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the radiopharmaceutical misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, and if not, why not, and if there was notification, what information was provided. The report shall not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the radiopharmaceutical misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.
(4) If the individual was notified, the licensee shall also furnish, within fifteen days after discovery of the radiopharmaceutical misadministration, a written report to the individual by sending either:
(a) A copy of the report that was submitted to the department; or
(b) A brief description of both the radiopharmaceutical misadministration and the consequences, as they may affect the individual, and a statement informing the individual that the report submitted to the department can be obtained from the licensee.
(5) Each licensee shall retain a record of each radiopharmaceutical misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the radiopharmaceutical misadministration, and the individual's referring physician, if applicable), the individual's Social Security number or

identification number if one has been assigned, a brief description of the radiopharmaceutical misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving radiopharmaceutical misadministrations, or to that individual's responsible relatives or guardians.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-239-025, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 92-06-008 (Order 245), § 246-239-025, filed 2/21/92, effective 3/23/92.]

WAC 246-239-040
Radiopharmaceuticals.

(1) Radioactive material to be administered to humans shall be obtained from a manufacturer or preparer licensed pursuant to WAC 246-235-100, 10 CFR 32.72 or equivalent regulation of an agreement state or licensing state; or prepared by an authorized nuclear pharmacist, a physician who is an authorized user for the radioactive material to be administered, or an individual under the supervision of either as permitted by statute.
(2) The provisions of this part notwithstanding:
(a) No radioactive material in gaseous form or for use as an aerosol is permitted except Technetium-99m pentetate used as an aerosol for lung function studies, or as specifically authorized by license condition. Radioactive aerosols must be administered with a closed, shielded system that either is vented to the outside atmosphere through an air exhaust or provides for collection and disposal of the aerosol; and
(b) No generator or reagent kit is authorized for preparation of any gaseous form or aerosol of the radioactive material, except as specifically authorized by license condition.
(3) Radioactive material to be administered to humans shall be assayed for activity to determine the dose within ten percent accuracy of the prescribed dose prior to being administered to patients.
(a) In the absence of a certificate from a supplier which specifies the activity of each dose, the license shall establish written procedures for the personnel to perform assays to an accuracy of ten percent of the prescribed dose prior to being administered to patients.
(b) The licensee shall maintain for inspection by the department, records of the results of each assay performed to determine the activity of each dose administered to a patient. Records shall be maintained for two years following performance of each assay.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-239-040, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-239-040, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040. 91-02-049 (Order 121), recodified as § 246-239-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 83-19-050 (Order 2026), § 402-34-100, filed 9/16/83.]

WAC 246-239-055
Release of individuals containing radiopharmaceuticals.

(1) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
(2) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:
(a) Guidance on the interruption or discontinuation of breast-feeding; and
(b) Information on the consequences of failure to follow the guidance.
(3) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:
(a) Using the retained activity rather than the activity administered;
(b) Using an occupancy factor less than 0.25 at 1 meter;
(c) Using the biological or effective half-life; or
(d) Considering the shielding by tissue.
(4) The licensee shall maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-239-055, filed 6/8/98, effective 7/9/98.]

WAC 246-240-010
Definitions.

As used in this chapter, the following definitions apply:
(1) "Authorized user" means a physician who is identified as an authorized user on a department, U.S. Nuclear Regulatory Commission or agreement state license that authorizes the medical use of radioactive material.
(2) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.
(3) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.
(4) "Prescribed dose" means:
(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
(b) For teletherapy, the total dose and dose per fraction as documented in the written directive; or
(c) For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.
(5) "Recordable therapy event" means the administration of:
(a) Radiation without a written directive where a written directive is required;
(b) Radiation where a written directive is required without daily recording of each radiation dose in the appropriate record;
(c) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by fifteen percent or more of the weekly prescribed dose; or
(d) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than ten percent of the prescribed dose.
(6) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
(7) "Therapy misadministration" means the administration of:
(a) A gamma stereotactic radiosurgery radiation dose:
(i) Involving the wrong individual or wrong treatment site; or
(ii) When the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;
(b) A teletherapy radiation dose:
(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose;
(iii) When the calculated weekly administered dose exceeds the weekly prescribed dose by thirty percent or more of the weekly prescribed dose; or
(iv) When the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total

prescribed dose;
(c) A brachytherapy radiation dose:
(i) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
(ii) Involving a sealed source that is leaking;
(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
(iv) When the calculated administered dose to the treatment site differs from the prescribed dose by more than twenty percent of the prescribed dose.
(6) "Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of radiation, except as specified in (d) of this subsection, containing the following information:
(a) For gamma stereotactic radiosurgery: Target coordinates, collimator size, plug pattern, and total dose;
(b) For teletherapy: The total dose, dose per fraction, treatment site, and overall treatment period;
(c) For high-dose-rate remote after loading brachytherapy: The radioisotope, treatment site, and total dose; or
(d) For all other brachytherapy, (i) prior to implantation: The radioisotope, number of sources, and source strengths; and (ii) after implantation but prior to completion of the procedure: The radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

[Statutory Aut ority: RCW 70.98.050. 98-13-037, § 246-240-010, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 92-06-008 (Order 245), § 246-240-010, filed 2/21/92, effective 3/23/92.]

WAC 246-240-015
Policy and procedures for therapy administration.

(1) Each licensee shall establish and maintain a written program to provide assurance that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The program must include written polices and procedures to meet the following specific objectives:
(a) That, prior to administration, a written directive is prepared for:
(i) Any teletherapy radiation dose;
(ii) Any gamma stereotactic radiosurgery radiation dose; or
(iii) Any brachytherapy radiation dose. A written revision to an existing written directive may be made for any therapeutic procedure provided the revision is dated and signed by the authorized user prior to the administration of radioactive material or radiation from radioactive material for that therapeutic use. If a delay would jeopardize the patient's health, and the authorized user is not personally present to administer the dose, an oral directive or oral revision to an existing written directive by the authorized user will be acceptable provided the oral directive or oral revision is documented immediately in the patient's chart or record, and the revised written directive is signed by the authorized user within forty-eight hours of the oral revision. Note: A written directive is not required when an authorized user personally assays and administers a dosage, provided the pertinent facts are documented as otherwise required;
(b) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;
(c) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
(d) That each administration is in accordance with the written directive; and
(e) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.
(2) The licensee shall:
(a) Develop procedures for and conduct a review of the therapy administration program including, since the last review, an evaluation of:
(i) A representative sample of patient and human research subject administrations;
(ii) All recordable events; and
(iii) All therapy misadministrations to verify compliance with all aspects of the therapy administration program; these reviews shall be conducted at intervals no greater than twelve months;
(b) Evaluate each of these reviews to determine the effectiveness of the therapy administration program and, if required, make modifications to meet the objectives of subsection (1) of this section; and
(c) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(3) The licensee shall evaluate and respond, within thirty days after the discovery of the recordable therapy event, to each recordable therapy event by:
(a) Assembling the relevant facts including the cause;
(b) Identifying what, if any, corrective action is required to prevent recurrence; and
(c) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.
(4) The licensee shall retain:
(a) Each written directive (provided, however, that such written directive is not required if the dose is both personally assayed and administered by the authorized user); and
(b) A record of each administered radiation dose where a written directive is required in subsection (1)(a) of this section, in an auditable form for three years after the date of the administration.
(5) The licensee may make modifications to the program to increase the program's efficiency provided the program's effectiveness is not decreased.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-240-015, filed 6/8/98, effective 7/9/98; 95-01-108, § 246-240-015, filed 12/21/94, effective 1/21/95.]

WAC 246-240-020
Interstitial, intracavitary and superficial applications.

(1) **Accountability, storage, and handling.**
(a) Except as otherwise specifically authorized by the department, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.
(b) Each licensee shall conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the department and shall include the activities, radionuclide(s), and serial numbers of radioactive sources, location of sources and devices, the date of the inventory, and the initials or name of the person performing the inventory.
(c) Each licensee shall follow the radiation safety and handling instructions approved by the department, the United States Nuclear Regulatory Commission, an agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.
(d) Each licensee shall assure that sealed therapy sources are not opened/breached, or physically modified while in the licensee's possession unless specifically authorized by license condition.
(2) **Testing sealed sources for leakage and contamination.**
(a) All sealed sources containing more than 100 microcuries (3.7 megabecquerels) of radioactive material with a half-life greater than thirty days, except Iridium-192 seeds encased in nylon ribbon, shall be tested for contamination and/or leakage at intervals not to exceed six months or at such other intervals as are approved by the department, the United States Nuclear Regulatory Commission, an agreement state or a licensing state and described by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer.
(b) Leak tests shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 becquerels) per twenty-four hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries or becquerels and maintained for inspection by the department.
(c) Any leak test conducted pursuant to (a) of this subsection which reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination or in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 becquerels) per twenty-four hours, shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and cause it

to be decontaminated and repaired or to be disposed of in accordance with department regulations. A report shall be filed within five days of the test with the department, describing the equipment involved, the test results, and the corrective action taken.

(3) **Radiation surveys.**

(a) The maximum exposure rate radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required under subsection (4) of this section.

(b) The exposure rate radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the department.

(c) The licensee shall assure that patients treated with Cobalt-60, Cesium-137, Iridium-192, Radium-226, or any other nonpermanent implants, including High Dose Rate (HDR), Medium Dose Rate (MDR), or Low Dose Rate (LDR) therapy systems used on an in-patient or out-patient basis, remain hospitalized until a source count and a radiation survey of the patient and the patient's room confirm that all implants have been removed and are accounted for immediately after removing the last source.

(4) **Signs and records.**

(a) In addition to the requirements of WAC 246-221-120, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions.

(b) The following information shall be included for the duration of the patient's treatment in the patient's official hospital medical record/chart:

(i) The radionuclide administered, number of sources, activity in millicuries or becquerels and time and date of administration;

(ii) The exposure rate at one meter, the time the determination was made, and by whom;

(iii) The radiation symbol; and

(iv) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under WAC 246-221-010.

(c) Information required by subsection (4)(b)(i) and (ii) of this section shall be retained for review by the department.

(d) A record of the survey conducted to confirm that all sources have been removed from a patient or human research subject prior to release shall be retained for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirem per hour and measured at one meter from the patient or human research subject, the survey instrument used, and the initials of the individual who made the survey.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-240-020, filed 6/8/98, effective 7/9/98; 94-06-017, § 246-240-020, filed 2/22/94, effective 3/25/94. Statutory Authority: RCW 70.98.050 and 70.98.080. 91-15-112 (Order 184), § 246-240-020, filed 7/24/91, effective 8/24/91. Statutory Authority: RCW 43.70.040.

91-02-049 (Order 121), recodified as § 246-240-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. 87-01-031 (Order 2450), § 402-32-020, filed 12/11/86; 83-19-050 (Order 2026), § 402-32-020, filed 9/16/83. Statutory Authority: RCW 70.98.050. 81-01-011 (Order 1570), § 402-32-020, filed 12/8/80; Order 1084, § 402-32-020, filed 1/14/76; Order 1, § 402-32-020, filed 1/8/69; Rules (part), filed 10/26/66.]

WAC 246-240-025
Release of individuals containing permanent implants.

(1) The licensee may authorize the release from its control of any individual who has permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).
(2) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).
(3) The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:
(a) Using an occupancy factor less then 0.25 at 1 meter; or
(b) Considering the shielding by tissue.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-240-025, filed 6/8/98, effective 7/9/98.]

WAC 246-240-050
Notifications, records, and reports of therapy misadministrations.

(1) The licensee shall notify by telephone the division of radiation protection at (206) 682-5327 no later than the next calendar day after the discovery of a therapy misadministration.
(2) The licensee also shall notify the referring physician and the individual receiving the therapy misadministration (or the individual's responsible relative or guardian) of the therapy misadministration not later than twenty-four hours after its discovery, unless the referring physician personally informs the licensee either that the physician will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the patient receiving the therapy misadministration cannot be reached within twenty-four hours, the licensee shall notify the individual as soon as possible thereafter. The lic see may not delay any appropriate medical care for the indi dual, including any necessary remedial care as a result of the therapy misadministration, because of any delay in notification.
(3) The licensee shall submit a written report to the department within fifteen days after discovery of the therapy misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the therapy misadministration; why it occurred; the effect on the individual; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual, and if not, why not, and if there was notification, what information was provided. The report shall not include the individual's name or other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the therapy misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.
(4) If the individual was notified, the licensee shall also furnish, within fifteen days after discovery of the therapy misadministration, a written report to the individual by sending either:
(a) A copy of the report that was submitted to the department; or
(b) A brief description of both the therapy misadministration and the consequences, as they may affect the individual, and a statement informing the individual that the report submitted to the department can be obtained from the licensee.
(5) Each licensee shall retain a record of each therapy misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the therapy misadministration, and that individual's referring physician), the individual's Social Security number or identification number if one has been assigned, a brief description of the therapy misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individual's receiving therapy misadministrations, or to that individual's responsible relatives or guardians.

[Statutory Authority: RCW 70.98.050. 98-13-037, § 246-240-050, filed 6/8/98, effective 7/9/98. Statutory Authority: RCW 70.98.050 and 70.98.080. 92-06-008 (Order 245), § 246-240-050, filed 2/21/92, effective 3/23/92.]