

**420-3-26-.03 Standards for Protection Against Radiation****General Provisions****(1) Purpose.**

(a) This Rule, 420-3-26-.03, establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These rules are issued pursuant to Act No. 582, Regular Session, 1963, as amended.

(b) The requirements of this Rule 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 Rule. However, nothing in this Rule shall be construed as limiting actions that may be necessary to protect health and safety.

(2) **Scope.** Except as specifically provided in other parts of these rules, this Rule applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this Rule do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or to voluntary participation in medical research programs.

**(3) Definitions.** As used in this Rule:

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

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

(c) "Adult" means an individual 18 or more years of age.

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

(e) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of this Rule.

2. To such a degree that an individual present in the area without respiratory

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protective equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

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

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

(h) "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 Table I, Columns 1 and 2, of Appendix B.

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

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

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

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

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(m) "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 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

(n) "Collective dose" is 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.

(o) "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 50-year period following the intake.

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

(q) "Constraint (dose commitment)" means a value above which specified licensee actions are required.

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

(s) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

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

(u) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits (1) release of the property for unrestricted use and termination of the license or (2) release of the property under restricted conditions and termination of the license.

(v) "Deep-dose equivalent" ( $H_d$ ), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm. ( $1000 \text{ mg/cm}^2$ ).

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

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(x) "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 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

(y) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

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

(aa) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

(bb) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

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

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

(ee) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials or machines which produce radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(ff) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(gg) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

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(hh) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

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

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

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

(ll) "Generally applicable environmental radiation standards" means standards issued by the 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.

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

(nn) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

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

(pp) "Individual" means any human being.

(qq) "Individual monitoring" means:

1. The assessment of dose equivalent by the use of devices designed to be worn by an individual;
2. The assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or
3. The assessment of dose equivalent by the use of survey data.

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(rr) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

(ss) "Inhalation class" [see "Class"].

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

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

(vv) "License" means a license issued by the Agency in accordance with the rules adopted by the Agency

(ww) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.

(xx) "Licensee" means any person who is licensed by the Agency in accordance with the rules and the Act.

(yy) "Limits (dose limits)" means the permissible upper bounds of radiation doses.

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

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

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

(ccc) "Minor" means an individual less than 18 years of age.

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

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

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

(ggg) "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), from voluntary participation in medical research programs, or as a member of the public.

(hhh) "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 other than the U. S. Nuclear Regulatory Commission, and other Federal Government Agencies licensed by the U. S. Department of Energy, and other than Federal Government Agencies licensed by the U. S. Nuclear Regulatory Commission.

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

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

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

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

(mmm) "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or dose from voluntary participation in medical research programs.

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

(ooo) "Quality factor" means the modifying factor listed in the table below that is used to derive dose equivalent from absorbed dose:

**QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES**

<u>TYPE OF RADIATION</u>	<u>Quality Factor (Q)</u>	<u>Absorbed Dose Equal to a Unit Dose Equivalent<sup>a</sup></u>
X, gamma, or beta radiation and high-speed electrons	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

<sup>a</sup>Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

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

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

(rrr) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

(sss) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirem) (0.05 Msv) in one hour at 30 centimeters from the radiation source or from the surface that the radiation

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penetrates.

(ttt) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at 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.

(uuu) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources, used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this rule.

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

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

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

(yyy) "Shallow-dose equivalent (H<sub>s</sub>), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>) averaged over an area of one square centimeter.

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

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

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

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

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

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

(ffff) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

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

(hhhh) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Grays) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.<sup>1</sup>

(iiii) "Week" means 7 consecutive days starting on Sunday.

(jjjj) "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 <sup>a</sup>
Whole Body	1.00 <sup>b</sup>

<sup>1</sup>At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem.

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<sup>a</sup> 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

<sup>b</sup> 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.

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

(llll) "Working level (WL)" is any combination of short lived radon daughters in one liter of air that will result in the ultimate emission of  $1.3E+5$  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.

(mmmm) "Working level month (WLM)" means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).

(nnnn) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. 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.

(4) **Implementation.**

(a) Any existing license or registration condition that is more restrictive than this Rule remains in force until there is an amendment or renewal of the license or registration.

(b) If a license or registration condition exempts a licensee or registrant from a provision of this Rule in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this Rule.

(c) If a license or registration condition cites provisions of this Rule in effect prior to January 1, 1994, which do not correspond to any provisions of this Rule, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

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**Radiation Protection Programs****(5) Radiation Protection Programs.**

(a) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Rule. See 420-3-26-.03(41) for recordkeeping requirements relating to these programs.

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

(c) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of 420-3-26-.03(5)(b) and notwithstanding the requirements of 420-3-26-.03(14), a constraint on air emissions of radioactive material to the environment, excluding radon-222 and daughters of radon, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 millirem (0.1 mSv) per year from those emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall file a report with the Agency as provided by 420-3-26-.03(53) and promptly take appropriate corrective action to ensure against recurrence.

**Occupational Dose Limits****(6) Occupational Dose Limits for Adults.**

(a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 420-3-26-.03(11), to the following dose limits:

1. An annual limit, which is the more limiting of:

(i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(i) A lens dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

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(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 420-3-26-.03(11)(e)1. and 2.

(c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

1. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

2. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a method approved by the Agency. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

32. When a protective apron is worn and monitoring is conducted as specified in 420-3-26-.03(18)(c), the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in 420-3-26-.03(6)(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

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

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose (see 420-3-26-.03(46) and to demonstrate compliance with the occupational dose limits.

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(e) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 420-3-26-.03(10)(e).

**(7) Compliance with Requirements for Summation of External and Internal Doses.**

(a) If the licensee or registrant is required to monitor pursuant to both 420-3-26-.03(18)(a) and (b), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 420-3-26-.03(18)(a) or only pursuant to 420-3-26-.03(18)(b), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 420-3-26-.03(7)(b),(c), and (d). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

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

1. The sum of the fractions of the inhalation ALI for each radionuclide, or
2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor,  $w_T$ , and the committed dose equivalent,  $H_{T,50}$ , per unit intake is greater than 10 percent of the maximum weighted value of  $H_{50}$  (i.e.  $w_T H_{T,50}$ , per unit intake for any organ or tissue).

(c) **Intake by Oral Ingestion.** If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) **Intake through Wounds or Absorption through Skin.** The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The

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intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 420-3- 26-.03(7)(d).

**(8) Determination of External Dose from Airborne Radioactive Material.**

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

(b) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

**(9) Determination of Internal Exposure.**

(a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 420-3-26-.03(18), take suitable and timely measurements of:

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

(b) Unless respiratory protective equipment is used, as provided in 420-3-26-.03(24), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

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

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

2. Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

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3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in 420-3-26-.03(9)(a)2. and 3., the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 420-3-26-.03(52) or 420-3-26-.03(53). This delay permits the licensee to make additional measurements basic to the assessments.

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

1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

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

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

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 420-3-26-.03(6) and in complying with the monitoring requirements in 420-3-26-.03(17)(b) and (c), and

2. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

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

1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

2. For an ALI and the associated DAC determined by the nonstochastic organ dose

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limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in 420-3-26-.03(6)(a)1.(ii) is met.

(10) **Determination of Prior Occupational Dose.**

(a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 420-3-26-.03(18), the licensee or registrant shall:

1. Determine the occupational radiation dose received during the current year; and
2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

1. The internal and external doses from all previous planned special exposures; and
2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and
3. All lifetime cumulative occupational radiation dose.

(c) In complying with the requirements of 420-3-26-.03(10)(a), a licensee or registrant may:

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

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(d) 1. The licensee or registrant shall record the exposure history as required by 420-3-26-.03(10)(a), on Agency Form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form Y or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form Y or equivalent indicating the periods of time for which data are not available.

2. Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this Rule in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Agency Form Y or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

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

1. In establishing administrative controls pursuant to 420-3-26-.03(6)(f) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

2. That the individual is not available for planned special exposures.

(f) The licensee or registrant shall retain the records on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.

(11) **Planned Special Exposures.** A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 420-3-26-.03(6) provided that each of the following conditions is satisfied:

(a) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(b) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

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(c) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

1. Informed of the purpose of the planned operation; and
2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 420-3-26-.03(6)(b) during the lifetime of the individual for each individual involved.

(e) Subject to 420-3-26-.03(6)(b), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

1. The numerical values of any of the dose limits in 420-3-26-.03(6)(a) in any year; and
2. Five times the annual dose limits in 420-3-26-.03(6)(a) during the individual's lifetime.

(f) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 420-3-26-.03(45) and submits a written report in accordance with 420-3-26-.03(54).

(g) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 420-3-26-.03(6)(a) but shall be included in evaluations required by 420-3-26-.03(11)(d) and (e).

(12) **Occupational Dose Limits for Minors.** The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 420-3-26-.03(6).

(13) **Dose Equivalent to an Embryo/Fetus.**

(a) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does

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not exceed 5 mSv (0.5 rem). See 420-3-26-.03(46) for recordkeeping requirements.

(b) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 420-3-26-.03(13)(a).

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

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

(d) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with 420-3-26-.03(13)(a) if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

(14) **Dose Limits for Individual Members of the Public.**

(a) Each licensee or registrant shall conduct operations so that:

1. 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 contribution from background radiation, from any medical administration the individual has received, from exposures to individuals administered radioactive material and released in accordance with 420-3-26-.07(41), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 420-3-26-.03(35),\* and

2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 420-3-26-.07(41), does not exceed 0.02 mSv (0.002 rem) in any one hour.

(b) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:

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\*Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994 and met the previous requirements of 5 mSv (0.5 rem) in a year.

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1. Demonstration of the need for and the expected duration of operations in excess of the limit in 420-3-26-.03(14)(a); and

2. The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and

3. The procedures to be followed to maintain the dose ALARA.

(d) In addition to the requirements of this Rule, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

(e) The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

**(15) Compliance with Dose Limits for Individual Members of the Public.**

(a) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 420-3-26-.03(14).

(b) A licensee or registrant shall show compliance with the annual dose limit in 420-3-26-.03(14) by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

2. Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

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

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(16) **Testing for Leakage or Contamination of Sealed Sources.**

(a) The licensee in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in 420-3-26-.03(16)(b), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee .

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use.

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005  $\mu\text{Ci}$ ) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001  $\mu\text{Ci}$ ) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005  $\mu\text{Ci}$ ) of a radium daughter which has a half-life greater than 4 days.

(b) A licensee need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

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2. Sealed sources containing only radioactive material as a gas;
3. Sealed sources containing 3.7 MBq (100  $\mu$ Ci) or less of beta or photon-emitting material or 370 kBq (10  $\mu$ Ci) or less of alpha-emitting material;
4. Sealed sources containing only hydrogen-3;
5. Seeds of iridium-192 encased in nylon ribbon; and
6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

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

(e) The following shall be considered evidence that a sealed source is leaking:

1. The presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination on any test sample.

2. Leakage of 37 Bq (0.001  $\mu$ Ci) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

3. The presence of removable contamination resulting from the decay of 185 Bq (0.005  $\mu$ Ci) or more of radium.

(f) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Rule.

(g) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 420-3-26-.03(58).

### **Surveys and Monitoring**

(17) **General.**

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- (a) Each licensee or registrant shall make, or cause to be made, surveys that:
  - 1. Are necessary for the licensee or registrant to comply with this Rule; and
  - 2. Are necessary under the circumstances to evaluate:
    - (i) The magnitude and extent of levels; and
    - (ii) Concentrations or quantities of radioactive material; and
    - (iii) The potential radiological hazards.

(b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

(c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 420-3-26-.03(6), with other applicable provisions of these, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

- 1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
- 2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(d) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

**(18) Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.**

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Rule. As a minimum:

(a) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

- 1. Adults likely to receive, in 1 year from sources external to the body, a dose in

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excess of 10 percent of the limits in 420-3-26-.03(6)(a); and

2. Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); and

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor, to determine compliance with 420-3-26-.03(9), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

2. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

(c) For individuals working with medical fluoroscopic equipment:

1. An individual monitoring device used to determine the dose to an embryo/fetus of a declared pregnant woman, pursuant to 420-3-26-.03(18)(a)2., shall be located under the protective apron at the waist. (Note: It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A certified expert, such as a medical physicist who is certified by the American Board of Radiology in Diagnostic Radiological Physics or in Radiological Physics should be consulted to determine the dose to the embryo/fetus for the occasions in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these rules, the value to be used for determining the dose to the embryo/fetus pursuant to 420-3-26-.03(13), for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert.)

2. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

3. When only one individual monitoring device is used to determine the effective

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dose equivalent for external radiation pursuant to 420-3-26-.03(6)(C)2., it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. (Note: The second individual monitoring device is required for a declared pregnant woman.)

### **Control of Exposure From External Sources in Restricted Areas**

#### **(19) Control of Access to High Radiation Areas.**

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

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

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

3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by 420-3-26-.03(19)(a) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

(d) The licensee or registrant shall establish the controls required by 420-3-26-.03(19)(a) and (c) in a way that does not prevent individuals from leaving a high radiation area.

(e) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

1. The packages do not remain in the area longer than 3 days; and

2. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

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

(g) A registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 420-3-26-.06 for x-rays in the healing arts, and 420-3-26-.09 for particle accelerators. Entrance or access to rooms is required to be controlled when equipment is in operation.

**(20) Control of Access to Very High Radiation Areas.**

(a) In addition to the requirements in 420-3-26-.03(19), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(b) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 420-3-26-.03(20)(a) if the registrant has met all the specific requirements for access and control specified in other applicable rules, such as, 420-3-26-.04 for industrial radiography, 420-3-26-.06 for x rays in the healing arts, and 420-3-26-.09 for particle accelerators.

**(21) Control of Access to Very High Radiation Areas -- Irradiators.**

(a) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(b) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

1. Each entrance or access point shall be equipped with entry control devices which:

(i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

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(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that would result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

2. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 420-3-26-.03(21)(b)1.:

(i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

3. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 420-3-26-.03(21)(b)3. and 4.

6. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly

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identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

7. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

8. Each area shall be checked by a radiation measurement to ensure, that prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

9. The entry control devices required in 420-3-26-.03(21)(b)1. shall be tested for proper functioning. See 420-3-26-.03(49) for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

10. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

11. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(c) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 420-3-26-.03(21)(b) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 420-3-26-.03(21)(b), such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 420-3-26-.03(21)(b). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an

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individual can gain access to the area where such sources of radiation are used.

(d) The entry control devices required by 420-3-26-.03(21)(b) and (c) shall be established in such a way that no individual will be prevented from leaving the area.

(22) **Use of Process or Other Engineering Controls.** The licensee shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

(23) **Use of Other Controls.** When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- (a) Control of access; or
- (b) Limitation of exposure times; or
- (c) Use of respiratory protection equipment; or
- (d) Other controls.

### **Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas**

#### **(24.1) Use of Individual Respiratory Protection Equipment.**

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to 420-3-26-.03(23):

1. Except as provided in 420-3-26-.03(24)(a)2., the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

2. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

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3. 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, 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 every 12 months thereafter, that the individual user is medically fit to use the respiratory protection equipment.
4. 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.
5. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.
6. The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.
  - (b) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 420-3-26-.03(23), provided that the following conditions, in addition to those in 420-3-26-.03(24)(a), are satisfied:
    1. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment

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with a protection factor greater than the peak concentration is inconsistent with the goal specified in 420-3-26-.03(23) of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

2. The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency 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.

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

(d) The licensee shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 420-3-26-.03(24)(a) or (b).

(24.2) **Use of Process or Other Engineering Controls.** The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

(24.3) **Use of Other Controls**

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

- 1. Control of access;
- 2. Limitation of exposure time;
- 3. Use of respiratory protection equipment; or

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## 4. Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' individual health and safety.

(24.4) **Use of Individual Respiratory Protection Equipment.** If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material:

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this Rule.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the Agency for authorized use of this equipment except as provided in this Rule. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;
2. Surveys and bioassays, as necessary, to evaluate actual intakes;
3. Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;
4. Written procedures regarding:
  - (i) Monitoring, including air sampling and bioassays;
  - (ii) Supervision and training of respirator users;
  - (iii) Fit testing;
  - (iv) Respirator selection;
  - (v) Breathing air quality;

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- (vi) Inventory and control;
  - (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
  - (viii) Recordkeeping; and
  - (ix) Limitations on periods of respirator use and relief from respirator use;
5. Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before:
- (i) The initial fitting of a face sealing respirator;
  - (ii) Before the first field use of non-face sealing respirators, and
  - (iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.
- (6) Fit testing, with fit factor greater than or equal to 10 times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the face-piece operating in a negative pressure mode.
- (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 also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.
  - (f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection devices and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a

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failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

1. Oxygen content (v/v) of 19.5-23.5 %;
2. Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;
3. Carbon monoxide (CO) content of 10 ppm or less;
4. Carbon dioxide content of 1,000 ppm or less; and
5. Lack of a noticeable odor.

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face - facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

**(24.5) Further Restrictions on the Use of Respiratory Protection Equipment.** The Agency may impose restrictions in addition to the provisions of 420-3-26-.03(23), 420-3-26-.03(24), and Appendix A to Rule 420-3-26-.03, in order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

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(24.6) **Application for Use of Higher Assigned Protection Factors.** The licensee shall obtain authorization from the Agency before using assigned protection factors in excess of those specified in Appendix A of Rule 420-3-26-.03. The Agency may authorize a licensee to use higher assigned protection factors upon receipt of an application that:

- (a) Describes the situation for which a need exists for higher protection factors; and
- (b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

### **Storage and Control of Licensed or Registered Sources of Radiation**

(25) **Security of Stored Sources of Radiation.** The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.

(26) **Control of Sources of Radiation not in Storage.**

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

(b) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

### **Precautionary Procedures**

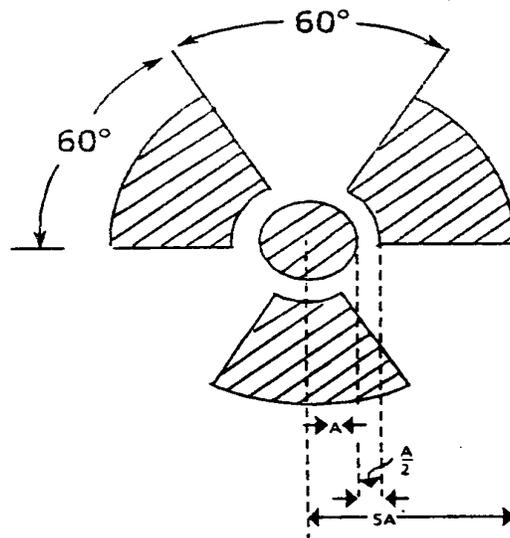
(27) **Caution Signs.**

(a) **Standard Radiation Symbol.** Unless otherwise authorized by the Agency, the symbol prescribed by 420-3-26-.03(27) shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

#### **RADIATION SYMBOL**

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.

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(b) **Exception to Color Requirements for Standard Radiation Symbol.**

Notwithstanding the requirements of 420-3-26-.03(27)(a), licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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

(28) **Posting Requirements.**

(a) **Posting of Radiation Areas.** The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) **Posting of High Radiation Areas.** The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) **Posting of Very High Radiation Areas.** The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." For each very high radiation area, created in a medical institution by the use of a registered medical particle accelerator, the word "Danger" may be substituted for the words "GRAVE DANGER".

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

(e) **Posting of Areas or Rooms in Which Licensed Radioactive Material is Used or Stored.** The licensee shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(29) **Exceptions to Posting Requirements.**

(a) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Rule; and
2. The area or room is subject to the licensee's or registrant's control.

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 420-3-26-.03(28) provided that the patient could be released from confinement pursuant to 420-3-26-.07(29) of these rules.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(d) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(30) **Labeling Containers and Radiation Machines.**

(a) The licensee shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the

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vicinity of the containers, to take precautions to avoid or minimize exposures.

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

(c) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(31) **Exemptions to Labeling Requirements.** A licensee is not required to label:

(a) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

(b) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

(c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Rule; or

(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation; <sup>\*\*</sup> or

(e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(f) Installed manufacturing or process equipment, such as piping and tanks.

(32) **Procedures for Receiving and Opening Packages.**

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 420-3-26-.03(32)(b) of these rules shall make arrangements to receive:

1. The package when the carrier offers it for delivery; or

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<sup>\*\*</sup> Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424.

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2. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(b) Each licensee shall:

1. Monitor the external surfaces of a labeled<sup>\*\*\*</sup> package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 420-3-26-.01(2)(a)103 of these rules; and

2. Monitor the external surfaces of a labeled<sup>3</sup> package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined in 420-3-26-.03(32)(b) of these rules; and

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

**Table of Exempt and Type A Quantities**

Exempt Quantity Limit (in millicuries)	Type A Quantity Limit (in curies)
$A^{****} \times 0.001$	$A_2$

(c) The licensee shall perform the monitoring required by 420-3-26-.03(32)(b) as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

1. Removable radioactive surface contamination that exceeds 0.01 microcurie (22,200 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package; or

2. Radiation levels are found on the external surface of the package in excess of 200

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\*\*\* Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

\*\*\*\* These quantities are defined as determined in 10 CFR Part 71, Appendix A. See footnote 3 on page 8.

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millirem per hour, or at three feet from the external surfaces of the package in excess of 10 millirem per hour.

(e) Each licensee shall:

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and
2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(f) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 420-3-26-.03(32)(b), but are not exempt from the monitoring requirement in 420-3-26-.03(32)(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

## **Waste Disposal**

### **(33) General Requirements.**

(a) A licensee shall dispose of licensed or registered material only:

1. By transfer to an authorized recipient as provided in 420-3-26-.03(38) of these rules, or to the U.S. Department of Energy; or
2. By decay in storage; or
3. By release in effluents within the limits in 420-3-26-.03(14); or
4. As authorized pursuant to 420-3-26-.03(34), 420-3-26-.3(35), 420-3-26-.03(36), or 420-3-26-.03(37).

(b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal; or
2. Treatment or disposal by incineration; or
3. Decay in storage; or
4. Disposal at a land disposal facility licensed pursuant to 420-3-26-.02(10)(p) of these rules; or

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5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

(34) **Method for Obtaining Approval of Proposed Disposal Procedures.** A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

(a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

(b) An analysis and evaluation of pertinent information on the nature of the environment; and

(c) The nature and location of other potentially affected facilities; and

(d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Rule.

(35) **Disposal by Release into Sanitary Sewerage.**

(a) A licensee may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble, or is readily dispersible biological material, in water; and

2. The quantity of licensed or registered radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

3. If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(ii) The sum of the fractions for each radionuclide required by 420-3-26-.03(35)(a)3.(i) does not exceed unity; and

4. The total quantity of licensed radioactive material that the licensee releases into the

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sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 420-3-26-.03(35)(a).

(36) **Treatment or Disposal by Incineration.** A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in 420-3-26-.03(37) or as specifically approved by the Agency pursuant to 420-3-26-.03(34).

(37) **Disposal of Specific Wastes.**

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

1. 1.85 kBq (0.05  $\mu$ Ci), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 1.85 kBq (0.05  $\mu$ Ci), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee shall not dispose of tissue pursuant to 420-3-26-.03(37)(a)2. in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with 420-3-26-.03(48).

(38) **Transfer for Disposal and Manifests**

(a) The requirements of this section and Appendix G to this rule, 420-3-26-.03, are designed to:

1. Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this rule, who ships low-level radioactive waste either directly, or indirectly through a waste collector or waste processor, to a low-level waste land disposal facility;

2. Establish a manifest tracking system; and

3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

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

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consignee in accordance with Appendix G of this rule.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II Appendix G to this rule.

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

(39) **Compliance with Environmental and Health Protection Regulations.** Nothing in 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38) relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38).

## Records

### (40) General Provisions.

(a) Each licensee or registrant shall use the units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Rule.

(b) In the records required by this rule, the licensee may record quantities in SI units in parentheses following each of the units specified in 420-3-26-.03(40)(a) of this rule. However, all quantities must be recorded as stated in rule 420-3-26-.03(40)(a) of this rule.

(c) Notwithstanding requirements of rule 420-3-26-.03(40)(a), when recording information on shipment manifests, as required by rule 420-3-26-.03(38)(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in rule 420-3-26-.03(40)(a).

(d) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Rule, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

### (41) Records of Radiation Protection Programs.

(a) Each licensee or registrant shall maintain records of the radiation protection program, including:

1. The provisions of the program; and

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2. Audits and other reviews of program content and implementation.

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)1. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)2. for 3 years after the record is made.

(42) **Records of Surveys.**

(a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 420-3-26-.03(17) and 420-3-26-.03(32)(b). The licensee or registrant shall retain these records for 3 years after the record is made.

(b) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

1. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 420-3-26-.03(24)(a)3.(i) and(ii); and

4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(43) **Records of Tests for Leakage or Contamination of Sealed Sources.** Records of tests for leakage or contamination of sealed sources required by 420-3-26-.03(16) shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

(44) **Records of Prior Occupational Dose.**

(a) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 420-3-26-.03(10) on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or

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registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.

(b) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

**(45) Records of Planned Special Exposures.**

(a) For each use of the provisions of 420-3-26-.03(11) for planned special exposures, the licensee or registrant shall maintain records that describe:

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

(b) The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

(c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

**(46) Records of Individual Monitoring Results.**

(a) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 420-3-26-.03(18), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:

1. The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

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2. The estimated intake of radionuclides. See 420-3-26-.03(7); and
3. The committed effective dose equivalent assigned to the intake of radionuclides;  
and
4. The specific information used to calculate the committed effective dose equivalent pursuant to 420-3-26-.03(9)(a) and (c); and 420-3-26-.03(18); and
5. The total effective dose equivalent when required by 420-3-26-.03(7); and
6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) **Recordkeeping Frequency.** The licensee or registrant shall make entries of the records specified in 420-3-26-.03(46)(a) at intervals not to exceed 1 year.

(c) **Recordkeeping Format.** The licensee or registrant shall maintain the records specified in 420-3-26-.03(46)(a) on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.

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

(e) The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

(f) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

**(47) Records of Dose to Individual Members of the Public.**

(a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (See 420-3-26-.03(14).

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(3)(48)(b) until the Agency terminates each pertinent license or registration requiring the record.

**(48) Records of Waste Disposal.**

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(a) Each licensee shall maintain records of the disposal of licensed radioactive material made pursuant to 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), and disposal by burial in soil, including burials authorized before January 1, 1994.

(b) The licensee shall retain the records required by 420-3-26-.03(48)(a) until the Agency terminates each pertinent license requiring the record.

**(49) Records of Testing Entry Control Devices for Very High Radiation Areas.**

(a) Each licensee or registrant shall maintain records of tests made pursuant to 420-3-26-.03(21)(b)9. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(49)(a) for 3 years after the record is made.

**(50) Form of Records.** Each record required by this Rule shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

## **Reports**

**(51) Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.**

(a) **Telephone Reports.** Each licensee or registrant shall report to the Agency by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

2. Within 30 days after its occurrence becomes known to the licensee lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.

3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or

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missing radiation machine.

(b) **Written Reports.** Each licensee or registrant required to make a report pursuant to 420-3-26-.03(51)(a) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and,

2. A description of the circumstances under which the loss or theft occurred; and

3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

5. Actions that have been taken, or will be taken, to recover the source of radiation; and

6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

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

(d) The licensee or registrant shall prepare any report filed with the Agency pursuant to 420-3-26-.03(51) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(52) **Notification of Incidents.**

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

1. An individual to receive:

(i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

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- (ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or
  - (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or
2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(b) **Twenty-Four Hour Notification.** Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

- 1. An individual to receive, in a period of 24 hours:
    - (i) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or
    - (ii) An eye dose equivalent exceeding 0.15 Sv (15 rem); or
    - (iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or
  - 2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.
- (c) The licensee or registrant shall prepare each report filed with the Agency pursuant to 420-3-26-.03(52) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.
- (d) Licensees or registrants shall make the reports required by 420-3-26-.03(52)(a) and (b) to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.
- (e) The provisions of 420-3-26-.03(52) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 420-3-26-.03(54).

(53) **Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.**

- (a) **Reportable Events.** In addition to the notification required by 420-3-26-.03(52),

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each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

1. Incidents for which notification is required by 420-3-26-.03(52); or
2. Doses in excess of any of the following:
  - (i) The occupational dose limits for adults in 420-3-26-.03(6); or
  - (ii) The occupational dose limits for a minor in 420-3-26-.03(12); or
  - (iii) The limits for an embryo/fetus of a declared pregnant woman in 420-3-26-.03(13);or
  - (iv) The limits for an individual member of the public in 420-3-26-.03(14); or
  - (v) Any applicable limit in the license or registration; or
  - (vi) The ALARA constraints for air emissions established under 420-3-26-.03(5)(d).
3. Levels of radiation or concentrations of radioactive material in:
  - (i) A restricted area in excess of applicable limits in the license or registration; or
  - (ii) An unrestricted area in excess of 10 times the applicable limit set forth in this Rule or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 420-3-26-.03(14); or
4. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) **Contents of Reports.**

1. Each report required by 420-3-26-.03(53)(a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
  - (i) Estimates of each individual's dose; and
  - (ii) The levels of radiation and concentrations of radioactive material involved; and
  - (iii) The cause of the elevated exposures, dose rates, or concentrations; and

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(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints generally applicable environmental standards, and associated license or registration conditions.

2. Each report filed pursuant to 420-3-26-.03(53)(a) shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 420-3-26-.03(13), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(c) All licensees or registrants who make reports pursuant to 420-3-26-.03(53)(a) shall submit the report in writing to the Agency.

(54) **Reports of Planned Special Exposures.** The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with 420-3-26-.03(11), informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 420-3-26-.03(45).

(55) [Reserved].

(56) **Reports of Individual Monitoring.**

(a) This section applies to each person licensed or registered by the Agency to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to 420-3-26-.02(10)(g) and 420-3-26-.04 of these rules; or

2. Receive radioactive waste from other persons for disposal pursuant to 420-3-26-.03(10)(p) of these rules; or

3. Possess or use at any time, for processing or manufacturing for distribution pursuant to 420-3-26-.02 or 420-3-26-.07 of these rules, radioactive material in quantities exceeding any one of the following quantities:

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Radionuclide	Activity <sup>a</sup>	
	Ci	Gbq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium- 99m	1,000	37,000

<sup>a</sup> The Agency may require as a license condition, or by rule, or order pursuant to 420-3-26-.03(60), reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

(b) Each licensee or registrant in a category listed in 420-3-26-.03(56) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 420-3-26-.03(18) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.

(c) The licensee or registrant shall file the report required by 420-3-26-.03(56)(b), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

**(57) Notifications and Reports to Individuals.**

(a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 420-3-26-.10(4) of these rules.

(b) When a licensee or registrant is required pursuant to 420-3-26-.03(53) to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of 420-3-26-.10(4)(a) of these rules.

**(58) Reports of Leaking or Contaminated Sealed Sources.** The licensee shall file a report within 5 days with the Agency if the test for leakage or contamination required pursuant to 420-3-26-.03(16) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

**(58.1) Reports of transactions Involving Nationally Tracked Sources**

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Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The manufacturer, model, and serial number of the source;
4. The radioactive material in the source;
5. The initial source strength in becquerels (curies) at the time of manufacture; and
6. The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The name and license number of the recipient facility and the shipping address;
4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
5. The radioactive material in the source;
6. The initial or current source strength in becquerels (curies);
7. The date for which the source strength is reported;
8. The shipping date;
9. The estimated arrival date; and
10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The name, address, and license number of the person that provided the source;
4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
5. The radioactive material in the source;
6. The initial or current source strength in becquerels (curies);
7. The date for which the source strength is reported;
8. The date of receipt; and
9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
4. The radioactive material in the source;
5. The initial or current source strength in becquerels (curies);
6. The date for which the source strength is reported;
7. The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;
2. The name of the individual preparing the report;
3. The waste manifest number;

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4. The container identification with the nationally tracked source.

5. The date of disposal; and

6. The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The on-line National Source Tracking System;

2. Electronically using a computer readable format;

3. By facsimile;

4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

5. By telephone with followup by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 and Category 2 nationally tracked sources shall report its initial inventory of such nationally tracked sources to the National Source Tracking System. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

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4. The radioactive material in the sealed source;
5. The initial or current source strength in becquerels (curies); and
6. The date for which the source strength is reported.

### **Radiological Criteria for License Termination**

#### **(59) General Provisions.**

(a) The criteria in this rule apply to the decommissioning of facilities licensed under 420-3-26-.02

(b) After a site has been decommissioned and the license terminated in accordance with the criteria in this rule, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this rule were not met and residual radioactivity remaining at the site could result in a significant threat to public health and safety.

(c) When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

(60) **Radiological Criteria for Unrestricted Use.** A site will be acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(61) **Criteria for License Termination Under Restricted Conditions.** A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 420-3-26-.03(59) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv)

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per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

1. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in rule 420-3-26-.02(26)(h)1;
2. Surety method, insurance, or other guarantee method as described in rule 420-3-26-.02(26)(h)2;
3. A statement of intent in the case of Federal, State, or local Government licensees, as described in rule 420-3-26-.02(26)(h)4; or
4. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with rule 420-3-26-.02(13)(m) and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

1. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee:

I. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) TEDE per year;

II. Will be enforceable; and

III. Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

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2. In seeking advice on the issues identified in rule 420-3-26-.03(60)(d)1., the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

1. 100 millirem (1 mSv) per year; or

2. 500 millirem (5 mSv) per year provided the licensee does the following:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem per year (1mSv per year) value of rule 420-3-26-.03(60)(e)1. Are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of rule 420-3-26-.03(60)(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those listed in rule 420-3-26-.03(60)(d).

**(62) Alternate Criteria for License Termination.**

(a) The Agency may terminate a license using alternate criteria greater than the dose criterion listed in rules 420-3-26-.03(59), 420-3-26-.03(60)(b), and 420-3-26-.03(d)1.(a), if the licensee:

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical,

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would be more than 100 millirem per year (1mSv per year), by submitting an analysis of possible sources of exposure;

2. Has employed to the extent practical restrictions on site use in accordance with rule 420-3-26-.03(60) in minimizing exposures at the site; and
  3. Reduces doses to ALARA levels, taking into account consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
  4. Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 420-3-26-.02(13)(m), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTO how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:
    - (i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
    - (ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
    - (iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.
- (b) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of Agency staff recommendations that will address any comments provided by Federal and other State Agencies including comments submitted by the public.
- (63) **Public Notification and Public Participation.** Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee, for release of a site pursuant to 420-3-26-.03(60) or 420-3-26-.03(61), or whenever the Agency deems such notice to be in the public interest, the Agency shall:
- (a) Notify and solicit comments from:
    1. Local and State government agencies in the vicinity of the site and other individuals who could be affected by the decommissioning of the site; and
    2. Alabama Department of Environmental Management for cases where the licensee proposes to release a site pursuant to 420-3-26-.03(62).

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(b) Publish a notice in local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to the individuals in the vicinity of the site, and solicit comments from affected parties.

(64) **Minimization of Contamination.** Applicants for licenses, other than renewals, after May 25, 2000, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, generation of radioactive waste.

Authority: §§ 22-14-4, 22-14-6, 22-14-8, and 22-14-9, Code of Alabama 1975.

Author: ~~Kirksey E. Whatley~~ Karl David Walter, ~~Director~~, Office of Radiation Control, Alabama Department of Public Health.

History: New 6-15-60; Revised 6-17-68, 3-17-71, 9-19-73; Repromulgated 8-21-74; Revised 5-21-75, 1-18-75; Recodified 6-11-78; Repromulgated and Revised 10-21-81; Repromulgated and Revised 12-31-83; Repromulgated and Revised 1-31-90; Repromulgated and Revised 2-1-92; Repealed and Repromulgated December 15, 1993; Repromulgated and Revised March 18, 1998. Revised effective May 25, 2000. Revised April 17, 2002.

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