#### CABINET FOR HEALTH AND FAMILY SERVICES

# Department for Public Health Division of Public Health Protection and Safety (Amended After Comments)

902 KAR 100:019. Standards for protection against radiation.

RELATES TO: KRS 211.842-211.852, 211.990(4)<del>[, ][10 C.F.R. 20.1001-20.1906, 20.2101-20.2204, 20.2206, Appendixes A, B-20.1001-20.2401, 40 C.F.R. 190, 49 C.F.R. 100-180, 173.403(m),(w), 173.421-173.424</del>]

STATUTORY AUTHORITY: KRS 194<u>A</u>.050(<u>1</u>),<del>[211.090,]</del> 211.844<del>[, 10 C.F.R. 10.1001-20.1906, 20.2101-20.2204, 20.2206, Appendixes A, B-20.1001-20.2401, 40 C.F.R. 190, 49 C.F.R. 100-180, 49 C.F.R. 173.403(m),(w), 173.421-173.424,]</del>

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.844 requires the cabinet for Health and Family Services to provide by administrative regulation for the registration [and licensing] of the possession or use of sources of ionizing or electronic product radiation Hand the handling and disposal of radioactive waste. This administrative regulation establishes standards for the protection of the user and general public against radiation exposure; and establishes standards for protection against ionizing radiation resulting from activities conducted by persons issued [licenses or] registrations by the cabinet; and [. This administrative regulation establishes standards to control the receipt, possession, use, transfer, and disposal of sources of radiation by a person[, licensee,] or registrant [so the total dose to an individual (including doses resulting from registered and unregistered)[licensed and unlicensed radioactive material and [ radiation sources other than background radiation) shall not exceed the standards for protection against radiation established in this administrative regulation].

Section 1. Radiation Protection Implementation.

- (1) This administrative regulation shall not limit actions required in order to protect against an immediate danger to public health and safety.
- (2) This administrative regulation shall apply to a person [lieensed or] registered by the cabinet to receive, possess, use, transfer, or dispose of sources of radiation.
- (3) The limits in this administrative regulation shall not apply to doses due to background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or voluntary participation in medical research programs.

Section 2. Radiation Protection Programs. A person[, licensee,] or registrant shall:

- (1) Develop, document, and implement a radiation protection program commensurate with the scope and extent of the person's activities and sufficient to ensure compliance with the provisions of this administrative regulation. [;]
- (2) Use procedures and engineering controls based upon sound radiation protection principles, to the extent practical, to achieve occupational doses and doses to members of the public that shall be as low as reasonably achievable (ALARA) pursuant to 902 KAR 100:015, Section 2.<del>[:1]</del>
- (3) Annually review the radiation protection program content and implementation [; and] [(4)] [Establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, to implement the ALARA requirements of subsection (2) of this section and the requirements of Section 10 of this administrative regulation.]

- [(a)] [Any constraint shall ensure that the highest dose that could be received by a person shall not exceed a dose in excess of ten (10) millirems (0.1 mSv) per year.] [(b)] [A licensee, if required to establish these constraints, shall report any exceedance as provided in Section 40 of this administrative regulation and shall take appropriate corrective action to ensure against recurrence].
- Section 3. Occupational Dose Limits for Adults.
  - (1) A person $[\frac{1}{5}]$  or registrant shall control the occupational dose to individual adults, except for planned special exposures as established in Section  $[\frac{5}{7}]$  of this administrative regulation, to:
    - (a) An annual limit, which shall be the more limiting of the:
      - 1. Total effective dose equivalent being equal to five (5) rems (0.05 SV); and
      - 2. Sum of the deep-dose equivalent and the committed dose equivalent to an individual organ or tissue, other than the lens of the eye, being equal to fifty (50) rems ((0.50) Sv); and
    - (b) The annual limits to the lens of the eye, the skin, and the extremities, which shall be:
      - 1. A lens dose equivalent of fifteen (15) rems (0.15 Sv); and
      - 2. A shallow-dose equivalent of fifty (50) rems (five-tenths (0.50) Sv) to the skin of the whole body or to the skin of an extremity.
  - (2) 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 as established in Section 5[7](3)(a) and (b) of this administrative regulation.
  - (3) The assigned deep-dose equivalent and shallow-dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow dose equivalent shall be the dose averaged over the contiguous ten (10) square centimeters of skin receiving the highest exposure. If the individual monitoring device was not in the region of highest potential 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.
  - (4) [Derived air concentration (DAC) and annual limit on intake (ALI) values are established in 10 C.F.R., 20, Appendix B, Table 1, and shall be used to:]
    - [(a)] [Determine the individual's dose as required in Section 34 of this administrative regulation; and]
    - [(b)] [Demonstrate compliance with the occupational dose limits.]
  - [(5)] [In addition to the annual dose limits, the person, licensee, or registrant shall limit the soluble uranium intake by an individual to ten (10) milligrams in a week in consideration of chemical toxicity as established in 10 C.F.R., 20 Appendix B.]
  - [(6)] A person[, lieensee,] 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 a person as described in Section 20[32] of this administrative regulation.
- Section 4. Compliance with [Requirements for] Summation of [External and Internal] Doses from Radiation Producing Machines and Radioactive Materials. A registrant who
  - [(1)] [If a] [licensee or registrant] is required to monitor for dose received by exposure to both radiation producing machines and radioactive materials[both Section 13(1) and (2) of this administrative regulation, the][licensee or registrant] shall demonstrate compliance with the dose limits by following the requirements of 902 KAR Chapter 100.

- [(2)] [If a licensee or registrant is required to monitor only by Section 13(1) or (2) of this administrative regulation, summation shall not be required to demonstrate compliance with the dose limits.]
- [(3)] [A licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting one (1) of the conditions specified in subsection (5) of this section and the conditions in subsections (6) and (7) of this section.]
- [(4)] [The dose equivalents for the lens of the eye, the skin, and the extremities shall not be included in the summation but shall be subject to separate limits established in Section 3 of this administrative regulation.]
- [(5)] [If the only intake of radionuclides occurs by inhalation, the total effective dose equivalent limit shall not be exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one (1) of the following, does not exceed unity:]
  - [(a)] [Sum of the fractions of the inhalation ALI for each radionuclide;]
  - [(b)] [Total number of derived air concentration-hours (DAC-hours) for radionuclides divided by 2,000; or]
  - [(e)] [Sum of the calculated committed effective dose equivalents to significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.]
- [(6)] [If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten (10) percent of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.]
- [(7)] [A licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.]

#### [Section 5.] [Determination of External Dose from Airborne Radioactive Material.]

- [(1)] [If determining the dose from airborne radioactive material, a licensee or registrant shall include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud.]
- [(2)] [If the airborne radioactive material includes radionuclides other than noble gases or the cloud of airborne radioactive material is not relatively uniform, airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep-dose equivalent.]
- [(3)] [The determination of the deep-dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.]

#### [Section 6.] [Determination of Internal Exposure.]

- [(1)] [For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee or registrant shall, if required by Section 13 of this administrative regulation, take suitable and timely measurements of:]
  - [(a)] [Concentrations of radioactive materials in the air in work areas;]
  - [(b)] [Quantities of radionuclides in the body;]
  - [(e)] [Quantities of radionuclides exercted from the body; or]
  - [(d)] [Combinations of these measurements.]
- [(2)] [A licensee or registrant shall assume an individual inhales radioactive material at the airborne concentration in which the individual is present, unless respiratory protective equipment is used, as provided in Section 19 of this administrative regulation, or the assessment of intake is based on bioassays.]

- [(3)] [If specific information on the physical and biochemical properties of the radionuclides taken into the body, or the behavior or material in an individual is known, a licensee or registrant may:]
  - [(a)] [Use the information to calculate the committed effective dose equivalent, and, if used, the licensee or registrant shall document the information in the individual's record;]
  - [(b)] [Upon prior approval by the cabinet, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (for example, acrosol size distribution or density); and]
  - [(e)] [Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a radionuclide, as provided in 10 C.F.R., 20 Appendix A, to the committed effective dose equivalent.]
- [(4)] [If a licensee or registrant chooses to assess intakes of Class Y material using the measurements provided in subsection (1)(b) or (c) of this section, the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven (7) months, unless otherwise required by Section 39 or 40 of this administrative regulation, in order to permit the licensee or registrant to make additional measurements basic to the assessments.]
- [(5)] [If the identity and concentration of radionuclides in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be the:]
  - [(a)] [Sum of the ratios of the concentration to the appropriate DAC value (D, W, Y) from 10 C.F.R., 20 Appendix B, for radionuclides in the mixture; or]
  - [(b)] [Ratio of the total concentration for radionuclides in the mixture to the most restrictive DAC value for a radionuclide in the mixture.]
- [(6)] [If the identity of radionuclides in a mixture is known, but the concentration of one (1) or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of a radionuclide in the mixture.]
- [(7)] [If a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if the:]
  - [(a)] [Licensee or registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in Section 3 of this administrative regulation and in complying with the monitoring requirements in Section 13(2) of this administrative regulation;]
  - [(b)] [Concentration of a disregarded radionuclide is less than ten (10) percent of its DAC; and]
  - [(e)] [Sum of these percentages for the disregarded radionuclides in the mixture does not exceed thirty (30) percent.]
- [(8)] [In order to calculate the committed effective dose equivalent, a licensee or registrant may assume that the inhalation of one (1) ALI or an exposure of 2,000 DAC-hours results in a committed effective dose equivalent of five (5) rems (0.05 Sv) for radionuclides having their ALIs or DACs based on the committed effective dose equivalent.]
  - [(a)] [If the ALI and the associated DAC are determined by the nonstochastic organ dose limit of fifty (50) rems (five-tenths (0.50) Sv), the intake of radionuclides that result in a committed effective dose equivalent of five (5) rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in 10 C.F.R., 20 Appendix B. A licensee or registrant may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent.]
  - [(b)] [If a licensee or registrant uses the stochastic ALIs, the licensee or registrant shall also demonstrate that the limit in Section 3(1)(a)2 of this administrative regulation is met.]

#### [Section 7.] Planned Special Exposures.

- (1) 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 Section 3 of this administrative regulation provided each of the following conditions are satisfied:
  - (a) The [licensee or ] registrant authorizes a planned special exposure only in an exceptional situation if alternatives that may 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 authorize the planned special exposure, in writing, before the exposure occurs; and
  - (c) Before a planned special exposure, the <del>[licensee or ]</del>registrant ensures that the individuals involved are:
    - 1. Informed of the purpose of the planned operation;
    - 2. Informed of the estimated doses, [and ] associated potential risks, [and ] specific radiation levels, or other conditions that may 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.
- (2) Prior to permitting an individual to participate in a planned special exposure, a <del>[licensee or ]</del> registrant shall ascertain prior doses as required by Section 20<del>[32]</del>(2) of this administrative regulation during the lifetime of the individual for each individual involved.
- (3) Subject to Section 3(2) of this administrative regulation, a [licensee or ] registrant shall not authorize a planned special exposure that shall cause an individual to receive a dose from planned special exposures and doses in excess of the limits to exceed:
  - (a) The numerical values of the dose limits in Section 3(1) of this administrative regulation in a year; and
  - (b) Five (5) times the annual dose limits in Section 3(1) of this administrative regulation during the individual's lifetime.
- (4) A <del>[licensee or ]</del>registrant shall:
  - (a) Maintain records of the conduct of a planned special exposure pursuant to Section 21[33] of this administrative regulation; and
  - (b) Submit a written report pursuant to Section 28[41] of this administrative regulation.
- (5) A [licensee or ] registrant shall record the best estimate of the dose resulting from the planned special exposure in the individual's record and inform the individual, in writing, of the dose within thirty (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 by Section 3(1) of this administrative regulation but shall be included in evaluations required by subsections (2) and (3) of this section [Section 7(2) and (3) of this administrative regulation].

<u>Section 6.</u> [Section 8.] Occupational Dose Limits for Minors. The annual occupational dose limits for minors shall be ten (10) percent of the annual dose limits specified for adult workers in Section 3 of this administrative regulation.

#### Section 7. [Section 9.] Dose Equivalent to an Embryo or Fetus.

- (1) A [licensee or ] registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five-tenths (0.5) rem (5 mSv). Recordkeeping requirements are established in Section 22[42] of this administrative regulation.
- (2) A [licensee or ] registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in subsection (1) of this section.

- (3) The dose equivalent to an embryo or fetus shall be taken as the sum of:
  - (a) The deep-dose equivalent to the declared pregnant woman; and
  - (b) The dose equivalent to the embryo or fetus resulting from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.
- (4) If the dose equivalent to the embryo or fetus is found to have exceeded five-tenths (0.5) rem (five (5) mSv), or is within 0.05 rem (five-tenths (0.5) mSv) of this dose, by the time the woman declares the pregnancy to a <u>registrant</u>, the licensee or registrant, the licensee or registrant shall be in compliance with subsection (1) of this section if the additional dose equivalent to the embryo or fetus does not exceed 0.05 rem (five-tenths (0.5) mSv) during the remainder of the pregnancy.

Section 8. [Section 10.] Radiation Dose Limits for Individual Members of the Public.

- (1) A <del>[licensee or ]</del>registrant shall conduct operations to ensure that the:
  - (a) Total effective dose equivalent to individual members of the public from [licensed,] registered [,] and other operations shall not exceed 0.1 rem (one (1) mSv) in a year, exclusive of the dose contributions from:
    - 1. Background radiation;
    - 2. A medical administration the individual received; and
    - 3. [An exposure to individuals administered radioactive material and released in accordance with 902 KAR 100:072, Section 27;]
    - [4.] Voluntary participation in medical research programs; and
    - [5.] [The licensee's or registrant's disposal of radioactive material into sanitary sewerage under 902 KAR 100:021, Section 3; and]
  - (b) Dose in an unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 902 KAR 100:072, Section 27,] shall not exceed 0.002 rem (0.02 mSv) in one (1) hour.
- (2) If a <del>[licensee or ]</del>registrant permits members of the public to have access to controlled areas, the limits for members of the public specified in this section shall apply to those individuals.
- (3) A [licensee, ] registrant[,] or applicant for [a license or ] registration may apply for prior authorization to operate up to an annual dose limit for an individual member of the public of five-tenths (0.5) rem (five (5) mSv). The application shall include [the following information]:
  - (a) Demonstration of the need for, and the expected duration of, operations in excess of the limit in subsection (1) of this section;
  - (b) A [licensee's or ]registrant's program to assess and control dose within the fivetenths (0.5) rem (five (5) mSv) annual limit; and
  - (c) The procedures to be followed to maintain the dose ALARA.
- (4) [In addition to the provisions of this administrative regulation, a person, licensee, or registrant subject to the provisions of U.S. Environmental Protection Agency's applicable environmental radiation standards in 40 C.F.R. 190 shall comply with those standards.]
- [(5)] The cabinet may impose additional restrictions on <u>the total allowable</u> radiation levels in unrestricted areas[ and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.]
- [(6)] [In addition to the requirements in subsection (1)(a) of this section, a licensee may permit visitors to an individual who cannot be released under 902 KAR 100:072, Section 27, to receive a radiation dose greater than one tenth (0.1) rem (1 mSv) if:]
  - [(a)] [The radiation dose received does not exceed five-tenths (0.5) rem (5 mSv); and]
  - [(b)] [The authorized user, as defined in 902 KAR 100:010, has determined before the visit that it is appropriate].

- <u>Section 9.</u> [Section 11.] Compliance with Dose Limits for Individual Members of the Public.
  - (1) To demonstrate compliance with the dose limits for individual members of the public in Section 8[10] of this administrative regulation, a [lieensee or ] registrant shall make or cause to be made surveys of [:]
    - [(a)] radiation levels in unrestricted and controlled areas[; and]
    - [(b)] [Radioactive materials in effluents released to unrestricted and controlled areas].
  - (2) A [licensee or ] registrant shall show compliance with the annual dose limit in Section 8[10] of this administrative regulation by:
    - (a) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered [licensed] operation shall not exceed the annual dose limit; or
    - (b) Demonstrating that [:]
      - [1.] [The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the restricted area shall not exceed the values specified in 10 C.F.R. 20, Appendix B; and]
      - [2.] if an individual were continually present in an unrestricted area, the dose from external sources shall not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (five-tenths (0.5) mSv) in a year.
  - [(3)] [Upon approval from the cabinet, a licensee or registrant may adjust the effluent concentration values in 10 C.F.R., 20 Appendix B, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (for example, acrosol size distribution, solubility, density, radioactive decay equilibrium, or chemical form).]

#### Section 10. [Section 12.] Surveys and Monitoring.

- (1) A <del>[licensee or]</del> registrant shall make or cause to be made, surveys that are:
  - (a) Necessary for the [licensee or ] registrant to comply with the provisions in this administrative regulation; and
  - (b) Reasonable under the circumstances to evaluate:
    - 1. The magnitude and extent of radiation levels; and
    - 2. [Concentrations or quantities of radioactive material; and]
    - [3.] The potential radiological hazards.
- (2) A [licensee or ] registrant shall ensure that instruments and equipment used for quantitative radiation measurements (for example, dose rate[ and effluent monitoring]) are calibrated periodically for the radiation measured.
- (3) Personnel dosimeters, except direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities, that require processing to determine the radiation doses used by [licensees or ] registrants to comply with Section 3 of this administrative regulation, other applicable provisions of 902 KAR Chapter 100, or conditions specified [in a license], shall be processed and evaluated by a dosimetry processor:
  - (a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
  - (b) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.
- <u>Section 11.</u> [Section 13.] Conditions Requiring Individual Monitoring of External [and Internal] Occupational Dose.
  - (1) A [licensee or] registrant shall monitor exposures to radiation [and radioactive material] at levels sufficient to demonstrate compliance with the occupational dose limits

of this administrative regulation.

- (2) At a minimum, the <del>[licensee or ]</del>registrant shall monitor occupational exposure to radiation, from <del>[licensed and unlicensed, ]</del>registered and unregistered radiation sources under the <del>[licensee's or ]</del>registrant's control, and shall supply and require the use of individual monitoring devices by:
  - (a) Adults likely to receive, in one (1) year from radiation sources external to the body, a dose in excess of ten (10) percent of the limits in Section 3(1) of this administrative regulation;
  - (b) Minors likely to receive, in one (1) year from 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 five-tenths (0.5) rem (5 mSv);
  - (c) 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 (1mSv). All of the occupational doses in Section 3 continue to be applicable to the declared pregnant worker as long as the embryo or fetus dose limit is not exceeded; and
  - (d) Individuals entering a high or very high radiation area.
- [(2)] [A licensee or registrant shall monitor, pursuant to Section 6 of this administrative regulation, the occupational intake of radioactive material by, and assess the committed effective dose equivalent to:]
  - [(a)] [Adults likely to receive, in one (1) year, an intake in excess of ten (10) percent of the applicable ALIs in 10 C.F.R., 20 Appendix B;]
  - [(b)] [Minors likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and]
  - [(e)] [Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).]

#### Section 12. [Section 14.] Control of Access to High Radiation Areas.

- (1) A [lieensee or ] registrant shall ensure that each entrance or access point to a high radiation area shall have at least one (1) of the following features:
  - (a) A control device that, upon entry into the area, shall cause the level of radiation to be reduced below the level an individual may receive a deep-dose equivalent of 0.1 rem (one (1) mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from a surface that the radiation penetrates;
  - (b) A control device that shall energize a conspicuous visible or audible alarm signal so the individual entering the high radiation area and the supervisor of the activity shall be made aware of the entry; or
  - (c) Entryways that shall be locked, except during periods that access to the areas is required, with positive control over each individual entry.
- (2) In place of the controls required by subsection (1) of this section for a high radiation area, a [licensee or ] registrant may substitute continuous direct or electronic surveillance that shall be capable of preventing unauthorized entry.
- (3) A [licensee or ] registrant may make a written request to the cabinet for approval of an alternative method for controlling access to high radiation areas. The cabinet may grant approval for a reasonable request if the alternative method is appropriately protective of health and safety. The cabinet may require additional information related to the request [apply to the cabinet for approval of alternative methods for controlling access to high radiation areas].
- (4) A <del>[licensee or ]</del>registrant shall establish the controls required by subsections (1) and
- (3) of this section that shall not prevent individuals from leaving a high radiation area.

- [(5)] [Control shall not be required for an 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 49 C.F.R. 100-180 if the packages will not remain in the area longer than three (3) days, and the dose rate at one (1) meter from the external surface of a package will not exceed 0.01 rem (0.1 mSv) per hour.]
- [(6)] [Control of entrance or access to rooms or other areas in hospitals shall not be required solely because of the presence of patients containing radioactive material if personnel are in attendance who:]
  - [(a)] [Take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this administrative regulation; and]
  - [(b)] [Operate within the ALARA provisions of the licensee's or registrant's radiation protection program.]
- [(7)] [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 this section if the registrant has met the specific requirements for access and control specified in 902 KAR 100:100, 100:115, and 100:155.]
- Section 13. [Section 15.] Control of Access to Very High Radiation Areas.
  - (1) In addition to the provisions in Section 12[14] of this administrative regulation, a [licensee or ]registrant shall institute additional measures to ensure that an individual shall not be able to gain unauthorized or inadvertent access to areas in which radiation levels may be encountered at 500 rads (five (5) grays) or more in one (1) hour at one (1) meter from a radiation source or a surface through which the radiation penetrates.
  - (2) A registrant shall not be required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as established in subsection (1) of this section if the registrant has met the specific requirements for access and control specified in 902 KAR 100:115, 100:136, 100:137, and 100:155.[100:100, 100:115, and 100:155.]

#### [Section 16.] [Control of Access to Very High Radiation Areas for Irradiators.]

- [(1)] [This section shall apply to radiation from sources of radiation used in sealed sources in nonself-shielded irradiators.]
- [(2)] [This section shall not apply to:]
  - [(a)] [Sources of radiation used in teletherapy, radiography, or completely self-shielded irradiators in which the source:]
    - [1.] [Is both stored and operated within the same shielding radiation barrier; and]
    - [2.] [In the designed configuration of the irradiator is always physically inaccessible to an individual and cannot create high levels of radiation in an area that is accessible to an individual; and]
  - [(b)] [Sources from which the radiation shall be incidental to some other use or to nuclear reactor-generated radiation.]
- [(3)] [Areas where radiation levels may exist in excess of 500 rads (five (5) grays) in one (1) hour at one (1) meter from a source of radiation used to irradiate materials shall meet the following requirements:]
  - [(a)] [An entrance or access point shall be equipped with entry control devices that:]
    - [1.] [Function automatically to prevent an individual from inadvertently entering the area if very high radiation levels exist;]
    - [2.] [Permit deliberate entry into the area only after a control device is actuated that eauses the radiation level within the area, from the source of radiation, to be reduced below a level where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (one (1) mSv) in one (1) hour; and]

- [3.] [Prevent operation of the source of radiation if the source would produce radiation levels in the area that may result in a deep-dose equivalent to an individual in excess of 0.1 rem (one (1) mSv) in one (1) hour.]
- [(b)] [Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subsection (3)(a) of this section:]
  - [1.] [The radiation level within the area, from the source of radiation, is reduced below a level where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (one (1) mSv) in one (1) hour; and]
  - [2.] [Conspicuous visible and audible alarm signals shall be generated to make an individual attempting to enter the area aware of the hazard, and at least one (1) 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:]
- [(e)] [A licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the source's shielded storage container:]
  - [1.] [The radiation level from the source of radiation shall be reduced below a level where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (one (1) mSv) in one (1) hour; and]
  - [2.] [Conspicuous visible and audible alarm signals shall be generated to make potentially affected individuals aware of the hazard, and a licensee, registrant, or at least one (1) 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;]
- [(d)] [If the shield for the stored source is a liquid, the licensee or registrant shall provide means to:]
  - [1.] [Monitor the integrity of the shield; and]
  - [2.] [Automatically signal loss of adequate shielding;]
- [(e)] [Physical radiation barriers that comprise permanent structural components, such as walls, that have no eredible probability of failure or removal in ordinary eircumstances need not meet the requirements of paragraphs (e) and (d) of this subsection;]
- [(f)] [An area shall be equipped with devices that automatically generate conspicuous visible and audible alarm signals:]
  - [1.] [To alert personnel in the area before the source can be put into operation;]
  - [2.] [In sufficient time for an individual in the area to operate a clearly identified control device, which is installed in the area and can prevent the source from being put into operation;]
- [(g)] [An area shall be controlled by use of administrative procedures and devices as are necessary to ensure that the area is cleared of personnel prior to use of the source;]
- [(h)] [An area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after use of the source of radiation, the radiation level from the source of radiation in the area is below a level where it is possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (one (1) mSv) in one (1) hour;]
- [(i)] [The entry control devices required in paragraph (a) of this subsection shall have been tested for proper functioning as follows:]
  - [1.] [Daily prior to initial operation with the source of radiation, unless operations were continued uninterrupted from a previous day;]
  - [2.] [Prior to resumption of operation of the source of radiation after an unintended interruption; and]
  - [3.] [By adherence to a submitted schedule for periodic tests of the entry control and warning systems;]

- [(j)] [A licensee or registrant shall not conduct operations if control devices are not functioning properly, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls; and]
- [(k)] [Entry and exit portals used in transporting materials to and from the irradiation area, and not intended for use by individuals, shall be controlled by devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by an individual through these portals. Exit portals for processed materials shall be equipped to detect and signal the presence of loose radiation sources earried toward an exit to automatically prevent loose radiation sources from being earried out of the area.]

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- [(a)] [Persons holding licenses or registrations, or applicants for licenses or registrations, for radiation sources may apply to the cabinet for approval of the use of alternative safety measures if they:]
  - [1.] [Are governed by the provisions of subsection (3) of this section; and]
  - [2.] [May be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with provisions of subsection (3) of this section (for example, those for the automatic control of radiation levels).]
- [(b)] [Alternative safety measures shall provide personnel protection equivalent to those specified in subsection (3) of this section.]
- [(e)] [At least one (1) of the alternative measures shall include an entry-preventing interlock control, based on a measurement of the radiation, that ensures the absence of high radiation levels before an individual may gain access to the area in which sources of radiation are used.]
- [(5)] [Entry control devices required by subsections (3) and (4) of this section shall be established in a way that an individual shall not be prevented from leaving the area.]

[Section 17.] [Use of Process or Other Engineering Controls. The licensee or registrant shall use, to the extent practicable, process or other engineering controls (such as containment, decontamination, or ventilation) to control the concentration of radioactive material in air.]

#### [Section 18.] [Use of Other Controls.]

- [(1)] [If 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, a licensee or registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one (1) or more of the following means:]
  - (a) [Control of access;]
  - [(b)] [Limitation of exposure times;]
  - (e) Use of respiratory protection equipment; or
  - (d) [Other controls.]
- [(2)] [If the licensee or registrant performs an ALARA analysis to determine if respirators should be used, the licensee or registrant may consider safety factors other than radiological factors. The licensee or registrant may also consider the impact of respirator use on workers' industrial health and safety.]

[Section 19.] [Use of Individual Respiratory Protection Equipment.]

[(1)] [If a licensee or registrant uses respiratory protection equipment to limit the intake of radioactive material:]

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[1.] [The licensee or registrant shall use only respiratory protection equipment that shall be tested and certified by the National Institute for Occupational Safety and Health (NIOSH); or]

- [2.] [Prior to using equipment that has not been tested or certified by NIOSH, or for which there exists no schedule for testing or certification, the licensee or registrant shall submit to the cabinet an application for authorized use of that equipment, except as provided in this administrative regulation.]
  - [a.] [The application shall include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated condition of use; and]
  - [b.] [The material and performance characteristics shall be demonstrated either by licensee or registrant testing or on the basis of reliable test information;]
- [(b)] [A licensee or registrant shall implement and maintain a respiratory protection program that shall include:]
  - [1.] [Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;]
  - [2.] [Surveys and bioassays, as appropriate, 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:]
    - [a.] [Respirator selection;]
    - [b.] [Supervision and training of respirator users;]
    - [e.] [Monitoring, including air sampling and bioassays;]
    - [d.] [Fit testing;]
    - [e.] [Breathing air quality;]
    - [f.] [Inventory and control;]
    - [g.] [Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;]
    - [h.] [Recordkeeping; and]
    - [i.] [Limitations on periods of respirator use and relief from respirator use;]
  - [5.] [Determination by a physician prior to initial fitting of a face scaling respirator, and either every twelve (12) months or periodically at a frequency determined by a physician, that the individual user shall be medically fit to use the respiratory protection equipment; and]
  - [6.] [Fit testing, with a fit factor ten (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 one (1) year. Fit testing shall be performed with the facepiece operating in the negative pressure mode;]
- [(e)] [A licensee or registrant shall issue a written policy statement on respirator usage covering the:]
  - [1.] [Use of process or other engineering controls, instead of respirators;]
  - [2.] [Routine, nonroutine, and emergency use of respirators; and]
  - [3.] [Periods of respirator use and relief from respirator use;]
- [(d)] [A licensee or registrant shall advise a respirator user that the user may leave the area for relief from respirator use in the event of:]
  - [1.] [Equipment malfunction;]
  - [2.] [Physical or psychological distress;]
  - [3.] [Procedural or communication failure;]
  - [4.] [Significant deterioration of operating conditions; or]
  - [5.] [Other conditions that may require relief;]
- [(e)] [A licensee or registrant, when selecting respiratory devices, shall:]
  - [1.] [Consider limitations appropriate to type and mode of use;]

- [2.] [Provide visual correction, adequate communication, low temperature work environments, and concurrent use of other safety or radiological equipment; and]
- [3.] [Use equipment in a way as not to interfere with the proper operation of the respirator;]
- [(f)] [Standby rescue persons shall:]
  - [1.] [Be required if one-piece atmosphere-supplying suits or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself;]
  - [2.] [Be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards;]
  - [3.] [Observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means); and]
  - [4.] [Be immediately available to assist them in ease of a failure of the air supply or for any other reason that requires relief from distress;]
- [(g)] [A sufficient number of standby rescue persons shall be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed;]
- [(h)] [Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by Compressed Gas Association in publication G-7.1, Commodity Specification for Air, and included in the regulations of the Occupational Safety and Health Administration (29 C.F.R. 1910.134(i)(1)(ii)(A) through (E)). Grade D quality of air criteria include:]
  - [1.] [Oxygen content (v/v) of 19.5-23.5 percent;]
  - [2.] [Hydrocarbon (condensed) content of five (5) milligrams per cubic meter of air or less;]
  - [3.] [Carbon monoxide (CO) content of ten (10) parts per million (ppm) or less;]
  - [4.] [Carbon dioxide content of 1,000 ppm or less; and]
  - [5.] [Lack of noticeable odor;]
- [(i)] [The licensee or registrant 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; and]
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  - [1.] [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.]
  - [2.] [If the dose is later found to be greater than the estimated dose, the corrected value shall be used.]
  - [3.] [If the dose is later found to be less than the estimated dose, the corrective value may be used.]
- [(2)] [The licensee shall obtain authorization from the cabinet before using assigned protection factors in excess of those specified in 10 C.F.R. 20, Appendix A. The cabinet may authorize a licensee to use higher assigned protection factors on receipt of an application that:]
  - (a) Describes the situation for which a need exists for higher protection factors; and
  - [(b)] [Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.]

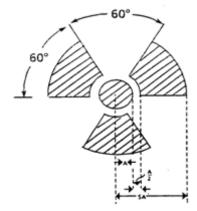
[Section 20.] [Further Restrictions on the Use of Respiratory Protection Equipment. The cabinet may impose restrictions in addition to those in Sections 18 and 19 of this administrative regulation and 10 C.F.R. 20, Appendix A to:]

- [(1)] [Ensure that the respiratory protection program of the licensee shall be adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and]
- [(2)] [Limit the extent to which a licensee shall use respiratory protection equipment instead of process or other engineering controls.]

[Section 21.] [Security of Sources of Radiation. A licensee or registrant shall secure from unauthorized removal or access, licensed materials stored in controlled or unrestricted areas.]

[Section 22.] [Control of Sources of Radiation Not in Storage. A licensee or registrant shall control and maintain constant surveillance of licensed or registered material in a controlled or unrestricted area and not in storage.]

Section 14. [Section 23.] Caution Signs and Standard Radiation Symbol.



**RADIATION SYMBOL** 

- (1) Unless otherwise authorized by the cabinet, the symbol established in this section shall use the colors magenta, purple, or black on yellow background. The symbol established in this section shall be the three (3) bladed design:
  - (a) Cross-hatched area shall be magenta, purple, or black; and
  - (b) The background shall be yellow.
- (2) [Exception to color requirements for standard radiation symbol. A licensee or registrant may label sources, source holders, or device components containing sources of radiation subjected to high temperatures with conspicuously etched or stamped radiation caution symbols and without a color requirement.]
- [(3)] Additional information on signs and labels. In addition to the contents of signs and labels prescribed in this section, a [licensee or ] registrant may 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.

#### Section 15. [Section 24.] Posting Requirements.

- (1) Posting of radiation areas. A <del>[licensee or ]</del>registrant shall post a radiation area with a conspicuous sign or signs bearing the radiation symbol and the words: "CAUTION, RADIATION AREA".
- (2) Posting of high radiation areas. A [licensee or ] registrant shall post a high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words: "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

- (3) Posting of very high radiation areas. A [licensee or ] registrant shall post a very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words: "GRAVE DANGER, VERY HIGH RADIATION AREA".
- [(4)] [Posting of airborne radioactivity areas. A licensee or registrant shall post an 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".]
- [(5)] [Posting of areas or rooms in which licensed or registered material shall be used or stored. A licensee or registrant shall post an area or room in which there is used or stored an amount of licensed or registered material exceeding ten (10) times the quantity of the material specified in 902 KAR 100:030 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".]
- <u>Section 16.</u> [Section 25.] Exceptions to Posting Requirements.
  - [(1)] A [licensee or ] registrant shall not be required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight (8) hours if the following conditions are met:
  - (1) [(a)] 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 radiation [or radioactive materials] in excess of the limits established in this administrative regulation; and
  - (2) [(b)] The area or room is subject to the [licensee's or ]registrant's control.
  - [(2)] [Rooms or other areas in hospitals occupied by patients shall not be required to be posted with caution signs pursuant to Section 24 of this administrative regulation if the patient could be released from licensee control in accordance with 902 KAR 100:072, Section 27.]
  - [(3)] [A room or area is not required to be posted with a caution sign because of the presence of a scaled source if the radiation level at thirty (30) centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.]
  - [(4)] [Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under Section 24 of this administrative regulation if:]
    - [(a)] [Access to the room is controlled pursuant to 902 KAR 100:072, Section 50; and]
    - [(b)] [Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this administrative regulation.]

#### [Section 26.] [Labeling Containers.]

- [(1)] [A licensee or registrant shall ensure a container of licensed or registered material bears a durable, clearly visible label with the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL".]
  - [(a)] [The label shall provide the following information:]
    - [1.] [Radionuclide present;]
    - [2.] [An estimate of the quantity of radioactivity;]
    - [3.] [Date the activity is estimated;]
    - [4.] [Radiation levels;]
    - [5.] [Kinds of materials; and]
    - [6.] [Mass enrichment.]
  - [(b)] [Information in this subsection shall permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.]

- [(2)] [A licensee or registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas:]
  - [(a)] [Remove or deface the radioactive material label; or]
  - [(b)] [Clearly indicate the container no longer contains radioactive materials.]

[Section 27.] [Exemptions to Labeling Requirements.]

- [(1)] [A licensee or registrant shall not be required to label:]
  - [(a)] [Containers holding licensed or registered material in quantities less than the quantities listed in 902 KAR 100:030;]
  - [(b)] [Containers holding licensed or registered material in concentrations less than those specified in 10 C.F.R. 20, Appendix B;]
  - [(e)] [Containers attended by an individual who takes precautions necessary to prevent the exposure of individuals in excess of the limits established by this administrative regulation;]
  - [(d)] [Containers if they are in transport and packaged and labeled in accordance with 49 C.F.R. Parts 100-180;]
  - [(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 (for example, containers in locations that include 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 chemical process equipment, piping, and tanks.]
- [(2)] [Labeling of packages containing radioactive materials shall be required by the U.S. Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article pursuant to 49 C.F.R. 173.403 and 173.421-173.424.]

[Section 28.] [Procedures for Receiving and Opening Packages.]

- [(1)] [A licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity pursuant to 902 KAR 100:010 shall make arrangements to receive:]
  - [(a)] [The package if the earrier offers it for delivery; or]
  - [(b)] [Notification of the arrival of the package at the carrier's terminal and take possession of the package expeditiously.]

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- [(a)] [A licensee or registrant shall monitor the external surfaces of a labeled package for:]
  - [1.] [Radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 902 KAR 100:010; and]
  - [2.] [Radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity defined in 902 KAR 100:010; and]
- [(b)] [All packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of potential contamination such as packages that are crushed, wet, or damaged.]
- [(3)] [A licensee or registrant shall perform the monitoring required by subsection (2) of this section as soon as practicable after receipt of the package, but not later than three (3) hours:]
  - [(a)] [After the package is received at the licensee's facility if received during the licensee's or registrant's normal working hours; or]
  - (b) From the beginning of the next working day if received after working hours.
- [(4)] [A licensee or registrant shall immediately notify the final delivery earrier and the Manager of the Radiation Health Branch by telephone if:]

- [(a)] [Removable radioactive surface contamination exceeds the limits of 902 KAR 100:070, Section 17; or]
- [(b)] [External radiation levels exceed the limits of 902 KAR 100:070, Section 17.]
- [(5)] [A licensee or registrant shall:]
  - [(a)] [Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and]
  - [(b)] [Ensure that the procedures are followed and due consideration is given to special instructions for the type of package being opened.]
- [(6)] [A licensee or registrant transferring special form sources in licensee or registrant owned or operated vehicles to and from a work site shall be exempt from the contamination monitoring requirements of subsection (2) of this section, but shall not be exempt from the survey requirement for measuring radiation levels that are required to ensure the source shall remain properly lodged in its shield.]

#### Section 17. [Section 29.] General Provisions for Records.

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  - (a) A [licensee or] registrant shall use the units roentgen[eurie], rad, and rem, including multiples and subdivisions, and shall clearly indicate the units of quantities on records required by this administrative regulation.
  - (b) Â
    - [1.] All quantities shall be recorded as stated in paragraph (a) of this section, except that the <u>registrant[licensee]</u> may record quantities in the International System of Units (SI) in parentheses following each of the units specified in paragraph (a) of this section.
    - [2.] [Information shall be recorded in SI or in SI and units as specified in paragraph (a) of this section when recording information on shipment manifests, as required in 902 KAR 100:021, Section 9.]
- (2) A [licensee or ] registrant shall make a clear distinction among the quantities entered on the records required by this administrative regulation, such as:
  - (a) Total effective dose equivalent;
  - (b) Shallow-dose equivalent;
  - (c) Eye dose equivalent;
  - (d) Deep-dose equivalent; and
  - (e) Committed effective dose equivalent.

#### Section 18. [Section 30.] Records of Radiation Protection Programs.

- (1) A [licensee or ] registrant shall maintain records of the radiation protection program, including:
  - (a) The provisions of the program; and
  - (b) Audits and other reviews of program content and implementation.
- (2) A <del>[licensee or ]</del>registrant shall retain records required by subsection (1)(a) of this section until the cabinet terminates each pertinent <u>registration[license]</u> requiring the record.
- (3) A [licensee or ] registrant shall retain records required by subsection (1)(b) of this section for at least three (3) years after the record is made.

#### Section 19. [Section 31.] Records of Surveys.

- (1) A <del>[licensee or ]</del>registrant shall:
  - (a) Maintain records showing the results of surveys and calibrations required by Section 10[Sections 12 and 28(2)] of this administrative regulation; and
  - (b) Retain records for at least three (3) years after the record is made.
- (2) A [licensee or ] registrant shall retain [the following records until the cabinet terminates the pertinent license or registration requiring the record:]

- [(a)] results of surveys to determine the dose from external sources of radiation and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents until the cabinet terminates the pertinent registration requiring the record[;]
- [(b)] [Results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;]
- [(e)] [Results of air sampling, surveys, and bioassays required pursuant to Section 19(1)(b)1. and 2. of this administrative regulation; and]
- [(d)] [Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment].

#### Section 20. [Section 32.] Determination of Prior Occupational Dose.

- (1) For an individual likely to receive, in a year, an occupational dose requiring monitoring under Section 11[13] of this administrative regulation, the [licensee or ]registrant shall:
  - (a) Determine the occupational radiation dose received during the current year; and
  - (b) Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- (2) Prior to permitting an individual to participate in a planned special exposure, a <del>[licensee or ]</del>registrant shall determine:
  - (a) The [internal and ] external doses from previous planned special exposures; and
  - (b) Doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.
- (3) In complying with the requirements of subsection (1) of this section, a [licensee or ]registrant may:
  - (a) Accept, as a record of the occupational dose 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 amount of an occupational dose the individual may have received during the current year;
  - (b) Accept, as the record of lifetime cumulative radiation dose, an up-to-date <u>Nuclear Regulatory Commission (NRC)[NRC]</u> Form 4, Cumulative Occupational Dose History, <u>available at https://www.nrc.gov/reading-rm/doc-collections/forms/index.html</u>, or equivalent, signed by the individual and counter-signed by an:
    - 1. Appropriate official of the most recent employer for work involving radiation exposure; or
    - 2. The individual's current employer if the individual is not employed by the [licensee or ]registrant; or
  - (c) 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, ]electronic media, or letter. If the authenticity of the transmitted report cannot be established, a [licensee or ]registrant shall request a written verification of the dose data.
- (4) A <del>[licensee or ]</del> registrant shall record the exposure history, as required by subsection (1) of this section, on NRC Form 4, Cumulative Occupational Dose History, or other clear and legible record, of the information required on that form.
  - (a) The form or record shall:
    - 1. Show each period the individual received occupational exposure to radiation or radioactive material; and
    - 2. Be signed by the individual who received the exposure.
  - (b) For each period a <del>[licensee or ]</del>registrant obtains reports, the <del>[licensee or ]</del>registrant shall use the dose shown in the report in preparing NRC Form 4, Cumulative

Occupational Dose History.

- (c) For a period in which a [licensee or ] registrant does not obtain a report, the registrant[licensee] shall place a notation on NRC Form 4, Cumulative Occupational Dose History, indicating the periods of time for which data are not available.
- (5) If a <u>registrant[lieensee]</u> is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the <del>[lieensee or ]</del>registrant shall assume:
  - (a) In establishing administrative controls under Section 3(4)[(6)] of this administrative regulation for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (twelve and five-tenths (12.5) mSv) for each quarter for which records were unavailable and the individual was engaged in activities that may have resulted in occupational radiation exposure; and
  - (b) That the individual is not available for planned special exposures.
- (6) A <del>[licensee or ]</del>registrant shall:
  - (a) Retain the records on NRC Form 4, Cumulative Occupational Dose History, or equivalent, at least until the cabinet terminates the pertinent [license or ] registration requiring this record; and
  - (b) Retain records used in preparing NRC Form 4, Cumulative Occupational Dose History, for at least three (3) years after the record is made.

#### Section 21. [Section 33.] Records of Planned Special Exposures.

- (1) For each use of the provisions of Section 5[7] of this administrative regulation for planned special exposures, a [licensee or ] registrant shall maintain records that include:
  - (a) The name of the management official who authorized the planned special exposure;
  - (b) A copy of the signed authorization; and
  - (c) Description of:
    - 1. The exceptional circumstances requiring the use of a planned special exposure;
    - 2. What actions were necessary;
    - 3. Why the actions were necessary;
    - 4. How doses were maintained ALARA;
    - 5. What individual and collective doses were expected to result; and
    - 6. The doses actually received in the planned special exposure.
- (2) A <del>[licensee or ]</del>registrant shall retain the records at least until the cabinet terminates the <del>[pertinent license or ]</del>registration requiring these records.

#### Section 22. [Section 34.] Records of Individual Monitoring Results.

- (1) A <del>[licensee or ]</del>registrant shall maintain records of doses received:
  - (a) By individuals for whom monitoring was required by Section 11[13] of this administrative regulation; and
  - (b) During planned special exposures, accidents, and emergency conditions.
- (2) The recordkeeping requirements shall include, if applicable:
  - (a) Deep-dose equivalent to the whole body;
  - (b) Lens dose equivalent;
  - (c) Shallow-dose equivalent to the skin and extremities; and
  - (d) [Estimated intake of radionuclides;]
  - [(e)] [Committed effective dose equivalent assigned to the intake of radionuclides;]
  - [(f)] [Specific information used to calculate the committed effective dose equivalent under Section 6(1) and (3), and Section 13 if required, of this administrative regulation;]
  - [(g)] Total effective dose equivalent, if required by Section 4 of this administrative regulation[; and]
  - [(h)] [Total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose].

- (3) A [licensee or ] registrant shall make entries of the records specified in subsection (1) of this section at least annually.
- (4) A [licensee or ] registrant shall maintain the records specified in subsection (1) of this section on NRC Form 5, Occupational Dose Record for a Monitoring Period, <u>available at https://www.nrc.gov/reading-rm/doc-collections/forms/index.html</u>, in accordance with the instructions for NRC Form 5, or in clear and legible records containing the information required by NRC Form 5.
- (5) The records required under this section shall be protected from public disclosure because of their personal privacy nature.
- (6) A <del>[licensee or ]</del>registrant shall maintain the:
  - (a) Records of dose to an embryo or fetus with the records of dose to the declared pregnant woman; and
  - (b) Declaration of pregnancy on file, which may be maintained separately from the dose records.
- (7) A [licensee or ] registrant shall retain each required form or record at least until the cabinet terminates the pertinent license or registration requiring the record.
- (8) Assessments of dose equivalent and records made using units in effect before a <del>[licensee's or ]</del>registrant's adoption of this administrative regulation need not to be changed.
- Section 23. [Section 35.] Records of Dose to Individual Members of the Public.
  - (1) A [licensee or ] registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public.
  - (2) A [lieensee or ] registrant shall retain the records required by subsection (1) of this section at least until the cabinet terminates the pertinent [lieense or ] registration requiring the record.

### [Section 36.] [Records of Testing Entry Control Devices for Very High Radiation Areas.] [(1)] [A licensee or registrant shall maintain records of tests made under Section 16(3)(i)

of this administrative regulation on entry control devices for very high radiation areas. These records shall include the date, time, and results of each test of function.

[(2)] [A licensee or registrant shall retain the records required by subsection (1) of this section for at least three (3) years after the record is made.]

#### Section 24. [Section 37.] Form of Records.

- (1) Records required by 902 KAR Chapter 100 shall be legible throughout the specified retention period.
- (2) The record shall be:
  - (a) The original; or
  - (b) A reproduced copy[; or]
  - [(e)] [A microform if the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period].
- (3) The record may be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period.
- (4) Records such as letters, drawings, and specifications shall include pertinent information such as stamps, initials, and signatures.
- (5) A <del>[licensee or ]</del>registrant shall maintain adequate safeguards against tampering with and loss of records.
- <u>Section 25.</u> [Section 38.] Reports of Theft or Loss of [Licensed or ] Registered Sources of Radiation.
  - (1) A registrant shall report to the cabinet a lost, stolen, or missing registered radiation producing machine [Telephone reports.]

- [(a)] [A licensee or registrant shall report by telephone as follows:]
  - [1.] [Immediately after its occurrence becomes known to the licensee or registrant, lost, stolen, or missing licensed or registered material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 902 KAR 100:030 under circumstances in which it appears to the licensee or registrant that an exposure may result to persons in unrestricted areas; or]
  - [2.] within thirty (30) days after the occurrence.
- (2) The report shall include:
  - (a) A description of the registered machine involved, including:
    - 1. Type of machine;
    - 2. Make and model of machine; and
    - 3. Maximum outputs;
  - (b) The date the loss or theft became known to the registrant; and
  - (c) A description of the circumstances under which the loss or theft occurred [of lost, stolen, or missing licensed or] registered [material] becomes known to the [licensee or] registrant, [licensed or registered material in a quantity greater than ten (10) times the quantity pursuant to 902 KAR 100:030 still missing at this time.]
  - [(b)] [Reports shall be made to the cabinet.]
- [(2)] [Written reports.]
  - [(a)] [A licensee or registrant required to make a report pursuant to subsection (1) of this section shall, within thirty (30) days after making the telephone report, make a written report setting forth the following information:]
    - [1.] [Description of the licensed or registered material involved, including:]
      - [a.] [Kind;]
      - [b.] [Quantity; and]
      - [c.] [Chemical and physical form;]
    - [2.] [Description of the circumstances under which the loss or theft occurred;]
    - [3.] [Statement of disposition, or probable disposition, of the licensed or registered material involved;]
    - [4.] [Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;]
    - [5.] [Actions that have been or shall be taken to recover the material; and]
    - [6.] [Procedures or measures that have been or shall be adopted to ensure against a recurrence of the loss or theft of licensed or registered material.]
  - (b) [Reports shall be made to the cabinet.]
- [(3)] [Subsequent to filing the written report, a licensee or registrant shall report additional substantive information on the loss or theft within thirty (30) days after the licensee or registrant learns of the information.]
- [(4)] [A licensee or registrant shall prepare and file a report with the cabinet as required by this section so that names of individuals who may have received exposure to radiation shall be stated in a separate and detachable part of the report].

#### <u>Section 26.</u> [Section 39.] Notification of Incidents.

- (1) Immediate notification. A [licensee or ]registrant shall immediately report an event involving <u>radiation producing machines[radioactive material]</u> possessed by the [licensee or ]registrant that may have caused, or threatens to cause, [one (1) or more of the following conditions:]
  - f(a) an individual to may receive:
  - (a) [1.] A total effective dose equivalent of twenty-five (25) rems (0.25 Sv) or more;
  - (b) [2.] A lens dose equivalent of seventy-five (75) rems (0.75 Sv) or more; or

- $(\underline{c})$  [3.] A shallow-dose equivalent to the skin or extremities of 250 rads (two and five-tenths (2.5) Gy) or more[;]
- [(b)] [The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual may have received an intake five (5) times the occupational annual limit on intake. The provisions of this paragraph shall not apply to locations in which personnel are not normally stationed during routine operations, such as in hot-cells or process enclosure;] [(c)] [A loss of one (1) working week or more of the operation of facilities affected; or] [(d)] [Damage to property in excess of \$200,000].
- (2) Twenty-four (24) hour notification. A [licensee or ] registrant shall, within twenty-four (24) hours of discovery of the event, report an event [involving loss of control of licensed or registered source of radiation possessed by the licensee or registrant ] that may have caused, or shall threaten to cause, [one (1) or more of the following conditions:]
  - $\frac{(a)}{(a)}$  an individual to receive, in a period of twenty-four (24) hours:
  - (a) [1.] A total effective dose equivalent exceeding five (5) rems (0.05 Sv);
  - (b) [2.] A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or
  - (c) [3.] A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (five-tenths (0.5) Sv)[;]
  - [(b)] [The release of radioactive material, inside or outside of a restricted area so that, had an individual been present for twenty-four (24) hours, the individual may have received an intake in excess of one (1) occupational annual limit on intake. The provisions of this paragraph shall not apply to locations in which personnel are not normally stationed during routine operations, such as in hot-cells or process enclosures;]
  - [(e)] [A loss of one (1) day or more of the operation of facilities affected; or]
  - [(d)] [Damage to property in excess of \$2,000].
- (3) A [licensee or ] registrant shall prepare and file a report with the cabinet as required by this section so that names of individuals who have received exposure to radiation [or radioactive material ] are stated in a separate and detachable part of the report.
- (4) <u>A [Licensees or]</u> registrant shall make reports required by subsections (1) and (2) of this section to the cabinet by telephone.
- (5) The provisions of this section shall not include doses that result from planned special exposures that are within the limits for planned special exposures, and are reported under Section <u>28[41]</u> of this administrative regulation.
- <u>Section 27.</u> [Section 40.] Reports of Exposures and [,] Radiation Levels [, and Concentrations of Radioactive Material] Exceeding the Limits.
  - (1) Reportable events. In addition to the notification required by Section <u>26[39]</u> of this administrative regulation, a <u>[licensee or ]</u>registrant shall submit a written report within thirty (30) days after learning of one (1) or more of the following occurrences:
    - (a) An incident for which notification shall be required by Section  $\underline{26[39]}$  of this administrative regulation; or
    - (b) Doses in excess of one (1) of the following:
      - 1. Occupational dose limits for adults in Section 3 of this administrative regulation;
      - 2. Occupational dose limits for a minor in Section  $\underline{6[8]}$  of this administrative regulation;
      - 3. Limits for an embryo or fetus of a declared pregnant woman in Section 7[9] of this administrative regulation;
      - 4. Limits for an individual member of the public in Section 8[10] of this administrative regulation; or
      - 5. Applicable limit in the <del>[license or]</del> registration; or
      - [6.] [ALARA constraints for air emissions established under Section 2(4);]

- (c) Levels of radiation for concentrations of radioactive material in:
  - 1. A restricted area in excess of an applicable limit in the [license or ] registration; or
  - 2. An unrestricted area in excess of ten (10) times an applicable limit set forth in this administrative regulation [, the lieense,] or the registration, regardless of whether exposure of an individual in excess of the limits in Section 8[10] of this administrative regulation occurs [; or]
- [(d)] [For a person, agency, or licensee subject to the provisions of 40 C.F.R. 190, levels of radiation or releases of radioactive material in excess of those standards, or conditions related to those standards].
- (2) Contents of reports.
  - (a) A report required by subsection (1) of this section shall describe the extent of exposure of individuals to radiation [and radioactive material, ]including, as appropriate:
    - 1. Estimates of each individual's dose;
    - 2. The levels of radiation [and concentrations of radioactive material] involved;
    - 3. The cause of the elevated exposures or [,] dose rates [, or concentrations]; and
    - 4. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits [, ALARA constraints and environmental standards, and associated license or registration conditions].
  - (b) A report filed under subsection (1) of this section shall include for each individual exposed:
    - 1. Name of the individual;
    - 2. Social Security number; and
    - 3. Date of birth.
  - (c) The report shall be prepared so that information is stated in a separate and detachable part.
  - (d) With respect to the limit for the embryo or fetus, the identifiers shall be of the declared pregnant woman.
- (3) A [licensee or ] registrant who makes a report under subsection (1) of this section shall submit the report, in writing, to the Manager of the Radiation Health Branch, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.

#### <u>Section 28.</u> [Section 41.] Reports of Planned Special Exposures.

- (1) A [licensee or ] registrant shall submit a written report to the Manager of the Radiation Health Branch, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621, within thirty (30) days following a planned special exposure conducted in accordance with Section 5[7] of this administrative regulation.
- (2) A <del>[licensee or ]</del>registrant shall:
  - (a) Inform the Manager of the Radiation Health Branch that a planned special exposure was conducted;
  - (b) Indicate the date the planned special exposure occurred; and
  - (c) Provide the information required by Section 21[33] of this administrative regulation.

#### Section 29. Incorporation by Reference.

- (1) The following material is incorporated by reference:
  - (a) "Cumulative Occupational Dose History", NRC Form 4, November 2020; and
  - (b) "Occupational Dose Record for Monitoring Period", NRC Form 5, January 2021.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, 8 a.m. until 4:30 p.m., Monday through Friday.

### (3) This material is also available at https://www.nrc.gov/reading-rm/doc-collections/forms/index.html.

[Section 42.] [Reports of Individual Monitoring.]

[(1)] [This section shall apply to persons licensed or registered by the cabinet to:]

[(a)] [Possess or use sources of radiation for purposes of radiography authorized by 902 KAR 100:100;]

[(b)] [Receive radioactive waste from other persons for disposal pursuant to 902 KAR 100:022; or]

[(e)] [Possess or use, for processing or manufacturing for distribution required by 902 KAR 100:058, byproduct material in amounts exceeding one (1) of the following quantities:]

Â [Quantity of Radionuclide<sup>a</sup> in curies] [Cesium-137]  $\frac{1}{1}$ [Cobalt-60] <del>[1]</del> [Gold-198] <del>[100]</del> [Iodine-131] <del>[1]</del> [Iridium-192] <del>[10]</del> [Krypton-85] [1,000][Promethium-147] [10] [Technetium-99m] [1,000]

[-atf necessary, the cabinet may require as a license or registration condition, KRS 211.842-211.852 or 902 KAR 100:015, Section 8, reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.]

[(2)] [A licensee or registrant in a category listed in subsection (1) of this section shall:]
[(a)] [Submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by Section 13 of this administrative regulation during that year; and]

[(b)] [Use Form NRC 5, Occupational Dose Record for a Monitoring Period, or other clear and legible record, which contains all the information required by Form NRC 5.]

[(3)] [A licensee or registrant may include additional data for individuals for whom monitoring may be provided, but not required.]

[(4)] [A licensee or registrant shall:]

[(a)] [File the report required by subsection (2) of this section covering the preceding year on or before April 30 of each year; and]

[(b)] [Submit the report to the Manager of the Radiation Health Branch, Department for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.]

[Section 43.] [Protection Factors for Respirators. Protection factors shall be determined as established in 10 C.F.R. 20, Appendix A.]

[Section 44.] [Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of radionuclides for occupational exposure, effluent concentrations, and concentrations for release to sanitary sewerage shall be determined as established in 10 C.F.R. 20, Appendix B.]

[Section 45.] [Material Incorporated by Reference.]

[(1)] [The following material is incorporated by reference:]

[(a)] ["Cumulative Occupational Dose History", NRC Form 4, June 2011;]

[(b)] ["Occupational Dose Record for a Monitoring Period", NRC Form 5, June 2011; and]

[(e)] ["Commodity Specification for Air", August 2004.]

[(2)] [This material may be inspected, copied, or obtained, subject to copyright law, at the Office of the Commissioner of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, 8 a.m. until 4:30 p.m., Monday through Friday.]

(20 Ky.R. 2460; Am. 2791; eff. 4-11-1994; 24 Ky.R. 1982; eff. 5-18-1998; 38 Ky.R. 348; 927; eff. 11-16-2011; 41 Ky.R. 885; 1581; eff. 2-5-2015; Cert. eff. 11-12-2021; 50 Ky.R.182, 1129; eff. 12-13-2023.)

STEVEN J. STACK, Commissioner ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 11, 2023 FILED WITH LRC: October 12, 2023 at 9:30 a.m.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

#### REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

#### **Contact Person: Krista Quarles**

#### (1) Provide a brief summary of:

#### (a) What this administrative regulation does:

This administrative regulation establishes standards for the protection of the user and general public against radiation exposure and establishes standards for protection against ionizing radiation resulting from activities conducted by persons issued registrations by the cabinet. This administrative regulation establishes standards to control the receipt, possession, use, transfer, and disposal of sources of radiation by a person or registrant so the total dose to an individual (including doses resulting from registered and unregistered radiation sources other than background radiation) shall not exceed the standards for protection against radiation established in this administrative regulation.

#### (b) The necessity of this administrative regulation:

Exposure to radiation can have long lasting effects on the individual's health. The occupational exposure controls and limits established in this administrative regulation ensure the individual is protected from an overexposure of radiation.

### (c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.844 requires the cabinet to provide by administrative regulation for the registration of the possession or use of sources of ionizing or electronic product radiation.

### (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation ensures those registered with the cabinet to possess or use sources of ionizing radiation are properly registered, and individual are properly monitored to avoid an overexposure to radiation.

### (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

#### (a) How the amendment will change this existing administrative regulation:

The amendment to this administrative regulation clarifies that the requirements for registration and monitoring are applicable to sources of ionizing radiation and those who work with those machines, updates the dose limits to current industry standards, and makes other changes necessary for KRS Chapter 13A compliance. The amended after comments version makes additional changes for KRS Chapter 13A compliance.

#### (b) The necessity of the amendment to this administrative regulation:

The amendment to this administrative regulation is necessary to avoid confusion regarding the applicability of the requirements for monitoring dose limits. Those who are licensed to possess radioactive materials should not be referencing this administrative regulation. This administrative regulation is applicable to those who are registered with the cabinet to possess and utilize sources of ionizing radiation.

#### (c) How the amendment conforms to the content of the authorizing statutes:

KRS 211.842(1) establishes the Cabinet for Health and Family Services as the radiation control agency for the State of Kentucky. KRS 211.844 requires the cabinet to provide by administrative regulation for the registration of the possession or use of sources of ionizing or electronic product radiation.

#### (d) How the amendment will assist in the effective administration of the statutes:

The amendment to this administrative regulation will ensure all those who are registered to possess and use sources of ionizing radiation are properly registered with the cabinet and will ensure any occupational exposure to radiation is properly monitored.

### (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

There are currently 4,250 registrants. Registrants include those in the fields of medicine, research, industry, as well as academia, and all employees who use sources of ionizing radiation in their employment.

- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
  - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Individuals who are registered to possess and use sources of ionizing radiation will need to be aware of the occupational exposure limits, and registrants will need to be aware of the exposure limit, signage, and reporting requirements.

### (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

There will be no cost to the regulated entities as compliance with this administrative regulation is currently a condition of registration.

### (c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Workers who use sources of ionizing radiation in their employment will be properly protected from overexposure to radiation.

### (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

#### (a) Initially:

This is an ongoing program, there are no initial costs.

#### (b) On a continuing basis:

This administrative regulation does not impact cost for the agency.

### (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The Radiation Health Branch is funded through a mix of state general fund dollars and the fees paid by registrants to possess and use sources of ionizing radiation.

## (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

And increase in fees or funding is not necessary to implement the requirements of this amended administrative regulation.

### (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees established in this administrative regulation.

#### (9) TIERING: Is tiering applied?

Tiering is not applied as the requirements of this administrative regulation are applied equally to all registrants.

#### **FISCAL NOTE**

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Radiation Health Branch in the Department for Public Health will be impacted by the amendment to this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050 and 211.844.

- (3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
  - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation does not generate revenue.

- (c) How much will it cost to administer this program for the first year? This administrative regulation does not impact cost for the agency.
- (d) How much will it cost to administer this program for subsequent years? This administrative regulation does not impact cost for the agency.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

**Expenditures (+/-):** 

Other Explanation:

- (4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.
  - (a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

Cost savings for the regulated entities will result from ensuring the occupational dose to employees does not exceed established limits. Overexposure to occupational sources of ionizing radiation can result in increased time away from work and other related health concerns for the employee.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

Registrants will continue to see costs savings by protecting workers from overexposure to occupational sources of ionizing radiation in subsequent years.

(c) How much will it cost the regulated entities for the first year?

There will be no cost to regulated entities in the first year as the requirements of this administrative regulation are not new requirements.

(d) How much will it cost the regulated entities for subsequent years?

There will be no change in the cost for regulated entities in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

**Expenditures (+/-):** 

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation does not have a major economic impact.