

APA-1  
11/96

**TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION**

Control 420 Alabama Department of Public Health

Rule Number 420-3-26-.01

Rule Title General Provisions

New  XXXX Amend  Repeal  Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? n/a

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer  Date 7/20/16



**FORM APA2**  
**11/96**

**STATE BOARD OF HEALTH**  
**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama Department of Public Health

**RULE NUMBER AND TITLE:** 420-3-26-.01, General Provisions

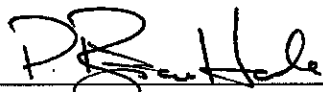
**INTENDED ACTION:** Amendment to Rule 420-3-26-.01

**SUBSTANCE OF PROPOSED ACTION:** To amend the rules to revise and make additions as needed to remain compatible with the U.S. Nuclear Regulatory Commission.

**TIME, PLACE, AND MANNER OF PRESENTING VIEWS:** A public hearing will be held at 9:00 a.m. on August 18, 2016, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

**FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE:** Written or oral comments will be received until the close of the record at 5:00 p.m. on September 2, 2016. All comments and requests for copies of the proposed rule should be addressed to the contact person listed below.

**CONTACT PERSON AT AGENCY:** David Walter, Director, Office of Radiation Control, Department of Public Health, 201 Monroe Street, Suite 1250, Montgomery, Alabama 36104. Telephone number (334) 206-5391.

  
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Brian Hale, Agency Secretary

## **420-3-26-.01 General Provisions**

(1) **Scope.** Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent, such person is subject to regulation by the U.S. Nuclear Regulatory Commission.<sup>1</sup> The provisions of Rule 420-3-26-.03 of this rule shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis or therapy by persons licensed to practice one or more of the healing arts within the authority granted them by healing arts statute or persons licensed to practice dentistry or podiatry within the authority granted them by licensing laws applying to dentists and podiatrists.

### (2) **Definitions.**

(a) As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain rule will be found in that rule.

1. "A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are listed in Rule 420-3-26-.03(32) of these rules.

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

3. "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 meV. For purposes of this definition, "particle accelerator" is an equivalent term.

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

5. "Act" means Act No. 582, Alabama Law, Regular Session, 1963. Codified as 22-14-1 Code of Alabama.

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

7. "Adult" means an individual 18 or more years of age.

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<sup>1</sup> Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

8. "Agency" means the Alabama State Board of Health.
9. "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).
10. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
11. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:
  - (i) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 420-3-26-.03 of these rules.
  - (ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.
12. "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.
13. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from licensed or registered sources regulated by the Agency.
14. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).
15. "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, quantities of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.
16. "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.
17. "Byproduct material" means:

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

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

(iii) Any discrete source of radium 226 that is produced, extracted or converted after extraction, for use for a commercial, medical, or research activity.

(iv) Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use in a commercial, medical, or research activity.

(v) Any discrete source of naturally occurring radioactive material, other than source material that the NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium 226 to the public health and safety or common defense and security, and is extracted or converted after extraction for use in a commercial, medical, or research activity.

18. "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these rules except at the beginning of a year.

19. "Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

20. "CFR" means Code of Federal Regulations.

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

22. "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

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

24. "Committed effective dose equivalent" (HE, 50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $HE,50 = \sum wT,HT,50$ ).

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

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

27. "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7E+10$  transformations per second (tps).

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

29. "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

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

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

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

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

34. "Effective dose equivalent (HE)" means the sum of the products of the dose equivalent to each organ or tissue (HT) and the weighting factor (wT) applicable to each of the body organs or tissues that are irradiated ( $HE = \sum wTHT$ ).

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

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

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

38. "Exposure" means being exposed to ionizing radiation or to radioactive material.

39. "Exposure" means the quotient of  $dQ$  by  $dm$  where " $dQ$ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " $dm$ " are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 420-3-26-.01(13), Units of Exposure and Dose for the special unit.

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

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

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

43. "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

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

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

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

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

48. "Healing arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.

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

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

51. "Individual" means any human being.

52. "Individual monitoring" means the assessment of:

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

(ii) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 420-3-26-.03].

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

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

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

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

57. "License" means a license issued by the Agency in accordance with the rules adopted by the Agency.

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



59. "Licensee" means any person who is licensed by the Agency in accordance with these rules and the Act.

60. "Licensing State" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

61. "Limits" [See "Dose limits"].

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

63. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Rule 420-3-26-.03(32) of these rules.

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

65. "Minor" means an individual less than 18 years of age.

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

67. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.<sup>2</sup>

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<sup>2</sup> For purposes of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

68. "Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix D of Rule 420-3-26-.03. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and which is not exempt from regulatory control. It does not mean radioactive material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold, but less than the Category 1 threshold.

69. "Natural radioactivity" means radioactivity of naturally occurring nuclides.

70. "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

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

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

73. "Particle accelerator" [See "Accelerator"].

74. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing other than the U.S. Nuclear Regulatory Commission, and other Federal Government Agencies licensed by the U. S Department of Energy, and other than Federal Government Agencies licensed by the U. S. Nuclear Regulatory Commission.

75. "Personnel monitoring equipment" [See "Individual monitoring devices"].

76. "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

77. "Physician" means an individual licensed by the State of Alabama to dispense drugs in the practice of medicine.

78. "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose

received as a patient from medical practices, or dose from voluntary participation in medical research programs.

79. "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

80. "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

81. "Quality factor" (Q) means the modifying factor, listed in Tables I and II of Rule 420-3-26-.01(13), that is used to derive dose equivalent from absorbed dose.

82. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

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

84. "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

85. "Radiation dose" [See "Dose"].

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

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

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

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

90. "Radiobioassay" [See "Bioassay"].

91. "Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these rules and the Act.

92. "Registration" means registration with the Agency in accordance with the rules adopted by the Agency.

93. "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

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

95. "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

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

97. "Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs per kilogram of air [See "Exposure" and 420-3-26-.03(13)].

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

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

100. "SI" means the abbreviation for the International System of Units.

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

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

103. "Source material" means:

(i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

104. "Source material milling" means any activity that results in the production of radioactive material.

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

106. "Special form radioactive material" means radioactive material that satisfies the following conditions:

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

(ii) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(iii) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

107. "Special nuclear material" means:

(i) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that<sup>3</sup> the U.S. Nuclear Regulatory Commission, pursuant to the

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<sup>3</sup> This wording is provided for states that cannot automatically adopt changes made by the U.S. Nuclear Regulatory Commission.

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

(ii) Any material artificially enriched by any of the foregoing but does not include source material.

108. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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

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

110. "Test" means the process of verifying compliance with an applicable regulation.

111. "These rules" mean Rules 420-3-26-.01 through 420-3-26-.14, inclusive.

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

113. "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in Rule 420-3-26-.03(46)(a)6. of these rules.

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

115. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

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

117. "Waste" means those low-level radioactive wastes containing source, special nuclear or other radioactive material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or radioactive material as defined in paragraphs (ii), (iii), (iv), and (v) of the definition of "Byproduct material" set forth in Rule 420-3-26-.01(2)(a)17.

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

119. "Week" means 7 consecutive days starting on Sunday.

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

121. "Worker" means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

122. "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3E+5$  MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

123. "Working level month" (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

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

(3) **Exemptions.**

(a) **General Provision.** The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) **U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors.** Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine that:

(i) ~~that~~ The exemption of the prime contractor or subcontractor is authorized by law; and

(ii) ~~that~~ Under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

**General Regulatory Requirements**

(4) **Records.** Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules. Records shall be maintained as long as specified in the rules or until the Agency authorizes disposal.



(5) **Inspections.**

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

(c) The Agency may immediately impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe these rules or provisions of the act.

(6) **Tests and Surveys.** Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) Sources of radiation;

(b) Facilities wherein sources of radiation are used or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

(7) **Additional Requirements.** The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

**Enforcement Requirements**

(8) **Violations.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(9) **Impounding.** Sources of radiation shall be subject to impounding pursuant to Section 15 of the Act.

(10) **Prohibited Uses.**

(a) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

(b) A shoe-fitting fluoroscopic device shall not be used.

(c) It shall be unlawful for any person to use, receive, own, or possess any source of radiation unless it is registered, licensed or exempted by the Agency and is operated in accordance with all applicable provisions of Rules 420-3-26-.01 through 420-3-26-.13 inclusive.

(d) Persons shall not be exposed to the useful x-ray beam except for healing arts purposes, each exposure of which shall be authorized by:

1. A licensed practitioner of the healing arts; or

2. A licensed physician's assistant, a certified registered nurse practitioner, or a certified nurse midwife subject to the rules of his/her licensure board.

3. Notwithstanding the above, the performance of x-ray backscatter scans on detainees entering or leaving a state, county or city detention facility are exempt from the requirements of 420-3-26-.01(10)(d)1. and 2., provided the x-ray backscatter devices are used in accordance with American National Standard ANSI/HPS N.43.17-2009 entitled *Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation* (available online at [www.hps.org/hpssc/N43Status.html](http://www.hps.org/hpssc/N43Status.html)).

(11) **Deliberate Misconduct.**

(a) Any licensee, registrant, applicant for a license or a certificate of registration, employee of a licensee, registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or registration, who knowingly provides to any licensee, registration holder, applicant, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registration holder's, or applicant's activities in these Rules, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, or order; or any term, condition, or limitation of any license or registration issued by the Agency; or

2. Deliberately submit to the Agency, a licensee, registrant, an applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(b) A person who violates paragraphs (a)1. or (a)2. of this rule will be subject to enforcement in accordance with procedures in Rule 420-3-26-.13.

(c) For the purposes of paragraph (a)1. of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, registrant, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license or registration issued by the Agency.

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

(12) **Communications.** All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Agency at its mailing address as follows:

Office of Radiation Control  
Alabama Department of Public Health  
P. O. Box 303017  
Montgomery, Alabama 36130-3017

(13) **Units of Exposure and Dose.**

(a) As used in these rules, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to  $2.58E-4$  coulomb per kilogram of air.

(b) As used in these rules, the units of dose are:

1. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

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

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

(b)(c) As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I  
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose <u>Equivalent<sup>a</sup></u>
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

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

(e)(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 420-3-26-.01(13)(c) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

## MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	Quality Factor <sup>a</sup> (Q)	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> rem <sup>-1</sup> )	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )
(thermal)			
2.5E-8	2	980E+6	980E+8
1E-7	2	980E+6	980E+8
1E-6	2	810E+6	810E+8
1E-5	2	810E+6	810E+8
1E-4	2	840E+6	840E+8
1E-3	2	980E+6	980E+8
1E-2	2.5	1010E+6	1010E+8
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8
1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

<sup>a</sup>Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

<sup>b</sup>Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

(14) **Units of Activity.** For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(a) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(b) One curie (Ci) =  $3.7E+10$  disintegrations or transformations per second (dps or tps) =  $3.7E+10$  becquerel (Bq) =  $2.22E+12$  disintegrations or transformations per minute (dpm or tpm).

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**Statutory Authority:** §§ 22-2-1, 22-2-2, 22-2-5, 22-2-6, 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, (*Code of Alabama, 1975*).

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