

## **Title 15: Mississippi State Department of Health**

### **Part 21: Division of Radiological Health**

#### **Subpart 78: Radiological Health**

#### **Chapter 1        REGULATIONS FOR CONTROL OF RADIATION IN MISSISSIPPI**

##### **Subchapter 1    General Provisions**

Rule 1.1.1    **Scope.** Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.<sup>1</sup>

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.2    **Definitions.** As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain section will be found in that section.

1. "A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a Type A package. "A<sub>2</sub>" means the maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Appendix A, Table A-1 of Subchapter 13 of these regulations or may be derived in accordance with the procedure prescribed in Appendix A of Subchapter 13 of these regulations.
2. "Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The units of absorbed dose are the rad and the gray (Gy).
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 radioactive material" means any material made radioactive by a particle accelerator.
5. "Acute" as used in this part, means a single radiation dose or multiple radiation dose occurring within a short time (24 hours or less).
6. "Act" means the Mississippi Radiation Protection Law of 1976.

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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 State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

7. "Activity" means the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).
8. "Adult" means an individual 18 or more years of age.

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9. "Agency" means the Mississippi State Department of Health.
10. "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 Subchapter 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).
11. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
12. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:
  - a. in excess of the derived air concentrations (DACs) specified in Subchapter 4 (10 CFR Part 20, Appendix B, Table 1) of these regulations; or
  - b. to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.
13. "Alert" means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.
14. "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 regulations 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 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.
15. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).
16. "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these regulations, "radiobioassay" is an equivalent term.
17. "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.

18. "Byproduct material" means:
- a. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;
  - b. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;
  - c. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity;
  - d. Any material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and
  - e. Any discrete source of naturally occurring radioactive material, other than source material, that the Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction for use in a commercial, medical, or research activity.
19. "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 regulations except at the beginning of a year.
20. "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.
21. "CFR" means Code of Federal Regulations"
22. "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.
23. "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.
24. "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. "Committed

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

25. "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.
26. "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.
27. "Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.
28. "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of  $3.7E+10$  transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) =  $0.001$  curie =  $3.7E+7$  tps. One microcurie (Ci) =  $0.000001$  curie =  $3.7E+4$  tps (See 1.1.16 for SI equivalent becquerel).
29. "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:
  - a. Release of the property for unrestricted use and termination of the license; or
  - b. Release of the property under restricted conditions and termination of the license.
30. "Deep dose equivalent" ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).
31. "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.
32. "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.
33. "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurements technology, survey, and statistical techniques.
34. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total

organ dose equivalent, or total effective dose equivalent. For purposes of these regulations, "radiation dose" is an equivalent term.

35. "Dose Commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.
36. "Dose equivalent ( $H_T$ )" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and the sievert (Sv).
37. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.
38. "Effective dose equivalent ( $H_E$ )" means the sum of the products of the dose equivalent to each organ or tissue ( $H_T$ ) and the weighting factor ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ ).
39. "Embryo/fetus" means the developing human organism from conception until the time of birth.
40. "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to sources of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
41. "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.
42. "Exposure" means being exposed to ionizing radiation or to radioactive material.
43. "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). The special unit of exposure is the roentgen (R) (See 1.1.15 for SI equivalent coulomb per kilogram).<sup>2</sup>

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<sup>2</sup> "When not underlined as above or indicated as 'exposure' (x), the term 'exposure' has a more general meaning in these regulations."

44. "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.
45. "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.
46. "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

47. "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.
48. "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 impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.
49. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).
50. "Hazardous waste" means those wastes designated as hazardous by the U.S. Environmental Protection Agency regulations in 40 CFR Part 261.
51. "Healing arts" means the professional disciplines authorized by the laws of this state to use sources of radiation in the diagnosis or treatment of human or animal diseases.
52. "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 millisievert) in 1 hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.
53. "Human use" means the internal or external administration of radiation or radioactive material to human beings.
54. "Individual" means any human being.
55. "Individual monitoring" means the assessment of:
  - a. Dose equivalent: (a) by the use of individual monitoring devices, or (b) by the use of survey data; or
  - b. 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 Subchapter 4).
56. "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), optically stimulated luminescence dosimeters (OSLs), pocket ionization chambers, and personal ("lapel") air sampling devices

57. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.
58. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
59. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body
60. "Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).
61. "License" means a license issued by the Agency in accordance with the regulations adopted by the Agency.
62. "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.
63. "Licensee" means any person who is licensed by the Agency in accordance with these regulations and the Act.
64. "Licensing State" means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.
65. "Limits" See "Dose limits".
66. "Lost or missing source of radiation" means a source of radiation whose location is unknown. This definition includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.
67. "Lot Tolerance Percent Defective" means the poorest quality in an individual inspection lot that should be accepted, expressed in percent defective.
68. "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 Subchapter 13 (10 CFR 71.4) of these regulations.
69. "Member of the public" means any individual except when that individual is receiving an occupational dose.
70. "Minor" means an individual less than 18 years of age.
71. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

72. "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 Subchapter 4 (10 CFR Part 20, Appendix E) of these regulations. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.
73. "Natural radioactivity" means radioactivity of naturally occurring nuclides.
74. "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.
75. "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Subchapter 7 (10 CFR 35.75) of these regulations, from voluntary participation in medical research programs, or as a member of the public.
76. "Offshore Waters" means that area of land and water, beyond Agreement States' Submerged Lands Act jurisdiction, on or above the U.S. Outer Continental Shelf.
77. "Package" means the packaging together with its radioactive contents as presented for transport.
78. "Particle accelerator" See "Accelerator".
79. "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 NRC and federal government agencies licensed or exempted by the NRC.
80. "Personnel monitoring equipment" See "Individual monitoring devices".
81. "Pharmacist" means an individual licensed by this State to compound and dispense drugs, prescriptions, and poisons.
82. "Physician" means an individual licensed by this State to dispense drugs in the practice of medicine.
83. "Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage



during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

84. "Public dose" means the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of the licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Subchapter 7 (10 CFR 35.75) of these regulations, or from voluntary participation in medical research programs.
85. "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.
86. "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.
87. "Quality factor" (Q) means the modifying factor, listed in Tables I and II of 1.1.15, that is used to derive dose equivalent from absorbed dose.
88. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).
89. "Radiation" means gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, high speed protons and other atomic particles and electromagnetic radiation consisting of associated and interacting electric and magnetic waves and ultrasonic waves.
90. "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 millisievert) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.
91. "Radiation dose" See "Dose".
92. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

93. "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.
94. "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.
95. "Radiobioassay" See "Bioassay".
96. "Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.
97. "Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.
98. "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.
99. "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee(s) control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of Subchapter 4 of these regulations.
100. "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).
101. "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.
102. "Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulomb per kilogram of air (see "Exposure" and 1.1.15).
103. "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
104. "Shallow dose equivalent" ( $H_s$ ), which applies to the external exposure of the skin of the whole body or the skin of an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>).
105. "SI" means the abbreviation for the International System of Units
106. "Sievert" (Sv) 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 sievert = 100 rems).

107. "Site area emergency" means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.
108. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.
109. "Source material" means:
- a. Uranium or thorium, or any combination thereof, in any physical or chemical form; or
  - b. 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.
110. "Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of byproduct material.
111. "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.
112. "Special form radioactive material" means radioactive material that satisfies the following conditions:
- a. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
  - b. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
  - c. 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 designed in accordance with the Nuclear Regulatory Commission requirements in effect on March 31, 1996, and constructed prior to April 1, 1998, may continue to be used. A special form encapsulation either designed or constructed after April 1, 1998, must meet requirements of this definition applicable at the time of its design or construction.
113. "Special nuclear material" means:
- a. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
  - b. Any material artificially enriched by any of the foregoing but does not include source material.

114. "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:

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

115. "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, calculations, and measurements of levels of radiation or concentrations of radioactive material present.
116. "Test" means the process of verifying compliance with an applicable regulation.
117. "These regulations" mean all sections of the Mississippi State Department of Health Regulations for Control of Radiation, Subpart 78 – Radiological Health.
118. "Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
119. "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 Subchapter 4 (10 CFR 20.2104) of these regulations.
120. "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).
121. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.
122. "Unrestricted area" means any area access to which is neither limited nor controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. For purposes of these regulations, "uncontrolled area" is an equivalent term.
123. "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a source of radiation or from any surface that the radiation penetrates.<sup>3</sup>

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<sup>3</sup> "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed

124. "Waste" means those low-level radioactive wastes containing source, special nuclear, or byproduct 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 byproduct material as defined in paragraphs (b.), (c.), (d.) and (e.) of the definition of byproduct material set forth in this section.

125. "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.
126. "Week" means 7 consecutive days starting on Sunday.
127. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.
128. "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.
129. "Working level" (WL) means any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of  $1.3\text{E}+5$  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.
130. "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).
131. "Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

*SOURCE: Miss. Code Ann. §45-14-11*

#### **Rule 1.1.3 Exemptions.**

1. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.
2. 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 regulations to the extent

that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

- a. 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;
- b. 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;
- c. 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
- d. 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:
  - 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.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.4     **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 regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.5     **Inspections.**

1. 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.
2. Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.6     **Tests.** 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:

1. sources of radiation;
2. facilities wherein sources of radiation are used or stored;
3. radiation detection and monitoring instruments; and
4. other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.7     **Reports.** Notwithstanding any other requirements for notification:

1.     **Immediate Report.** Each licensee shall notify the Agency as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).
2.     **Twenty-Four Hour Report.** Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:
  - a.     An unplanned contamination event that:
    - i.       requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;
    - ii.      involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Subchapter 4 of these regulations for the material; and
    - iii.     has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.
  - b.     An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
  - c.     An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:



- i. the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Subchapter 4 of these regulations for the material; and
  - ii. the damage affects the integrity of the licensed material or its container.
- 3. **Twenty-Four Hour Report.** Each licensee or registrant shall notify the Agency within 24 hours after the discovery of an event in which equipment is disabled or fails to function as designed when:
  - a. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
  - b. The equipment is required to be available and operable when it is disabled or fails to function; and
  - c. No redundant equipment is available and operable to perform the required safety function.
- 4. **Preparation and Submission of Reports.** Reports made by licensees or registrants in response to the requirements of this section must be made as follows:
  - a. Licensees or registrants shall make reports required by 1.1.7(1), (2), and (3) by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:
    - i. the caller's name and call back telephone number;
    - ii. a description of the event, including the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
    - iii. the exact location of the event;
    - iv. the date and time of the event;
    - v. the isotopes, quantities, and chemical and physical form of the licensed material involved; and
    - vi. any personnel radiation exposure data available.
  - b. **Written Report.** Each licensee or registrant who makes a report required by 1.1.7(1), (2), or (3) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations

may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. The reports must include the following:

- i. a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
- ii. the exact location of the event;
- iii. the isotopes, quantities and chemical and physical form of the licensed material involved;
- iv. date and time of the event;
- v. corrective actions taken or planned and the results of any evaluations or assessments; and
- vi. the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.8 **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 regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.9 **Enforcement Requirements 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 misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by Section 45-14-37 of the Act.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.10 **Enforcement Requirements Impounding.** Sources of radiation shall be subject to impounding pursuant to Section 45-14-23 of the Act.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.11 **Enforcement Requirements Prohibited Uses.**

1. A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Sources and Devices maintained by the

Agency or accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health.

2. A shoe-fitting fluoroscopic device shall not be used.
3. Sources of radiation shall not be used to expose any individual solely for training or demonstration purposes.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.1.12 Deliberate Misconduct.**

1. Any licensee, certificate holder, quality assurance program approval holder, or registrant; applicant for a license, certificate, quality assurance program approval, or registration; employee of a licensee, certificate holder, quality assurance program approval holder, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee, certificate holder, quality assurance program approval holder, or registrant or applicant, who knowingly provides to any licensee, certificate holder, quality assurance program approval holder, registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's, registrant's or applicant's activities in these regulations, may not:
  - a. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license, certificate, approval or registration issued by the Agency; or
  - b. Deliberately submit to the Agency, a licensee, certificate holder, quality assurance program approval holder, registrant, an applicant, or a licensee's, certificate holder's, quality assurance program approval holder'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.
2. A person who violates 1.1.12(1)(a) or (1)(b) of this section may be subject to enforcement action in accordance with the procedures in 1.1.17 and Chapter 45-14-37 of the Act.
3. For the purposes of 1.1.12(1)(a) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:
  - a. Would cause a licensee, certificate holder, quality assurance program approval holder, registrant or applicant to be in violation of any rule,

regulation, or order; or any term, condition, or limitation, of any license or registration issued by the Agency; or

- b. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, registrant, applicant, contractor, or subcontractor.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.13 **Interpretations.** Except as specifically authorized by the Agency in writing, no interpretation of these regulations by an officer or employee of the Agency other than a written interpretation by the legal counsel will be recognized to be binding upon the Agency.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.14 **Communications.** All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Division of Radiological Health at its office located at 3150 Lawson Street, P.O. Box 1700, Jackson, Mississippi, 39215-1700.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.1.15 **Units of Exposure and Dose.**

1. As used in these regulations, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to  $2.58 \times 10^{-4}$  coulomb per kilogram of air.
2. As used in these regulations, the units of dose are:
  - a. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).
  - b. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).
  - c. 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 sievert).
  - d. 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 sievert = 100 rems).
3. As used in these regulations, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

**TABLE I**  
**QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES**

Equal to TYPE OF RADIATION Equivalent <sup>a</sup>	Quality Factor (Q)	Absorbed Dose a Unit Dose
X-ray, 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 rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

4 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rem per hour or sievert per hour, as provided in 1.1.15(3), 1 rem (0.01 sievert) of neutron radiation of unknown energies may, for purposes of these regulations, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in rad or gray to dose equivalent in rem or sievert.

**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-2rem-1)	Fluence per Unit Dose Equivalent <sup>b</sup> (neutrons cm-2Sv-1)
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(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

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<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.

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*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.1.16 Units of Activity.** For purposes of these regulations, activity is expressed in the special unit of curie (Ci), or in the SI unit of becquerel (Bq) or their multiples, or disintegrations or transformations per unit of time.

1. One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).
2. 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).

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.1.17 Hearings and Judicial Review.** In any proceedings under these regulations for granting, denying, suspending, revoking, or amending any license or registration,

or for determining compliance with rules and regulations of the Agency, the Agency shall afford an opportunity for a hearing upon the request of any person whose interest may be affected by the proceeding, and shall admit any such person as a party to such a hearing. Any order or decision of the Agency regarding the granting, denying, suspending, revoking or amending any license or registration as provided by these regulations, shall be subject to review by writ of certiorari to the Circuit Court of Hinds County, Mississippi, at the instance of any party in interest. The filing of the appeal shall, in all cases, be with a bond, with security for all costs, as approved by the judge or clerk of the court, and shall operate as a stay of any such order or decision until the court directs otherwise. The court may review all the facts and, in disposing of the issue before it, may modify, affirm or reverse the order or decision of the Agency in whole or in part.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.1.18 Fees**

1. Application Fees
  - a. Each applicant or amendment thereto for which a fee is prescribed shall be accompanied by a remittance in the full amount of the fee. No application or amendment thereto shall be accepted or processed prior to payment of the full amount specified. No license, registration, or variance shall be issued, unless otherwise authorized by the Director of Radiological Health
  - b. Payment of the prescribed annual fee does not automatically renew the license or registration, or approval for which the fee is paid. License renewal applications must be filed in accordance with Rule 1.2.6 and/or Subchapter 3 (10 CFR 30.37).
2. Annual Fees
  - a. All activities for which an annual fee is provided shall be subject to the payment of such fee by the due date indicated on the invoice.
3. Reciprocal Agreements—Licenses and Registrants
  - a. Persons operating within Mississippi under the provision of Rule 1.2.10 and/or Subchapter 17 (10 CFR 150.20) shall submit to the Mississippi State Department of Health Division of Radiological Health the annual fee of the applicable category before the first entry into the state. The fee will allow reciprocal recognition of the license or registration for one year from the date of receipt.
4. Determination of Fee

- a. The fee for each applicable category is listed in Appendix A.
  - b. In the case of licenses that authorize more than one activity, the total fee will be for the activity assigned the higher fee.
  - c. Licenses that are amended and that result in a change in the Appendix A category to a higher fee category license shall be assessed the entire fee for that type of license effective with the amendment.
  - d. Electronic products that are in storage are subject to the same initial application fee and annual fee unless the X-ray unit is rendered permanently incapable of producing radiation and this fact is documented in writing to the Mississippi State Department of Health Division of Radiological Health.
  - e. Electronic products that are no longer possessed by the registrant (e.g., sold, donated, or transferred) shall not be subject to the annual fee, provided written documentation is received by the invoice due date, which includes the name address, and telephone number to whom possession was transferred.
5. Methods of Payment
- a. All payments must be made by electronic methods of payment.
  - b. Electronic Methods of Payment
    - 1. Persons wishing to make payments using the electronic pay method shall access the department's website and follow the instructions provided on the website.
    - 2. Persons wishing to make payments using the electronic funds transfer (EFB) method shall contact the Office of Finance and Administration for further instructions.
  - c. Cash is not an acceptable form of payment.
6. Payments and Penalties.
- a. All fees due to Radiological Health are required to be paid in full within forty-five (45) days of the invoiced fee due date.
  - b. Failure to pay all fees due within the forty-five (45) days shall cause the licensee/registrant to be in violation of these regulations and subject to a penalty fee equal to a maximum of two (2) times the amount of the fee due and payable plus an amount necessary to reimburse the costs of delinquent fee collection which may include administrative hearings for failure to pay the fee within ninety (90) days of the invoice due date.
7. Effective Date



- a. The schedule of fees prescribed herein shall be effective on June 1, 2019.
8. Multiple Locations
- a. Those persons possessing licenses or registrations that name multiple locations where sources of radiation are stored, used, or otherwise possessed, shall be subject to an additional fee of 10 percent of the annual fee for each such location within the state of Mississippi, not to exceed an amount equal to the annual fee.

*SOURCE: Miss. Code Ann. §45-14-31*

## **Appendix A                      Schedule of Fees**

<b>License Category 1</b>	<b>Application/Annual Fee</b>
Industrial Radiography	\$3675
Broad Scope Medical	\$3675
Nuclear Pharmacy	\$3675
NORM Decontamination	\$3675
General License Distribution	\$3675
Broad Scope Industrial	\$3675
Waste Compaction/transfer	\$3675
Waste Repackaging	\$3675
 <b>License Category 2</b>	
Broad Scope Educational	\$1890
Environmental Tracer Studies	\$1890
Research & Development	\$1890
Educational Research & Development	\$1890
Medical Therapeutic	\$1890
Teletherapy	\$1890
Gamma-Knife/Stereotactic Radio Surgery	\$1890
Waste Receipt/Transfer	\$1890
 <b>Specific License Fees</b>	
Civil Defense	\$661
Other Specific	\$793
Well logging	\$3306
Radioactive markers/collars	\$460
Irradiator (self-shielded)	\$1190
Irradiator (Panoramic pool or source exposed)	\$6612

Fixed In-Plant Gauges	\$1265
Pipe wall thickness Gauges	\$1265
Portable densitometer gauge	\$1265
Portable Industrial Gauge (Troxler)	\$793
Gauge Services (Repair, Installation, Removal, etc.)	\$1265
Medical Nuclear Medicine (Diagnostic only)	\$1454
Medical Eye Applicator/Bone Mineral Analyzer	\$661
Medical Mobile Nuclear Services	\$2645
Medical Satellite Facility	\$793
Gas Chromatograph	\$396
NORM Removal (Pipe cleaning)	\$1322
Waste Disposal	\$460000

### **Specific License Fees (continued)**

Waste Incineration	\$7935
Nuclear Laundry	\$5290
Licenses that authorize the possession, use and/or processing of source material for extraction of metals other than uranium or thorium. (greater than or equal to 150 kilograms)	\$12650
Licenses that authorize the possession, use and/or processing of source material for extraction of metals other than uranium or thorium. (less than 150 kilograms)	\$5750
Reciprocal License Fee	Same as Fees Above
Each Additional Storage and/or Use Area	10% of Licensing Fee

### **General Licenses**

Gauges/certain measuring	\$195.00
Gas Chromatographs	\$132.00
Static Eliminators/ion generating	\$132.00
Source material/Depleted Uranium	\$132.00
In Vitro/clinical	\$132.00
All other General Licenses	\$132.00

### **Registrations**

X-Ray Fees	
Industrial/non-healing arts	\$115/tube
Educational	\$97/tube
Healing Arts/Veterinary	\$115/tube
Computed tomography, fluoroscopic, and mammographic	\$150.00
X-Ray Industrial Radiography	\$793.00
X-Ray Services	\$396.00
Accelerators	\$989.00

Therapeutic X-Ray	\$575.00
Neutron Generators	\$690.00

### **Nuclear Reactor**

Possessing a Nuclear Regulatory Commission license or permit authorizing a nuclear reactor in the State of Mississippi for commercial production of electrical energy utilizing special nuclear material sufficient to form a critical mass, shall pay an annual fee of \$145739.00 for each such reactor so licensed or permitted.	\$145739.00
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## **Subchapter 2      Registration of Radiation Machines Facilities And Services**

### **Rule 1.2.1      Purpose and Scope.**

1. This section provides for the registration of radiation machines and facilities and for the registration of persons providing radiation machine installation, servicing, and/or services.
2. In addition to the requirements of this section, all registrants are subject to the applicable provisions of other sections of these regulations.

*Source: MS Code Ann. §45-14-3*

### **Rule 1.2.2      Definitions.**

1. "Facility" means the location at which one or more devices or sources are installed and are under the same administrative control.
2. "Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

*Source: MS Code Ann. §45-14-3*

### **Rule 1.2.3      Exemptions.**

1. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5  $\mu$  Sv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall be exempt.
2. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this section.

3. Domestic television receivers are exempt from the requirements of this section.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.4 Shielding Plan Review.**

1. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation for diagnostic or therapeutic purposes shall be submitted to the Agency for review and approval. The required information is denoted in Appendices A and B of this Subchapter.
2. The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.
3. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 1.4.1, of these regulations.
4. After installation of a radiation machine, the registrant shall maintain for inspection by the Agency:
  - a. the maximum rated technique factors of each x-ray system control panel;
  - b. scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
    - i. the results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or
    - ii. the type and thickness of materials, or lead equivalency, of each protective barrier.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.2 Registration of Radiation Machines and Facilities.** Each person having a radiation machine facility shall:

1. Apply for registration of such facility with the Agency prior to the operation of a radiation machine facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions.

2. Designate on the application form an individual to be responsible for radiation protection.
3. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 1.2.6(4) to his radiation machine facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 1.2.6.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.3     Application for Registration of Servicing and Services.**

1. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration of such services with the Agency prior to furnishing or offering to furnish any such services.
2. Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.
3. Each person applying for registration under this section shall specify:
  - a. that he has read and understands the requirements of these regulations;
  - b. the services for which he is applying for registration;
  - c. the training and experience that qualify him to discharge the services for which he is applying for registration;
  - d. the type of measurement instruments to be used, frequency of calibration, and source of calibration; and
  - e. the type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.
4. For the purpose of 1.2.6, services may include but shall not be limited to:
  - a. installation and/or servicing of radiation machines and associated radiation machine components,
  - b. calibration of radiation machines or radiation measurement instruments or devices,
  - c. radiation protection or health physics consultations or surveys, and
  - d. personnel dosimetry services.

5. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.4 Issuance of Notice of Registration.**

1. Upon a determination that an applicant meets the requirements of the regulations, the Agency shall issue a notice of registration.
2. The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.5 Expiration of Notice of Registration.** Except as provided by 1.2.9(2), each notice of registration shall expire at the end of the specified day in the month and year stated therein.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.6 Renewal of Notice of Registration.**

1. Application for renewal of registration shall be filed in accordance with 1.2.5 or 1.2.6.
2. In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.7 Report of Changes.** The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.8 Approval Not Implied.** No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 1.2.5 or 1.2.6. and no person shall state or imply that any activity under such registration has been approved by the Agency.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.9 Assembler and/or Transfer Obligation.**

1. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the Agency within 15 days of:<sup>2</sup>
  - a. the name and address of persons who have received these machines;
  - b. the manufacturer, model, and serial number of each radiation machine transferred; and
  - c. the date of transfer of each radiation machine.
2. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

*Source: MS Code Ann. §45-14-3*

**Rule 1.2.10 Out-Of-State Radiation Machines.**

1. Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Agency at least 3 days before such machine is to be used in the State. The notice shall include:
  - a. the type of radiation machine;
  - b. the nature, duration, and scope of use;
  - c. the exact location(s) where the radiation machine is to be used; and
  - d. states in which this machine is registered.
2. If, for a specific case, the 3 day period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.
3. The person referred to in 1.2.13(1) shall:
  - a. comply with all applicable regulations of the Agency;

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<sup>2</sup> In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30(d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

- b. supply the Agency with such other information as the Agency may reasonably request; and
- c. not operate within the State on a temporary basis in excess of 180 calendar days per year.

*Source: MS Code Ann. §45-14-3*



## **APPENDIX A**

### **Information On Radiation Shielding Required For Plan Reviews**

In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

- I. The plans should show, as a minimum, the following:
  - a. The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.
  - b. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
  - c. The dimensions of the room(s) concerned.
  - d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
  - e. The make and model of the x-ray equipment and the maximum technique factors, and the energy waveform (single phase, three phase, etc.).
  - f. The type of examination(s) or treatment(s) which will be performed with the equipment.
- II. Information on the anticipated workload of the x-ray system(s) in mA-minutes per week.
- III. A report showing all basic assumptions used in the development of the shielding specifications.

## **APPENDIX B**

### **Design Requirements For An Operator's Booth**

#### **I. Space Requirements:**

- a. The operator shall be allotted not less than 7.5 square feet (0.70m<sup>2</sup>) of unobstructed floor space in the booth.
- b. The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).
- c. The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- d. The booth shall be located or constructed such that unattenuated direct scatter radiation originating from the examination table or at the wall cassette holder will not reach the operator's position in the booth.

#### **II. Structural Requirements:**

- a. The booth walls shall be permanently fixed barriers of at least 7 feet (2.1 m) high.
- b. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- c. Shielding shall be provided to meet the requirements of Subchapter 4 of these regulations.

#### **III. X-Ray Exposure Control Placement:**

- a. The x-ray exposure control for the system shall be fixed within the booth and:
- b. Shall be at least 40 inches (1.0 m) from any open edge of the booth wall which is nearest to the examining table.
- c. Shall allow the operator to use the majority of the available viewing windows.

#### **IV. Viewing System Requirements:**

- a. Each booth shall have at least one viewing device which will:
  - i. Be so placed that the operator can view the patient during any exposure, and
  - ii. Be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "x-ray on" warning sign that will be

lighted anytime the rotor of the x-ray tube is activated. Alternatively, an interlock must be present such that exposures are prevented unless the door is closed.

b. When the viewing system is a window, the following requirements also apply:

- i. It shall have a viewing area of at least 1 square foot (0.093 m<sup>2</sup>).
- ii. Regardless of size or shape, at least 1 square foot of the window area must be centered no less than 2 feet (0.61 m) from the open edge of the booth and no less than 5 feet (1.52 m) from the floor.
- iii. The window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

c. When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B.IV(A).

d. When the viewing system is by electronic means:

- i. The camera shall be so located as to accomplish the general requirements of Appendix B.IV(A), and
- ii. There shall be an alternate viewing system as a backup for the primary system

## **Subchapter 3      Licensing of Radioactive Material**

### **Rule 1.3.1      Purpose and Scope.**

This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 30: 30.1, 30.2, 30.3, 30.4 (with the exception referenced in No. 1 below), 30.7, 30.9, 30.10, 30.11, 30.12, 30.13, 30.14, 30.15, 30.18, 30.19, 30.20, 30.21, 30.22, 30.31, 30.32, 30.33, 30.34, 30.35, 30.36, 30.37, 30.38, 30.39, 30.41, 30.50, 30.51, 30.52, 30.53, 30.61, 30.62, 30.70, 30.71, and 30.72 and Appendix A through Appendix E to Part 30, with the following exceptions and additions:

1. Not adopted by reference is Title 10 Code of Federal Regulations 30.4 Paragraph (2) Common defense and security, in the definition of “Commencement of Construction”, Paragraph 9(ii) Common defense and security, in the definition of “Construction”, 30.21(c), 30.34(d), 30.34(e)(1), 30.34(e)(3), and 30.41(b)(6).
2. Requirements in Title 10 Code of Federal Regulations Part 30 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", "NRC regional office", or "administrator of the appropriate regional office" appear in Title 10 Code of Federal Regulations Part 30, substitute the words "Mississippi State Department of Health" except when used in Title 10 Code of Federal Regulations 30.12, 30.21(c), 30.34(h)(1), and 30.50(c)(1).
4. Title 10 Code of Federal Regulations 30.7 employee protection also applies to violations of Mississippi State Department of Health Regulations for the Control of Radiation Subchapter 10.
5. "Act" includes Mississippi Radiation Protection Law of 1976.
6. Mississippi State Department of Health form number 707 E , "Application for Radioactive Material License" (Medical Uses) or form number 844 E "Application for Radioactive Material License" (Other Uses), must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 30.
7. Mississippi State Department of Health form number 935, "Notice to Employees", must be posted instead of NRC form 3 that is specified in Title 10 Code of Federal Regulations Part 30.

8. Mississippi State Department of Health form number 843 must be used instead of NRC form 244 that is specified in Title 10 Code of Federal Regulations Part 30.
9. Mississippi State Department of Health form number 1061, "Certificate of Disposition of Radioactive Materials", must be used instead of NRC form 314 as specified in Title 10 Code of Federal Regulations Part 30.
10. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 4 Standards For Protection Against Radiation**

Rule 1.4.1 This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 20: 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1008, 20.1101, 20.1201, 20.1202, 20.1203, 20.1204, 20.1206, 20.1207, 20.1208, 20.1301, 20.1302, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.1501, 20.1502, 20.1601, 20.1602, 20.1701, 20.1702, 20.1703, 20.1704, 20.1705, 20.1801, 20.1802, 20.1901, 20.1902, 20.1903, 20.1904, 20.1905, 20.1906, 20.2001, 20.2002, 20.2003, 20.2004, 20.2005, 20.2006, 20.2007, 20.2008, 20.2101, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and 20.2302, Appendix A through C to Part 20, Appendix E to Part 20, and Appendix G to Part 20, with the following exceptions:

1. Not adopted by reference are 20.1406 (b), 20.1905(g), 20.2203(c), and 20.2206(a)(1), (a)(3), (a)(4), and (a)(5).
2. All of the requirements in Subchapter 4 apply to both licensees and registrants. A reference in Title 10 Code of Federal Regulations Part 20 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", a reference to "licensed material(s)" includes "registered source of radiation", and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the department and is legally obligated to register with the department pursuant to Regulations for Control of Radiation in Mississippi and Mississippi Code Annotated § 45-14-13. "Registration" means the notification of the Mississippi State Department of Health of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.2.5.
3. Where the words "NRC", "commission", "administrator of the appropriate NRC regional office", "administrator of the nearest commission regional office", or "NRC regional office" appear in Title 10 Code of Federal Regulations Part 20, substitute the words " Mississippi State Department of Health".
4. Requirements in Title 10 Code of Federal Regulations Part 20 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
5. "Act" includes the Mississippi Radiation Protection Law of 1976.

6. Mississippi State Department of Health form number 933, "cumulative occupational exposure history", must be used instead of NRC form 4 as specified in Title 10 Code of Federal Regulations Part 20.
7. Mississippi State Department of Health form number 934, "occupational radiation exposure for a monitoring period", must be used instead of NRC form 5 as specified in Title 10 Code of Federal Regulations Part 20.
8. NRC form 748 shall not be used as described in Title 10 Code of Federal Regulations Part 20.
9. The words "in the Federal Register and" shall be omitted from Title 10 Code of Regulations 20.1405(b).

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 5. Radiation Safety Requirements For Industrial Radiographic Operations**

- Rule 1.5.1 Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 34: 34.1, 34.3, 34.11, 34.13, 34.20, 34.21, 34.23, 34.25, 34.27, 34.29, 34.31, 34.33, 34.35, 34.41, 34.42, 34.43, 34.45, 34.46, 34.47, 34.49, 34.51, 34.53, 34.61, 34.63, 34.65, 34.67, 34.69, 34.71, 34.73, 34.75, 34.79, 34.81, 34.83, 34.85, 34.87, 34.89, 34.101, and 34.111 and Appendix A to Part 34, with the following exceptions:
1. All of the requirements in Subchapter 5 apply to both licensees and registrants. A reference in Title 10 Code of Federal Regulations Part 34 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed material" includes "registered source of radiation". "Registrant" means any person who is registered with the Mississippi State Department of Health and is legally obligated to register with the department pursuant to Section 45-14-13 of the Mississippi Code of 1972, Annotated. "Registration" means the notification of the Mississippi State Department of Health of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.2.5.
  2. Where the words "NRC", "commission", "Nuclear Regulatory Commission", "United States Nuclear Regulatory Commission", "NRC Regional Administrator", "NRC regional office", "administrator of the appropriate Nuclear Regulatory Commission's regional office", or "NRC's Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety" appear in Title 10 Code of Federal Regulations Part 34, substitute the words "Mississippi State Department of Health".
  3. Requirements in Title 10 Code of Federal Regulations Part 34 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
  4. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License", or form number 802 "Application for Ionizing Radiation" must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 34.
  5. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.



*SOURCE: Miss. Code Ann. §45-14-11*

## **SubChapter 6      X-Rays In The Healing Arts**

Rule 1.6.1      **Scope.** This section establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with Mississippi statutes to engage in the healing arts or veterinary medicine. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.6.2      **Definitions.** As used in this section, the following definitions apply:

1. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
2. "Added filtration" means any filtration which is in addition to the inherent filtration.
3. "Aluminum equivalent" means the thickness of type 1100 aluminum alloy<sup>3</sup> affording the same attenuation, under specified conditions, as the material in question.
4. "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.
5. "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.
6. "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").
7. "Barrier" (See "Protective barrier").
8. "Beam axis" means a line from the source through the centers of the x-ray fields.
9. "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

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<sup>3</sup> The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

10. "C-Arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.
11. "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.
12. "Certified components" means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
13. "Certified system" means any x-ray system comprised totally of certified components.
14. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.
15. "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a sample population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[ \sum_{i=1}^n \frac{(X_i - \bar{X})^2}{(n-1)} \right]^{1/2}$$

where

- |           |   |   |
|-----------|---|---|
| s         | = | Estimated standard deviation of the population. |
| $\bar{X}$ | = | Mean Value of observations in sample.           |
| $X_i$     | = | $i^{\text{th}}$ observation in sample.          |
| n         | = | Number of observations in sample.               |

16. "Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.
17. "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for setting the technique factors.
18. "Cooling curve" means the graphical relationship between heat units stored and cooling time.
19. "CT" (See "Computed tomography").

20. "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
21. "Detector" (See "Radiation detector").
22. "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.
23. "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.
24. "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.
25. "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").
26. "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.
27. "Equipment" (See "X-ray equipment").
28. "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field."
29. "Filter" means material placed in the useful beam to absorb preferentially selected radiations.
30. "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.
31. "Focal spot" means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.
32. "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
33. "Gonad shield" means a protective barrier for the testes or ovaries.
34. "Half-value layer" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other

than any which might be present initially in the beam concerned, is deemed to be excluded.

35. "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.
36. "HVL" (See "Half-value layer").
37. "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
38. "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.
39. "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.
40. "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
41. "Irradiation" means the exposure of a living being or matter to ionizing radiation.
42. "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons].
43. "Kilovolts peak" (See "Peak tube potential").
44. "kVp" (See "Peak tube potential").
45. "kWs" means kilowatt second.
46. "Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions as lead.
47. "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:
  - a. the useful beam; and
  - b. radiation produced when the exposure switch or timer is not activated.

48. "Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:
- a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds, or the minimum obtainable from the unit, whichever is larger.
  - b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
  - c. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
49. "Light field" means the area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the radiation field.
50. "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l) / V_l$$

where

$V_n$  = No-load line potential and  
 $V_l$  = Load line potential.

51. "mA" means milliamperere.
52. "mAs" means milliamperere second.
53. "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
54. "Mobile x-ray equipment" (See "X-ray equipment").
55. "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment.
56. "PBL" See "Positive beam limitation."

- 57. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
- 58. "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- 59. "Phototimer" means a method for controlling radiation exposures to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").
- 60. "PID" (See "Position indicating device").
- 61. "Portable x-ray equipment" (See "X-ray equipment").
- 62. "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
- 63. "Positive beam limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustment.
- 64. "Primary protective barrier" (See "Protective barrier").
- 65. "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.
- 66. "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
  - a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.
  - b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
  - c. "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.
- 67. "Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge, training, and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

- 68. "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
- 69. "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
- 70. "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.
- 71. "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.
- 72. "Rating" means the operating limits as specified by the component manufacturer.
- 73. "Recording" means producing a permanent form of an image resulting from x-ray photons.
- 74. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").
- 75. "Secondary protective barrier" (See "Protective barrier").
- 76. "Shutter" means a device attached to the tube housing assembly which can totally intercept the entire cross section area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- 77. "SID" (See "Source-image receptor distance").
- 78. "Source" means the focal spot of the x-ray tube.
- 79. "Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.
- 80. "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- 81. "Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- 82. "SSD" means the distance between the source and the skin entrance plane of the patient.
- 83. "Stationary x-ray equipment" (See "X-ray equipment").

84. "Stray radiation" means the sum of leakage and scattered radiation.
85. "Technique factors" means the following conditions of operation:
- a. for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
  - b. for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
  - c. for CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
  - d. for CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
  - e. for all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.
86. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
87. "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.
88. "Tube" means an x-ray tube, unless otherwise specified.
89. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
90. "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
91. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.
92. "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.



93. "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
94. "X-ray exposure control" means a device, switch, button, or other similar means by which an operator initiates and/or terminates the radiation exposure.
95. "X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:
  - a. "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
  - b. "Portable x-ray equipment" means x-ray equipment designed to be hand carried.
  - c. "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.
96. "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
97. "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.
98. "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
99. "X-ray subsystem" means any combination of two or more components of an x-ray system.
100. "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.6.3 General and Administrative Requirements.**

1. **Radiation Safety Requirements.** The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

- a. An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic purposes (if so directed by the Agency).
- b. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Appendix A for a list of subject matters pertinent to this requirement. The Agency may use interview, observation and/or testing to determine compliance.
- c. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:
  - i. patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;
  - ii. type and size of the film or screen-film combination to be used;
  - iii. type and focal distance of the grid to be used, if any;
  - iv. source to image receptor distance to be used (except for dental intraoral radiography); and
  - v. type and location of placement of patient shielding (i.e., gonad, etc.) to be used.
- d. The registrant of a facility shall establish and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.
- e. Except for human patients who cannot be moved out of the room, only the staff and ancillary personnel, or other persons, required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
  - i. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material.
  - ii. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material.

- iii. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material, or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.
- f. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- g. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
  - i. exposure of an individual for training, demonstration, or other non-healing-arts purposes; and
  - ii. exposure of an individual for the purpose of healing arts screening except as authorized by 1.6.3(1)(k).
- h. When a patient or film must be provided with auxiliary support during a radiation exposure:
  - i. mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 1.6.3(1)(d), shall list individual projections where holding devices cannot be utilized;
  - ii. written safety procedures, as required by 1.6.3(1)(d), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
  - iii. the human holder shall be instructed in personal radiation safety and protected as required by 1.6.3(1)(e);
  - iv. no individual shall be used routinely to hold film or patients;
  - v. in those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material;
  - vi. when an animal must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices,

such as leaded aprons and gloves, and shall be positioned such that no part of his or her body shall be struck by the useful beam; and

- vii. each facility must have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
- i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.
  - i. The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of standard film packets for intraoral use in dental radiography.
  - ii. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
  - iii. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.
  - iv. X-ray systems subject to 1.6.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters except for veterinary systems.
  - v. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:
    - vi. Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray.
  - vii. If of the focused type, be of the proper focal distance for the SIDs being used.
- j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 1.4.5 and 1.4.7 of these regulations. In addition:
  - i. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
    - i. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

- ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by 1.4.6 of these regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
  - ii. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
- k. **Healing Arts Screening.** Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Agency. When requesting such approval, that person shall submit the information outlined in Appendix B of this Subchapter. If any information submitted to the Agency becomes invalid or outdated, the Agency shall be immediately notified.

**1. Information and Maintenance Record and Associated Information.** The registrant shall maintain the following information for each x-ray system for inspection by the Agency:

- i. model and serial numbers of all major components, and user's manuals for those components;
  - ii. tube rating charts and cooling curves;
  - iii. records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and
  - iv. a copy of all correspondence with this Agency regarding that x-ray system.
- m. **X-Ray Log.** Each facility shall maintain an x-ray log containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
- n. A sign shall be posted in a conspicuous area so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician should be notified. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are taken.

**2. X-ray Film Processing Facilities and Practices.** Each installation using a radiographic x-ray system and using analog image receptors (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

- a. Manually developed film:
  - i. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and
  - ii. The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature chart below:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5 ½
18.9	66	5 ½
18.3	65	6
17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

- iii. Devices shall be utilized which will:
  - i. Indicate the actual temperature of the developer; and
  - ii. Signal the passage of a preset time appropriate to the developing time required.

b. Automatic Processors and Other Closed Processing Systems:

- i. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the chart below:

Developer Temperature (Degrees)		Minimum Immersion Time:*(Seconds)
°C	°F	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

\*Immersion time only, no crossover time included.

- ii. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

c. **Other Requirements**

- i. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.
- ii. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.02 for mammography) when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

- iii. Darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.
- iv. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
  - i. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
  - ii. Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.
  - iii. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.6.4     **General Requirements for all Diagnostic X-Ray Systems.** In addition to other requirements of this section, all diagnostic x-ray systems shall meet the following requirements:

1. **Warning Label.** The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
2. **Battery Charge Indicator.** On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
3. **Leakage Radiation from the Diagnostic Source Assembly.** The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8  $\mu\text{C/kg}$ ) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If leakage technique factors cannot be set on the control panel, then compliance shall be determined by measuring leakage at maximum kVp and an appropriate mAs.



4. **Radiation from Components Other Than the Diagnostic Source Assembly.** The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516  $\mu\text{C/kg}$ ) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

5. **Beam Quality.**

a. **Half-value Layer.**

- i. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

<u>X-ray tube voltage</u>	<u>(kilovolt peak)</u>	<u>Minimum HVL (mm of Al)</u>		
Designed Operating Range	Measured Operating Potential	Dental Systems	Medical X-ray Systems Manufactured before 06/10/2006	Medical X-ray Systems Manufactured after 06/10/2006
Below 50	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
50 to 70	51	1.5	1.3	1.3
	60	1.5	1.5	1.5
	70	1.5	2.1	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

- ii. For capacitor energy storage equipment, compliance with the requirements of 1.6.4(5) shall be determined with the maximum

quantity of charge per exposure. This will be deemed to have been met if a mAs of 5-10 has been used.

- iii. The required minimal half-value-layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.
- b. **Filtration Controls.** For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by 1.6.4(5)(a) is in the useful beam for the given kVp which has been selected.
- 6. **Multiple Tubes.** Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- 7. **Mechanical Support of Tube Head.** The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.
- 8. **Technique Indicators.**
  - a. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.
  - b. The requirements of 1.6.4(8)(a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
- 9. **Locks.** All position locking, holding, and centering devices on x-ray system components shall function as intended.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.6.5 **Fluoroscopic X-Ray Systems.** All fluoroscopic x-ray systems shall be image intensified and meet the following requirements:

- 1. **Limitation of Useful Beam.**
  - a. **Primary Barrier.**

- i. The fluoroscopic imaging assembly used shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
- ii. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

b. **Fluoroscopic Beam Limitation.**

- i. For certified fluoroscopic systems, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
- ii. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.
- iii. For uncertified fluoroscopic systems without a spot film device, the requirements of 1.6.5(1)(b)(i) apply.
- iv. Other requirements for fluoroscopic beam limitation:
  - i. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustments of the x-ray field.
  - ii. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less.
  - iii. If provided, stepless adjustment shall provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less.
  - iv. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image

receptor; compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

- v. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- c. **Spot Film Beam Limitation.** Spot-film devices which are certified components shall meet the following additional requirements:
  - i. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.
  - d. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters.
  - e. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.
  - f. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
  - g. **Override.** If a means exists to override any of the automatic x-ray field size adjustments required in 1.6.5(1)(b), and (c) that means:
    - i. shall be designed for use only in the event of system failure;
    - ii. shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
    - iii. shall be clearly and durably labeled as follows:

## FOR X-RAY FIELD

### LIMITATION SYSTEM FAILURE

2. **Activation of the Fluoroscopic Tube.** X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
3. **Exposure Rate Limits.**
  - a. **Entrance Exposure Rate Allowable Limits.**
    - i. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:
      - i. During recording of fluoroscopic images, or
      - ii. When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
    - ii. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:
      - i. During recording of fluoroscopic images, or
      - ii. When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A

continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

iii. Compliance with the requirements of 1.6.5(3) shall be determined as follows:

i. If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

ii. If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

iii. For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

iv. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the center line of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam limiting device or spacer no closer than 15 centimeters to the center line of the x-ray table.

b. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both maximum and typical values, as follows.<sup>4</sup>

i. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

ii. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 1.6.3(1)(l)(iii) The measurement results shall be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

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<sup>4</sup> Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.

- iii. Conditions of periodic measurement of maximum entrance exposure rate are as follows:
  - i. the measurement shall be made under the conditions that satisfy the requirements of 1.6.5(3)(a)(iii);
  - ii. the kVp, mA, and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate; and
  - iii. the x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.
- iv. Conditions of periodic measurement of typical entrance exposure rate are as follows:
  - i. the measurement shall be made under the conditions that satisfy the requirements of 1.6.5(3)(a)(iii);
  - ii. the kVp and mA shall be typical of clinical use of the x-ray system; and
  - iii. the x-ray system(s) that incorporates automatic exposure rate control shall have an appropriate phantom placed in the useful beam to produce a milliamperage and/or kilovoltage typical of the use of the x-ray system.

#### **4. Barrier Transmitted Radiation Rate Limits.**

- a. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall not exceed 2 milliroentgens (0.516  $\mu\text{C/kg}$ ) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
- b. **Measuring Compliance of Barrier Transmission.**
  - i. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

- ii. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
  - iii. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
  - iv. Compression devices and movable grids shall be removed from the useful beam during the measurement.
- 5. **Indication of Potential and Current.** During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.
- 6. **Source-to-Skin Distance.** The SSD shall not be less than:
  - a. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;
  - b. 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;
  - c. 30 centimeters on all mobile fluoroscopes; and
  - d. 20 centimeters for all mobile fluoroscopes used for specific surgical procedures.
- 7. **Fluoroscopic Timer.**
  - a. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.
  - b. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.
- 8. **Control of Scattered Radiation.**
  - a. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
  - b. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities,



shall be exposed to the unattenuated scattered radiation emanating from above the table top unless that individual:

- i. is at least 120 centimeters from the center of the useful beam; or
- ii. the radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 1.6.3(1)(h)(vii).

- c. The Agency may grant exemptions to 1.6.5(8)(b) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Agency shall not permit such exemption. See Appendix C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

9. **Spot Film Exposure Reproducibility.** Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of 1.6.6(4) when operating in the spot film mode.

10. **Radiation Therapy Simulation Systems.** Radiation therapy simulation systems shall be exempt from all the requirements of 1.6.5(1), 1.6.5(3), 1.6.5(4), and 1.6.5(7) provided that:

- a. such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
- b. systems which do not meet the requirements of 1.6.5(7) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.6.6     **Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, Computed Tomography, or Mammography Systems.**

1. **Beam Limitation.** The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam-limiting device has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

- a.     **General Purpose Stationary and Mobile X-Ray Systems.**

- i. The use of a variable-field beam limiting device providing stepless, independent adjustment of at least two dimensions of the x-ray field is required.
  - ii. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
  - iii. The Agency may grant an exemption on noncertified x-ray systems to 1.6.6(1)(a)(i) and (ii) provided the registrant makes a written application for such exemption and in that application:
    - i. demonstrates it is impractical to comply with 1.6.6(1)(a)(i) and (ii); and
    - ii. the purpose of 1.6.6(1)(a)(i) and (ii) will be met by other methods.
- b. **Additional Requirements for Stationary General Purpose X-Ray Systems.** In addition to the requirements of 1.6.6(1)(a), all stationary general purpose x-ray systems shall meet the following requirements:
  - i. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent.
  - ii. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.
  - iii. Indication of field size dimension and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
- c. **X-Ray Systems Designed for One Image Receptor Size.** Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2

percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

d. **Radiographic Systems Other Than Those Designated in 1.6.6(1)(a),(b), and (c).**

- i. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
- ii. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.
- iii. 1.6.6(1)(d)(i) and (ii) may be met with a system that meets the requirements for a general purpose x-ray system as specified in 1.6.6(1)(a) or, when alignment means are also provided, may be met with either:
  - i. an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
  - ii. a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

## 2. **Radiation Exposure Control**

- a. **Exposure Initiation.** Means shall be provided to initiate the radiation exposure by a positive action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such a positive action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

- b. **Exposure Termination.** Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
  - i. **Manual exposure control.** An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("dead-man" switch) except for:
    - i. exposure of 1/2 second or less; or
    - ii. during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
  - ii. **Automatic exposure control.** When an automatic exposure control is provided:
    - i. indication shall be made on the control panel when this mode of operation is selected;
    - ii. if the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;
    - iii. the minimum exposure time for all equipment other than that specified in 1.6.6(2)(b)(ii)(ii) shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;
    - iv. either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except that when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
    - v. a visible signal shall indicate when an exposure has been terminated at the limits required by 1.6.6(2)(ii)(iv), and manual resetting shall be required before further automatically timed exposures can be made.
- c. **Exposure Indication.** Means shall be provided for visual indication of x-ray production observable at or from the operator's protected position

whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

- d. **Exposure Duration (Timer) Reproducibility.** With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time ( $T_{\max}$ ) and the minimum exposure time ( $T_{\min}$ ) shall be less than or equal to 10% of the average exposure time ( $\bar{T}$ ), when four timer tests are performed:

$$(T_{\max} - T_{\min}) \leq 0.10\bar{T}$$

- e. **Exposure Control Location.** The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

**f. Operator Protection, Except Veterinary Systems.**

- i. **Stationary systems.** Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.
- ii. **Mobile and portable systems.** Mobile and portable x-ray systems which are:
  - i. used continuously for greater than one week in the same location, i.e., a room or suite shall be considered as stationary systems under 1.6.6(2)(f)(i); and
  - ii. used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet (2 m) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly during the exposure.
- iii. **Operation Protection for Veterinary Systems.** All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a 6.5 foot (2 m) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly during exposures.

- 3. **Source-to-Skin Distance.** All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.
- 4. **Exposure Reproducibility.** When all technique factors are held constant, including control panel selections associated with automatic exposure control (phototiming) systems, the coefficient of variation of exposure for both manual and phototimed

systems shall not exceed 0.05. This requirement shall be deemed to have been met, if, when four exposures are made at identical technique factors, the difference between the maximum exposure ( $E_{max}$ ) and the minimum exposure ( $E_{min}$ ) shall be less than or equal to 10% of the average exposure( ):

$$(E_{max} - E_{min}) \leq 0.10\bar{E}$$

5. **Radiation from Capacitor Energy Storage Equipment in Standby Status.**

Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516  $\mu$ C/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6. **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

7. **Linearity, Uncertified X-Ray Systems Only.** The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

- a. **Equipment having independent selection of x-ray tube current (mA).**  
The average ratios of exposure to the indicated milliamperere-seconds product mR/mAs (C/kg/mAs) obtained at any two tube current settings shall not differ by more than 0.10 times their sum. This is:

$$| \bar{X}_1 - \bar{X}_2 | \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs (C/kg/mAs) values obtained at any two tube current settings.

- b. **Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector.**  
The average ratios of exposure to the indicated milliamperere-seconds product mR/mAs (C/kg/mAs) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$$| \bar{X}_1 - \bar{X}_2 | \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs (C/kg/mAs) values obtained at any two mAs selector settings.

- c. **Measuring compliance.** Determination of compliance shall be based on 4 exposures, of no less than 0.05 seconds each, taken within a time period of one hour, at each of the two settings.

These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

8. **Additional Requirements Applicable to Certified Systems Only.** Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

- a. **Linearity.** When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$| \bar{X}_1 - \bar{X}_2 | \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs (C/kg/mAs) values obtained at each of 2 consecutive tube current settings.

- b. **Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.**
- i. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 cm shall be equal to or less than 5 centimeters by 5 centimeters.
- ii. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.
- c. **Beam Limitation for Portable X-Ray Systems.** Beam limitation for portable x-ray systems shall meet the beam limitation requirements of 1.6.6(1)(a) and 1.6.6(7)(b).

- d. **Field Limitation and Alignment on Stationary General Purpose X-Ray Systems.** For stationary, general purpose x-ray systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c):
- i. Positive beam limitation (PBL) shall be provided whenever all the following conditions are met:
    - i. The image receptor is inserted into a permanently mounted cassette holder;
    - ii. The image receptor length and width are each less than 50 centimeters;
    - iii. The x-ray beam axis is within plus or minus 3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within plus or minus 3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;
    - iv. The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus 3 degrees;
    - v. Neither tomographic nor stereoscopic radiography is being performed; and
    - vi. The PBL system has not been intentionally overridden. This override provision is subject to 1.6.6(8)(d)(iii).
  - ii. Positive beam limitation (PBL) shall prevent the production of x-rays when:
    - i. Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 1.6.6(8)(d)(v), from the corresponding image receptor dimensions by more than 3 percent of the SID; or
    - ii. The sum of the length and width differences as stated in 1.6.6(8)(d)(ii)(i) without regard to sign exceeds 4 percent of the SID.
  - iii. If a means of overriding the positive beam limitation (PBL) system exists, that means:
    - i. Shall be designed for use only in the event of PBL system failure or if the system is being serviced; and



- ii. If in a position that the operator would consider it part of the operational controls or if it is referenced in the operator's manual or in other materials intended for the operator,
  - i. shall require that a key be utilized to defeat the PBL;
  - ii. shall require that the key remain in place during the entire time the PBL system is overridden; and
  - iii. shall require that the key or key switch be clearly and durably labeled as follows:

#### FOR X-RAY FIELD LIMITATION

#### SYSTEM FAILURE

- iv. Compliance with 1.6.6(8)(d)(ii) shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 1.6.6(8)(d)(i) are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.
- v. The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.
- vi. The positive beam limitation system shall be designed such that if a change in image receptor does not cause an automatic return to positive beam limitation function as described in 1.6.6(8)(d)(ii), then any change of image receptor size or SID must cause the automatic return.

- e. **Timers.** Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

- 9. **Tube Stands for Portable X-Ray Systems.** A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.6.7 Intraoral Dental Radiographic Systems.** In addition to the provisions of 1.6.3 and 1.6.4, the requirements of 1.6.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 1.6.6.

1. **Source-to-Skin Distance (SSD).** X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:
  - a. 18 centimeters if operable above 50 kVp; or
  - b. 10 centimeters if not operable above 50 kVp.
2. **Field Limitation.**
  - a. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and
  - b. An open ended PID (position indicating device) shall be used on new dental x-ray equipment purchased after the effective date of these regulations.
3. **Radiation Exposure Control for Certified and Noncertified Systems.**
  - a. **Exposure Initiation.**
    - i. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and
    - ii. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
  - b. **Exposure Termination.**
    - i. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
    - ii. An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less.
    - iii. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero".
  - c. **Exposure Indication.** Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

- d. **Exposure Duration (Timer) Reproducibility.** With a timer setting of 0.5 seconds or less, the difference between the maximum exposure time ( $T_{\max}$ ) and the minimum exposure time ( $T_{\min}$ ) shall be less than or equal to 10% of the average exposure time ( ), when four  $\bar{T}$  mer test are performed:

$$(T_{\max} - T_{\min}) \leq 0.10\bar{T}$$

- e. **Exposure Control Location and Operation Protection.**

- i. Stationary x-ray systems shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and
- ii. Mobile and portable x-ray systems which are:
  - i. used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 1.6.7(3)(e)(i); and
  - ii. used for less than one week in the same location, shall be provided with either a protective barrier at least 6.5 feet (2m) high for operator protection, or means to allow the operator to be at least 12 feet (3.7 m) from the tube housing assembly while making exposures.

4. **Exposure Reproducibility.** The coefficient of variation shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made within a period of one hour at identical technique factors, the difference between the maximum exposure value ( $E_{\max}$ ) and the minimum exposure value ( $E_{\min}$ ) shall be less than or equal to 10% of the average exposure ( ):  $\bar{E}$

$$(E_{\max} - E_{\min}) \leq 0.10\bar{E}$$

5. **Linearity.** When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated millampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$| \bar{X}_1 - \bar{X}_2 | \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

$$\bar{X}_i$$

where  $\bar{X}_1$  and  $\bar{X}_2$  are the average mR/mAs (C/kg/mAs) values obtained at each of 2 consecutive tube current settings.

6. **Accuracy.** Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.
7. **kVp Limitations.** Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.
8. **Administrative Controls.**
  - a. Patient and film holding devices shall be used when the techniques permit.
  - b. The tube housing and the PID shall not be hand held during an exposure.
  - c. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 1.6.7(2).
  - d. Dental fluoroscopy without image intensification shall not be used.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.6.8 Veterinary Medicine Radiographic Installations.**

1. **Equipment.**
  - a. The protective tube housing shall be equivalent to the requirements of 1.6.4(3).
  - b. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.
  - c. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
  - d. A device shall be provided to terminate the exposure after a preset time or exposure.
  - e. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83 m) from the animal during all x-ray exposures.

2. **Structural Shielding.** All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to assure compliance with 1.4.5 of these regulations.
3. **Operating Procedures.**
  - a. The operator shall stand well away from the useful beam and the animal during radiographic exposures.
  - b. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required.
  - c. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and he shall be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.6.9 Computed Tomography X-Ray Systems.**

1. **Definitions.** In addition to the definitions provided in 1.1.2 and 1.6.2 of these regulations, the following definitions shall be applicable to 1.6.9:
  - a. "Computed tomography dose index" means the integral from  $-7T$  to  $+7T$  of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

where:

- |        |   |   |
|--------|---|---|
| $z$    | = | Position along a line perpendicular to the tomographic plane. |
| $D(z)$ | = | Dose at position $z$ .  |
| $T$    | = | Nominal tomographic section thickness.                        |
| $n$    | = | Number of tomograms produced in a single scan.                |

This definition assumes that the dose profile is centered around  $z = 0$  and that, for a multiple tomogram system, the scan increment between adjacent scans is  $nT$ .

- b. "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{(\mu_x - \mu_w)}{(CTN)_x - (CTN)_w}$$

where:

- $\mu_x$  = Linear attenuation coefficient of the material of interest.  
 $\mu_w$  = Linear attenuation coefficient of water.  
 $(CTN)_x$  = CTN of the material of interest.  
 $(CTN)_w$  = CTN of water.

- c. "CS" (See "Contrast scale").
- d. "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 1.6.2.
- e. "CTDI" (See "Computed tomography dose index").
- f. "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.
- g. "CTN" (See "CT number").
- h. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

- $k$  = A constant<sup>5</sup>  
 $\mu_x$  = Linear attenuation coefficient of the material of interest.  
 $\mu_w$  = Linear attenuation coefficient of water.

- i. "Dose profile" means the dose as a function of position along a line.
- j. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

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<sup>5</sup> The constant has a normal value of 1,000 when the Hounsfield scale of CTN is used.

k. "Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

l. "Noise" means the standard deviation of the fluctuations in *CTN* expressed as a percentage of the attenuation coefficient of water. Its estimate ( $S_n$ ) is calculated using the following expression:

$$S_n = \frac{(100 \times CS \times s)}{\mu_w}$$

where:

$CS$  = Contract scale.

$\mu_w$  = Linear attenuation coefficient of water.

$s$  = Estimated standard deviation of the *CTN* of picture elements in a specified area of the CT image.

m. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

n. "Picture element" means an elemental area of a tomogram.

o. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

p. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

q. "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

r. "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

s. "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

t. "Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

u. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

- v. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

## **2. Requirement for Equipment.**

### **a. Termination of Exposure.**

- i. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
- ii. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 1.6.9(2)(a)(i).
- iii. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

### **b. Tomographic Plane Indication and Alignment.**

- i. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
- ii. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
- iii. If a device using a light source is used to satisfy 1.6.9(2)(b)(i) or (ii), the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

### **c. Beam-On and Shutter Status Indicators and Control Switches.**

- i. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
- ii. Each emergency button or switch shall be clearly labeled as to its function.



- d. **Indication of CT Conditions of Operation.** The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.
- e. **Extraneous Radiation.** When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 1.6.4(3).
- f. **Maximum Surface CTDI Identification.** The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.
- g. **Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.**
  - i. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.
  - ii. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
  - iii. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.
  - iv. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

### 3. Facility Design Requirements.

- a. **Aural Communication.** Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- b. **Viewing Systems.**

- i. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
- ii. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

#### **4. Surveys, Measurements, Spot Checks and Operating Procedures.**

##### **a. Surveys.**

- i. All CT x-ray systems installed after the effective date of these regulations and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- ii. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Agency upon request.

##### **b. Radiation Measurements.**

- i. The measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert.
- ii. The measurement of the radiation output of the CT x-ray system shall be performed annually and after any change or replacement of components which could cause a change in the radiation output.
- iii. The measurement of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.
- iv. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:
  - i. CT dosimetry phantom(s) shall be right circular cylinders of polymethyl-methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0

centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

- ii. CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.
- iii. Any effects on the doses measured to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.
- iv. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.
- v. The measurement of the radiation output shall be required for each type of head, body, or whole-body scan performed at the facility.
- vi. Measurement of the radiation output shall meet the following requirements:
  - i. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.
  - ii. The  $CTDI^6$  along the two axes specified in 1.6.9(4)(b)(iv)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of

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<sup>6</sup>For the purpose of determining the CTDI, the manufacturer's statements as to the nominal tomographic section thickness for that particular system may be utilized.

maximum surface *CTDI* identified. The CT conditions of operation shall correspond to typical values used by the registrant.

iii. The spot checks specified in 1.6.9(4)(c) shall be made.

vii. Procedures for the measurement of radiation output shall be in writing. Records of measurements performed shall be maintained for inspection by the Agency.

c. **Spot Checks.**

i. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

ii. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean *CTN* for water or other reference material.

iii. All spot checks shall be included in the measurement required by 1.6.9(4)(b) and at time intervals and under system conditions specified by a qualified expert.

iv. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform measurements required by 1.6.9(4)(b). The images shall be retained, until a new measurement is performed, in two forms as follows:

i. photographic copies of the images obtained from the image display device; and

ii. images stored in digital form on a storage medium compatible with the CT x-ray system.

v. Written records of the spot checks performed shall be maintained for inspection by the Agency.

d. **Operating Procedures.**

i. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

- ii. Information shall be available at the control panel regarding the operation of the system and measurements of radiation output. Such information shall include the following:
  - i. dates of the latest measurements and spot checks and the location within the facility where the results of those tests may be obtained;
  - ii. instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;
  - iii. the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
  - iv. a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.
- iii. If the measurement or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those permitted by established written instructions of the qualified expert.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.6.10 **Mammography X-Ray Systems – Adoption by reference of several sections in 21 Code of Federal Regulations Part 900 Subpart B §900.12.** 21 Code of Federal Regulations §900.12(b), §900.12(c), §900.12(d), §900.12(e)(1), §900.12(e)(2), §900.12(e)(3), §900.12(e)(4), §900.12(e)(5), §900.12(e)(6), §900.12(e)(7), §900.12(e)(8), §900.12(e)(9), §900.12(e)(10), §900.12(e)(11), §900.12(e)(12), §900.12(f)(1), §900.12(f)(2), and §900.12(i) are adopted by reference as they exist on May 11, 2017, with the following exceptions:

- 1. Medical Records and Mammography Reports. In addition to the requirements of 21 Code of Federal Regulations §900.12(c),
  - a. Language in mammography reports and lay letters provided to patients receiving mammogram services furnished by the entity performing the mammography services directly to patients under the federal Mammography Quality Standards Act, 42 USC Section 263b shall be in compliance with the U.S. Food & Drug Administration’s Mammography Quality Standards Act.

- b. Entities providing mammogram services shall consult guidelines and standards developed by the American College of Radiology, the American College of Obstetricians and Gynecologists and the American Cancer Society when developing any additional information the entity deems necessary for inclusion in mammography reports and lay letters. Any additional information provided in the report shall be evidence-based, consistent with accepted medical standards, and with the U.S. Food & Drug Administration's Mammography Quality Standards Act. Entities shall conduct an annual review of any forms provided to ensure compliance with FDA requirements.

*SOURCE: Miss. Code Ann. §45-14-11*

## **APPENDIX A**

### **Determination Of Competence**

The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment.

- I. Familiarization With Equipment.
  - a. Identification of controls.
  - b. Function of each control.
  - c. How to use a technique chart.
- II. Radiation Protection.
  - a. Collimation.
  - b. Filtration.
  - c. Gonad shielding and other patient protection devices if used.
  - d. Restriction of x-ray tube radiation to the image receptor.
  - e. Personnel protection.
  - f. Grids.
- III. Film Processing.
  - a. Film speed as related to patient exposure.
  - b. Film processing parameters.
  - c. Quality Assurance Program.
- IV. Emergency Procedures.
  - a. Termination of exposure in event of automatic timing device failure.
- V. Proper use of Personnel Dosimetry, if Required.
- VI. Understanding Units of Radiation.

## **APPENDIX B**

### **Information To Be Submitted By Persons Proposing To Conduct Healing Arts Screening**

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

- I. Name and address of the applicant and, where applicable, the names and addresses of agents within this State.
- II. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.
- III. A detailed description of the x-ray examinations proposed in the screening program.
- IV. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
- V. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations.
- VI. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures for the x-ray examinations to be performed.
- VII. A description of the diagnostic x-ray quality control program.
- VIII. A copy of the technique chart for the x-ray examination procedures to be used.
- IX. The qualifications of each individual who will be operating the x-ray system(s).
- X. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
- XI. The name and address of the individual who will interpret the radiograph(s).
- XII. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
- XIII. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.
- XIV. An indication of the frequency of screening and the duration of the entire screening program.



## **APPENDIX C**

### **Exemptions From Shielding For Certain Fluoroscopic Procedures**

- I. Myelograms
- II. Arthrograms
- III. Angiograms
- IV. Percutaneous nephrostomies
- V. Biliary drainage procedures
- VI. Percutaneous cholangiograms
- VII. T-tube cholangiograms
- VIII. Sinograms or fistulograms
- IX. Fluoroscopic biopsy procedures

## APPENDIX D

### Actual ( $f_{\text{eff}}$ ) and Nominal ( $f_{\text{nom}}$ ) Focal Spot Sizes necessary to achieve an Object Plan Spatial Resolution of 12.5 cycles/mm at the Chest Wall

SID (cm)	Magnification	$f_{\text{eff}}$ (mm)	$f_{\text{nom}}$ (mm)
80	1.07	1.2	0.6
65	1.08	1.1	0.5
50	1.11	0.85	0.4
--	1.5	0.23	0.15
--	2.0	0.15	0.10

## Subchapter 7      Medical Use of Byproduct Material

### Subchapter 7      Medical Use of Byproduct Material

Rule 1.7.1      **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 35: 35.1, 35.2, 35.5, 35.6, 35.7, 35.10, 35.11, 35.12, 35.13, 35.14, 35.15, 35.18, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.49, 35.50, 35.51, 35.55, 35.57, 35.59, 35.60, 35.61, 35.63, 35.65, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.100, 35.190, 35.200, 35.204, 35.290, 35.300, 35.310, 35.315, 35.390, 35.392, 35.394, 35.396, 35.400, 35.404, 35.406, 35.410, 35.415, 35.432, 35.433, 35.457, 35.490, 35.491, 35.500, 35.590, 35.600, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.657, 35.690, 35.1000, 35.2024, 35.2026, 35.2040, 35.2041, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433, 35.2605, 35.2610, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35.3067, and 35.3204 with the following exceptions:

1.      Not adopted by reference are Title 10 Code of Federal Regulations  
         35.11(c)(1) and 35.13(a)(1).
2.      Requirements in Title 10 Code of Federal Regulations Part 35 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3.      Where the words "NRC", "commission", "NRC regional office", or  
         "director, office of nuclear material safety and safeguards" appear in Title  
         10 Code of Federal Regulations Part 35, substitute the words  
         "Mississippi  
         State Department of Health".
4.      "Act" includes the Mississippi Radiation Protection Law of 1976.
5.      Mississippi State Department of Health form number 707 E ,  
         "Application for Radioactive Material License" (Medical Uses) or form  
         number 844 E "Application for Radioactive Material License" (Other  
         Uses), must be used instead of NRC form 313 as specified in Title 10  
         Code of Federal Regulations Part 35.
6.      For references to Title 10 Code of Federal Regulations Parts 170 and  
         171, see Mississippi State Department of Health Regulations for the  
         Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 8      Radiation Safety Requirements For Analytical X-Ray Equipment**

Rule 1.8.1      **Purpose and Scope.** This section provides special requirements for analytical x-ray equipment. The requirements of this section are in addition to, and not in substitution for, applicable requirements in other sections of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.8.2      **Definitions.** As used in this section, the following definitions apply:

1. "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.
2. "Analytical x-ray system" means a group of components utilizing x- or gamma-rays to determine the elemental composition or to examine the microstructure of materials.
3. "Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
4. "Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.
5. "Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.
6. "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.
7. "Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

*SOURCE: Miss. Code Ann. §45-14-11*

### **General Regulatory Provisions and Specific Requirements**

Rule 1.8.3     **Equipment Requirements.**

1. **Safety Device.** A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open- beam configurations. A registrant may apply to the Agency for an exemption from the requirements of a safety device. Such application shall include:
  - a. a description of the various safety devices that have been evaluated;
  - b. the reason each of these devices cannot be used; and
  - c. a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.
2. **Warning Devices**
  - a. Open-beam configurations shall be provided with a readily discernible indication of:
    - i. x-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or
    - ii. shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.
  - b. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:
    - i. near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or
    - ii. in the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.
  - c. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after June 30, 1978, warning devices shall have fail-safe characteristics.
3. **Ports.** Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.
4. **Labeling.** All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

- a. **"CAUTION - HIGH INTENSITY X-RAY BEAM"**, or words having a similar intent, on the x-ray source housing; and
  - b. **"CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED"**, or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or
  - c. **"CAUTION - RADIOACTIVE MATERIAL"**, or words having a similar intent, on the source housing in accordance with 1.4.29 of these regulations if the radiation source is a radionuclide.
5. **Shutters.** On open-beam configurations installed after January 12, 1980, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.
  6. **Radiation Source Housing.** Each radiation source housing shall be subject to the following requirements:
    - a. Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
    - b. Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.
  7. **Generator Cabinet.** Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5  $\mu$ Sv) in one hour.

*SOURCE: Miss. Code Ann. §45-14-11*

#### Rule 1.8.4 **Area Requirements**

1. **Radiation Levels.** The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 1.4.14 of these regulations. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.
2. **Surveys**

- a. Radiation surveys, as required by 1.4.17 of these regulations, of all analytical x-ray systems sufficient to show compliance with 1.8.4(1) shall be performed:
    - i. upon installation of the equipment, and at least once every 12 months thereafter;
    - ii. following any change in the initial arrangement, number, or type of local components in the system;
    - iii. following any maintenance requiring the disassembly or removal of a local component in the system;
    - iv. during the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
    - v. any time a visual inspection of the local components in the system reveals an abnormal condition; and
    - vi. whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 1.4.6 of these regulations.
  - b. Radiation survey measurements shall not be required if a registrant can demonstrate compliance with 1.8.4(1) to the satisfaction of the Agency.
3. Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with 1.4.29 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.8.5 Operating Requirements.**

- 1. **Procedures.** Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.
- 2. **Bypassing.** No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar intent, shall be placed

on the radiation source housing.

3. **Repair or Modification of X-Ray Tube Systems.** Except as specified in 1.8.5(2), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.
4. **Radioactive Source Replacement, Testing, or Repair.** Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission (NRC), an Agreement State, or a Licensing State.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.8.6 Personnel Requirements.**

1. **Instruction.** No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction in and demonstrated competence as to:
  - a. identification of radiation hazards associated with the use of the equipment;
  - b. significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
  - c. proper operating procedures for the equipment;
  - d. recognition of symptoms of an acute localized exposure; and
  - e. proper procedures for reporting an actual or suspected exposure.
2. **Personnel Monitoring**
  - a. Finger or wrist dosimetric devices shall be provided to and shall be used by:
    - i. analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and
    - ii. personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system



is disassembled or removed.

- b. Reported dose values shall not be used for the purpose of determining compliance with 1.4.6 of these regulations unless evaluated by a qualified expert.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 9 Radiation Safety Requirements for Particle Accelerators**

### **Rule 1.9.1 Purpose and Scope**

1. This Section establishes procedures for the registration and the use of particle accelerators.
2. In addition to the requirements of this section, all registrants are subject to the requirements of Subchapters 1, 2, 4, and 10 of these regulations. Registrants engaged in industrial radiographic operations are subject to the requirements of Subchapter 5 of these regulations, and registrants and/or licensees engaged in the healing arts are subject to the requirements of Subchapters 6, 7 and 15 of these regulations. Registrants whose operations result in the production of radioactive material are subject to the requirements of Subchapter 3 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.2 Registration Requirements.** No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to Subchapter 2 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.3 General Requirements for the Issuance of a Registration for Particle Accelerators.** In addition to the requirements of Subchapter 2 of these regulations, a registration application for use of a particle accelerator will be approved only if the Agency determines that:

1. the applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this section and Subchapters 4 and 10 of these regulations in such a manner as to minimize danger to public health and safety or property;
2. the applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

3. the issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 1.9.4;
4. the applicant has appointed a radiation safety officer;
5. the applicant and the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses;
6. the applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Agency; and
7. the applicant has an adequate training program for operators of particle accelerators.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.9.4     **Reserved.**

Rule 1.9.5     **Reserved.**

Rule 1.9.6     **Limitations.**

1. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:
  - a. has been instructed in radiation safety and shall have demonstrated an understanding thereof;
  - b. has received copies of and instruction in this section and the applicable requirements of Subchapters 4 and 10 of these regulations, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and
  - c. has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.
2. The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

*SOURCE: Miss. Code Ann. §45-14-11*

Rule 1.9.7     **Shielding and Safety Design Requirements.**

1. A qualified expert, acceptable to the Agency, shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.
2. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 1.4.6 and 1.4.14 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.8 Particle Accelerator Controls and Interlock Systems.**

1. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.
2. Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.
3. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.
4. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.
5. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.
6. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.9 Warning Devices**

1. Each location designated as high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.
2. Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior

to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

3. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 1.4.30 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.10 Operating Procedures.**

1. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
2. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.
3. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the Agency.
4. Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.
5. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
  - a. authorized by the radiation safety committee and/or radiation safety officer;
  - b. recorded in a permanent log and a notice posted at the accelerator control console; and
  - c. terminated as soon as possible.
6. A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.11 Radiation Monitoring Requirements.**

1. There shall be available, at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

2. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.
3. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a read-out at the control panel.
4. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.
5. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.
6. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.
7. All surveys shall be made in accordance with the written procedures established by a qualified expert, acceptable to the Agency, or the radiation safety officer.
8. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the Agency.

*SOURCE: Miss. Code Ann. §45-14-11*

**Rule 1.9.12 Ventilation Systems.**

1. Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Subchapter 4, Appendix B, Table I of these regulations.
2. A registrant, as required by 1.4.15 of these regulations, shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in Subchapter 4, Appendix B, Table I of these regulations, except as authorized pursuant to 1.4.15(3) of these regulations. For purposes of 1.9.12(2), concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable.

*SOURCE: Miss. Code Ann. §45-14-11*

**Subchapter 10 Notices, Instructions, and Reports to Workers; Inspections**

**Rule 1.10.1 Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 19: 19.1, 19.2,

19.3, 19.5, 19.11, 19.12, 19.13, 19.14, 19.15, 19.16, 19.17, 19.18, 19.20, 19.31, and 19.32, with the following exceptions:

1. Not adopted by reference is Title 10 Code of Federal Regulations 19.11(a), where it references “except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter”, (b), (e) where it references “each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter” and 19.14(a).
2. All of the requirements in Subchapter 10 apply to both licensees and registrants. A reference in Title 10 Code of Federal Regulations Part 19 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed radioactive material" includes "registered source of radiation". "Registrant" means any person who is registered with the Mississippi State Department of Health and is legally obligated to register with the department pursuant to Section 45-14-13 of the Mississippi Code of 1972, Annotated. "Registration" means the notification of the Mississippi State Department of Health of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.2.5.
3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", "administrator of the appropriate commission regional office", "administrator of the appropriate regional office", "regional office administrator", "executive director for operations", "regional administrator of the appropriate United States Nuclear Regulatory Commission regional office", or "agency" appear in Title 10 Code of Federal Regulations Part 19, substitute the words "Mississippi State Department of Health".
4. "Act" includes Mississippi Radiation Protection Law of 1976.
5. Mississippi State Department of Health form number 935, "Notice to Employees", must be posted in place of NRC form 3 that is specified in Title 10 Code of Federal Regulations Part 19.
6. Where Title 10 Code of Federal Regulations Part 19 specifies contacting the United States Nuclear Regulatory Commission, contact the Division of Radiological Health, Mississippi State Department of Health.

*Source: Miss. Code Ann. §45-14-11*

## **Subchapter 11    Licensing of Naturally Occurring Radioactive Materials (Norm)**

Rule 1.11.1    **Purpose.** This section establishes radiation protection standards for the possession, use, transfer, transport, storage and disposal of naturally occurring radioactive materials, NORM, not subject to regulation under the Atomic Energy Act of 1954, as amended.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.2    **Scope.** These regulations apply to any person who engages in the extraction, mining, beneficiating, processing, use, transfer, transport, storage, waste generation or disposal of NORM in such a manner as to alter the chemical properties or physical state of the NORM or its potential exposure pathways to humans.

1.    The regulations in this section address the introduction of NORM into materials or products in which neither the NORM nor the radiation emitted from the NORM is considered to be beneficial to the materials or products. The manufacture and distribution of materials or products containing NORM in which the NORM and/or its associated radiation(s) is considered to be a beneficial attribute are licensed under the provisions of Subchapter 3.
2.    These regulations also apply to sludges and scale deposits in tubulars and equipment and to soil or water contaminated by the cleaning of scale deposits. These regulations include the contamination of soil from produced waters.
3.    This section also addresses waste generation, waste management, transfer, and disposal with regard to both inactive and active sites and facilities involved in storage and/or cleaning of tubulars and contaminated equipment. In the case of closed or inactive pits, surveys are required only at the time of transfer for unrestricted use.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.3    **Definitions.** As used in this section, the following definitions apply:

1.    "Beneficial attribute" or "beneficial to the product" means the radioactivity of the product is necessary to the use of the product.
2.    "Beneficiating" means the processing of materials for the purpose of altering the chemical or physical properties to improve the quality, purity or assay grade.
3.    "Decontamination" means the removal of NORM contaminants from surfaces or equipment to reduce levels of radiation.
4.    "Decontamination facility" means a facility that provides services to reduce

levels of NORM contamination.

5. "Equipment" means tubulars, wellheads, separators, condensers, or any other related apparatus associated with the potential enhancement of NORM.
6. "Facility" means all contiguous land and structures, other appurtenances, and improvements on land or water that contain NORM.
7. "Fluid" means any material or substance which flows or moves, whether in a semi-solid, liquid, sludge, gas, or any other form or state.
8. "Naturally occurring radioactive material (NORM)" means any nuclide which is radioactive in its natural physical state (i.e., not man-made), but does not include byproduct, source or special nuclear material.
9. "Product" means something produced, made, manufactured, refined, or benefited.
10. "Storage" means the containment of NORM waste in such a manner as not to constitute disposal of NORM waste.
11. "Technologically enhanced" means natural sources of radiation which would not normally appear without some technological activity not expressly designed to produce radiation.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.4 Exemptions.**

1. Persons who receive, possess, use, process, transfer, transport, store, distribute, and dispose of NORM are exempt from the requirements of these regulations if:
  - a. The materials contain, or are contaminated at, concentrations less than 5 picocuries per gram of radium - 226 or radium - 228 above background; or, concentrations less than 30 picocuries per gram (1.11 kBq/kg) of technologically enhanced radium-226 or radium-228, averaged over any 100 square meters, provided the radon emanation rate does not exceed 20 picocuries (740 mBq) per square meter per second, or 150 picocuries per gram (5.55 kBq/kg) of any other NORM radionuclide, provided that these concentrations are not exceeded at any time; or
  - b. Equipment does not exceed 25 microroentgens per hour above background radiation at any accessible point.
2. Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Agency pursuant to 1.11.15(1) or an equivalent license issued by another Licensing State are exempt from these regulations.



3. The manufacturing, distribution, use, transportation, and disposal of potassium and potassium compounds which have not been isotopically enriched in the radionuclide K-40 are exempt from the requirements of these regulations.
4. The wholesale and retail distribution (including custom blending), possession, and use of the following products or materials are exempt from the requirements of these regulations;
  - a. Phosphate and potash fertilizer; and
  - b. Phosphogypsum for agricultural uses provided such commercial distribution and uses meet the requirements of 40 CFR 61.204.
5. The possession, use, and transportation of natural gas, and natural gas products, and crude oil, and crude oil products as a fuel are exempt from the requirements of these regulations. The manufacturing and distribution of natural gas and crude oil and natural gas and crude oil products are exempt from the specific license requirements of this section but are subject to the general license requirements in 1.11.10, 1.11.11, and 1.11.12.
6. Produced waters from crude oil and natural gas production are exempt from the requirements of these regulations if the produced waters are reinjected in a well approved by the Mississippi State Oil and Gas Board and Mississippi Department of Environmental Quality and as a Class II Injection and Disposal well.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.5 **Reserved.**

Rule 1.11.6 **Radiation Survey Instruments.**

1. Radiation survey instruments used to determine exposure rates pursuant to this section shall be capable of measuring 1 microrentgen per hour through at least 500 microrentgens per hour.
2. Radiation survey instruments used to make surveys required by this section shall be calibrated and operable.
3. Each radiation survey instrument shall be calibrated:
  - a. by person licensed by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission to perform such service;
  - b. at energies and radiation levels appropriate for the licensee's use;
  - c. at intervals not to exceed six months and after each instrument

servicing other than battery replacement; and

- d. to demonstrate an accuracy within plus or minus 20 percent of the true radiation level on each scale.
4. Records of these calibrations shall be maintained for 3 years after the calibration date for inspection by the Agency.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.7 **Reserved.**

Rule 1.11.8 **Reserved.**

Rule 1.11.9 **Reserved.**

Rule 1.11.10 **General Licenses.**

1. A general license is hereby issued to mine, extract, receive, possess, own, use, process, and transfer NORM not exempted in 1.11.4 without regard to quantity. This general license does not authorize the manufacturing or distribution of products containing NORM in concentrations greater than those specified in 1.11.4(1) nor the disposal of wastes from other persons.
2. Facilities and equipment contaminated with NORM in excess of the levels set forth in Appendix A of this section shall not be released for unrestricted use. The decontamination of equipment, facilities and land shall be performed only by persons specifically licensed by the Agency or another Licensing State to conduct such work. Each general licensee shall establish and submit to this Agency written procedures for performing on-site maintenance on contaminated equipment, components and facilities and for surveying (or screening) equipment, components and facilities prior to release for unrestricted use to ensure that the levels in Appendix A of this section are not exceeded.
3. person shall transfer land for unrestricted use contaminated with technologically enhanced radium-226 or radium-228, averaged over any 100 square meters, in which the radon emanation rate is less than 20 picocuries (740 mBq) per square meter per second and in which the concentrations of technologically enhanced radium-226 or radium-228 are in excess of 30 picocuries per gram (1.11 kBq/kg), averaged over a maximum depth of 15 cm of soil below the surface. No person shall transfer land contaminated with technologically enhanced radium-226 or radium-228, averaged over any 100 square meters, in which the radon emanation rate is 20 picocuries (740 mBq) per square meter per second or more and in which concentrations of technologically enhanced radium-226 or radium-228 are in excess of:
  - a. 5 pCi/g (185 Bq/kg), averaged over the first 15 cm of soil below the

surface; and

- b. 15 pCi/g (555 Bq/kg), averaged over 15 cm thick layers of soil more than 15 cm below the surface.
4. Equipment contaminated with NORM in excess of the levels set forth in Appendix A of this section may be released for maintenance and/or overhaul provided the recipient is specifically licensed to perform the activity on contaminated equipment.
5. The decontamination of equipment and facilities, as described in 1.11.13(2), shall only be performed by persons specifically licensed by the Agency or another Licensing State to conduct such work.
6. The transfer of NORM not exempt from these regulations from one general licensee to another general licensee shall be authorized by the Agency if:
  - a. The equipment and facilities contaminated with NORM are to be used by the recipient for the same purpose or at the same site;
  - b. The transfer of control or ownership of land contaminated with NORM includes an annotation of the deed records to indicate the presence of NORM; or
  - c. The materials being transferred are ores or raw materials for processing or refinement.
7. Transfers made under 1.11.10(6)(i) do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of NORM contamination or material present, evaluating the hazards of the NORM, informing the general licensee receiving the NORM of these assessments and evaluations, and maintaining records required by these regulations prior to and up to the time of documented transfers.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.11 Protection of Workers and the General Population.** Each person subject to the general license in 1.11.10 or a specific license shall conduct operations in compliance with the standards for radiation protection set out in Subchapters 4 and 10, except for disposal, which shall be governed by 1.11.12.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.12 Disposal and Transfer of Waste for Disposal.**

1. Each person subject to the general license in 1.11.10 or a specific license shall manage and dispose of wastes containing NORM:

- a. in accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes;
  - b. in a manner equivalent to the requirements for uranium and thorium byproduct materials in 40 CFR 192;
  - c. by transfer of the wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or
  - d. in accordance with alternate methods authorized by the Agency upon application or upon the Agency's initiative.
2. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Subchapter 4 of these regulations.
  3. Transfers of waste containing NORM for disposal shall be made only to a person specifically authorized to receive such waste.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.13 Specific Licenses.**

1. Unless otherwise exempted under the provisions of 1.11.4 or licensed under the provisions of Subchapter 3 of the regulations, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this section or pursuant to equivalent regulations of another Licensing State.
2. Persons conducting the following activities involving equipment or facilities contaminated with NORM in excess of the levels set forth in Appendix A of this section and land contaminated with radium-226 or radium-228 in excess of the limits set forth in 1.11.10(3) shall be specifically licensed pursuant to the requirements of this section:
  - a. Decontamination of equipment, facilities, and land; or
  - b. Disposal of the resulting waste.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.14 Filing Application for Specific Licenses.** Applications for specific licenses shall be filed in accordance with 1.3.8 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.15 Requirements for the Issuance of Specific Licenses.**

1. In addition to the requirements set forth in 1.3.9, and application for a specific license to decontaminate equipment, land, or facilities contaminated with NORM in excess of the levels set forth in 1.11.4(1), 1.11.10(3), or Appendix A of this section, as applicable and to dispose of the resulting waste will be approved if:
  - a. The applicant has adequately addressed the following items in the application:
    - i. Procedures and equipment for protection of workers;
    - ii. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;
    - iii. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and
    - iv. Method of disposing of the NORM removed from contaminated equipment, facilities, and/or land.
2. An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these regulations pursuant to 1.11.4(2), will be approved if:
  - a. The NORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and
  - b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in 1.11.16. The information shall include:
    - i. A description of the material or product and its intended use or uses;
    - ii. The type, quantity, and concentration of NORM in each material or product;
    - iii. The chemical and physical form of the NORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;
    - iv. An analysis of the solubility in water and body fluids of the NORM in the material or product;

- v. The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;
- vi. The degree of access of human beings to the material or product during normal handling, use, and disposal;
- vii. The total quantity of NORM expected to be distributed annually in the material or product;
- viii. The expected useful life of the material or product;
- ix. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;
- x. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;
- xi. The results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels, and any other changes in safety features;
- xii. The estimated external radiation doses and dose commitments relevant to the safety criteria in 1.11.16 and the basis for such estimates;
- xiii. A determination that the probabilities with respect to doses referred to 1.11.16 meet the safety criteria;
- xiv. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and
- xv. Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the radiation safety of the material or product.

3. Notwithstanding the provisions of 1.11.16(2), the Agency may deny an application for a specific license if the end uses of the product are frivolous or cannot

be reasonably foreseen.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.16 Safety Criteria.** An applicant for a license under 1.11.15(2) shall demonstrate that the product is designed and will be manufactured so that:

1. In normal use and disposal, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of NORM, excluding radon and radon decay products, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column I of 1.11.17
2. In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation, and servicing of the material or product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of NORM, excluding radon, in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column II of 1.11.17
3. In normal use, disposal, handling, and storage, it is unlikely that the radon released from the material or product will result in an increase in the average concentration in air of more than 0.4 picocurie per liter (14.8Bq/m<sup>3</sup>).
4. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the material or product from wear and abuse likely to occur in normal handling and use of the material or product during its useful life.

<u>Table of Organ Doses.</u>		
	Column I*	Column II*
<u>Part of Body</u>	<u>Dose in Rem</u>	<u>Dose in Rem</u>
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005 (0.05 mSv)	0.5 (5 mSv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075 (0.75 mSv)	7.5 (75 mSv)

Other organs	0.015 (0.15 mSv)	1.5 (15 mSv)
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\*Dose limit is the dose above background from the product.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.17 Issuance of Specific Licenses.** The Agency will issue a specific license in accordance with 1.3.14 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.18 Conditions of Licenses Issued Under 1.11.15.**

1. Each license issued pursuant to this section shall be subject to all the requirements set forth in 1.3.15.
2. Each person licensed by the Agency pursuant to this section is subject to the general license provisions of 1.11.11.
3. In addition to the requirements set forth in 1.3.15 each person listed under 1.11.15(2) shall:
  - a. Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Agency;
  - b. Label or mark each unit to identify the manufacturer, processor, producer, or initial transferor of the material or product and the NORM in the material or product; and
  - c. Maintain records identifying, by name and address, each person to whom NORM is transferred for use under 1.11.4(2) or the equivalent regulations of another Licensing State, and stating the kinds, quantities and uses of NORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending December 31, and shall be filed within 30 days thereafter. If no transfers of NORM have been made pursuant to 1.11.15(2) during the reporting period, the report shall so indicate.

*SOURCE: Miss. Code Ann. §45-14-3*

**Rule 1.11.19 Expiration and Termination of Licenses.** Each licensee shall comply with the provisions in 1.3.16 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*



Rule 1.11.20 **Renewal of License.** Applications for renewal of specific licenses shall be filed in accordance with 1.3.17 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.21 **Amendment of Licenses at Request of Licensee.** Applications for amendment of a license shall be filed in accordance with 1.3.18 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.22 **Agency Action on Application to Renew and Amend.** In considering an application by a licensee to renew or amend the license, the Agency will apply the criteria set forth in 1.3.19 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.23 **Modification and Revocation of Licenses.** The terms and conditions of all licenses shall be subject 1.3.25 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

Rule 1.11.24 **Reciprocal Recognition of Licenses.** The out-of-state licensee shall comply with the provisions of 1.3.26 of these regulations.

*SOURCE: Miss. Code Ann. §45-14-3*

## APPENDIX A

### Acceptable Surface Contamination Levels For Norm

<u>RADIONUCLIDE</u> <sup>a</sup>	<u>AVERAGE</u> <sup>bef</sup>	<u>MAXIMUM</u> <sup>bdfg</sup>	<u>REMOVABLE</u> <sup>bcef</sup>
U-nat, U-235, U-238, and asso- ciated products (including Po-210), except Ra-226, Th-230, Ac-227, and Pa-231	5,000 dpm alpha/100 cm <sup>2</sup>	15,000 dpm alpha/100 cm <sup>2</sup>	1,000 dpm alpha/100 cm <sup>2</sup>
Transuranics, Ra-226, Ra-228, Th-230 Th-228, Pa-231, Ac-227	100 dpm/ 100 cm <sup>2</sup>	300 dpm/ 100 cm <sup>2</sup>	20 pm/ 100 cm <sup>2</sup>
Th-nat, Th-232, Ra-223, Ra-224, U-232	1,000 dpm/ 100 cm <sup>2</sup>	3,000 dpm/ 100 cm <sup>2</sup>	200 dpm/ 100 cm <sup>2</sup>
Beta-gamma emitters (radionuclides with decay modes other than alpha emission or spontaneous fission, including Pb-210), except others noted above.	5,000 dpm beta, gamma/100 cm <sup>2</sup>	15,000 dpm beta, gamma/100 cm <sup>2</sup>	1,000 dpm beta, gamma/100 cm <sup>2</sup>

- (a) Where surface contamination by both alpha and beta-gamma emitting radionuclides exists, the limits established for alpha and beta-gamma emitting radionuclides should apply independently.
- (b) As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- (c) Measurements of average contamination levels should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.
- (d) The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.

- (e) The amount of removable radioactive material per 100 cm<sup>2</sup> of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
- (f) The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2 µGy/hr) at 1 cm and 1.0 mrad/hr (10 µGy/hr) at 1 cm respectively, measured through not more than 7 milligrams per square centimeter of total absorber.
- (g) Equipment containing NORM shall not exceed a maximum radiation exposure level of 25 microroentgens per hour above background radiation at any accessible point.

## **Subchapter 12    Licensing And Radiation Safety Requirements For Irradiators**

Rule 1.12.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 36: 36.1, 36.2 (with the exception referenced in No. 1 below), 36.11, 36.13, 36.15, 36.17, 36.19, 36.21, 36.23, 36.25, 36.27, 36.29, 36.31, 36.33, 36.35, 36.37, 36.39, 36.41, 36.51, 36.53, 36.55, 36.57, 36.59, 36.61, 36.63, 36.65, 36.67, 36.69, 36.81, and 36.83, with the following exceptions:

1.     Not adopted by reference is Title 10 Code of Federal Regulations 36.2 Paragraph (2) Common defense and security, in the definition of “Commencement of Construction” and Paragraph 9(ii) Common defense and security, in the definition of “Construction.”
2.     Requirements in Title 10 Code of Federal Regulations Part 36 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3.     Where the words "NRC", "commission", or "NRC regional office" appear in Title 10 Code of Federal Regulations Part 36, substitute the words "Mississippi State Department of Health".
4.     "Act" includes Mississippi Radiation Protection Law of 1976.
5.     Mississippi State Department of Health form number 844 E "Application for Radioactive Material License" must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 36.
6.     For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 13    Packaging and Transportation of Radioactive Materials**

Rule 1.13.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 71: 71.0, 71.3, 71.4, 71.5, 71.7, 71.8, 71.9, 71.10, 71.12, 71.13, 71.14, 71.15, 71.17, 71.21, 71.22, 71.23, 71.47, 71.81, 71.83, 71.85, 71.87, 71.88, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.106, 71.127, 71.129, 71.131, 71.133, 71.135, and 71.137 and Appendix A to Part 71, with the following exceptions:

1. Not adopted by reference are Title 10 Code of Federal Regulations 71.0(d), 71.14(b), 71.85(a), (b), and (c), 71.91(b), and 71.101(c)(2), (d), and (e).
2. The terms “certificate of compliance”, “certificate holder”, and “applicant” in the provisions of Title 10 Code of Federal Regulations Part 71 are used only in relation to the Nuclear Regulatory Commission as the Nuclear Regulatory Commission is the sole authority for approving and issuing a Part 71 package Certificate of Compliance.
3. Requirements in Title 10 Code of Federal Regulations Part 71 that apply to "licensed material" or "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
4. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", or "administrator of the appropriate regional office" appear in Title 10 Code of Federal Regulations Part 71, substitute the words "Mississippi State Department of Health" except when used in Title 10 Code of Federal Regulations 71.5(b), 71.10, 71.17 (c)(3), and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, and 71.97(c), (c)(3)(iii), and (f).
5. Title 10 Code of Federal Regulations 71.9 employee protection also applies to violations of Mississippi State Department of Health Regulations for Control of Radiation in Mississippi Subchapter 10.
6. Mississippi State Department of Health form number 935, "notice to employees", must be posted instead of NRC form 3 that is specified in Title 10 Code of Federal Part 71.

*SOURCE: Miss. Code Ann. §45-14-11*

## Subchapter 14    Licenses and Radiation Safety Requirements for Well Logging

- Rule 1.14.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 39: 39.1, 39.2, 39.11, 39.13, 39.15, 39.17, 39.31, 39.33, 39.35, 39.37, 39.39, 39.41, 39.43, 39.45, 39.47, 39.49, 39.51, 39.53, 39.55, 39.61, 39.63, 39.65, 39.67, 39.69, 39.71, 39.73, 39.75, 39.77, and 39.91, with the following exceptions:
1. All of the requirements in Subchapter 14 apply to both licensees and registrants. A reference in Title 10 Code of Federal Regulations Part 39 to "license" includes "registration", a reference to "licensee" includes "registrant", a reference to "licensed" includes "registered", and a reference to "licensed material" includes "registered source of radiation". "Registrant" means any person who is registered with the Mississippi State Department of Health and is legally obligated to register with the department pursuant to Section 45-14-13 of the Mississippi Code of 1972, Annotated. "Registration" means the notification of the Mississippi State Department of Health of possession of a source of radiation and the furnishing of information with respect thereto, in accordance with Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.2.5.
  2. Where the words "NRC", "commission", or "NRC regional office" appear in Title 10 Code of Federal Regulations Part 39, substitute the words "Mississippi State Department of Health".
  3. Requirements in Title 10 Code of Federal Regulations Part 39 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
  4. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License", or form number 802 "Application for Ionizing Radiation" must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 39.
  5. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 15 Therapeutic Radiation Machines**

### **Rule 1.15.1 Scope and Applicability.**

1. This section establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of these regulations.
2. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training/experience criteria established by 1.15.3.(3)

*SOURCE: Miss. Code Ann. §45-14-11*

### **Rule 1.15.2 Definitions.** As used in this section, the following definitions apply:

1. "Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad (see "Rad").
2. "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.
3. "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.
4. "Added filtration" means any filtration which is in addition to the inherent filtration.
5. "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of  $dE$  by  $dM$ , where  $dE$  is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass  $dM$ . Kerma is measured in the same unit as absorbed dose.
6. "Barrier" (See "Protective barrier").
7. "Beam axis" means the central ray of the useful radiation beam that passes through the isocenter and the source of radiation.
8. "Beam-limiting device" means a field defining collimator which provides a means to restrict the dimensions of the useful beam.
9. "Beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.
10. "Beam scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

11. "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.
12. "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.
13. "Contact therapy system" means a therapeutic radiation machine with a short source to skin distance (SSD), usually less than 5 centimeters.
14. "Detector" (See "Radiation detector").
15. "Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.
16. "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.
17. "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.
18. "Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to 1.15.6.
19. "Gantry" means that part of a system supporting and allowing movements of the radiation head about a center of rotation.
20. "Gray (Gy)" means the special name for the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray. [1 Gy=100 rad].
21. "Half-value layer (HVL)" means the thickness of a specified material which attenuates under narrow beam conditions, x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material.
22. "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.
23. "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
24. "Irradiation" means the exposure of a living being or matter to ionizing radiation.
25. "Isocenter" means the center of the smallest sphere through which the useful beam axis passes.



26. "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]
27. "Lead equivalent" means the thickness of the material in question affording the same attenuation, under specified conditions, as lead.
28. "Leakage radiation" means radiation emanating from the therapeutic source assembly except for the useful beam.
29. "Light field" means the area illuminated by light, being the locus of points at which the illumination exceeds a specific or specified level, simulating the radiation field.
30. "mA" means milliamperes.
31. "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]
32. "Monitor unit (MU)" (See "Dose monitor unit").
33. "Moving beam radiation therapy" means radiation therapy with continuous displacement of the radiation source relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.
34. "Nominal treatment distance" means:
  - a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
  - b. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.
35. "Patient" means an individual subjected to machine produced external beam radiation for the purposes of medical therapy.
36. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.
37. "Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.
38. "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

39. "Practical range of electrons" corresponds to classical electron range where the only contribution to dose is from bremsstrahlung x-rays. Precise definition may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.
40. "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.
41. "Primary protective barrier" (See "Protective barrier").
42. "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
- a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.
  - b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.
43. "Radiation detector" means a device which, in the presence of radiation provides, by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
44. "Radiation head" means the structure from which the useful beam emerges.
45. "Radiation Therapy Physicist" means an individual qualified in accordance with 1.15.3(4).
46. "Redundant dose monitoring combination" means a combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a preselected number of dose monitor units.
47. "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.
48. "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

49. "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.
50. "Secondary protective barrier" (See "Protective barrier").
51. "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.
52. "Shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
53. "Sievert (Sv)" means the special name for the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert [1 Sv=100 rem].
54. "Simulator (radiation therapy simulation system)" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
55. "Source" means the region and/or material from which the radiation emanates.
56. "Source-skin distance (SSD)" means the distance measured along the central ray from the center of the front surface of the radiation source to the surface of the irradiated object or patient. [See also Target-skin distance]
57. "Stationary beam radiation therapy" means radiation therapy without displacement of the radiation source relative to the patient during irradiation.
58. "Stray radiation" means the sum of leakage and scattered radiation.
59. "Target" means that part of an x-ray tube or particle accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.
60. "Target-skin distance (TSD)" means the distance measured along the central ray from the center of the front surface of the x-ray target to the surface of the irradiated object or patient. [See also Source-skin distance]
61. "Tenth-value layer (TVL)" means the thickness of a specified material which attenuates under broad beam conditions, x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material.
62. "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

63. "Therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy.
64. "Tube" means an x-ray tube, unless otherwise specified.
65. "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
66. "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.
67. "Virtual source" means a point from which radiation appears to originate.
68. "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the radiation field.
69. "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.3 General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.**

1. **Administrative Controls.** The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of Subchapter 15 are met in the operation of the therapeutic radiation machine(s).
2. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients.
3. **Training for External Beam Radiation Therapy Authorized User.** The registrant for any therapeutic radiation machine subject to 1.15.6 or 1.15.7 shall require the authorized user to be a physician who:
  - a. Is certified in:
    - i. Radiology or therapeutic radiology by the American Board of Radiology;
    - ii. Radiation oncology by the American Osteopathic Board of Radiology;

- iii. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
  - iv. Therapeutic Radiology by the Canadian Royal College of Physicians and Surgeons; or
- b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
- i. Radiation physics and instrumentation;
    - i. Radiation protection;
    - ii. Mathematics pertaining to the use and measurement of radioactivity; and
    - iii. Radiation biology.
  - ii. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
    - i. Review of the full calibration measurements and periodic quality assurance checks;
    - ii. Preparing treatment plans and calculating treatment times;
    - iii. Using administrative controls to prevent misadministrations;
    - iv. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
    - v. Checking and using survey meters.
  - iii. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

- i. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
    - ii. Selecting proper dose and how it is to be administered;
    - iii. Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
    - iv. Post administration follow-up and review of case histories.
  - c. Notwithstanding the requirements of 1.15.3(3)(a) and 1.15.3(3)(b), the registrant for any therapeutic radiation machine subject to 1.15.6 may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis.
  - d. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.
4. **Training for Radiation Therapy Physicist.** The registrant for any therapeutic radiation machine subject to 1.15.6 or 1.15.7 shall require the Radiation Therapy Physicist to:
- a. Be registered with the Agency, under the provisions of Subchapter 2 of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units.
  - b. Be certified by the American Board of Radiology in:
    - i. Therapeutic radiological physics;
    - ii. Roentgen-ray and gamma-ray physics;
    - iii. X-ray and radium physics; or
    - iv. Radiological physics; or
  - c. Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
  - d. Be certified by the Canadian College of Medical Physics; or

- e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 1.15.4(1), 1.15.6(16), 1.15.6(17), 1.15.7(20), and 1.15.7(21) under the supervision of a Radiation Therapy Physicist during the year of work experience; or
- f. Hold a bachelor's degree in a physical science and have completed 1 additional year of full-time training in therapeutic radiological physics and also 2 years of full-time work experience under the supervision of a Radiation Therapy Physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 1.15.4(1), 1.15.6(16), 1.15.6(17), 1.15.7(20), and 1.15.7(21) under the supervision of a Radiation Therapy Physicist during the 2 years of work experience.

Agency review of applicants in this category will only be on a case-by-case basis and additional information may be required for the Agency to determine if the applicant is qualified to function as a Radiation Therapy Physicist.

## **5. Qualifications of Operators**

- a. Individuals who will be operating a therapeutic radiation machine for medical use shall be American Registry of Radiologic Technologists (ARRT) Registered Radiation Therapy Technologists. Individuals who are not ARRT Registered Radiation Therapy Technologists shall submit evidence that they have satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology. ARRT Registered Radiologic Technologists, who have been working for two years or more in radiation therapy, will be allowed three years from the effective date of these regulations to fulfill the above listed requirements.<sup>7</sup>
  - b. The names and training of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of 2 years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.
6. Written safety procedures and rules shall be developed by a Radiation Therapy Physicist and shall be provided to each individual operating a therapeutic radiation machine, including any restrictions of the operating technique required for the safe

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<sup>7</sup> "Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

7. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who is specifically identified on the Certificate of Registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.
8. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of Subchapter 15, these individuals are also subject to the requirements of 1.4.5, 1.4.10, and 1.4.18.
9. **Information and Maintenance Record and Associated Information.** The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:
  - a. Report of acceptance testing;
  - b. Records of surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by Subchapter 15, as well as the name(s) of person(s) who performed such activities;
  - c. Records of major maintenance and modifications performed on the therapeutic radiation machine after the effective date of these regulations, as well as the name(s) of person(s) who performed such services; and
  - d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.
10. **Records Retention.** All records required by Subchapter 15 shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in Subchapter 15. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.4 General Technical Requirements for Facilities Using Therapeutic Radiation Machines.**

1. **Protection Surveys.**
  - a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with



an operable radiation measurement survey instrument calibrated in accordance with 1.15.8. The radiation protection survey shall be performed by, or under the direction of, a Radiation Therapy Physicist or a Certified Health Physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation:

- i. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 1.4.6(1); and
  - ii. Radiation levels in unrestricted areas do not exceed the limits specified in 1.4.14(1) and 1.4.14(2).
- b. In addition to the requirements of 1.15.4(1)(a), a radiation protection survey shall also be performed prior to any subsequent medical use and:
  - i. After making any change in the treatment room shielding;
  - ii. After making any change in the location of the therapeutic radiation machine within the treatment room;
  - iii. After relocating the therapeutic radiation machine; or
  - iv. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.
- c. The survey record shall indicate all instances where the facility, in the opinion of the Radiation Therapy Physicist or a Certified Health Physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey;
- d. If the results of the surveys required by 1.15.4(1)(a) or 1.15.4(1)(b) indicate any radiation levels in excess of the respective limit specified in 1.15.4(1)(a), the registrant shall lock the control in the "OFF" position and not use the unit:
  - i. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

- ii. Until the registrant has received a specific exemption from the Agency.

2. **Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program.** If the survey required by 1.15.4(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 1.4.14(1) of these regulations, before beginning the treatment program the registrant shall:

- a. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 1.4.14(1) of these regulations;
- b. Perform the survey required by 1.15.4(1) again; and
- c. Include in the report required by 1.15.4(4) the results of the initial survey, a description of the modification made to comply with 1.15.4(2)(a), and the results of the second survey; or
- d. Request and receive a registration amendment under 1.4.14(3) of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 1.4.14(1) of these regulations.

3. **Dosimetry Equipment.**

- a. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated for Cobalt-60 by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;
- b. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 1.15.4(3)(a). This comparison shall have been performed within the previous 12 months (6 months if the dosimetry system is an ionization chamber) and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 1.15.4(3)(a); and
- c. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 1.15.4(3)(a) and 1.15.4(3)(b), the correction factors that were determined, the names of the individuals who performed the calibration,

intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision of, a Radiation Therapy Physicist.

4. **Reports of External Beam Radiation Therapy Surveys and Measurements.** The registrant for any therapeutic radiation machine subject to 1.15.6 or 1.15.7 shall furnish a copy of the records required in 1.15.4(1) and 1.15.4(2) to the Agency within 30 days following completion of the action that initiated the record requirement.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.5 Quality Management Program.**

1. In addition to the definitions in 1.15.2, the following definitions are applicable to a quality management program:
  - a. "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.
  - b. "Misadministration" means the administration of an external beam radiation therapy dose:
    - i. Involving the wrong patient, wrong treatment modality, or wrong treatment site;
    - ii. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
    - iii. When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or
    - iv. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.
  - c. "Recordable event" means the administration of an external beam radiation therapy dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.
  - d. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.
2. **Scope and Applicability.** Each applicant or registrant subject to 1.15.6 or 1.15.7 shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user.

The quality management program shall include written policies and procedures to meet the following specific objectives:

- a. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;
  - i. Notwithstanding 1.15.5(2)(a), a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;
  - ii. Notwithstanding 1.15.5(2)(a), if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision; or
  - iii. Notwithstanding 1.15.5(2)(a), if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.
- b. Prior to each administration, the patient's identity is verified, by more than one method, as the individual named in the written directive;
- c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;
- d. Each administration is in accordance with the written directive; and
- e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

**3. Submission of Quality Management Program**

- a. Each applicant subject to 1.15.6 or 1.15.7 shall submit a quality management program to the Agency as part of the application required by Subchapter 2 of these regulations. The registrant shall implement the program upon issuance of a Certificate of Registration by the Agency.
- b. Each existing registrant subject to 1.15.6 or 1.15.7 shall, within 30 days of the effective date of these regulations, submit to the Agency a written

certification that a quality management program has been implemented, as well as a copy of said program.

4. As a part of the quality management program, the registrant shall:
  - a. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;
  - b. Conduct these reviews at intervals not to exceed 12 months;
  - c. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of 1.15.5(2); and
  - d. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for 3 years.
5. The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:
  - a. Assembling the relevant facts including the cause;
  - b. Identifying what, if any, corrective action is required to prevent recurrence; and
  - c. Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.
6. The registrant shall retain:
  - a. Each written directive; and
  - b. A record of each administered radiation dose, in an auditable form, for 3 years after the date of administration.
7. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The registrant shall furnish the modifications to the Agency within 30 days after the modification has been made.
8. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:
  - a. Notify the Agency by telephone no later than the next calendar day after discovery of the misadministration;

- b. Submit a written report to the Agency within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;
  - c. Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;
  - d. Retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and
  - e. If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the registrant.
9. Aside from the notification requirement, nothing in 1.15.5(8) affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.6 Therapeutic Radiation Machines of Less Than 500 kV.**

1. **Leakage Radiation.** When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:
  - a. 5-50 kV Systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.
  - b. >50 and <500 kV Systems. The leakage air kerma rate measured at a distance of 1 meter from the source in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.
2. **Permanent Beam-Limiting Devices.** Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.
3. **Adjustable or Removable Beam-Limiting Devices.**
  - a. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used.
  - b. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.
4. **Filter System.** The filter system shall be so designed that:
  - a. Filters cannot be accidentally displaced at any possible tube orientation;
  - b. For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;
  - c. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour under any operating conditions; and
  - d. Each filter shall be marked as to its material of construction and its thickness.
5. **Tube Immobilization.**
  - a. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

- b. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.
- 6. **Source Marking.** The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.
- 7. **Beam Block.** Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.
- 8. **Timer.** A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.
  - a. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;
  - b. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
  - c. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
  - d. The timer shall permit accurate presetting and determination of exposure times as short as 1 second;
  - e. The timer shall not permit an exposure if set at zero;
  - f. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
  - g. The timer shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.
- 9. **Control Panel Functions.** The control panel, in addition to the displays required by other provisions in 1.15.6 shall have:
  - a. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
  - b. An indication of whether x-rays are being produced;
  - c. Means for indicating x-ray tube potential and current;



- d. The means for terminating an exposure at any time;
  - e. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and
  - f. For therapeutic radiation machines manufactured after the effective date of these regulations, a positive display of specific filter(s) in the beam.
10. **Multiple Tubes.** When a control panel may energize more than one x-ray tube:
- a. It shall be possible to activate only one x-ray tube at any time;
  - b. There shall be an indication at the control panel identifying which x-ray tube is activated; and
  - c. There shall be an indication at the tube housing assembly when that tube is energized.
11. **Source-to-Skin Distance (SSD).** There shall be a means of determining the central axis SSD to within 1 centimeter and of reproducing this measurement to within 2 millimeters thereafter.
12. **Shutters.** Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.
13. **Low Filtration X-ray Tubes.** Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present to indicate that the dose rate is very high.
14. **Facility Design Requirements for Therapeutic Radiation Machines Capable of Operating in the Range 50 kV to 500 kV.** In addition to shielding adequate to meet requirements of 1.15.9, the treatment room shall meet the following design requirements:
- a. **Aural Communication.** Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.
  - b. **Viewing Systems.** Provision shall be made to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. The therapeutic

radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

15. **Additional Requirements.** Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

- a. All protective barriers shall be fixed except for entrance doors or beam interceptors;
- b. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
- c. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
- d. When any door referred to in 1.15.6(15)(c) is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 100 mrad (1 mGy) per hour.

16. **Full Calibration Measurements.**

- a. Full calibration of a therapeutic radiation machine subject to 1.15.6 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:
  - i. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
  - ii. At intervals not exceeding 1 year; and
  - iii. Before medical use under the following conditions:
    - i. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and
    - ii. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
- b. To satisfy the requirement of 1.15.6(16)(a), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69,

"Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

- c. A registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

**17. Periodic Quality Assurance Checks.**

- a. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to 1.15.6, which are capable of operation at greater than 150 kV.
- b. To satisfy the requirement of 1.15.6(17)(a), quality assurance checks shall meet the following requirements:
  - i. The registrant shall perform quality assurance checks in accordance with written procedures established by the Radiation Therapy Physicist; and
  - ii. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified 1.15.6(16)(a). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 1.15.6(16)(a) shall be stated.
- c. The cause for a parameter exceeding a tolerance set by the Radiation Therapy Physicist shall be investigated and corrected before the system is used for patient irradiation.
- d. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Radiation Therapy Physicist's quality assurance check procedures, the system shall be recalibrated as required in 1.15.6(16)(a).
- e. The registrant shall use the dosimetry system described in 1.15.4(3) to make the quality assurance check required in 1.15.6(17)(b).
- f. The registrant shall have the Radiation Therapy Physicist review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month. The Radiation Therapy Physicist shall promptly notify

the registrant in writing of the results of each radiation output quality assurance check. The registrant shall keep a copy of each written notification for 3 years.

- g. Therapeutic radiation machines subject to 1.15.6 shall have safety quality assurance checks of each external beam radiation therapy facility performed at intervals not to exceed 1 month.
- h. To satisfy the requirement of 1.15.6(17)(g), safety quality assurance checks shall ensure proper operation of:
  - i. Electrical interlocks at each external beam radiation therapy room entrance;
  - ii. Proper operation of the "BEAM-ON" and termination switches;
  - iii. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;
  - iv. Viewing systems; and
  - v. Electrically operated treatment room doors from inside and outside the treatment room.
- i. The registrant shall promptly repair any system identified in 1.15.6(17)(h) that is not operating properly.
- j. The registrant shall maintain a record of each quality assurance check required by 1.15.6(17)(a) and 1.15.6(17)(g) for 3 years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

**18. Operating Procedures.**

- a. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 1.15.6(16) and 1.15.6(17) have been met;
- b. Therapeutic radiation machines shall not be left unattended unless it is secured pursuant to 1.15.6(9)(e);
- c. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

- d. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;
  - e. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and
  - f. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 1.4.6 of these regulations.
19. **Possession of Survey Instrument(s).** The registrant authorized to use a therapeutic radiation machine in accordance with 1.15.6 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10  $\mu$ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 1.15.8.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.7 Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).**

- 1. **Possession of Survey Instrument(s).** A registrant authorized to use a therapeutic radiation machine in accordance with 1.15.7 shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10  $\mu$ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated in accordance with 1.15.8.
- 2. **Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.**
  - a. The absorbed dose rate due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius 2 meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose rate on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified;

- b. Except for the area defined in 1.15.7(2)(a), the absorbed dose rate in tissue (excluding that from neutrons) at 1 meter from the electron path between the source and the target or electron window shall not exceed 0.5 percent of the absorbed dose rate in tissue on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified;
- c. The neutron absorbed dose rate outside the useful beam shall be kept as low as practicable. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 800 square centimeters; and
- d. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 1.15.7(2)(a) through 1.15.7(2)(c) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Agency.

### 3. **Leakage Radiation Through Beam-Limiting Devices.**

- a. **Photon Radiation.** All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that:
  - i. At the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeters by 10 centimeters radiation field.
  - ii. For fields of any size in which the maximum area shielded by the beam-limiting devices exceeds 500 square centimeters, the product of the average absorbed dose due to leakage radiation through the beam-limiting devices and the maximum area protectable by the beam-limiting devices shall not exceed one tenth (0.1) of the product of the maximum absorbed dose on the central axis of the useful beam and the area of the useful beam for a radiation field of 10 centimeters by 10 centimeters. All values of absorbed dose and area are referred to the nominal treatment distance.
- b. **Electron Radiation.** All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the following limits apply:
  - i. The absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- i. An average of 2 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply in the area between a line 4 centimeters outside the periphery of the geometrical radiation field and the border of the maximum area protectable by the electron applicator; and
- ii. A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply in the area between a line 2 centimeters outside the periphery of the geometrical radiation field and the border of the maximum area protectable by the electron applicator.
- ii. For fields of any size in which the maximum area shielded by the electron applicator exceeds 1000 square centimeters, the product of the average absorbed dose due to leakage radiation through the electron applicators and the maximum area protectable by the electron applicators shall not exceed two tenths (0.2) of the product of the maximum absorbed dose on the central axis of the useful beam and the area of the useful beam for a radiation field of 10 centimeters by 10 centimeters. All values of absorbed dose and area are referred to the nominal treatment distance.

**c. Measurement of Leakage Radiation.**

- i. **Photon Radiation.** Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently, and the leakage radiation from each set shall not exceed a maximum of 2 percent anywhere in the area protectable by that beam-limiting device.
- ii. **Electron Radiation.** Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding 1 square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using 1 centimeter of tissue equivalent build up material.
- d. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

4. **Filters/Wedges.**

- a. Each filter and/or wedge which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is damaged, the wedge transmission factor shall be redetermined;
- b. If the absorbed dose rate information required by 1.15.7(9) relates exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools;
- c. For equipment manufactured after the effective date of these regulations which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:
  - i. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
  - ii. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
  - iii. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and
  - iv. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

5. **X-Ray Stray Radiation in the Useful Electron Beam.** For equipment manufactured after the effective date of these regulations, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

6. **Beam Monitors.** All therapeutic radiation machines subject to 1.15.7 shall be provided with beam monitoring devices. The sensors for this device shall be fixed in the useful beam during treatment, (or interlocked) to indicate the air kerma rate or dose rate.

- a. Equipment manufactured after the effective date of these regulations shall be provided with at least two independently powered integrating dose



meters. Alternatively, a common power supply may be used if the production of radiation is terminated upon failure of any common element.

- b. Equipment manufactured on or before the effective date of these regulations shall be provided with at least one radiation detector. This detector shall be incorporated into a primary beam monitoring system;
- c. The detector and the system into which that detector is incorporated shall meet the following requirements:
  - i. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
  - ii. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;
  - iii. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and
  - iv. For equipment manufactured after the effective date of these regulations, the design of the beam monitoring systems shall ensure that the:
    - i. Malfunctioning of one system shall not affect the correct functioning of the secondary system; and
    - ii. Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.
  - v. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after the effective date of these regulations, each display shall:
    - i. maintain a reading until intentionally reset;
    - ii. have only one scale and no electrical or mechanical scale multiplying factors;
    - iii. utilize a design such that increasing dose is displayed by increasing numbers; and
    - iv. In the event of power failure, the beam monitoring information required in 1.15.7(6)(c)(v)(iii) displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

7. **Beam Symmetry.**

- a. Bent-beam linear accelerators subject to 1.15.7 shall be provided with auxiliary device(s) to monitor beam symmetry;
- b. The device(s) referenced in 1.15.7(7)(a) shall be able to detect field asymmetry greater than 10 percent; and
- c. The device(s) referenced in 1.15.7(7)(a) shall be configured to terminate irradiation if the specifications in 1.15.7(7)(b) cannot be maintained.

8. **Selection and Display of Dose Monitor Units.**

- a. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel;
- b. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;
- c. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and
- d. For equipment manufactured after the effective date of these regulations, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

9. **Air Kerma Rate/Absorbed Dose Rate.** For equipment manufactured after the effective date of these regulations, a system shall be provided whose readings the air kerma rate or absorbed dose rate at a reference point in the treatment volume can be calculated. [The radiation detectors specified in 1.15.7(6) may form part of this system.] In addition:

- a. The dose monitor unit dose rate shall be displayed at the treatment control panel;
- b. If the equipment can deliver under any conditions, an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant; and
- c. For equipment manufactured after the effective date of these regulations, if the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the

radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy).

10. **Termination of Irradiation by the Beam Monitoring System or Systems During Stationary Beam Radiation Therapy.**
  - a. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;
  - b. If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and
  - c. For equipment manufactured after the effective date of these regulations, an indicator on the control panel shall show which monitoring system has terminated irradiation.
11. **Termination Switches.** It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.
12. **Interruption Switches.** If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
13. **Timer.** A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.
  - a. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;
  - b. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;
  - c. For equipment manufactured after the effective date of these regulations, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary for the operator to reset the preset time selector; and
  - d. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

14. **Selection of Radiation Type.** Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
- a. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
  - b. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;
  - c. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;
  - d. An interlock system shall be provided to prevent irradiation with x-rays except to obtain a verification film, when electron applicators are fitted;
  - e. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
  - f. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
15. **Selection of Energy.** Equipment capable of generating radiation beams of different energies shall meet the following requirements:
- a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
  - b. The measured energy value selected shall be displayed (MV for photons and MeV for electrons) at the treatment control panel before and during irradiation; and
  - c. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.
16. **Selection of Stationary Beam Radiation Therapy or Rotational Arc Radiation Therapy.** Therapeutic radiation machines capable of both stationary beam radiation therapy and rotational arc radiation therapy shall meet the following requirement:
- a. Irradiation shall not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;
  - b. The mode of operation shall be displayed at the treatment control panel;
  - c. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

- d. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;
- e. Rotational arc radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:
  - i. For equipment manufactured after the effective date of these regulations, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 15 degrees of arc differs by more than 20 percent from the selected value;
  - ii. For equipment manufactured after the effective date of these regulations, where gantry angle terminates the irradiation in rotational arc radiation therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle and total angle relationship;
  - iii. For equipment manufactured after the effective date of these regulations, an interlock shall be provided to prevent the gantry moving more than 5 degrees beyond the selected angular limits during rotational arc radiation therapy; and
  - iv. For equipment manufactured after the effective date of these regulations, an interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise rotational arc radiation therapy.
- f. Where the beam monitor system terminates the irradiation in rotational arc radiation therapy, the termination of irradiation shall be as required by 1.15.7(10); and
- g. For equipment manufactured after the effective date of these regulations, an interlock system shall be provided to terminate irradiation if movement of the gantry:
  - i. occurs during stationary beam radiation therapy; or
  - ii. stops during rotational arc radiation therapy unless such stoppage is a preplanned function.

17. **Facility Design Requirements for Therapeutic Radiation Machines Operating above 500 kV.** In addition to shielding adequate to meet requirements of 1.15.9, the following design requirements are made:

- a. **Protective Barriers.** All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;
- b. **Control Panel.** In addition to other requirements specified in Subchapter 15, the control panel shall also:
  - i. Be located outside the treatment room;
  - ii. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
  - iii. Provide an indication of whether radiation is being produced; and
  - iv. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine;
- c. **Viewing Systems.** Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;
- d. **Aural Communications.** Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;
- e. **Room Entrances.** Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";
- f. **Entrance Interlocks.** Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;
- g. **Beam Interceptor Interlocks.** If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 1.4.14(1), and 1.4.14(2) of these regulations, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);
- h. **Emergency Cutoff Switches.** At least one (1) "scram button" or other emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation

and mechanical motion. This switch is in addition to the termination switch required by 1.15.7(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

- i. **Safety Interlocks.** All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and
- j. **Surveys for Residual Radiation.** Surveys for residual activity, shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

18. **Radiation Therapy Physicist Support.**

- a. The services of a Radiation Therapy Physicist shall be utilized in facilities having therapeutic radiation machines with energies of 500 kV and above. The Radiation Therapy Physicist shall be responsible for:
  - i. Full calibration(s) required by 1.15.7(20) and protection surveys required by 1.15.4(1);
  - ii. Supervision and review of dosimetry;
  - iii. Beam data acquisition and storage for computerized dosimetry, and supervision of its use;
  - iv. Quality assurance, including quality assurance check review required by 1.15.7(21)(e) of these regulations;
  - v. Consultation with the authorized user in treatment planning, as needed; and
  - vi. Perform calculations/assessments regarding misadministrations.
- b. If the Radiation Therapy Physicist is not a full-time employee of the registrant, the operating procedures required by 1.15.7(19) shall also specifically address how the Radiation Therapy Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Radiation Therapy Physicist can be contacted.

19. **Operating Procedures.**

- a. No individual other than the patient shall be in the treatment room during treatment of a patient or during any irradiation for testing or calibration purposes;
- b. Therapeutic radiation machines shall not be made available for medical use unless the requirements of 1.15.4(1), 1.15.7(20), and 1.15.7(21) have been met;
- c. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
- d. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and
- e. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

**20. Full Calibration Measurements.**

- a. Full calibration of a therapeutic radiation machine subject to 1.15.7 shall be performed by, or under the direct supervision of, a Radiation Therapy Physicist:
  - i. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
  - ii. At intervals not exceeding 1 year; and
  - iii. Before medical use under the following conditions:
    - i. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be easily discerned; and
    - ii. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.
  - iv. Notwithstanding the requirements of 1.15.7(20)(a)(iii):
    - i. Full calibration of therapeutic radiation machines with multi-energy and/or multi-mode capabilities is required only for those modes and/or energies that are not within their acceptable range; and
    - ii. If the repair, replacement or modification does not affect all modes and/or energies, full calibration shall be performed on



the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 1.15.7(20)(a)(iii)(i).

- b. To satisfy the requirement of 1.15.7(1)(a), full calibration shall include all measurements required for annual calibration by American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";
- c. The registrant shall use the dosimetry system described in 1.15.4(3) to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in 1.15.7(20)(b) may then be made using a dosimetry system that indicates relative dose rates; and
- d. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the Radiation Therapy Physicist responsible for performing the calibration.

**21. Periodic Quality Assurance Checks.**

- a. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 1.15.7 at intervals not to exceed 1 week;
- b. To satisfy the requirement of 1.15.7(21)(a), quality assurance checks shall include determination of all parameters for periodic quality assurance checks contained in American Association of Physicists in Medicine (AAPM) Report 13, "Physical Aspects of Quality Assurance in Radiation Therapy";
- c. The registrant shall use a dosimetry system which has been intercompared within the previous 6 months with the dosimetry system described in 1.15.4(3) to make the periodic quality assurance checks required in 1.15.7(21)(b);
- d. The registrant shall perform periodic quality assurance checks required by 1.15.7(21)(a) in accordance with procedures established by the Radiation Therapy Physicist;
- e. The registrant shall review the results of each periodic radiation output check according to the following procedures:
  - i. The authorized user and Radiation Therapy Physicist shall be immediately notified if any parameter is not within its acceptable

range. The therapeutic radiation machine shall not be made available for subsequent medical use until the Radiation Therapy Physicist has determined that all parameters are within their acceptable range;

- ii. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or Radiation Therapy Physicist within 3 treatment days; and
  - iii. The Radiation Therapy Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 1 month;
- f. Therapeutic radiation machines subject to 1.15.7 shall have safety quality assurance checks of each radiation therapy facility performed at intervals not to exceed 1 week;
- g. To satisfy the requirement of 1.15.7(21)(f), safety quality assurance checks shall ensure proper operation of:
- i. Electrical interlocks at each external beam radiation therapy room entrance;
  - ii. Proper operation of the "BEAM-ON", interrupt and termination switches;
  - iii. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
  - iv. Viewing systems;
  - v. Electrically operated treatment room door(s) from inside and outside the treatment room; and
  - vi. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.
- h. The registrant shall promptly repair any system identified in 1.15.7(21)(g) that is not operating properly; and
- i. A registrant shall maintain a record of each quality assurance check required by 1.15.7(21)(a) and 1.15.7(21)(g) for 3 years. The record shall include the

date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.8 Calibration and Check of Survey Instruments.**

1. A registrant shall ensure that the survey instruments used to show compliance with this Subchapter have been calibrated before first use, annually, and following repair.
2. To satisfy the requirements of 1.15.8(1), the registrant shall:
  - a. Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source;
  - b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of scale rating; and
  - c. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.
3. To satisfy the requirements of 1.15.8(2), the registrant shall:
  - a. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and
  - b. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.
4. A registrant shall check each survey instrument for proper operation with the dedicated check source each day of use. The registrant is not required to keep records of these checks.
5. The registrant shall retain a record of each calibration required in 1.15.8(1) for 3 years. The record shall include:
  - a. A description of the calibration procedure; and
  - b. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction

factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

6. The registrant may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by 1.15.8(5) shall be maintained by the registrant.

*Source: Miss. Code Ann. §45-14-11*

**Rule 1.15.9 Shielding and Safety Design Requirements.**

1. Each therapeutic radiation machine subject to 1.15.6 or 1.15.7 shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 1.4.6 and 1.4.14 of these regulations.
2. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix A.

*Source: Miss. Code Ann. §45-14-11*

## APPENDIX A

### INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

#### I. ALL THERAPEUTIC RADIATION MACHINES

- A. Basic facility information including: name, telephone number and Agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).
- B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.
- C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

#### II. THERAPEUTIC RADIATION MACHINES UP TO 150 kV (PHOTONS ONLY)

In addition to the requirements listed in Section I. above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications, including the make, model and serial number of the therapeutic radiation machine, as well as the maximum technique factors.
- B. The maximum design workload for the facility, including the total anticipated number of exposures/films per day and/or week, as well as the type of treatment(s) or examination(s) which will be performed with the therapeutic radiation machine.
- C. A facility blueprint/drawing indicating: scale [0.25 inch = 1 foot is typical]; direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 400.06 of these regulations.
- D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

- F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, entry door(s) and shielding material in the facility.]
- (1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.
  - (2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

### III. THERAPEUTIC RADIATION MACHINES OVER 150 kV

In addition to the requirements listed in Section I. above, therapeutic radiation machine facilities which produce photons with a maximum energy in excess of 150 kV and/or electrons and/or protons or other subatomic particles shall submit shielding plans which contain, as a minimum, the following additional information:

- A. Equipment specifications including manufacturer, model number, and serial number of the therapeutic radiation machine, rad/gray or rem/sievert per minute at the isocenter and the energy(s) and type(s) of radiation produced [i.e., photon, electron]. The source to isocenter distance shall be specified.
- B. Maximum design workload for the facility including total weekly radiation output, [expressed in rad/gray or rem/sievert per minute at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.
- C. Facility blueprint/drawing [including both floor plan and elevation views] indicating relative orientation of the therapeutic radiation machine, scale [0.25 inch = 1 foot is typical], type(s) and thickness of shielding material(s), direction of North, the locations and size of all penetrations through each shielding barrier [ceiling, walls and floor], as well as details of the door(s) and maze.
- D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.
- F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy [i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed], workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that primary beam will intercept each permanent barrier [walls, floor and ceiling] and "allowed" radiation exposure in both restricted and unrestricted areas.

- G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition [i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze] and shielding material in the facility.
  - (1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.
  - (2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

#### IV. NEUTRON SHIELDING

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

- A. The structural composition, thickness and location of all neutron shielding material.
- B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.
- C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition [i.e. restricted and unrestricted areas, entry door(s) and maze] and neutron shielding material utilized in the facility.
  - (1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.
  - (2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.
- D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

#### V. REFERENCES

- A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).
- B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

- C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

**Subchapter 16 Physical Protection of Category 1 and Category 2 Quantities  
of  
Radioactive Material**

Rule 1.16.1 **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 37: 37.1, 37.3, 37.5, 37.11, 37.21, 37.23, 37.25, 37.27, 37.29, 37.31, 37.33, 37.41, 37.43, 37.45, 37.47, 37.49, 37.51, 37.53, 37.55, 37.57, 37.71, 37.73, 37.75, 37.77, 37.79, 37.81, 37.101, 37.103, 37.105, with the following exceptions:

1. Not incorporated by reference is Title 10 Code of Federal Regulations 37.11(b).
2. Where the word "NRC" appears in Title 10 Code of Federal Regulations 37.31(d), 37.43(c)(3)(iii), 37.57(a), 37.57(c), 37.77 [with the exception of "the NRC's Web site" in 37.77(a)(1), and 37.81(g)], substitute the words " Division of Radiological Health, Mississippi State Department of Health".
3. Where the word "Commission" appears in Title 10 Code of Federal Regulations 37.5 (definitions of "byproduct material" and "person"), 37.11(a), 37.43(a)(3), 37.43(c)(1)(ii), 37.101, 37.103, and 37.105, substitute the words " Division of Radiological Health, Mississippi State Department of Health".
4. Where the words "NRC regional office" appear in Title 10 Code of Federal Regulations 37.41(a)(3) and 37.81, substitute the words " Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213".
5. Where the words "appropriate NRC regional office listed in § 30.6(a)(2) of this chapter" appear in Title 10 Code of Federal Regulations 37.45(b), substitute the words "Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213".
6. Where the words "NRC's Operational Center (301-816-5100)" appear in Title 10 Code of Federal Regulations 37.57(a), 37.57(b), and 37.81, substitute the words "Division of Radiological Health, Mississippi State Department of Health (601) 987-6893".



7. Where the words "NRC's Operational Center" appear in Title 10 Code of Federal Regulations 37.81, substitute the words "Division of Radiological Health, Mississippi State Department of Health (601) 987-6893".
8. Where the words "NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. The notification to the NRC may be made by email to RAMQC\_SHIPMENTS@nrc.gov or by fax to 301-816-5151" appear in Title 10 Code of Federal Regulations 37.77(a)(1), substitute the words "Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213, (fax) 601-987-6887".
9. Where the words "NRC's Director of Nuclear Security, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in Title 10 Code of Federal Regulations 37.77(c)(1), substitute the words "Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213".
10. Where the words "NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in Title 10 Code of Federal Regulations 37.77(c)(2) and 37.77(d), substitute the words "Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213".
11. Where the words "Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001" appear in Title 10 Code of Federal Regulations 37.81(g), substitute the words "Director, Division of Radiological Health, Mississippi State Department of Health, 3150 Lawson Street, Jackson, Mississippi 39213".
12. Requirements in Title 10 Code of Federal Regulations Part 37 that apply to "byproduct material" also apply to naturally occurring or accelerator- produced radioactive material.
13. "Act" includes Mississippi Radiation Protection Law of 1976.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 17          Reciprocal Recognition of Licenses and Registrations**

Rule 1.17.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 150: 10 Code of Federal Regulations 150.1, 150.2, 150.3, 150.11, 150.20, 150.31, and 150.32 are adopted by reference as they exist in its most current revision, with the following exceptions:

1.      Not adopted by reference is Title 10 Code of Federal Regulations 150.3 definition of foreign obligations.
2.      Requirements in Title 10 Code of Federal Regulations Part 150 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3.      Where the words "NRC", "commission", "nuclear regulatory commission", "regional administrator", "United States Nuclear Regulatory Commission", "region", or "regional administrator of the United States Nuclear Regulatory Commission regional office" appear in Title 10 Code of Federal Regulations Part 150, substitute the words "Mississippi State Department of Health" except when used in section 150.5.
4.      "Act" includes Mississippi Radiation Protection Law of 1976.
5.      Mississippi State Department of Health form number 1043, "Notice of Intent" radioactive material (and radiation source registration) reciprocity request, must be used instead of nuclear regulatory commission form 241 as specified in Title 10 Code of Federal Regulations Part 150.
6.      Where the words "non-agreement states", "areas of exclusive federal jurisdiction within agreement states", or "offshore waters" are used in Title 10 Code of Federal Regulations 150.20(a)(1)(i), (ii), (iii), (b), (b)(3), and (b)(4) substitute the words "state of Mississippi".
7.      Where the words "agreement states license" are used in Title 10 Code of Federal Regulations 150.20 also add the words "nuclear regulatory commission license". Where the words "license issued by an agreement state" are used in Title 10 Code of Federal Regulations 150.20 also add the words "license issued by the nuclear regulatory commission". Where the words "license from an agreement state" are used in Title 10 Code of Federal Regulations 150.20 also add the words "license from the nuclear regulatory commission".
8.      The words "for the first time in a calendar year" are stricken from Title 10 Code of Federal Regulations 150.20(b)(1).

9. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 18      Domestic Licensing of Source Materials**

**Rule 1.18.1      Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 40: 40.1, 40.2, 40.3, 40.4 (with exception referenced in No. 1 below), 40.7, 40.9, 40.10, 40.11, 40.12, 40.13, 40.14, 40.20, 40.21, 40.22, 40.25, 40.26, 40.31, 40.32, 40.34, 40.35, 40.36, 40.41, 40.42, 40.43, 40.44, 40.45, 40.46, 40.51, 40.54, 40.55(a), (b),(c), (d), and (e), 40.60, 40.61, 40.62, 40.63, 40.65, and 40.71 and Appendix A to Part 40, with the following exceptions:

1. Not adopted by reference are Title 10 Code of Federal Regulations 40.4 Paragraph (2) Common defense and security, in the definition of “Commencement of Construction”, Paragraph 9(ii) Common defense and security, in the definition of “Construction”, the definition of “Foreign obligations”, and the definition of “Reconciliation”; 40.12(b); 40.13(c)(5)(iv); 40.31(j), (k), (l); and (m); and 40.32(d) and (g) and those portions of paragraph (e) which apply to uranium enrichment and uranium hexafluoride facilities, 40.41(d),(e)(1), (e)(3), (g) and (h); and 40.51(b)(6); and Appendix A, criterion 11A through F and criterion 12.
2. Requirements in Title 10 Code of Federal Regulations Part 40 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", "NRC regional administrator", or "administrator of the appropriate regional office" appear in Title 10 Code of Federal Regulations Part 40, substitute the words "Mississippi State Department of Health" except when used in Title 10 Code of Federal Regulations 40.11.
4. Title 10 Code of Federal Regulations Part 40 employee protection also applies to violations of Mississippi State Department of Health Regulations for the Control of Radiation Subchapter 10.
5. "Act" includes Mississippi Radiation Protection Law of 1976.
6. Mississippi State Department of Health form number 935, "Notice to Employees", must be posted instead of NRC form 3 that is specified in Title 10 Code of Federal Regulations Part 40.

7. Mississippi State Department of Health radioactive material license form number 843 must be used instead of NRC form 244 that is specified in Title 10 Code of Federal Regulations Part 40.
8. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License" must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 40.
9. Mississippi State Department of Health form number 1061, "Certificate of Disposition of Radioactive Materials", must be used instead of NRC form 314 as specified in Title 10 Code of Federal Regulations Part 40.
10. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 19      Domestic Licensing of Special Nuclear Material**

- Rule 1.19.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 70: 70.1, 70.2, 70.3, 70.4 (with the exception referenced in No. 1 below), 70.7, 70.9, 70.10, 70.11, 70.12, 70.17, 70.18, 70.19, 70.20, 70.21, 70.22, 70.23, 70.25, 70.31, 70.32, 70.33, 70.34, 70.35, 70.36, 70.38, 70.39, 70.41, 70.42, 70.50, 70.51, 70.56, and 70.81, with the following exceptions:
1. The following are not adopted by reference: Title 10 Code of Federal Regulations 70.1(c), (d), and (e); 70.4 Paragraph (2) Common defense and security, in the definition of "Commencement of Construction", and Paragraph 9(ii) Common defense and security, in the definition of "Construction"; 70.20a; 70.20b; 70.21(a)(1), (c), (f), (g), and (h); 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m), and (n); 70.23(a)(6), (a)(7), (a)(8), (a)(9), (a)(10), (a)(11), (a)(12), and (b); 70.23a; 70.25(a)(1); 70.31(c), (d), and (e); 70.32(a)(1), (a)(4), (a)(5), (a)(6), (a)(7), (b)(1), (b)(3), (b)(4), (c), (d), (e), (f), (g), (h), (i), (j), and (k); 70.42(b)(6); and 70.51(c).
  2. Requirements in Title 10 Code of Federal Regulations Part 70 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
  3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", "NRC regional administrator", "NRC regional office", "administrator of the appropriate nuclear regulatory commission's regional office", "administrator of the appropriate regional office", or "nuclear regulatory commission's office of nuclear material safety and safeguards, division of

industrial and medical nuclear safety" appear in Title 10 Code of Federal Regulations Part 70, substitute the words "Mississippi State Department of Health".

4. Title 10 Code of Federal Regulations 70.7 employee protection also applies to violations of Mississippi State Department of Health Regulations for Control of Radiation in Mississippi Subchapter 10.
5. "Act" includes the Mississippi Radiation Protection Law of 1976.
6. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License" (Other Uses), must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 70.
7. Mississippi State Department of Health form number 935, "notice to employees", must be posted instead of NRC form 3 that is specified in Title 10 Code of Federal Regulations Part 70.
8. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 20      General Domestic Licenses for Byproduct Material**

Rule 1.20.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 31: 31.1, 31.2, 31.5, 31.6, 31.7, 31.8, 31.9, 31.10, 31.11, and 31.12, with the following exceptions:

1. Not adopted by reference is Title 10 Code of Federal Regulations 31.6(a).
2. Requirements in Title 10 Code of Federal Regulations Part 31 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3. Where the words "NRC", "commission", "nuclear regulatory commission", "United States Nuclear Regulatory Commission", or "director of nuclear material safety and safeguards" appear in Title 10 Code of Federal Regulations Part 31, substitute the words "Mississippi State Department of Health" except when used in Title 10 Code of Federal Regulations 31.8(c)(2) and 31.11(d)(2).

4. Mississippi State Department of Health radioactive material license form number 1096 must be used instead of NRC form 483 that is specified in Title 10 Code of Federal Regulations Part 31.
5. References in Title 10 Code of Federal Regulations Part 31 to specific licenses issued by an agreement state also include specific licenses issued by the United States Nuclear Regulatory Commission.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 21      Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material**

Rule 1.21.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 32: 32.1, 32.2, 32.3, 32.13, 32.24, 32.51, 32.51(a), 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.59, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, 32.211, and 32.301, with the following exceptions:

1. Not adopted by reference is Title 10 Code of Federal Regulations 32.1(c)(1).
2. Requirements in Title 10 Code of Federal Regulations Part 32 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3. Where the words "NRC", "commission", "NRC regional office", or "director of nuclear material safety and safeguards" appear in Title 10 Code of Federal Regulations Part 32, substitute the words "Mississippi State Department of Health" except when used in 32.51(a)(3)(iii), 32.54(a), 32.58, 32.71(d), 32.72(b)(5), and 32.74(a)(3).
4. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License" must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 32.
5. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Subchapter 22      Specific Domestic Licenses of Broad Scope for Byproduct Material**

Rule 1.22.1    **Purpose.** This Regulation adopts by reference the current revision of the following sections in Title 10 Code of Federal Regulations Part 33: 33.1, 33.11,

33.12, 33.13, 33.14, 33.15, 33.16, 33.17, and 33.100, with the following exceptions:

1. Requirements in Title 10 Code of Federal Regulations Part 33 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
2. Where the word "commission" appears in Title 10 Code of Federal Regulations Part 33, substitute the words "Mississippi State Department of Health".
3. "Act" includes the Mississippi Radiation Protection Law of 1976.
4. Mississippi State Department of Health form number 844 E "Application for Radioactive Material License", must be used instead of NRC form 313 as specified in Title 10 Code of Federal Regulations Part 33.
5. For references to Title 10 Code of Federal Regulations Parts 170 and 171, see Mississippi State Department of Health Regulations for the Control of Radiation in Mississippi Rule 1.1.18 for applicable fee.

*SOURCE: Miss. Code Ann. §45-14-11*

## **Chapter 2            REGULATIONS FOR TANNING FACILITIES**

### **Subchapter 1       Regulations of Tanning Equipment & Facilities**

#### **Rule 2.1.1       Purpose and Scope.**

1. This Chapter provides for the registration of tanning equipment and tanning facilities and regulation of the maintenance and operation of tanning facilities.
2. In addition to the requirements of this Chapter, all registrants are subject to the applicable provision of other Chapters of these regulations.
3. Nothing in this Chapter shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or use commensurate with the licensed practitioner's use of a healing art.

*Source: Miss. Code Ann. §45-14-11*

#### **Rule 2.1.2       Definitions.** The following terms are defined for purposes of this Chapter.

1. "Act" means the Mississippi Radiation Protection Law of 1976.
2. "Agency" means the Mississippi Department of Health.
3. "CFR" means Code of Federal Regulations.
4. "Consumer" means any member of the public who is provided access to a tanning facility in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning facility as a condition or benefit of membership or access.
5. "FDA" means U.S. Food and Drug Administration.
6. "Healing arts" means the professional disciplines authorized by the laws of this state to use sources of radiation in the diagnosis or treatment of human or animal diseases.
7. "Individual" means any human being.
8. "Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.
9. "Operator" means an individual designated by the Registrant to control operation of the tanning facility and to instruct and assist the consumer in the proper operation of the tanning equipment.



10. "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.
11. "Radiation" means ultraviolet radiation in these regulations.
12. "Radiation machine" means any device capable of producing radiation.
13. "Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these regulations and the Act.
14. "Registration" means registration with the Agency in accordance with regulations adopted by the Agency.
15. "Tanning equipment" means ultraviolet lamps and equipment containing ultraviolet lamps intended to induce skin tanning through the irradiation of any part of the living human body.
16. "Tanning facility" means any location, place, area, structure or business which provides consumers access to tanning equipment.
17. "These regulations" means all chapters of the Mississippi State Board of Health Environmental Regulations Division 800-Radiological Health, Subpart 78-Radiation, Chapter 2, Regulations For Tanning Facilities.
18. "Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers.

*Source: Miss. Code Ann. §45-14-11*

**Rule 2.1.3 Exemptions.**

1. **General:** The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety.
2. Equipment intended for purposes other than the deliberate exposure of parts of the living body to ultraviolet radiation, and which produce or emit ultraviolet radiation incidental to its proper operation are exempt from the provisions of this Chapter.
3. Radiation machines while in transit or storage incidental thereto are exempt from the provisions of this Chapter.

*Source: Miss. Code Ann. §45-14-11*

**Rule 2.1.4 Application for Registration of Tanning Facilities.**

1. Each person having a tanning facility shall apply for registration of such facility with the Agency within thirty (30) days following the effective date of these regulations or thereafter prior to the operation of a tanning facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and the accompanying instructions.
2. The Agency shall require at least the following information on the Application for Registration of Tanning Facilities form:
  - a. Name, address and telephone number of the following:
    - i. the tanning facility;
    - ii. the owner(s) of the tanning facility.
  - b. The manufacturer, model number, and type of each ultraviolet lamp or tanning equipment located within the facility.
  - c. The geographic areas within the State to be covered, if the facility is mobile.
  - d. Name of the tanning equipment supplier, installer, and service agent.
  - e. A signed and dated certification that the applicant has read and understands the requirements of these regulations.
  - f. A copy of operating and safety procedures unique to facility operation.
3. Each applicant shall provide such additional information as the Agency may reasonably require.

*Source: Miss. Code Ann. §45-14-11*

**Rule 2.1.5 Issuance of Certificate of Registration.**

1. Upon determination that an applicant meets the requirements of these regulations, the Agency shall issue a certificate of registration.
2. The Agency may incorporate in the certificate of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of tanning equipment and tanning facilities as it deems appropriate or necessary.
3. No person shall operate a tanning facility until the Agency has issued the certificate of registration.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.6     **Expiration of Certificate of Registration.** Except as provided in 2.1.7 (2), each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.7     **Renewal of Certificate of Registration.**

1.     Application for renewal of registration shall be filed in accordance with 2.1.4.
2.     In any case in which a registrant, not less than 30 days prior to the expiration of his existing certificate of registration, has filed an application in proper form for renewal, such existing certificate of registration shall not expire until the application status has been finally determined by the Agency.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.8     **Report of Changes.** The registrant shall notify the Agency in writing before making any change which would render the information reported pursuant to 2.1.4 (2) (a), (b), (c) and (g), contained in the application for registration and/or the certificate of registration, no longer accurate. This requirement shall not apply to changes involving replacement of designated original equipment lamp types with lamps which have been certified with the FDA as "equivalent (lamps under the FDA regulations and policies applicable at the time of replacement of the lamps. The facility owner shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.9     **Transfer of Certificate of Registration.** No certificate of registration shall be transferable from one person to another or from one tanning facility to another.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.10    **Approval Not Implied.** No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 2.1.4, and no person shall state or imply that any activity under such registration has been approved by the Agency.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.11    **Denial, Suspension, or Revocation of Certificate of Registration.** The Agency may, for good cause shown, deny, suspend or revoke a certificate of registration sought or issued pursuant to these regulations for any of the following reasons:

1.     Failure of reports, plans or specifications to show that the tanning facility will be constructed, operated or maintained in accordance with the requirements of these regulations;

2. Submission of incorrect, false or misleading information in the application, reports, plans, or specifications;
3. Failure to construct, operate or maintain the tanning facility in accordance with the application, plans and specifications approved by the Agency except as such maintenance may involve the replacement of lamps by "equivalent" lamps which have been defined in 2.1. 8;
4. Operation of the tanning facility in a way that causes or created a nuisance or hazard to the public health or safety;
5. Violation of any rules, regulations, standards, or requirements adopted by the Agency;
6. Violation of any condition upon which the certificate of registration was issued;
7. Failure to allow duly authorized agents of the Agency to conduct inspections at reasonable hours and in a reasonable manner;
8. Failure to pay any registration or inspection fees.
9. Failure of the tanning equipment to comply with the Federal Performance Standard for Sunlamp Products and Ultraviolet Lamps intended for use in Sunlamp Products 21 CFR 1040.20.

Rule 2.1.12 **Hearing:** If any certificate of registration is denied, suspended, or revoked, the applicant or registrant may request a hearing in accordance with Chapter 45-14-21, Mississippi Code of 1972, Annotated.

*Source: Miss. Code Ann. §45-14-11*

Rule 2.1.13 **Construction and Operation of Tanning Facilities.** Unless otherwise ordered or approved by the Agency, each tanning facility shall be constructed, operated, and maintained to meet the following minimum requirements:

1. **Physical facilities**

- a. The following warning sign shall be posted in the immediate proximity (within 1 meter) of each piece of tanning equipment and it shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the user can easily view the warning sign before energizing the ultraviolet light generating equipment:

**DANGER - ULTRAVIOLET RADIATION**

- b. Follow instructions.

- c. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.
- d. Wear protective eyewear.
- e. **FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.**
- f. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight.
- g. If you do not tan in the sun, you are unlikely to tan from the use of this product.
- h. The lettering on each warning sign shall be at least ten (10) millimeters high for all words showing in capital letters and at least five (5) millimeters high for all lowercase letters.
- i. Only tanning equipment manufactured and certified to comply with 21 CFR Part 1040, Chapter
- j. 1040.20, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products", shall be used in tanning facilities. Compliance shall be based on the standard in effect at the time of manufacture as shown on the device identification label required by 21 CFR Part 1010, Chapter 1010.3.
- k. Each tanning equipment shall have a timer which complies with the requirements of 21 CFR Part 1040, Chapter 1040.20(c) (2). The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time. No timer interval shall have an error greater than  $\pm 10\%$  of the maximum timer interval for the product.
- l. Tanning equipment shall meet the National Fire Protection Association's National Electrical Code.
- m. There shall be physical barriers to protect consumers from injury induced by touching or breaking the lamps.
- n. Additional requirements for stand-up booths:
  - i. there shall be physical barriers or other means such as handrails or floor markings to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.

- ii. the construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.
- iii. access to the booth shall be of rigid construction. Doors shall open outwardly. Handrails and nonslip floors shall be provided.
- o. Tanning equipment electrical circuit shall be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL).

## 2. **Protective goggles**

- a. Each consumer shall be provided with protective goggles and instructions for the use.
- b. Protective goggles shall meet the requirements of 21 CFR Part 1040, Section 1040.20 (c) (5).
- c. Protective goggles shall be properly sanitized before each use. Exposure to the ultraviolet radiation produced by the tanning equipment itself is not considered a sanitizing agent.
- d. Each consumer shall wear the protective goggles as instructed.

## 3. **Operation**

- a. An operator must be present when tanning equipment is operated.
- b. Prior to initial exposure each consumer shall be provided the opportunity to read a copy of the warning specified in 2.1.12 (1) (a). The operator shall then request that the consumer sign a statement that the information has been read and understood. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.
- c. A record shall be kept by the facility operator of each consumer's total number of tanning visits and tanning times.
- d. A written report of any tanning injury shall be forwarded to the Agency within five [5] working days of the occurrence or knowledge thereof. The report shall include:
  - i. the name of the affected individual;
  - ii. the name and location of the tanning facility involved;
  - iii. the nature of the injury; and
  - iv. name and address of health care provider, if any;

- v. any other information considered relevant to the situation.
- e. No consumer under sixteen years of age shall be allowed to use the tanning facility unless he or she provides a consent form signed by the parent or legal guardian. The parent or guardian shall have been provided with the basic information required under 2.1.12.
- f. Defective or burned-out lamps or filters shall be replaced with a type intended for use in that device as specified on the product label on the tanning equipment, or, with lamps or filters that are "equivalent" under the FDA regulations and policies applicable at the time of lamp manufacture.
- g. Each operator must be adequately trained. Proof of training must be maintained in the facility and available for inspection. Training shall include:
  - i. the requirements of these regulations;
  - ii. procedures for correct operation of the facility;
  - iii. recognition of injury or overexposure;
  - iv. manufacturer's procedures for operation and maintenance of tanning equipment;
  - v. emergency procedures in case of injury.
  - vi. A list of operators trained in accordance with 2.1.12 (3) (g) shall be maintained and available at the facility.

*Source: Miss. Code Ann. §45-14-11*

**Rule 2.1.14 Enforcement and Penalties.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued there under. Any person who willfully violates any provisions of the Act, or any regulation, or order issued there under, may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by Section 45-14-37 of the Act.

*Source: Miss. Code Ann. §45-14-11*

**Rule 2.1.15 Communications.** All communications and reports concerning these regulations, and applications filed there under, should be addressed to the Division of Radiological Health at its office located at 3150 Lawson Street, P. O. Box 1700, Jackson, Mississippi, 39215-1700.

*Source: Miss. Code Ann. §45-14-11*