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ARCHIVED

**IDAPA 16
TITLE 02
CHAPTER 27**

16.02.27 - IDAHO RADIATION CONTROL RULES

000. LEGAL AUTHORITY.

The Idaho Legislature, under the following Sections of statute has granted authority to the Board of Health and Welfare and the Director of the Department to adopt rules related to x-ray producing machines in order to protect the health of the people of Idaho. Sections 56-1041 and 56-1043, Idaho Code, grant authority to the Board of Health and Welfare to adopt radiation control rules. Section 56-1041, Idaho Code, establishes the Department as the designated agency to regulate, license, and control radiation associated with x-ray machines. Section 56-1044, Idaho Code, requires that radiation machines for mammography be registered with the Department, as provided in rule. Section 56-1046, Idaho Code, grants authority to the Department to establish record-keeping and reporting requirements for those who possess or use an x-ray machine. Section 56-1003, Idaho Code, grants authority to the Director to supervise and administer laboratories. Section 56-1007, grants authority to the Department to charge and collect fees established by rule. (4-6-15)

001. TITLE.

The title of these rules is IDAPA 16.02.27, "Idaho Radiation Control Rules." Except as otherwise specifically provided, these rules apply to all persons who possess, use, transfer, own or acquire any radiation machine. (4-6-15)

002. WRITTEN INTERPRETATIONS.

There are no written interpretations for this chapter of rules. (4-6-15)

003. ADMINISTRATIVE APPEALS.

Administrative appeals are governed by IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (4-6-15)

004. INCORPORATION BY REFERENCE.

The documents referenced in Subsections 004.01 through 004.03 of this rule are used as a means of further clarifying these rules. These documents are incorporated by reference and are available online as provided, or may be reviewed at the Department of Health and Welfare, Idaho Bureau of Laboratories at 2220 Old Penitentiary Road, Boise, Idaho 83712-8299. (4-6-15)

01. National Council of Radiation Protection (NCRP) Report No. 147. National Council of Radiation Protection (NCRP) Report No. 147, entitled: "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to Ten (10) MeV," issued November 19, 2004, by the National Council on Radiation Protection and Measurement. This document may be obtained from: NCRP Publications, 7910 Woodmont, Bethesda, MD 20814, e-mail: NCRPpubs@NCRPonline.org, phone: 1-301-657-2652, Ext. 14. (4-6-15)

02. Mammography Quality Standards Act Regulations, Part 900. The Mammography Quality Standards Act Regulations, Part 900, located at 21 CFR 900.12 as authorized by 21 U.S.C. 360i, 360nn, 374(e), and 42 U.S.C. 263b. A copy of these regulation may be ordered from the U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, phone: 1-888-INFO-FDA (1-888-463-6332). These regulations are available online at <http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110906.htm#s9001>. (4-6-15)

03. Suggested State Regulations for Control of Radiation, Volume 1. This publication is being adopted with the exclusions, modifications, and additions listed below in Subsections 004.03.a through 004.03.k of this rule. Suggested State Regulations for Control of Radiation, Volume 1, is published by the Conference of Radiation Control Program Directors, Inc., 1030 Burlington Lane, Suite 4B, Frankfort, Kentucky 40601. It is also available online at <http://www.crcpd.org/SSRCRs/default.aspx>. (4-6-15)

a. Part A -- General Provisions (March 2003). Modifications have been made to this Part. See Sections 100 - 199 of these rules. (4-6-15)

b. Part B -- Registration [Licensure] of Radiation Machine Facilities, [Services] - And Associated

Healthcare Professionals (February 2009). Exclusions and modifications have been made to this Part. See Sections 200 - 299 of these rules. (4-6-15)

c. Part C -- Licensing of Radioactive Material (March 2010). This Part is excluded from incorporation. (4-6-15)

d. Part D -- Standards for Protection Against Radiation (March 2003). The following Sections of this Part are incorporated: 1101a, 1101b, 1101c, 1201a, 1201b, 1201c, 1201f, 1206, 1207, 1208, 1301, 1501, 1502, 1503, 1601, 1602, 1901, 1902, 1903, 1904c, 2102, 2103a, 2104, 2105, 2106, 2107a, 2110, 2201, 2202, 2203, 2204, 2205, and 2207b. (4-6-15)

e. Part E -- Radiation Safety Requirements for Industrial Radiographic Operations (February 1999). Exclusions have been made to this Part. See Sections 400 - 499 of these rules. (4-6-15)

f. Part F -- Diagnostic X-rays and Imaging Systems in the Healing Arts (May 2009). This Part is incorporated with no exclusions, modifications, or additions. (4-6-15)

g. Part G -- Use of Radionuclides in the Healing Arts (March 2003). This Part is excluded from incorporation. (4-6-15)

h. Part H -- Radiation Safety Requirements for Analytical X-ray Equipment (January 1991). This Part is incorporated with no exclusions, modifications, or additions. (4-6-15)

i. Part I -- Radiation Safety Requirements For Particle Accelerators (January 1991). This Part is excluded from incorporation. (4-6-15)

j. Part J -- Notices, Instructions and Reports to Workers; Inspections (March 2003). This Part is incorporated with no exclusions, modifications, or additions. (4-6-15)

k. Parts M through Z. These Parts are excluded from incorporation. (4-6-15)

005. OFFICE -- OFFICE HOURS -- MAILING ADDRESS -- STREET ADDRESS -- TELEPHONE -- INTERNET WEBSITE.

01. Office Hours. Office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, except holidays designated by the State of Idaho. (4-6-15)

02. Mailing Address. The mailing address for the business office is Idaho Department of Health and Welfare, P.O. Box 83720, Boise, Idaho 83720-0036. (4-6-15)

03. Street Address. (4-6-15)

a. The business office of the Idaho Department of Health and Welfare is located at 450 West State Street, Boise, Idaho 83702. (4-6-15)

b. The Idaho Bureau of Laboratories is located at 2220 East Old Penitentiary Road, Boise, ID 83712-8299. (4-6-15)

04. Telephone. (4-6-15)

a. The telephone number for the Idaho Department of Health and Welfare is (208) 334-5500. (4-6-15)

b. The telephone number for the Idaho Bureau of Laboratories is (208) 334-2235. (4-6-15)

05. Internet Websites. (4-6-15)

a. The Department internet website is found at <http://www.healthandwelfare.idaho.gov>. (4-6-15)

- b. The Idaho Bureau of Laboratories internet website is found at <http://www.statelab.idaho.gov>. (4-6-15)

006. CONFIDENTIALITY OF RECORDS AND PUBLIC RECORDS REQUESTS.

01. Confidential Records. Any information about an individual covered by these rules and contained in the Department's records must comply with IDAPA 16.05.01, "Use and Disclosure of Department Records." (4-6-15)

02. Public Records. The Department will comply with Title 74, Chapter 1, Idaho Code, when requests for the examination and copying of public records are made. Unless otherwise exempted, all public records in the custody of the Department are subject to disclosure. (4-6-15)

007. -- 049. (RESERVED)

050. LICENSING.
Sections 050 through 099 provide for the licensing of radiation machines. (4-6-15)

051. SCOPE.
Radiation producing machines, unless exempt under Section B.4 of the Suggested State Regulations for Control of Radiation incorporated under Section 004 of these rules, must be licensed with the Radiation Control Agency in accordance with the requirements of Sections B.6 through B.9, of the Suggested State Regulations for Control of Radiation, as applicable. (4-6-15)

052. FEES.

01. Radiation Licensing Fees. Radiation facility fees apply to each person or facility owning, leasing, storing, or using radiation-producing machines. This fee is assessed on the same cycle as inspections and consists of a base licensing fee and a per tube charge. Fees are due within thirty (30) calendar days of the renewal date. A late charge of fifty (\$50) dollars will be assessed at thirty-one (31) days past the renewal date. If the fees are not paid by day ninety-one (91) past the renewal date, licensure will be terminated.

X-Ray Renewal Cycle and Facility Fees			
Facility Type	Renewal Cycle	Facility Fee	Per Tube Fee
Hospital, Clinic, Medical Practice	2 Years	\$50	\$25
Dental, Chiropractic, Podiatric, Veterinary Practice	4 Years		
Industrial, research, academic/educational, or security	10 Years		

(4-6-15)

02. X-Ray Shielding Plan Review and Fee. Facilities housing X-ray producing devices and regulated under these rules must obtain a review of their shielding plan by a qualified expert. A copy of this review, to include a floor plan and site specific shielding calculations, must be submitted to the Radiation Control Agency within thirty (30) days of receipt. Facilities may request a departmental review of the X-ray shielding calculations and floor plan by the Radiation Control Agency. A \$350 fee will be charged for this service. (4-6-15)

03. Radiation Safety Program Fee. If a facility or group of facilities under one administrative control

employs one or more full-time individuals whose positions are entirely devoted to in-house radiation safety, the facility may pay a flat annual facility fee of \$1000 instead of the licensing fees required in Subsection 052.01 of this rule. In addition, annual submittal of documentation of evidence of an ongoing and functioning quality control program must be submitted for review and approval. (4-6-15)

053. APPLICATION FOR LICENSE.

In addition to the requirements detailed in the incorporated reference, Section B, the following is required with application for use of x-ray producing devices. (4-6-15)

01. Responsible Authority. All applications must be signed by the responsible authority (RA) over the x-ray producing device. Required qualifications of the RA can be found in Section B.6c of the SSRCR. (4-6-15)

02. Application For License. Application for license must be on forms furnished by the Radiation Control Agency and must contain: (4-6-15)

a. Name of the owner, organization or person having administrative control and responsibility for use (responsible authority); and (4-6-15)

b. Address and telephone number where the machine is located; and if the radiation producing machine is used as a mobile device, a central headquarters must be used. (4-6-15)

c. A designation of the general category of use, such as dental, medical, industrial, veterinary, and research; and (4-6-15)

d. The manufacturer, model number, and type of machine; and (4-6-15)

e. Name of the radiation machine supplier, installer, and service agent. (4-6-15)

f. Name of an individual to be responsible for radiation protection, when applicable. (4-6-15)

03. Qualifications for Authorized Operation, Service, and Repair of X-ray Machines. The responsible authority must prohibit any person from operating, performing maintenance, or furnishing servicing or services to an x-ray producing machine under his authority that is not properly trained, certified, or licensed to do so. The responsible authority must obtain and retain documentation for a minimum of 2 years that all operation, service, repair, and maintenance of x-ray producing machine(s) under their authority are done so by a qualified individual or entity. (4-6-15)

04. Operator Qualifications. No individual will be permitted to act as an operator of a particular machine until such individual has received an acceptable amount of training in radiation safety as it applies to that machine and is approved by the Radiation Protection Supervisor or Radiation Safety Officer. Operators will be responsible for: (4-6-15)

a. Keeping radiation exposure to himself and to others as low as is practical; and (4-6-15)

b. Being familiar with safety procedures as they apply to each machine; and (4-6-15)

c. Wearing of personnel monitoring devices, if applicable; and (4-6-15)

d. Notifying the Radiation Protection Supervisor or Radiation Safety Officer of known or suspected excessive radiation exposures to himself or others. (4-6-15)

05. Minimum Safety Requirements. Unless otherwise specified within these or the incorporated rules, the following are the minimum safety requirements for personnel acting as radiographers or radiographers assistants. (4-6-15)

a. Licensees must not permit any individuals to act as radiographers as defined in these rules until such individuals: (4-6-15)

- i. Have received copies of and instructions in the licensee's operating and emergency procedures; and have demonstrated understanding thereof; and (4-6-15)
- ii. Have been instructed in the subjects outlined in Subsection 06. of this rule, and have demonstrated understanding thereof; and (4-6-15)
- iii. Have received copies of and instruction in the correct execution of these rules and have demonstrated understanding thereof; and (4-6-15)
- iv. Have demonstrated competence to use the specific radiation machine(s), related handling tools, and survey instruments which will be employed in their assignment. (4-6-15)
- v. Have demonstrated an understanding of the instructions in this section by successful completion of a written test and a field examination on the subjects covered. (4-6-15)
- b.** Licensees must not permit any individuals to act as a radiographer's assistant as defined in these rules until such individuals: (4-6-15)
 - vi. Have received copies of and instructions in the licensee's operating and emergency procedures; and have demonstrated understanding thereof; and (4-6-15)
 - vii. Have demonstrated competence to use under the personal supervision of the radiographer the radiation machine(s) and radiation survey instrument(s) which will be employed in their assignment. (4-6-15)
 - viii. Have demonstrated an understanding of the instructions in this section by successfully completing a written or oral test and a field examination on the subjects covered. (4-6-15)
- c.** Records of the above training, including copies of written tests and dates of oral tests and field examinations, must be maintained for inspection by the Radiation Control Agency for three (3) years following termination of employment. (4-6-15)
- d.** Each licensee must conduct an internal audit program to ensure that the Radiation Control Agency's conditions and the licensee's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits must be performed at least quarterly, and each radiographer must be audited at least annually. Records of internal audits must be maintained for inspection by the Agency for two (2) years from the date of the audit. (4-6-15)
- 06. Subjects to Be Covered During the Instruction of Radiographers.** (4-6-15)
 - a.** Fundamentals of Radiation Safety, to include at least: (4-6-15)
 - i. Characteristics of gamma and x-radiation; and (4-6-15)
 - ii. Units of radiation dose (millirem); and (4-6-15)
 - iii. Bioeffects of excessive exposure of radiation; and (4-6-15)
 - iv. Levels of radiation from radiation machines; and (4-6-15)
 - v. Methods of controlling radiation dose, including: (4-6-15)
 - (1) Working time; and (4-6-15)
 - (2) Working distances; and (4-6-15)
 - (3) Shielding; and (4-6-15)

- vi. Radiation Protection Standards; and (4-6-15)
 - b.** Radiation Detection Instrumentation, to include at least: (4-6-15)
 - i. Use of radiation surveys instruments, including: (4-6-15)
 - (1) Operation; and (4-6-15)
 - (2) Calibration; and (4-6-15)
 - (3) Limitations; and (4-6-15)
 - ii. Survey techniques; and (4-6-15)
 - iii. Use of Personnel Monitoring Equipment, including: (4-6-15)
 - (1) Film badges, TLDs; and (4-6-15)
 - (2) Pocket dosimeters; and (4-6-15)
 - (3) Pocket chambers; and (4-6-15)
 - c.** Radiographic Equipment, to include at least: (4-6-15)
 - i. Operation and control of x-ray equipment; and (4-6-15)
 - d.** The Requirements of Pertinent Federal regulations and State rules; and (4-6-15)
 - e.** The Licensee's Written Operating and Emergency Procedures; and (4-6-15)
 - f.** Case histories of radiography accidents. (4-6-15)
- 07. Modification, Revocation, and Termination of Licensees.** Pursuant to amendments to the Act, departmental rules or regulations, or orders issued by the Radiation Control Agency, the terms and conditions of all licenses are subject to amendment, revision, or modification, and are subject to suspension or revocation. (4-6-15)
- a.** Any license can be revoked, suspended, modified, or denied, in whole or in part. (4-6-15)
 - i. For any materially false statement: (4-6-15)
 - (1) In the application; or (4-6-15)
 - (2) In any statement of fact required under provisions of the Act or under these rules; or (4-6-15)
 - ii. Because of conditions revealed: (4-6-15)
 - (1) Within the application; any report, record, or inspection; or (4-6-15)
 - (2) By any other means which would warrant the Radiation Control Agency to refuse to grant a license on an original application; or (4-6-15)
 - iii. For violations of or failure to observe any of the terms and conditions: (4-6-15)
 - (1) Of the Act; or (4-6-15)
 - (2) Of the license; or (4-6-15)

- (3) Of any rule; or (4-6-15)
- (4) Of any regulation; or (4-6-15)
- (5) Of an order of the Radiation Control Agency. (4-6-15)

b. Except in cases of willful violation or in which the public health, interest or safety requires otherwise, no license can be modified, suspended, or revoked unless such issues have been called to the attention of the licensee in writing and the licensee afforded the opportunity to demonstrate or achieve compliance with all lawful requirements. (4-6-15)

08. Emergency Action. If the Radiation Control Program Director finds the public health, safety or welfare requires emergency action, the Director will incorporate findings in support of such action in a written notice of emergency revocation issued to the licensee. Emergency revocation is effective upon receipt by the licensee. Thereafter, if requested by the licensee in writing, the Director will provide the licensee a revocation hearing and prior notice thereof. Such hearings are conducted in accordance with IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (4-6-15)

054. -- 099. (RESERVED)

100. GENERAL PROVISIONS.

Sections 100 through 199 of these rules will be used for exclusions, modifications, and additions to Part A of the Suggested State Regulations for Control of Radiation, Volume 1, as incorporated in Section 004 of these rules. (4-6-15)

101. SCOPE.

Modification to Part A, Section A.1. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided that nothing in these regulations applies to any person to the extent such person is subject to regulation by the Nuclear Regulatory Commission. (4-6-15)

102. DEFINITIONS.

Additions to Part A, Section A.2. (4-6-15)

01. Act. "Act" means Section 56-1053, Idaho Code. (4-6-15)

02. Agency. "Agency" means the Idaho Department of Health and Welfare. (4-6-15)

103. VIOLATIONS.

Modification to Part A, Section A.8. Any person who willfully violates any provision of the Act is subject to penalties under Section 56-1053, Idaho Code. (4-6-15)

104. IMPOUNDING.

Modification to Part A, Section A.9. Sources of radiation are subject to impounding under Section 56-1052, Idaho Code. (4-6-15)

105. COMMUNICATIONS.

Modification to Part A, Section A.12. All communications and reports concerning these rules, and applications filed under these rules, must be addressed to the Agency at Radiation Control Section, Idaho Department of Health and Welfare, Bureau of Laboratories, 2220 Old Penitentiary Road, Boise, Idaho 83712-8299. (4-6-15)

106. -- 199. (RESERVED)

200. LICENSURE OF RADIATION MACHINE FACILITIES, (SERVICES) - AND ASSOCIATED HEALTHCARE PROFESSIONALS.

Sections 200 through 299 of these rules will be used for exclusions, modifications, and additions to Part B of the

Suggested State Regulations for Control of Radiation, Volume 1, as incorporated in Section 004 of these rules. (4-6-15)

201. LICENSURE OF RADIATION MACHINE FACILITIES.
Exclusion to Part B, Section B.6. Subsection B.6.b is excluded from incorporation. (4-6-15)

202. RECIPROCAL RECOGNITION OF OUT-OF-STATE RADIATION MACHINES.
Modifications and additions to Part B, Section B.16. (4-6-15)

01. Modification to Part B, Section B.16.a.iv. States in which this machine is registered or licensed. (4-6-15)

02. Addition to Part B, Section B.16 -- New Subsection d. The owner or person having possession of any radiation producing machine registered or licensed by a federal entity or state other than Idaho, or both, planning to establish regular operations in Idaho, must complete registration of the machine with the Agency within thirty (30) days after taking residence and prior to operation of the machine. Thirty (30) days prior to the expiration date of any out-of-state license for any radiation producing machine, the owner must apply to the Agency for a machine license. (4-6-15)

203. -- 400. (RESERVED)

400. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS.
Sections 400 through 499 of these rules will be used for exclusions, modifications, and additions to Part E of the Suggested State Regulations for Control of Radiation, Volume 1, as incorporated in Section 004 of these rules. (4-6-15)

401. LICENSING AND REGISTRATION REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS.
Exclusions to Part E, Section E.5. Subsections E.5.b.i and E.5.b.ii, are excluded from incorporation. (4-6-15)

402. LEAK TESTING AND REPLACEMENT OF SEALED SOURCES.
Part E, Section E.10 is excluded from incorporation. (4-6-15)

403. QUARTERLY INVENTORY.
Part E, Section E.11 is excluded from incorporation. (4-6-15)

404. LABELING, STORAGE, AND TRANSPORTATION.
Exclusions to Part E, Section E.14. Subsections E.14.a, E.14.b, and E.14.d, are excluded from incorporation. (4-6-15)

405. CONDUCTING INDUSTRIAL RADIOGRAPHIC OPERATIONS.
Exclusion to Part E, Section E.15. Subsection E.15.d is excluded from incorporation. (4-6-15)

406. RECORDS OF LEAK TESTING OF SEALED SOURCES AND DEVICES CONTAINING DU.
Part E, Section E.27 is excluded from incorporation. (4-6-15)

407. RECORDS OF QUARTERLY INVENTORY.
Part E, Section E.28 is excluded from incorporation. (4-6-15)

408. UTILIZATION LOGS.
Part E, Section E.29 is excluded from incorporation. (4-6-15)

409. LOCATION OF DOCUMENTS AND RECORDS.
Exclusions to Part E, Section E.37. Subsections E.37.b.iii, E.37.b.xi, and E.37.b.xii are excluded from incorporation. (4-6-15)

410. NOTIFICATIONS.
Exclusions to Part E, Section E.38. Subsections E.38.a.i, and E.38.a.ii are excluded from incorporation. (4-6-15)

411. APPLICATION AND EXAMINATIONS.

Part E, Section E.39 is excluded from incorporation. (4-6-15)

412. CERTIFICATION IDENTIFICATION (ID) CARD.

Part E, Section E.40 is excluded from incorporation. (4-6-15)

413. RECIPROCITY.

Part E, Section E.41 is excluded from incorporation. (4-6-15)

414. SPECIFIC REQUIREMENTS FOR RADIOGRAPHIC PERSONNEL PERFORMING INDUSTRIAL RADIOGRAPHY.

Part E, Section E.42 is excluded from incorporation. (4-6-15)

415. -- 599. (RESERVED)

600. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS.

Sections 600 through 699 of these rules will be used for exclusions, modifications, and additions to Part J of the Suggested State Regulations for Control of Radiation, Volume 1, as incorporated in Section 004 of these rules.

(4-6-15)

601. -- 999. (RESERVED)

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