IDAPA 16 – IDAHO DEPARTMENT OF HEALTH AND WELFARE

Division of Public Health

16.02.27 – Idaho Radiation Control Rules

Who does this rule apply to?
Facilities that own and operate x-ray producing machines, hospitals, clinics, dental offices, veterinarians, chiropractors, podiatrists, industry, academic institutions, security, and the public.

What is the purpose of this rule?
The intent of these rules is to regulate, license, control, and collect fees for x-ray radiation emitting machines used for mammography, diagnostic imaging, industrial quality control, research, and security, to protect the health and safety of the people of Idaho. 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.

What is the legal authority for the agency to promulgate this rule?
This rule implements the following statutes passed by the Idaho Legislature:

Public Assistance and Welfare -
- Section 56-1006, Idaho Code – Department of Health and Welfare: Title superseded

Public Assistance and Welfare-
Department of Health and Welfare:
- Section 56-1041, Idaho Code – State X-Ray Control Agency
- Section 56-1043, Idaho Code – Rules – Licensing Requirements & Procedure – Registration of X-Ray Producing Machines – Exemptions from Registration or Licensing

Where can I find information on Administrative Appeals?
Administrative appeals and contested cases are governed by the provisions of the Idaho Administrative Procedures Act, Chapter 52, Title 67, Idaho Code, and IDAPA 62.01.01, "Idaho Rules of Administrative Procedure."

How do I request public records?
Unless exempted, all public records are subject to disclosure by the Department that will comply with Title 74, Chapter 1, Idaho Code, upon requests. Confidential information may be restricted by state or federal law, federal regulation, and IDAPA 16.05.01, "Use and Disclosure of Department Records."

Who do I contact for more information on this rule?

Idaho Department of Health and Welfare
Bureau of Laboratories
2220 Old Penitentiary Road
Boise, ID 83712-8299

P.O. Box 83720
Boise, ID 83720-0036
Phone: (208) 334-2235
Fax: (208) 334-4765
Email: statelab@dhw.idaho.gov
Webpage: https://statelab.idaho.gov

This rule chapter will be reviewed in compliance with Section 67-5292, Idaho Code, and in accordance with the 8-year rule review schedule linked here.

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000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of Sections 56-1003, 56-1007, 56-1041, 56-1043, 56-1044, and 56-1046, Idaho Code. (7-1-26)

001. SCOPE.
To define licensure, education, quality assurance, and safety requirements for X-ray machines. (7-1-26)

002. DEFINITIONS.

01. Department. The Idaho Department of Health and Welfare. (7-1-26)

02. Qualified Expert. An individual who meets nationally recognized radiation safety standards and has specific training in shielding design and X-ray safety. (7-1-26)

03. Radiation Safety Program. A documented program that ensures compliance with radiation protection standards, including safety procedures, training and quality control. (7-1-26)

003. LICENSE REQUIREMENTS AND APPLICATION.

01. Federal Facilities. All X-ray machines except those owned and operated at federal facilities or exempted under Section 56-1046(4), Idaho Code, must be licensed with the Department. (7-1-26)

02. License Application. Facilities must complete a license application approved by the Department. (7-1-26)

03. Insurance and Financial Responsibility. Applicants must provide documentation of adequate insurance coverage and financial responsibility to ensure compliance with safety standards and regulatory obligations. (7-1-26)

004. LICENSE RENEWAL AND FEES.

01. License Renewal. X-ray licensees must comply with the renewal cycles and fees as determined in the following table:

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

(7-1-26)

02. Licensing Fee Due Dates and Late Penalties. Fees are due within thirty (30) calendar days of the renewal date. A late fee of fifty ($50) 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. (7-1-26)

03. Radiation Safety Program Flat Fee. A facility or group of facilities under one administrative control that has a full-time in-house radiation safety program that includes X-ray machines, may pay a flat annual facility fee of one thousand dollars ($1,000) instead of the base and per tube fees. Facilities must submit annual documentation of their quality assurance and quality control program for review by the Department. (7-1-26)

04. Recognition of Other Licenses. The Department will recognize out-of-state or federally licensed X-ray machines until the next required renewal cycle, when such licenses meet equivalent safety and operational standards to minimize duplicative licensing requirements. Facilities with federal or out-of-state licenses must register with the Department within thirty (30) days. (7-1-26)

005. X-RAY SHIELDING PLAN APPROVAL.
Facilities housing X-ray machines must have a qualified expert conduct a site-specific shielding plan. A copy of this plan, including the floor plan and site-specific shielding calculations, must be submitted to the Department within thirty (30) days before conducting imaging procedures on patients. (7-1-26)

006. ON-SITE INSPECTION.
Qualified representatives of the Department are authorized to inspect the premises and operations of all licensed X-ray facilities to determine the adequacy of their shielding, quality control, quality assurance, safety, training, and other X-ray control programs. Department representatives will issue a written inspection report of findings, list items requiring a response, and specify the response timeframes required to maintain licensure. (7-1-26)

007. X-RAY MACHINE QUALITY CONTROL AND QUALITY ASSURANCE.

01. Quality Control. Licensed facilities must follow all X-ray machine manufacturer's required quality control procedures. Quality control records must be available for review by the Department and retained for at least two (2) license renewal cycles. (7-1-26)

02. Quality Assurance. Licensed facilities must have a written quality assurance plan documenting how quality control records are reviewed, safety procedures are followed, and X-ray machine operators are appropriately trained. (7-1-26)

008. X-RAY MACHINE PERFORMANCE STANDARDS.

01. Radiation Output. X-ray machines must have a consistent radiation output within specified limits. (7-1-26)

02. Image Quality. The machines must produce high-quality images with sufficient contrast, resolution, and minimal noise. (7-1-26)

03. Safety Features. X-ray machines must include the following safety features: (7-1-26)

a. Beam Lighting Devices: to restrict the X-ray beam to the area of interest and reduce patient exposure; (7-1-26)

b. Warning Lights and Signals: to indicate when the machine is in operation; and (7-1-26)

c. Interlocks: to prevent accidental exposure by ensuring that the X-ray beam is only activated when the machine is properly configured. (7-1-26)

04. Maintenance and Calibration. Regular maintenance and calibration of X-ray machines are required to ensure they operate within specified performance standards. (7-1-26)

05. Compliance. X-ray machines used for human imaging must comply with (a) or (b) and must comply with (c): (7-1-26)

a. U.S. Food and Drug Administration (FDA): FDA regulations on radiation-emitting products. (7-1-26)

b. International Electrotechnical Commission (IEC): IEC standards for medical electrical equipment. (7-1-26)

c. Documentation of compliance should be maintained for two (2) license renewal periods and be made available for inspection by regulatory authorities. (7-1-26)

009. X-RAY FACILITY AND OPERATOR TRAINING REQUIREMENTS.

01. Facility Requirements. Licensed facilities must: (7-1-26)

a. Post notice standards for protection against radiation in the facility; (7-1-26)

b. Keep radiation exposure as low as is practical; (7-1-26)

c. Provide written, site-specific, emergency procedures; (7-1-26)

d. Provide written, site-specific, safety procedures as they apply to each machine; (7-1-26)

e. Provide written, site-specific, operating procedures as they apply to each machine; (7-1-26)

f. Provide and document staff training; and (7-1-26)

g. Ensure personnel wear monitoring devices, if applicable. (7-1-26)

02. Operator Training Requirements. No individual will be permitted to operate an X-ray machine until they have completed training and proven competency in radiation safety topics. Licensed facilities must retain written training records for each X-ray machine operator. Training records for current and former X-ray operators must be made available upon request. Training records must be retained for a minimum of two (2) license renewal cycles. X-ray operator training must include the following topics: (7-1-26)

a. Fundamental of radiation safety; (7-1-26)

b. Characteristics of gamma and X-radiation; (7-1-26)

c. Units of radiation dose (millirem); (7-1-26)

d. Bioeffects of excessive exposure to radiation; (7-1-26)

e. Levels of radiation emitted from X-ray machines; (7-1-26)

f. Methods of controlling radiation dose including working time, distance, and shielding; (7-1-26)

g. State and federal radiation protection standards; (7-1-26)

h. Proper use of site-specific radiation survey instruments; (7-1-26)

i. Use of personnel monitoring equipment; (7-1-26)

j. Proper use of site-specific X-ray machines; and (7-1-26)

k. Site-specific operating and emergency procedures. (7-1-26)

010. LICENSE MODIFICATION, SUSPENSION, OR REVOCATION.

The Department may modify, suspend, or revoke an X-ray license if materially false statements are made by the licensee on the application, for failure to respond to inspection findings in a timely manner, or if the Department finds that the X-ray producing device is used in a fashion that endangers patients, facility staff, or the public. (7-1-26)

011. -- 999. (RESERVED)