**R313. Environmental Quality, Waste Management and Radiation Control, Radiation.**

**R313-16. General Requirements Applicable to the Installation, Registration, Inspection, and Use of Radiation Machines.**

**R313-16-200. Purpose and Authority.**

(1) The purpose Rule R313-16 is to prescribe requirements governing the installation, registration, inspection, and use of sources of electronically produced ionizing radiation. Rule R313-16 provides for the registration of individuals providing inspection services to a facility where one or more radiation machines are installed or located.

(2) Rule R313-16 is adopted pursuant to Subsections 19-3-104(4) and 19-3-104(9).

**R313-16-215. Definitions.**

"Qualified expert" means an individual having the knowledge and training to measure regulatory parameters on radiation machines, to evaluate radiation safety programs, to evaluate radiation levels, and to give advice on radiation protection needs while conducting inspections of radiation machine facilities registered with the Division. Qualified experts are not considered employees or representatives of the Division of Waste Management and Radiation Control or the State.

"Sorting Center" means a facility in which radiation machines are in storage until they are shipped out of state.

"Storage" means a condition in which a radiation machine is not being used for an extended period of time, and has been made inoperable.

**R313-16-220. Exemptions.**

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of Rule R313-16, providing the dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 mrem (5.0 uSv) per hour at five centimeters from accessible surfaces of the equipment.

(2) Radiation machines while in transit are exempt from the requirements of Section R313-16-230. See Section R313-16-250 for other applicable requirements.

(3) Television receivers are exempt from the requirements of Rule R313-16.

(4) Radiation machines while in the possession of a manufacturer, assembler, or a sorting center are exempt from the requirements of Section R313-16-230.

(5) Radiation machines owned by an agency of the Federal Government are exempt from the requirements of Rule R313-16.

**R313-16-225. Responsibility for Radiation Safety Program.**

(1) The registrant shall be ultimately responsible for radiation safety, but may designate another person to implement the radiation safety program. When, in the director's opinion, neither the registrant nor the registrant's designee is sufficiently qualified to ensure safe use of the machine; the director may order the registrant to designate another individual who has adequate qualifications.

(2) The registrant or the registrant's designee shall:

(a) develop a detailed program of radiation safety that assures compliance with the applicable requirements of Rule R313, including Section R313-15-101;

(b) have instructions given concerning radiation hazards and radiation safety practices to individuals who may be occupationally exposed;

(c) have surveys made and other procedures carried out as required by Rule R313; and

(d) keep a copy of any reports, records, and written policies and procedures required by Rule R313.

**R313-16-230. Registration of Radiation Machines.**

(1) Ionizing radiation producing machines not exempted by Section R313-16-220 shall be registered with the director.

(2) Registration shall be required annually in accordance with a schedule established by the director.

(3) Registration is achieved when the director receives the following:

(a) a current and complete application for registration of radiation machines submitted electronically through the division's website or using form DWMRC-10; and

(b) annual registration fees.

(4) Registration for the current fiscal year shall be acknowledged by the director through receipts for the remittance of the registration fee.

**R313-16-231. Additional Requirements for the Issuance of a Registration for Particle Accelerators Excluding Therapeutic Radiation Machines (See Rule R313-30).**

(1) In addition to the requirements of Section R313-16-230, a registrant who proposes to use a particle accelerator shall submit an application to the Director containing the following:

(a) information demonstrating that the applicant, by reason of training and experience, is qualified to use the accelerator in question for the purpose requested in a manner that will minimize danger to public health and safety or the environment;

(b) a discussion which demonstrates that the applicant's equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or the environment;

(c) the name and qualifications of the individual, appointed by the applicant, to serve as radiation safety officer pursuant to Section R313-35-140;

(d) a description of the applicant's or the staff's experience in the use of particle accelerators and radiation safety training; and

(e) a description of the radiation safety training the applicant will provide to particle accelerator operators.

**R313-16-233. Notification of Intent to Provide Servicing and Services.**

(1) Persons engaged in the business of installing or offering to install radiation machines or engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall notify the Director of the intent to provide these services within 30 days following the effective date of this rule or, thereafter, prior to furnishing or offering to furnish these services.

(2) The notification shall specify:

(a) that the applicable requirements of these rules have been read and understood;

(b) the services which will be provided;

(c) the training and experience that qualify for the discharge of the services; and

(d) the type of measurement instrument to be used, frequency of calibration, and source of calibration.

(3) For the purpose of Section R313-16-233, services may include but shall not be limited to:

(a) installation or servicing of radiation machines and associated radiation machine components; and

(b) calibration of radiation machines or radiation measurement instruments or devices.

(4) Individuals shall not perform the services listed in Subsection R313-16-233(3) unless they are specifically stated for that individual on the notification of intent required in Subsection R313-16-233(1) and the complete information required by Subsection R313-16-233(2) has been received by the Director.

**R313-16-235. Designation of Registrant.**

The owner or lessee of a radiation machine is the registrant. The registrant shall be responsible for penalties imposed under the Director's escalated enforcement authority, see Rule R313-14.

**R313-16-240. Reciprocal Recognition of Registration or License.**

Radiation machines from jurisdictions other than the State of Utah may be operated in this state for a period of less than 30 days providing that the requirements of Section R313-16-280 have been met and providing they are properly registered or licensed with the State Agency having jurisdiction over the office directing the activities of the individuals operating the radiation machines. Radiation machines operating under reciprocity may be inspected pursuant to Section R313-16-290.

**R313-16-250. Report of Changes.**

The registrant shall send written notification within 14 working days to the Director when:

(1) there are changes in location or ownership of a radiation machine;

(2) radiation machines are retired from service;

(3) radiation machines are put in storage or returned to service from storage; or

(4) modifications in facility or equipment are made that might reasonably be expected to effect compliance under the terms of these rules.

**R313-16-260. Approval Not Implied.**

Registration does not constitute approval of activities performed under the registration and no person shall state or imply that activities under the registration have been approved by the Director.

**R313-16-270. Transferor, Assembler, or Installer Obligation.**

(1) Persons who sell, lease, transfer, lend, dispose, assemble, or install a radiation machine in this state shall notify the Director within 14 working days of the following:

(a) the name and address of the person who received the machine and also the name and address of the new registrant of the machine if not the same;

(b) the manufacturer, model, and serial number of the master control of the radiation machine and the number of x-ray tubes transferred; and

(c) the date of transfer of the radiation machine.

(2) Radiation machine equipment or accessories shall not be installed if the equipment will not meet the requirements of these rules when installation is completed.

(3) Reporting Compliance. Assemblers who install one or more components into a radiation machine system or subsystem, shall certify that the equipment meets the standards of these rules. A copy of this certification shall be transmitted to the purchaser and to the Director within 14 working days following the completion of the installation.

(4) Certification can be accomplished by providing the following in conjunction with the information required by Section R313-16-250 and Subsection R313-16-270(1):

(a) the full name and address of the assembler and the date of assembly or installation;

(b) a statement as to whether the equipment is a replacement for other equipment, in addition to other equipment, or new equipment in a new facility;

(c) an affirmation that the applicable rules have been met;

(d) a statement of the type and intended use of the radiation machine system or subsystem, for example "radiographic-stationary general purpose x-ray;" and

(e) a list of the components which were assembled or installed into the radiation machine system or subsystem, identifying the components by type, manufacturer, model number, and serial number.

**R313-16-275. Obligation of Equipment Registrant or Recipient of New Equipment.**

The registrant of a radiation machine shall not allow the equipment to be put into operation until it has been determined that the facility in which it is installed meets the shielding and design requirements of Rule R313-28; see Sections R313-28-32, R313-28-200 and R313-28-450.

**R313-16-280. Out-of-State Radiation Machines.**

(1) Whenever a radiation machine is to be brought into the state, for either temporary or extended use, the person proposing to bring the machine into the state shall give written notice to the Director at least three working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the manufacturer model and serial number of the master control; the nature, duration, and scope of use; and the exact location where the radiation machine is to be used. If, for a specific case, the three working-day period would impose an undue hardship, the person may, upon application to the Director, obtain permission to proceed sooner.

(2) In addition, the out-of-state person shall:

(a) comply with the applicable portions of these rules;

(b) supply the Director other information as the Director requests.

**R313-16-290. Inspection of Radiation Machines and Facilities.**

(1) Registrants shall assure that radiation machines registered pursuant to Section R313-16-230 are compliant with the rules in Rule R313-16. Radiation machines, facilities, and radiation safety programs are subject to inspection to assure compliance with Rule R313-16 and to assist in lowering radiation exposure to as low as reasonably achievable levels, see Section R313-15-101. Inspections may be performed by representatives of the director or by independent qualified experts.

(2) Inspections may, at the director's discretion, be done after the installation of equipment, or after a change in the facility or equipment that might cause a significant change in radiation output or hazards. Inspections may be completed in accordance with the schedule as defined in Table 1.

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| Table 1 | |
| FACILITY TYPE | MAXIMUM TIME BETWEEN INSPECTIONS |
| Hospital or Radiation Therapy Facility | One year |
| Medical or Veterinary Facility using Fluoroscopic or Computed Tomography (CT) Units | One year |
| Medical Facility Using General Radiographic Devices | Two years |
| Chiropractic | Two years |
| Dental | Five years |
| Podiatry | Five years |
| Veterinary except those using Fluoroscopic or Computed Tomography (CT) Units | Five years |
| Industrial Facility with High or Very High Radiation Areas Accessible to Individuals | One year |
| Industrial Facility Using Cabinet X-ray Units or Units Designed for Other Industrial Purposes | Five years |
| Other | One to Five years |

(3) The registrant, in a timely manner, shall pay the appropriate inspection fee after completion of the inspection.

(4) Ionizing radiation producing machines that have been officially placed in storage are exempt from inspection fees but are subject to visual verification of their status by representatives of the director.

**R313-16-291. Inspection Services.**

Registrants shall only utilize qualified experts who have been registered by the Director in accordance with Section R313-16-293. Registrants may also utilize inspectors from the Division of Waste Management and Radiation Control in lieu of registered qualified experts.

**R313-16-292. Minimum Qualifications for Registration of Inspection Services.**

A qualified expert who is engaged in the business of furnishing or offering to furnish inspection services at facilities shall meet the training and experience criteria developed by the Director. At a minimum, the training and experience shall include:

(1) Bachelor's degree in health physics, chemistry, biology, physical or environmental science plus one year full-time paid professional related experience, such as performing radiation safety evaluations in a hospital.

(a) An advanced degree in a related field may be substituted for one year of required experience; or

(2) Five years full-time paid professional, directly related work experience.

**R313-16-293. Application for Registration of Inspection Services.**

(1) Each qualified expert who is providing or offering to provide inspection services at facilities registered with the director shall finish an application for registration electronically or on a form prescribed by the director and shall submit the information required by the director as stated. A qualified expert shall finish the registration process before providing services.

(2) Individuals applying for registration under Section R313-16-293 shall personally sign and submit to the director an attestation statement or attest electronically:

(a) that they have read and understand the requirements of Title R313; and

(b) that they will document inspection items defined by the director on a form prescribed by the director; and

(c) that they will follow guidelines for the evaluation of x-ray equipment defined by the director; and

(d) that, except for those facilities where a registered qualified expert is a full-time employee, they will limit inspections to facilities where they have no direct conflict of interest; and

(e) that radiation exposure measurements and peak tube potential measurements will be made with instruments that have been calibrated biennially by the manufacturer of the instrument or by a calibration laboratory accredited in x-ray calibration procedures by the American Association of Physicians in Medicine, American Association for Laboratory Accreditation, Conference of Radiation Control Program Directors, Health Physics Society or the National Voluntary Laboratory Accreditation Program; and

(f) that the calibration of radiation exposure measuring and peak tube potential measuring instruments used to evaluate compliance of x-ray systems with the requirements of Title R313 will include at least secondary level traceability to a National Institute of Standards and Technology, or similar international agency, transfer standard instrument or transfer standard source; and

(g) that they will make available to representatives of the director documents concerning the calibration of any radiation exposure measuring or peak tube potential measuring instrument used to evaluate compliance of x-ray systems; and

(h) that they will submit to the director, within 30 calendar days after completion of an inspection or in accordance with another schedule approved in writing by the director, a written report of compliance or noncompliance; and

(i) that reports of items of noncompliance will include:

(i) the name of the facility inspected; and

(ii) the date of the inspection; and

(iii) the manufacturer, model number, and serial number or Utah identification number of the control unit for the radiation machine; and

(iv) the requirements of Title R313 that were not in compliance; and

(v) the manner that the facility or radiation machine failed to meet the requirements; and

(vi) a signed commitment from the registrant of the radiation machine facility that the problem will be fixed within 30 days of the date the written report of noncompliance is submitted to the director; and

(vii) that the reports of compliance or noncompliance will contain a statement signed by the qualified expert acknowledging under penalties of law that the information contained in the report is truthful, accurate, and complete; and

(viii) that they acknowledge that they are subject to Section R313-16-300.

(3) Individuals applying for registration under Section R313-16-293 shall attach to their application a copy of two inspection reports that demonstrate their work product follows the evaluation guidelines defined by the director pursuant to Subsection R313-16-293(2)(c). The inspection reports shall pertain to inspections performed within the last two years.

**R313-16-294. Issuance of Registration Certificate for Inspection Services.**

Upon a determination that an applicant meets the requirements of these rules, the Director shall issue a registration certificate for inspection services.

**R313-16-295. Expiration of Registration Certificates for Inspection Services.**

A registration certificate for inspection services shall expire at the end of the day on the date stated therein.

**R313-16-296. Renewal of Registration Certificate for Inspection Services.**

(1) Timely renewal of a registration certificate for inspection services is possible when:

(a) the qualified expert files an application for renewal of a registration certificate for inspection services 30 days in advance of the registration certificate expiration date and in accordance with Section R313-16-293, and

(b) the qualified expert attaches to the application documentation that they performed a minimum of two inspections in Utah under these rules each year the previous registration certificate was in effect. An applicant who did not complete the minimum number of inspections in Utah may, as an alternative, attach to the application documentation that they performed four inspections at facilities in other states. These four inspections shall demonstrate their work product follows the evaluation guidelines defined by the Director pursuant to Subsection R313-16-293(2)(c).

(2) A registered qualified expert who allows a registration certificate to expire is no longer a qualified expert and may not perform inspection services that will be accepted by the Director. Reapplication may be accomplished pursuant to Section R313-16-293.

**R313-16-297. Revocation of Registration Certificate for Inspection Services.**

A registration certificate for inspection services may be revoked by the Director for any matter of deliberate misconduct pursuant to Section R313-16-300 or for misfeasance, malfeasance or nonfeasance.

**R313-16-300. Deliberate Misconduct.**

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

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

(b) Deliberately submit to the Director, a registrant, an applicant, or a 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 Director.

(2) A person who violates Subsections R313-16-300(1)(a) or (b) may be subject to enforcement action in accordance with Rule R313-14.

(3) For the purposes of Subsection R313-16-300(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a registrant or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any registration issued by the Director; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a registrant, applicant, contractor, or subcontractor.

**KEY: x-rays, inspections**

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