MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
RADIATION SAFETY SECTION
IONIZING RADIATION RULES

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PART 1~~3~~2. MISCELLANEOUS ~~SOURCES~~ RADIATION MACHINES

R325.5481. Purpose and scope.

Rule 481. (1) This part establishes ~~radiation safety~~ requirements governing the use of ~~for~~ miscellaneous radiation machines ~~sources and for persons utilizing such sources~~ not exempted under ~~rules 31 to 33~~ R325.531 to $325.533 and not specifically covered elsewhere by these rules.

(2) This part applies to all persons who use ~~sources of~~ radiation machines ~~not specifically covered by the other parts~~ specified in subrule (1) of this rule.

(3) In addition to the requirements of this part all persons ~~and activities covered by this part~~ are subject to the ~~applicable~~ provisions of parts ~~1, 2, 4 and 5~~ 1through 4.

R325.xxxx. Definitions.

Rule xxx. (1) As used in this part:

(a) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

(b) "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.

(c) "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.

(d) "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.

(e) "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.

(f) "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.

(g) "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.

ANALYTICAL X-RAY ~~SOURCES~~MACHINES

R325.5482. X-ray equipment.

~~**Rule 482. (1)** Tube housing leakage from analytical x-ray sources shall not exceed 0.5 milliroentgen per hour at a 5 centimeter distance from the surface of the tube housing with the beam ports blocked and the tube operating at its leakage technique factors. Also, radiation originating from the high voltage power supplies shall not exceed this limit.~~

~~**(2)** For instruments in which the primary x-ray beam is completely enclosed, the radiation shall be less than 2 mR per hour at a distance of 25 centimeters from the cabinet surface.~~

~~**(3)** For enclosed equipment, interlocks shall be provided on all access panels which will terminate exposure and prevent operation while the panel is removed.~~

~~**(4)** For open beam analytical x-ray equipment:~~

~~**(a)** X-ray diffraction cameras shall have the appropriate ports arranged so that the camera collimating system shall be in place before the x-ray tube can be energized or the shutter can be opened.~~

~~**(b)** An adapter between the x-ray tube and the collimator of the diffractometer camera or other accessory shall provide the same protection as required by subrule (1).~~

~~**(c)** Safety interlocks shall never be used as routine cut-off switches during normal operation. They shall be operated as safety devices only, and tested periodically. When the interlock system does turn off the x-ray beam, it shall be necessary to reset the "on" switch at the control panel to resume operation.~~

~~**(d)** Tube head ports which are not in use shall be secured in a closed position and interlocked to the x-ray generator or warning system.~~

~~**(e)** The shutter indicator shall be conspicuously displayed to disclose the "open" or "closed" position of the shutter.~~

~~**(f)** The instrument shall display a conspicuous warning label such as "CAUTION RADIATION - THIS EQUIPMENT PRODUCES X-RADIATION WHEN ENERGIZED."~~

~~**(g)** A red warning light shall indicate "X-RAY ON" when the equipment is producing x-rays. Other signal lights or alarms shall operate only to indicate a malfunction which may produce a radiation, electrical or other hazard.~~

Rule 482. (1) 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 department for an exemption from the requirement 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.

(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) Open-beam configurations shall be provided with a readily discernible indication of:

(a) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(b) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(3) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.

(4) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after [effective date of this regulation], warning devices shall have fail-safe characteristics.

(5) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(6) 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.

(b) "CAUTION RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube.

(7) On open-beam configurations installed after [effective date of this regulation], 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.

(8) 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.

(9) Each beam port cover, or accessory 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. This limit shall be met at any specified tube rating.

(10) Each x-ray generator (high voltage power supply) 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 uSv) in one hour.

(11) For enclosed equipment, interlocks shall be provided on all access panels and sample chamber covers which shall terminate exposure and prevent operation while the panel is removed. (Old subrule 3)

Updated equipment requirements above are from SSRCR Part H.3 and its proposed draft revision which is in process.

R325.5483. Area Requirements.

Rule 483. 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 Part 4 of these regulations. These levels shall be met at any specified tube rating.

From SSRCR Section H.4a

R325.5484. Administrative procedures.

Rule 484. A radiation protection supervisor shall be appointed to be responsible for radiation safety. ~~This individual shall not normally operate the x-ray equipment. He or his designated representative~~ The radiation protection supervisor shall:

(a) Insure that operational and maintenance procedures are followed.

(b) Provide instruction in safety practices for all individuals working with the x-ray equipment, and those working in the immediate area or periodically review the safety instruction provided for such individuals.

(c) Maintain a personnel monitoring system, if required under Rule 487.

(d) Review, approve and supervise modifications or replacement of parts for the x-ray apparatus.

(e) ~~Conduct such surveys and tests as necessary to certify compliance with these rules, including any specific registration conditions and maintain records thereof for examination by the department.~~ Conduct, or cause to be conducted, radiation surveys of all analytical x-ray systems sufficient to show compliance with the rules at the following times.

(i) Upon installation of the equipment, and not less than once every 12 months thereafter.

(ii) Following a change in the initial arrangement, number, or type of local components in the system.

(iii) Following 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 a local component in the system is disassembled or removed.

(v) When a visual inspection of the local components in the system reveals an abnormal condition .

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in Part ? (stand for protect) of these rules.

Subrule (e) merged in from SSRCR Section H.4b

(2) 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.

(3) Means shall be provided to physically secure analytical x-ray equipment to prevent unauthorized personnel from activating the system.

(4) 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 a manner other than that specified in the procedures unless the individual has obtained written approval of the radiation protection supervisor.

(5) No individual shall bypass a safety device or interlock unless the individual has obtained the written approval of the radiation protection supervisor. This 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, and at the control switch.

(6) Except as approved in writing by the radiation protection supervisor, 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 shall remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

Subrules 2 through 6 taken from SSRCR H.4 and H.5

R325.5485. Operators.

Rule 485. An individual shall not be permitted to operate or maintain analytical x-ray equipment unless the individual has received instruction in and demonstrated competence as to:~~act as the operator of analytical x-ray equipment until he has received training in radiation safety and has been approved by the radiation protection supervisor or his designated representative. The operator shall also demonstrate competence in the use of the machine and radiation survey instruments.~~

(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 these cases.

(c) Proper operating procedures for the equipment.

(d) Recognition of symptoms of an acute localized exposure.

(e) Proper procedures for reporting an actual or suspected exposure.

Subrule 1 taken from SSRCR Section H.6a

~~**(2)** The operator shall be responsible for complying with all procedures associated with the x-ray equipment.~~

~~**R325.5486. Operating procedures.**~~

~~**Rule 486.** A set of operating procedures shall be posted on or adjacent to the machine, written in understandable, concise language.~~

Operating procedures merged with Administrative procedures due to similarities.

R325.5487~~6~~. Personnel monitoring.

Rule 487~~6~~. ~~An operator of analytical x-ray equipment shall be provided with finger or wrist radiation monitoring devices. Any person coming in contact with equipment capable of exposing a major portion of the body shall be required to wear whole-body monitoring equipment at all times. Personnel coming in contact with this equipment shall be warned of the nature and type of physiological effects that may be expected when overexposed to radiation.~~**(1)** Finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device which prevents entry of any part of the body into the primary beam path; and

(b) 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.

(2) A person coming in contact with equipment capable of exposing a major portion of the body shall be required to wear whole-body monitoring equipment at all times.

Subrule 1 replaced with SSRCR section H.6bi suggested revision and an important part of subrule 1 is retained as subrule 2. From SSRCR revision rationale: PERSONNEL MONITORING IS NOT NECESSARY FOR ANALYTICAL X-RAY EQUIPMENT EXCEPT WHEN ALIGNMENT IS BEING PERFORMED ON OPERATING, NON-COPPER TARGET X-RAY UNITS. THE SIZE OF THE RADIATION FIELD IN ANALYTICAL UNITS LIMITS THE EFFECTIVENESS OF PERSONNEL MONITORING. IN ADDITION, MOST ANALYTICAL X-RAY UNITS USE COPPER TARGETS, FOR WHICH THE CHARACTERISTIC X-RAY IS TOO WEAK TO PENETRATE THE DEAD LAYER OF SKIN.

COLD-CATHODE GAS DISCHARGE TUBES

This sections modifications are clarification improvements only.

R325.5491. Rules applicable.

Rule 491. Cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x-radiation are subject to the requirements of ~~rules 492 to 495~~ R325.5492 to R325.5495.

R325.5492. Exposure rate limit.

Rule 492. (1) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 ~~mR/hr~~ milliroentgen per hour at a distance of 30 centimeters from ~~any point on~~ the external surface of the tube, as measured ~~in accordance with rule 493~~ under R325.5493.

(2) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x-radiation, with the beam blocking device in the open position, shall not exceed π (Pi) steradians.

R325.5493. Measurements.

Rule 493. (1) Compliance with the exposure rate limit specified in rule ~~492 (1)~~ R325.5492(2) shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension ~~exceeding~~ greater than 20 centimeters.

(2) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of 30 centimeters from ~~any point on~~ the external surface of the enclosure ~~under the following conditions~~ provided:

(a) In the case of enclosures containing tubes designed primarily to demonstrate the production of x-radiation, measurements shall be made with ~~any~~ the beam blocking device in the beam blocking position or,

(b) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of ~~such~~ the enclosure in the position which would maximize external exposure levels.

R325.5494. Test conditions.

Rule 494. (1) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer. If the manufacturer's instructions are not available, measurements shall be made under power source settings which maximize the leakage radiation.

(2) Measurements shall be made with the tube operated under forward and reverse polarity.

R325.5495. Instructions, labels and warnings.

Rule 495. (1) ~~Manufacturers shall provide, or cause to be provided, with~~ For each tube to which ~~rules 492 to 495~~ R325.5492 to R325.5495 are applicable, appropriate safety instructions, and instructions for the use of the tube, including the specification of a power source for use with the tube, shall be provided.

(2) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and; (a) in the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (b) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(3) The tag or label required by subrule (2) of this rule shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

~~**X-RAY FILM IDENTIFICATION MARKERS**~~

~~**R325.5501. General provisions.**~~

~~**Rule 501. (1)** All devices utilizing sources of radiation for the purpose of marking x-ray film for identification purposes shall be subject to the requirements of this rule.~~

~~**(2)** The radiation source and all objects exposed thereto shall be within a permanent enclosure.~~

~~**(3)** Reliable interlocks shall be provided to prevent access to the enclosure during irradiation.~~

~~**(4)** The radiation exposure at any accessible position 5 centimeters from the outside surface of the enclosure shall not exceed 0.5 mR in any 1 hour.~~

~~**(5)** A person in the environs of the installation shall not be exposed more than the maximum permissible dose equivalent specified in rule 205.~~

~~**(6)** Before a new installation is placed in operation a radiation protection survey shall be conducted in accordance with rule 221. A written report of this initial survey shall be submitted to the department and approved before a certificate of registration for the devices is issued.~~

~~**(7)** A record of the survey required by subrule (6) shall be maintained at the installation for examination by the department.~~

ELECTRON MICROSCOPES

R325.5505. Equipment.

Rule 505. (1) During ~~any phase of~~ operation of an electron microscope at the maximum rated continuous tube current for the maximum rated peak tube potential the radiation exposure rate as measured in air at a distance of 5 centimeters from any accessible point on the external surface of the microscope shall not exceed 0.5 ~~mR~~ milliroentgen per hour.

(2) Interlocks shall be provided on all potential radiation hazard access panels which ~~will~~ shall terminate exposure and prevent operation while the panel is removed.

(3) The instrument shall display a conspicuous warning label such as CAUTION RADIATION - THIS EQUIPMENT PRODUCES X-RADIATION WHEN ENERGIZED.

R325.5506 Administrative procedures.

Rule 506. A radiation protection supervisor shall be appointed to be responsible for radiation safety. ~~This individual shall not normally operate the electron microscope. He or his~~ The radiation protection supervisor or designated representative shall:

(a) Insure that operational and maintenance procedures are followed.

(b) Provide instruction in safety practices for all persons working with the electron microscope, and those working in the immediate area.

~~**(c)** Maintain a personnel monitoring system if provided.~~

(c) Review, approve, and supervise modifications or replacement of parts for the electron microscope.

(d) Conduct ~~such~~ surveys and tests as necessary to certify compliance with these rules, including ~~any~~ specific registration conditions and maintain records thereof for examination by the department.

R325.5507. Operators.

Rule 507. (1) An individual shall not be permitted to act as operator of an electron microscope unless ~~he~~ the individual has demonstrated to the satisfaction of the radiation protection supervisor or his designated representative:

(a) Competence in the safe use of the instrument.

(b) Awareness of the potential radiation hazard which could result from improper adjustment or misuse of the instrument.

~~**(2)** The operator shall be responsible for complying with all procedures associated with the instrument.~~

Redundant.

R325.5508. Operating procedures.

Rule 508. A set of operating procedures shall be posted on or adjacent to the electron microscope, written in understandable, concise language. ~~Appropriate precautions for the safe handling of uranyl salts or other radioactive biological stains shall be included if such substances are used.~~

~~[*Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance are under the purview of the Michigan Department of Consumer & Industry Services.*]~~

OTHER MISCELLANEOUS SOURCES

R325.5511. Registration Conditions.

Rule 511. Types of radiation ~~sources~~ machines and uses not specifically covered by these rules shall be subject to specific requirements designated by the department in the form of ~~license or~~ registration conditions for the protection of public health, safety and property until such time that these rules are amended to specifically cover such sources and uses.