DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

RADIATION SAFETY SECTION

(By authority conferred on the department of public health by section 13521 of Act No. 368 of the Public Acts of 1978, as amended, and section 48 of Act No. 306 of the Public Acts of 1969, as amended, being SS333.13521 and 24.248 of the Michigan Compiled Laws)

PART 11. PARTICLE ACCELERATOR INSTALLATIONS

R 325.5431. Purpose and scope.

Rule 431. (1) This part establishes procedures for the licensing or registration of particle accelerators, a classification system for particle accelerator installations and use, and radiation safety requirements for persons utilizing all types of particle accelerators except those specifically exempted from this part.

(2) This part applies to all licensees and registrants who use particle accelerators for any purpose other than those exempted under rule 432.

(3) In addition to the requirements of this part, all licensees and registrants are subject to the applicable provisions of the other parts.

History: 1979 AC.

R 325.5432. Definitions.

Rule 432. (1) "Particle accelerator" or "accelerator", as used in this part, means a radiation machine designed for or capable of accelerating electrically charged particles, such as electrons, protons or deuterons, with an electrical potential in excess of 1 MeV. Radiation machines designed and used exclusively for the production of electron beams or x- radiation for any of the following purposes except those capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 are excluded from this definition:

(a) The diagnosis or treatment of patients.

(b) Industrial radiography.

(c) Examination of the microscopic structure of materials.

(d) Manufacturing process control.

(e) Research and development.

(f) Demonstration of scientific principles for educational purposes.

(2) "Radiation protection supervisor" means 1 specific individual appointed by the licensee or registrant who has been delegated the responsibility and authority to govern the operation of the accelerator in such a manner as to comply with the provisions of this part and part 5 and to enforce any written procedures approved by the department.

[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.]

History: 1979 AC.

LICENSE OR REGISTRATION

R 325.5435. General provisions.

Rule 435. (1) Except as otherwise provided in these rules, a person shall not manufacture, produce, own, receive, acquire, possess, use, transport, transfer or dispose of a research, production, processing or

treatment particle accelerator capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 unless authorized in a specific license issued pursuant to part 2.

(2) Each person having a particle accelerator subject to this part shall comply with the registration requirements of part 4 unless the particle accelerator is licensed by a specific license issued pursuant to part 2.

[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.]

History: 1979 AC.

CLASSIFICATION

R 325.5437. Class enumeration.

Rule 437. (1) For the purpose of licensing or registering and approving particle accelerator installations they shall be classified as class AA, class A, class B, or class C.

(2) For the purpose of licensing or registering and approving mobile or portable particle accelerators intended for limited use at temporary job site locations this use shall be classified as class D operation.

History: 1979 AC.

R 325.5438. Class AA installations.

Rule 438. (1) In class AA installations the accelerator and objects exposed thereto shall be contained within a permanent enclosure.

(2) The enclosure shall be constructed such that the radiation exposure dose equivalent rate as measured in air at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 2 millirems per hour under conditions of maximum radiation output permitted by the design or operating characteristics of the accelerator.

(3) Mechanical or electrical limiters shall limit movement or alignment of the accelerated beam within the enclosure if necessary to comply with subrule (2).

(4) A personnel barrier posted in accord with rules 224 to 231 restricting access to the roof of the enclosure shall meet the requirement of subrule (2).

(5) Reliable interlocks shall be provided which will prevent anyone from opening the enclosure while the accelerator is in operation or which will terminate machine operation should anyone open the enclosure. These interlocks shall comply with rule 448.

(6) Enclosures of sufficient size to permit human occupancy shall be provided with visible or audible signals or both within the enclosure which are activated a minimum of 5 seconds before accelerator operation. Persons shall at all times be able to escape from within the enclosure.

(7) An individual shall not be permitted to remain within the enclosure while the accelerator is in operation except as a human patient undergoing radiation treatment.

(8) Protective enclosures and equipment shall be kept in good repair.

(9) Electron beam welders shall meet class AA requirements.

(10) Class AA approval permits unlimited use at maximum capacity.

History: 1979 AC.

R 325.5439. Class A installations.

Rule 439. (1) Class A installations shall comply with all requirements of rule 438 except for a permissible exposure dose equivalent rate of 7 millirems per hour at any accessible external point.

(2) A personnel monitoring device, such as a film badge dosimeter or thermoluminescent dosimeter, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(3)Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(4) Class A approval permits unlimited use at maximum capacity.

History: 1979 AC.

R 325.5440. Class B installations.

Rule 440. (1) Class B installations shall comply with all requirements of rule 439.

(2) Accelerator beam current and potential controls shall be mechanically or electrically limited so as not to exceed the normal operating conditions as specified by the applicant at the time of application for specific license or registration.

(3) Class B approval permits unlimited use under normal operating conditions as specified by subrule (2).

History: 1979 AC.

R 325.5441. Class C installations.

Rule 441. (1) Class C installations shall comply with all requirements of rule 439 except for a permissible exposure dose equivalent rate of 50 millirems per hour at any accessible external point.

(2) The maximum weekly accelerator beam on time shall be established by the department under the conditions specified by the registrant at the time of application for specific license or registration.

(3) Warning signs shall be posted in those areas outside the enclosure in which the radiation exposure dose equivalent rate in air at any accessible external point exceeds 2 millirems per hour under conditions of maximum radiation output permitted by the design or limited operating characteristics of the accelerator.

(4) A daily usage log shall be maintained to record machine operation.The record shall be available at the accelerator site for examination by the department.

History: 1979 AC.

R 325.5442. Class D operations.

Rule 442. (1) Particle accelerator operations conducted under conditions not meeting the provisions and requirements of rules 438 to 441 shall be classified as class D operations and shall not be operated longer than 30 days unless written authorization is granted by the department.

(2) Written authorization in the form of a specific license or registration condition may be granted by the department for class D operations longer than 30 days but not longer than 6 months at any 1 location when an undue and unnecessary hardship may result from the 30 day limitation. Written request by the applicant for this authorization is required and shall describe the hardship involved as well as provide written assurance of compliance with the requirements of these rules for class D operation. This assurance shall be in the form of satisfactory written procedures which shall be approved by the department before the issuance of a specific license or certificate of registration.

History: 1979 AC.

SAFETY REQUIREMENTS FOR THE USE

OF PARTICLE ACCELERATORS

R 325.5445. General provisions.

Rule 445. (1) Rules 445 to 455 establish radiation safety requirements for the use of particle accelerators. The provisions of such rules are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) A licensee or registrant shall be responsible for assuring that all requirements of this part are met.

History: 1979 AC.

R 325.5446. Limitations.

Rule 446. (1) A licensee or registrant shall not permit an individual to act as an accelerator operator until the individual:

(a) Has been instructed in radiation safety and has demonstrated an understanding thereof.

(b) Has received copies of and instruction in this part and the applicable requirements of part 5, pertinent license or registration conditions, and the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof.

(c) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

(2) The radiation safety committee or the radiation protection supervisor shall have the authority to terminate the operations at an accelerator facility or of a class D operation if this action is deemed necessary to protect health and minimize danger to public health and safety or property.

History: 1979 AC.

R 325.5447. Shielding.

Rule 447. (1) The design and shielding specifications for an accelerator shall be submitted and approved before issuance of a license by the department. After construction and installation the radiation safety of the installation shall be established by a protection survey conducted in accord with rule 221. A written report of the initial survey shall be submitted to the department and approved in writing before continued operation of the accelerator.

(2) Each accelerator installation shall be provided with such primary or secondary barriers as are necessary to assure compliance with rules 203, 205 and 211.

History: 1979 AC.

R 325.5448. Accelerator controls and interlock systems.

Rule 448. (1) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

(2) All entrances or openings into a target room or other high radiation areas shall be provided with interlocks.

(3) When an 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 interlock has been tripped, and lastly at the main control console.

(4) A safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

(5) A safety interlock shall be fail safe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

(6) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. This cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

History: 1979 AC.

R 325.5449. Warning devices.

Rule 449. (1) Locations designated as high radiation areas, and entrances to these locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(2) Except in installations designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds before the possible creation of a high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(3) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with rules 224 to 233.

History: 1979 AC.

R 325.5450. Equipment control and operations.

Rule 450. (1) A particle accelerator shall not be left unattended without locking the control panel in some manner which will prevent its use by unauthorized persons.

(2) A building housing a fixed particle accelerator shall not be left unattended without locking the building or portions thereof in some manner which will prevent unauthorized entry into the control room or target room, or any access to areas which may contain induced radioactivity resulting from accelerator operation.

(3) A mobile or portable particle accelerator shall not be left unattended without locking the room or building in which it is housed in some manner which will prevent its removal by unauthorized persons.

(4) Access to or possession of keys or combinations used to comply with the requirements of subrules (1) to (3) shall be limited to specific authorized persons approved by the radiation protection supervisor.

(5) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or during periodic testing of the interlock system.

(6) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 3 months. Results of these tests shall be maintained for inspection by the department at the accelerator installation.

(7) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and on file at each accelerator installation.

(8) If for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(a) Authorized by the radiation protection supervisor pursuant to rule 241.

(b) Recorded in a permanent log and a notice posted at the accelerator control console.

(c) Terminated as soon as possible.

(9) A copy of the operating and the emergency procedures shall be maintained at the accelerator control panel.

History: 1979 AC.

R 325.5452. Radiation surveys.

Rule 452. (1) A license or registrant shall maintain at each accelerator installation or class D operation appropriate calibrated and operable portable radiation monitoring instruments to make physical radiation surveys as required by this part and part 5.

(2) These instruments shall be capable by design, calibration and operation of measuring the intensity of the various types and energies of radiation produced by the accelerator. These instruments shall be tested for proper operation at the beginning of each day they are to be used and calibrated at intervals not to exceed 3 months.

(3) During repair or calibration of a radiation monitoring instrument, a spare calibrated and operable instrument shall be provided or accelerator operations which require the instrument shall be terminated until required instrumentation is available.

(4) A radiation protection survey shall be performed and documented in accord with rule 221 when changes have been made in shielding, operation, equipment or occupancy of adjacent areas, and periodically to check for unknown changes and malfunctioning equipment.

(5) Radiation levels in all accessible high radiation areas shall be continuously monitored except in installations designed for human exposure. The monitoring devices shall be independent and capable of providing a remote and local readout with visual or audible alarms or both at the control panel and at the monitoring stations.

(6) All area monitors shall be calibrated at established periodic intervals approved by the department.

(7) Whenever applicable, periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(8) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

(9) All area surveys shall be made in accordance with the written procedures established by a health physics consultant or the radiation protection supervisor of the accelerator facility and approved by the department.

(10) Records of all radiation protection surveys, calibration results, instrumentation tests and smear results shall be kept current and on file at each accelerator facility.

[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.]

History: 1979 AC.

R 325.5455. Special precautions.

Rule 455. A licensee or registrant shall not permit dismantling, repair or servicing of any portion of the accelerator or changing of target materials by any persons unless such persons have been approved for such activity by the radiation protection supervisor. The radiation protection supervisor shall determine that such persons are:

(a) Qualified by training or experience to conduct such activities safely with respect to potential radiation hazards.

(b) Knowledgeable regarding the potential hazards of induced radioactivity.

(c) Provided with appropriate monitoring instruments and dosimeters.

(d) Informed of any special procedures or precautions necessary to protect themselves and others from radiation exposure or spread of contamination.

History: 1979 AC.

PART 13. MISCELLANEOUS SOURCES

R 325.5481. Purpose and scope.

Rule 481. (1) This part establishes radiation safety requirements for miscellaneous radiation sources and for persons utilizing such sources not exempted under rules 31 to 33 and not specifically covered elsewhere by these rules.

(2) This part applies to all persons who use sources of radiation not specifically covered by the other parts.

(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.

History: 1979 AC.

ANALYTICAL X-RAY SOURCES

R 325.5482. 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.

History: 1979 AC.

R 325.5484. 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 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.

(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.

History: 1979 AC.

R 325.5485. Operators.

Rule 485. (1) An individual shall not be permitted 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.

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

History: 1979 AC.

R 325.5486. Operating procedures.

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

History: 1979 AC.

R 325.5487. Personnel monitoring.

Rule 487. 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.

History: 1979 AC.

COLD-CATHODE GAS DISCHARGE TUBES

R 325.5491. 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.

History: 1979 AC.

R 325.5492. Exposure rate limit.

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

(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 ? (Pi) steradians.

History: 1979 AC.

R 325.5493. Measurements.

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

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

(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 enclosure in the position which would maximize external exposure levels.

History: 1979 AC.

R 325.5494. Test conditions.

Rule 494. (1) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

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

History: 1979 AC.

R 325.5495. Instructions, labels and warnings.

Rule 495. (1) Manufacturers shall provide, or cause to be provided, with each tube to which rules 492 to 495 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.

(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) shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

History: 1979 AC.

X-RAY FILM IDENTIFICATION MARKERS

R 325.5501. 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.

History: 1979 AC.

ELECTRON MICROSCOPES

R 325.5505. 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 per hour.

(2) Interlocks shall be provided on all potential radiation hazard access panels which will 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.”

History: 1979 AC.

R 325.5506. 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 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.

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

(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.

History: 1979 AC.

R 325.5507. Operators.

Rule 507. (1) An individual shall not be permitted to act as operator of an electron microscope unless he 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.

History: 1979 AC.

R 325.5508. 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.]

History: 1979 AC.

OTHER MISCELLANEOUS SOURCES

R 325.5511. License or registration conditions.

Rule 511. Types of radiation sources 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.

History: 1979 AC.