MICHIGAN DEPARTMENT OF PUBLIC HEALTH

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 1. GENERAL PROVISIONS

R 325.5001. Purpose and scope

Rule 1. These rules, except as otherwise specifically provided, apply to all persons who own, receive, acquire, possess, use or transfer any source of radiation in this state. Regulation by the state of source material, byproduct material and special nuclear material in quantities not sufficient to form a critical mass is subject to an agreement between the state and the NRC and to 10 CFR Part 150 of NRC regulations. These rules do not apply to a person to the extent that the person is subject to regulation by the NRC. A person is subject to these rules unless specifically exempted under the act.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5002. Hearing procedure.

Rule 2. (1) Prior to the issuance of an order, the department shall afford opportunity for hearing which shall be conducted pursuant to Act No. 306 of the Public Acts of 1969 as amended being §§24.201 et. seq. of the Michigan Compiled Laws.

(2) In a contested case, the department shall conduct a hearing as provided in Act No. 306 of the Public Acts of 1969 as amended.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5003. Definitions Ab to Ai.

Rule 3. (1) "Absorbed dose" means the energy imparted to matter by radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad.

(2) "Accelerator" or "particle accelerator" 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.
(3) "Accelerator material" means any material made radioactive by exposing it in a particle accelerator.
(4) "Act" means Act No. 305 of the Public Acts of 1972 being §§325.451 et. seq. of the Michigan Compiled Laws. The terms defined in the Act have the same meanings when used in these rules.
(5) "Agreement material" means "byproduct material", "source material", or "special nuclear material in quantities not sufficient to form a critical mass" which is subject to regulation by this state under an agreement between the NRC and this state pursuant to section 274 of the federal atomic energy act of 1954, as amended, being 42. U.S.C. §2021 (Supp. 1973).
(6) "Agreement state" means a state with which the NRC has entered into an effective agreement pursuant to section 274b of the federal atomic energy act of 1954, as amended, being 42 U.S.C. §2021 (Supp. 1973).
(7) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors or gases.
(8) "Airborne radioactivity area" means a room, enclosure or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in column 1, table I of rules 261 to 269 or a room, enclosure or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25% of the amounts specified in column 1, table I of rules 261 to 269.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5004. Definitions Al to Au.
Rule 4. (1) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy with nominal chemical composition of 99.00% minimum aluminum and 0.12% copper which will provide the same attenuation, under specified conditions, as the material in question.
(2) "Atomic Energy Commission" or "AEC" means the United States atomic energy commission, which was abolished by Section 104 of the federal energy reorganization act of 1974, being Public Law 93-438. See nuclear regulatory commission.
(3) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other material with the same aluminum equivalent.
(4) "Authorized recipient" means any person licensed or otherwise authorized in writing by the department, the federal government or any agency thereof, or an agreement state to possess radioactive material or as authorized to the extent permitted by exemption from these rules.
(5) "Automatic exposure control" means a device which automatically controls 1 or more technique factors in order to obtain at a preselected location a required quantity of radiation.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5005. Definitions B.
Rule 5. (1) "Barrier" includes a primary protective barrier, a secondary protective barrier or a personnel barrier.

(2) "Beam axis" means a line from the source through the centers of the x-ray or gamma-ray fields.
(3) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray or gamma-ray field.
(4) "Byproduct material" means any radioactive material, except special nuclear material, yielded in or made radioactive by exposing it to the radiation incident to the process of producing or utilizing special nuclear material.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5006. Definitions C.
Rule 6. (1) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be arranged so that a day is not included in more than 1 calendar quarter nor is a day in any 1 year omitted from inclusion within a calendar quarter. A licensee or registrant shall not change the method observed by him of determining calendar quarters for purposes of these rules except at the beginning of a calendar year.
(2) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}}\left[\sum_{i=1}^{n}\frac{\left(X_i - \overline{X}\right)^2}{n-1}\right]^{\frac{1}{2}}$$

where: s = Estimated standard deviation of the population.
$\overline{X}$ = Mean value of observations in sample.
X_i = i th observation in sample.
n = Number of observations in sample.

(3) "Controlled area" means a restricted area.
(4) "Cooling curve" means the graphical relationship between heat units stored and cooling time.
(5) "Curie" means the quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations per second (dps). Commonly used submultiples of the curie (Ci) are the millicurie (mCi), the microcurie (μCi) and the nanocurie (nCi). One millicurie = 0.001 curie = 3.7×10^7 dps. One microcurie = 0.000001 curie = 3.7×10^4 dps. One nanocurie = 0.000000001 curie = 37 dps. Curie is the special unit of measurement of radioactivity.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5007. Definitions D.
Rule 7. (1) "Department" means the department of public health.
(2) "Diagnostic source assembly" means a diagnostic tube housing assembly with a beam-limiting device attached.
(3) "Diagnostic type tube housing" means an x-ray tube housing constructed so that the leakage radiation at a distance of 1 meter from the tube target does not exceed 0.10 roentgen per hour

under the following conditions:
(a) For capacitor energy storage equipment when operated at is leakage technique factors.
(b) For field emission equipment rated for pulsed operation when operated at its leakage technique factors.
(c) For all other equipment when operated at 70 kVp and 10 milliamps or its calculated equivalent.
(4) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.
(5) "Dose" means absorbed dose or dose equivalent as appropriate.
(6) "Dose equivalent" means the absorbed dose in rads times certain modifying factors and is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ from small amounts of radiation. The special unit of dose equivalent is the rem.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5008. Definitions E and F.
Rule 8. (1) "Electrically grounded" means provided with an electrically conducting connection which joins the electrical circuit or equipment to the earth or to the nearest available conducting body which serves in place of the earth.
(2) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of 1 sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. The special unit of exposure is the roentgen.
(3) "Exposure rate" means the exposure per unit of time, such as R/min, mR/h.
(4) "Facility" means the location at which 1 or more devices or sources of radiation are installed or located within 1 building or under 1 roof and are under the same administrative control.
(5) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
(6) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiation.
(7) "Fluoroscopic imaging assembly" means a component which comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.
(8) "Food and drug administration" or "FDA" means the United States food and drug administration established by the federal food, drug and cosmetic act of 1938, as amended, being Public Law 75-717.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5009. Definitions G and H.
Rule 9. (1) "General purpose radiographic x-ray system" means a radiographic x-ray system which, by design or use, is not limited to radiographic examination of specific anatomical regions.

(2) "Half-value layer" or "HVL" means the thickness of specified material which attenuates the beam of radiation to an extent that the exposure rate is reduced to 1/2 of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
(3) "High radiation area" means an area, accessible to individuals, in which there exists such radiation, that an individual could receive in any 1 hour a dose in excess of 100 millirems.
(4) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5010. Definitions I.
Rule 10. (1) "Image receptor" means a device, such as a fluorescent screen or radiographic film, which transfers incident x-ray photons into a visible image or into another form which can be made into a visible image by further transformations.
(2) "Individual" means a human being.
(3) "Inspection" means an official examination or observation to determine compliance with the act, these rules, license conditions, registration conditions or orders of the department.
(4) "Installation" means a location, having boundaries specified by the licensee or registrant, where for a period of more than 30 days, 1 or more sources of radiation are used, operated or stored. A part of a building, an entire building, a plant or plant site may be designated as an installation.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5011. Definitions L.
Rule 11. (1) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.
(2) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
(a) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.
(b) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.
(c) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.
(3) "Level" means radiation flux or intensity at a specific point. It is sometimes expressed in terms of the dose an individual would receive if he were at that point or location.
(4) "License" means a license issued pursuant to parts 2 or 3 except where otherwise specified.
(5) "Light field" means the area of intersection of the light beam from the beam-limiting device and 1 of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is 1/4 of the maximum in the

intersection.
(6) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,
Percent line-voltage regulation $=100 (V_n - V_i)/V_i$
Where: V_n = No-load line potential and
V_i = Load line potential.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5012. Definitions M to O.
Rule 12. (1) "Manufactured" means produced or prepared for use or sale by an industrial manufacturing process. It includes factory assembly of components but does not include assembly of manufactured parts at the site of use.
(2) "Maximum line current" means the rms current in the supply line of an x-ray machine operating at its maximum rating.
(3) "Naturally occurring material" means radioactive material found radioactive in the normal isotopic distribution of elements rather than rendered radioactive by artificial means.
(4) "Nuclear regulatory commission" or "NRC" means the United States nuclear regulatory commission established by section 201 of the federal energy reorganization act of 1974, being Public Law 93-438.
(5) "Occupational dose" means the dose received in the course of occupational exposure as calculated or estimated from dosimeters.
(6) "Occupational exposure" means radiation exposure received by an individual in a restricted area, or in the course of employment in which the individual's duties involve being exposed to radiation. It does not include exposure of an individual to radiation for the purpose of diagnosis or therapy of the individual.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5013. Definitions P.
Rule 13. (1) "Particle accelerator" or "accelerator" 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) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(3) "Personnel barrier" means a barrier which restricts personnel from potential radiation exposure by restricting access to the vicinity of a source of radiation.
(4) "Personnel monitoring equipment" means a device such as a film badge, pocket dosimeter or thermoluminescent dosimeter (TLD) designed to be worn or carried by an individual for the purpose of estimating the radiation dose received by him.
(5) "Physician" means an individual licensed by this state to prescribe or dispense drugs in the practice of medicine.
(6) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5014. Definitions Ra.
Rule 14. (1) "Rad" means 1/100 of a joule of absorbed radiation energy per kilogram of material, or 100 ergs per gram and is the special unit of absorbed dose.
(2) "Radiation" means ionizing radiation.
(3) "Radiation area" means an area, accessible to individuals, in which there exists such radiation that an individual could receive in any 1 hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.
(4) "Radiation machine" means a device capable of producing radiation except that which produces radiation only from radioactive material.
(5) "Radiation monitoring" means the periodic or continuous determination of the exposure rate or contamination level in an area (area monitoring) or of the dose received by an individual (personnel monitoring).
(6) "Radiation protection supervisor" means the individual specified by the licensee or registrant who has the authority and the responsibility for radiation protection.
(7) "Radiation worker" means an individual assigned work with or around sources of radiation or who, during the performance of his assigned duties, receives or is likely to receive a dose in any calendar quarter in excess of 300 millirems.
(8) "Radioactivity" means the property of certain isotopes of the basic elements of spontaneously emitting nuclear particles or gamma radiation or of emitting x-radiation following orbital electron capture or of undergoing spontaneous fission.
(9) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.
(10) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.
(11) "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.
(12) "Rating" means the operating limits specified by the manufacturer.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5016. Definitions Re to Ro.
Rule 16. (1) "Recording" means producing a permanent form of a radiographic image resulting

from x-ray or gamma-ray photons.
(2) "Rem" means the absorbed dose in rads multiplied by appropriate modifying factors which are determined by the quality of radiation and the conditions of exposure and is the special unit of dose equivalent. For the purpose of these regulations, each of the following is considered to be equivalent to a dose of one rem:
(a) An exposure of 1 roentgen of x or gamma radiation.
(b) A dose of 1 rad due to x, gamma or beta radiation.
(c) A dose of 0.1 rad due to neutrons or high energy protons.*
(d) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

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* If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron absorbed dose in rads, 1 rem of neutron radiation may, for purposes of these regulations, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to 1 rem may be estimated from the following table:

Neutron Flux Dose Equivalents

Neutron Energy (Mev)	Number of neutrons per square centimeter for a dose equivalent of 1 rem (neutron/cm^2)	Average flux to deliver 100 millirem in 40 hours (neutrons/cm^2 per second)
Thermal	970 x 10^6	670
0.0001	720 x 10^6	500
0.005	820 x 10^6	570
0.02	400 x 10^6	280
0.1	120 x 10^6	80
0.5	43 x 10^6	30
1.0	26 x 10^6	18
2.5	29 x 10^6	20
5.0	26 x 10^6	18
7.5	24 x 10^6	17
10.0	24 x 10^6	17
10 to 30	14 x 10^6	10

(3) "Research and development" means theoretical analysis, exploration or experimentation; or the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. This definition does not apply to human use.
(4) "Response time" means the time required for an instrument system to reach 90% of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change

in radiation flux from zero sufficient to provide a steady state midscale reading.
(5) "Restricted area" or "controlled area" means an area access to which is controlled by a licensee or registrant for purposes of protection of individuals from exposure to radiation or radioactive materials. It does not include an area used for residential quarters, although a separate room in a residential building may be set apart as a restricted area.
(6) "Roentgen" means 2.58×10^{-4} Coulombs/kilogram of air and is the special unit of exposure.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5017. Definitions Se to So.
Rule 17. (1) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.
(2) "Secondary protective barrier" means the material placed in the path of scattered and leakage radiation to reduce the radiation exposure for protection purposes.
(3) "Shall" means required to comply with these rules pursuant to the act and enforceable under the act and Act No. 306 of the Public Acts of 1969 as amended.
(4) "Should" means recommended when practicable to meet optimum radiation safety standards.
(5) "Source" as applied to x-ray means the focal spot of the x-ray tube.
(6) "Source-image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.
(7) "Source material" means uranium or thorium, or any combination thereof, in any physical or chemical form; or ores which contain by weight 1/20 of 1% (0.05%) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.
(8) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5018. Definitions Sp to Su.
Rule 18. (1) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of the ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175\ (\text{grams contained U - 235})}{350} + \frac{50\ (\text{grams U - 233})}{200} + \frac{50\ (\text{grams Pu})}{200} = 1$$

(2) "Stationary equipment" means equipment which is installed in a fixed location.
(3) "Survey" means a critical evaluation of a facility or area incident to the production, use, release, disposal, or presence of sources of radiation under a specific set of conditions to

determine actual or potential radiation hazards. When appropriate, the evaluation includes tests, physical examination, source inventory and accountability, and measurements of levels of radiation or concentration of radioactive material present.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5019. Definitions T.

Rule 19. (1) "Technique factors" means the conditions of operation. They are specific as follows:

(a) For the capacitor energy storage equipment, peak tube potential in kV, and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses.

(c) For all other equipment, peak tube potential in kV,

and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(2) "Test" means a procedure for determining the characteristics or condition of a source of radiation, or circumstances relative thereto.

(3) "Therapeutic type tube housing" means:

(a) For x-ray therapy equipment not capable of operating at 500 kVp or above, an x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of 1 meter from the source does not exceed 1 roentgen per hour when the tube is operated at its leakage technique factors.

(b) For x-ray therapy equipment capable of operation at 500 kVp or above, an x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of 1 meter from the source does not exceed 0.1% of the useful beam dose rate at 1 meter from the source for any of its operating conditions.

(4) "Thermoluminescent dosimeter" or "TLD" means a device used for radiation monitoring which measures integrated dose by the principle of thermoluminescence.

(5) "These rules" means all parts.

(6) "Tube" means an x-ray tube, unless otherwise specified.

(7) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when they are contained within the tube housing.

(8) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5020. Definitions U and V.

Rule 20. (1) "Unrefined and unprocessed ore" means ore in its natural form before any processing, such as grinding, roasting, beneficiating or refining.

(2) "Unrestricted area" or "uncontrolled area" means an area access to which is not controlled by a licensee or registrant for purposes of protection of individuals from exposure to radiation or

radioactive materials, or an area used for residential quarters.
(3) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
(4) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given source-image receptor distance.
(5) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5021. Definitions X-ray.
Rule 21. (1) "X-ray apparatus" means any source of x-ray and its high voltage supply.
(2) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-ray tube or both. It includes equipment which controls the technique factors of any x-ray exposure.
(3) "X-ray equipment" means an x-ray system, subsystem or component thereof.
(4) "X-ray field" means that area of the intersection of the useful beam and any 1 of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is 1/4 of the maximum in the intersection.
(5) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices and other appropriate elements.
(6) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
(7) "X-ray subsystem" means any combination of 2 or more components of an x-ray system for which there are requirements specified in these rules.
(8) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5025. Prefixes.
Rule 25. The following prefixes are used in these rules to mean the numbers indicated:

Symbol	Prefix	Quantity	Symbol	Prefix	Quantity
d	deci	$(=10^{-1})$	da	deka	$(=10)$
c	centi	$(=10^{-2})$	h	hect	$(=10^{2})$
m	milli	$(=10^{-3})$	k	o	$(=10^{3})$

μ	micr	(=10^{-6})	M	kilo	(=10^{6})
p	o	(=10^{-9})	G	meg	(=10^{9})
f	nano	(=10^{-12})	T	a	(=10^{12})
a	pico	)		giga	)
	femt	(=10^{-15})		tera	
	o	)			
	atto	(=10^{-18})			

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

EXEMPTIONS

R 325.5031. Departmental action.
Rule 31. Upon application therefore or upon its own initiative, the department may grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5032 Carriers.
Rule 32. A common or contract carrier, freight forwarder, warehouseman, and the United States postal service are exempt from theses rules to the extent that they transport or store agreement material in the regular course of carriage for another or storage incident thereto.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5033. Nuclear regulatory commission contractors.
Rule 33. An NRC contractor or subcontractor of the following categories operating in this state is exempt from these rules to the extent that the contractor or subcontractor under his contract receives, acquires, possesses, uses or transfers sources of radiation:
(a) A prime contractor performing work for the NRC at United States government-owned or controlled sites.
(b) A prime contractor performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof.
(c) A prime contractor using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel.
(d) Any other prime contractor or subcontractor when the state and the NRC jointly determine that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and that the exemption of such contractor or subcontractor is otherwise appropriate.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

RECORDS, INSPECTIONS, TESTS AND ENFORCEMENT

R 325.5041. Records.

Rule 41. A licensee or registrant shall keep records showing the receipt, transfer and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5042 Inspections.

Rule 42. (1) Under authority of section 5(1) of the act, the department may enter at all reasonable times upon private or public property to conduct compliance investigations.

(2) Under authority of section 5(2) of the act, the department may obtain a warrant if necessary for search of property or seizure of sources of radiation or evidence of a violation of the act or any rule or license.

(3) A licensee or registrant shall make available to the department for inspection, all records maintained pursuant to these rules.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5043. Impounding.

Rule 43. Sources of radiation are subject to impounding pursuant to section 5 of the act.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5044. Tests.

Rule 44. A licensee or registrant shall perform upon instructions from the department and shall permit the department to perform such reasonable tests as the department deems appropriate or necessary including tests of:

(a) Sources of radiation.

(b) Facilities wherein sources of radiation are used or stored.

(c) Radiation detection and monitoring instruments.

(d) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5045. Additional requirements.

Rule 45. The department, by rule or order, may impose upon a licensee or registrant requirements in addition to those set forth in these rules that it deems appropriate or necessary to minimize danger to public health and safety or property.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5046. Violations.
Rule 46. (1) Under authority of section 9 of the act the department may seek a court order enjoining violation of or directing compliance with the act or any rule or order issued thereunder. (2) Under authority of section 10 of the act, a person who performs any act for which licensing or registration is required pursuant to these rules when that person is not licensed, registered, or exempted, is guilty of a misdemeanor and may be fined, imprisoned or both. This provision shall not be effective until 90 days after the effective date of these rules.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5047. Communications.
Rule 47. Communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Michigan Department of Public Health, Division of Radiological Health, 3423 North Logan Street, P.O. Box 30195, Lansing, Michigan 48909.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

R 325.5049. Rescission.
Rule 49. The rules of the department entitled "Use of Radioactive Isotopes, X-radiation and All Other Forms of Ionizing Radiation," being R 325.1301 to R 325.1326 of the Michigan Administrative Code and appearing on pages 3173 to 3203 of the 1964-65 Annual Supplements to the Code, are rescinded.

History: 1954 ACS 85, Eff. Dec. 3, 1975; 1954 ACS 98 Eff. Mar 9, 1979.

DEPARTMENT OF CONSUMER & 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 2. LICENSING OF RADIOACTIVE MATERIAL

R 325.5051. Purpose and scope.

Rule 51. (1) This part provides for the licensing of radioactive material. A person shall not own, receive, acquire, possess, use or transfer radioactive material except as authorized in a specific or general license issued pursuant to this part or as otherwise provided in this part.

(2) In addition to the requirements of this part, a licensee is subject to the requirements of parts 1 and 5. A licensee engaged in industrial radiographic operations is subject to the requirements of part 6, a licensee using certain particle accelerators is subject to part 11, and a licensee using sealed sources in the healing arts is subject to the requirements of part 12.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL

R 325.5074. Exempt quantities.

Rule 74. (1) Except as provided in subrules (3) and (4), a person is exempt from these rules to the extent that he owns, receives, acquires, possesses, uses or transfers a byproduct, naturally occurring or accelerator material in individual quantities each of which does not exceed the applicable quantity set forth in rule 147.

(2) A person who possesses radioactive material formerly received or acquired under the general license provided in 10 CFR Part 31, § 31.4 of the NRC regulations is exempt from the requirements for a license set forth in this part to the extent that he owns, possesses, uses or transfers such radioactive material.

(3) Subrule (1) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(4) A person, for purposes of commercial distribution, shall not transfer radioactive material in the individual quantities set forth in rule 147, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under subrule (1) or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC pursuant to section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under subrule (1) or the equivalent regulations of the NRC or an agreement state.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

SPECIFIC LICENSES

R 325.5101. Applications.

Rule 101. (1) An application for a specific license shall be filed on a form prescribed by the department and shall be accompanied by the appropriate license fee as specified in rules 141 to 145.

(2) The application shall be signed by the applicant or licensee or a person authorized to act for and on his behalf.

(3) An application for a license may include a request for a license authorizing 1 or more activities.

(4) In his application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the department if the references are clear and specific.

(5) The department at any time after the filing of the original application, and before the expiration of the license, may require further statements in order to enable the department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

(6) The application and documents submitted to the department may be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5102. General requirements for specific licenses.

Rule 102. The department shall approve a license application if it determines all of the following:

(a) The applicant or the designated individual user is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property.

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

SPECIAL REQUIREMENTS FOR ISSUANCE OF CERTAIN SPECIFIC LICENSES

R 325.5117a. Particle accelerator licenses.

Rule 117a. (1) A particle accelerator capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 shall not be operated in a manner likely to produce such quantities of radioactive material unless a person is authorized to operate in a specific license issued pursuant to this rule.

(2) A particle accelerator licensed pursuant to this rule is exempt from registration under part 4.

(3) Subject to rule 122 a person shall submit an application for a specific license to operate a particle accelerator subject to this rule in accordance with rule 101.

(4) The department shall issue a specific license for a particle accelerator subject to licensing under this rule when it determines all of the following:

(a) The applicant will have an adequate program for training accelerator operators and submits to the department a schedule or description of the program which specifies the:

(i) Initial training.

(ii) Periodic training.

(iii) On-the-job training.

(iv) Means to be used by the licensee to determine the operator's knowledge and understanding of and ability to comply with department rules and licensing requirements, and the operating and emergency procedures of the applicant.

(b) The applicant has established and submits to the department satisfactory written operating and emergency procedures.

(c) The applicant will have an adequate internal inspection system, or other management control, to assure that license provisions, rules and the applicant's operating and emergency procedures are followed by operators and all other individuals associated with the accelerator operation.

(d) The applicant submits to the department a description of his overall organizational structure pertaining to the particle accelerator program, including specified delegations of authority and responsibility for operation of the program.

(e) The applicant has applied for or has been issued a valid license to own, receive, acquire, possess, use and transfer radioactive material produced or used in connection with accelerator operation.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5118. Issuance of specific licenses.

Rule 118. (1) As used in this rule the term "as it deems appropriate or necessary" means as the department determines is appropriate or necessary in order to minimize danger to public health and safety or property; and prevent loss or theft of material subject to this part.

(2) Upon a determination that an application meets the requirements of the act and these rules the department shall issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(3) The department may incorporate in any license at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary.
(4) The department may require such reports and the keeping of such records, and may provide for such inspections of activities under the license as it deems appropriate or necessary.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5119. Specific terms and conditions of licenses.
Rule 119. (1) A license issued under this part is subject to all the provisions of the act, now or hereafter in effect, and to all rules and orders of the department.
(2) A license issued or granted under this part and a right to possess or utilize radioactive material granted by a license issued under this part shall not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department, after securing full information finds that the transfer is in accordance with the provisions of the act, and gives its consent in writing.
(3) A person licensed by the department under this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5120. Expiration, renewal and amendment of licenses.
Rule 120. (1) Except as provided in subrule (3), each specific license expires at the end of the day, in the months and year stated therein.
(2) An application for renewal of a specific license shall be filed in accordance with rule 101.
(3) If a licensee, not less than 30 days before expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license does not expire until the application has been finally determined by the department.
(4) An application for amendment of a license shall be filed in accordance with rule 101 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

(5) In considering an application by a licensee to renew or amend his license, the department shall apply the criteria set forth in rules 102 to 111, or rules 112 to 117.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5122. Radioactive material other than agreement material possessed before these rules.

Rule 122. A person who, on the effective date of these rules, possesses naturally occurring or accelerator-produced radioactive material or a particle accelerator for which a specific license is required by this part or the act is deemed to possess a like license issued under this part and the act. The license expires 90 days after the effective date of these rules; however, if within the 90 days the person possessing the material files an application in proper form for a license, the existing license does not expire until the application has been finally determined 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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5124. Modification, revocation, and termination of licenses.

Rule 124. (1) The terms and conditions of a license are subject to amendment, revision or modification or the license may be suspended or revoked by reason of amendments to the act, or by reason of rules and orders issued by the department.

(2) A license may be revoked, suspended or modified, in whole or in part, for:

(a) A material false statement in the application or any statement of fact required under the act.

(b) A condition revealed by the application or statement of fact or any report, record or inspection or other means which would warrant the department to refuse to grant a license on an original application.

(c) A violation of, or failure to observe any of the terms and conditions of the act, the license, or any rule or order of the department.

(3) Except in a case of willfulness or where the public health, interest or safety requires otherwise, a license shall not be modified, suspended or revoked unless, before the institution of proceedings therefor, facts or conduct which may warrant the action have been called to the attention of the license in writing and the licensee has been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(4) The department may terminate a specific license upon request submitted by the licensee to the department in writing.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

LICENSE FEES

R 325.5141. Application fees.

Rule 141. (1) A license application for which a fee is prescribed in rule 144 shall be accompanied by a remittance in the full amount of the fee unless the applicant has been exempted from fee payment under rule 143.

(2) An application will not be accepted for filing or processed before payment of the full amount specified unless exempted from fee payment. An application for which a remittance is not received may be returned to the applicant.

(3) All application fees shall be retained irrespective of the department's disposition of the application or a withdrawal of the application.

(4) The application fee serves as the license fee for the first year after issuance of the license irrespective of the time interval between date of application and date of issuance.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5142. Annual fees.

Rule 142. (1) An annual license fee is payable 1 year after the date of issuance of the license and annually thereafter.

(2) The annual fee shall be submitted in a timely manner so that its receipt is assured on or before the due date in order to maintain the license in effect.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5143. Exemptions.

Rule 143. (1) Application fees or annual fees are not required for licenses applied for by, or issued to:

(a) An agency of this state or any political subdivision thereof for radioactive material or accelerators to be used primarily for services rendered on a charitable basis or in connection with a facility used primarily for charitable purposes.

(b) A nonprofit educational institution for radioactive material or accelerators to be used exclusively for teaching or training purposes or in connection with a facility used exclusively for teaching or training purposes.

(2) Application fees or annual fees are not required for licenses authorizing the use of source material as shielding only in devices and containers, but all other licensed radioactive material in the device or container is subject to the fees prescribed in rule 144 unless otherwise exempted under this rule.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5144 Fee schedule.

Rule 144. Applicants for specific radioactive material licenses and licensees issued these licenses shall pay the appropriate license fees and shall be subject to the footnotes specified in the following fee schedule unless exempted under rule 143.

[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance are under the purview of the Michigan Department of Licensing and Regulatory Affairs.]

SCHEDULE OF RADIOACTIVE MATERIAL LICENSE FEES

Category of License [1]	Application Fee [2]	Annual Fee [3] [4]
1. Special Nuclear Material: [5]		
A. Special licenses for special nuclear material in quantities not sufficient to form a critical mass, except those licenses covered by categories 4A, 4B, 5A, 6A, 7A, 7B, 7C, 7D, or 8A.	$200	$200
2. Source Material:		
A. Specific licenses for source material for use in milling operations and licenses for refining mill concentrates to uranium hexafluoride.	$10,000	$10,000
B. Specific licenses for source material in quantities greater than 50 kilograms except licenses for storage only and licenses for use only of source material in counterweights.	$150	$150
C. All other specific licenses for source material, except those licenses covered by categories 4A, 4B, 6A, 7A, 7B, 7C, 7D, or 8A.	$75	$75

Category of License [1]	Application Fee [2]	Annual Fee [3] [4]
3. Radioactive Material Other than Special Nuclear Material or Source Material: [6]		
A. Specific licenses for source material for use in milling operations and licenses for refining mill concentrates to uranium hexafluoride	$2,000	$2,000
B. Specific licenses for possession and use of radioactive material for processing, or manufacturing of items containing radioactive material where no product safety evaluation is required or quantities of radioactive material for commercial distribution except exempt quantities as defined in rule 74.	$1,000	$1,000
C. Specific licenses for radioactive material for industrial radiography operations at one location.	$300	$300
D. Specific licenses for radioactive material for industrial radiography operations at more than one location.	$600	$600
E. Specific licenses for possession and use of radioactive material in quantities of less than 10,000 curies in sealed sources for irradiation of materials.	$100	$100
F. Specific licenses for possession and use of radioactive material in quantities of 10,000 curies or more in sealed sources for irradiation of materials.	$200	$200
G. Specific licenses issued pursuant to rule 107 to distribute items containing radioactive material or quantities of radioactive material to persons generally licensed under rules 84 to 92 except, specific licenses authorizing redistribution of items which have been manufactured or imported under a specific license and licensed by the department, the NRC or an agreement state for distribution to persons generally licensed under rules 84 to 92.	$300	$300
H. Specific licenses for possession and use of radioactive material for research and development, except those licenses covered by categories 3A or 3B, and licenses covered by categories 7B, 7C, or 7D authorizing medical research.	$250	$250
I. Non-human use of radium.	$50	$50
J. All other specific radioactive material licenses except those in categories 4A, 4B, 5A, 6A, 7A, 7B, 7C, 7D, or 8A.	$50	$50
4. Waste Disposal:		
A. Waste disposal licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee by land burial.	$3,000	$3,000

Category of License [1]	Application Fee [2]	Annual Fee [3] [4]
B. Waste disposal licenses specifically authorizing the receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee by transfer to another person authorized to receive such material.	$400	$400
5. Well Logging, Well Surveys and Tracer Studies:		
A. Specific licenses for possession and use of radioactive material for well logging, well surveys and tracer studies.	$250	$250
6. Nuclear Laundries:		
A. Specific licenses for commercial collection and laundry of items contaminated with radioactive material.	$500	$500
7. Human Use:		
A. Specific licenses for human use of radioactive material in sealed sources contained in teletherapy devices.	$150	$150
B. Specific licenses for human use of radium in sealed sources for brachytherapy.	$100	$100
C. Specific licenses issued to medical institutions for human use of radioactive material, except licenses in categories 7A or 7B.	$200	$200
D. Specific licenses issued to physicians for human use of radioactive material, except licenses in categories 7A or 7B.	$100	$100
8. Civil Defense:		
A. Specific licenses for possession and use of radioactive material for civil defense activities.	$35	$35
9. Particle Accelerators:[7]		
A. Specific licenses for particle accelerators for production of radioactive material for transfer to other persons.	$2,000	$2,000
B. Specific licenses for particle accelerators for production of radioactive material not to be transferred to other persons except for disposal.	$1,500	$1,500
C. Specific licenses for particle accelerators used exclusively for high-energy research. (Research and development).	$1,000	$1,000
D. Specific licenses for particle accelerators used exclusively for food processing or materials processing or control.	$500	$500
E. Specific licenses for particle accelerators for human use.	$300	$300
F. All other specific licenses for particle accelerators.	$250	$250

FOOTNOTES
To
Schedule of Radioactive Material License Fees

[1] Amendments based on applications filed after the due date of the annual license fee reducing the scope of a licensee's program or cancelling a license, will not entitle the licensee to a partial refund of an annual fee that has been paid by the licensee for the year in which such amendment or cancellation occurs. Applications for amendments increasing the scope of a program to a higher fee category will not be accepted for filing unless accompanied by the prescribed fee less the amount of the currently prescribed fee for the activities already licensed.

[2] Applications for specific licenses covering more than 1 fee category shall be accompanied by the prescribed fee for each category.

[3] Payment of the prescribed annual fee does not automatically renew the license for which the fee is paid. Renewal applications shall be filed in accordance with the requirements of rule 120. Applications for reissuance of licenses that have expired because a timely renewal application was not filed shall be accompanied by the prescribed application fee.

[4] The annual fee will be waived where an application is filed to cancel the license prior to the due date of the annual fee, and the amount of the annual fee will be reduced where an application is filed to amend the license to reduce its scope before the due date of the annual fee. *However*, an annual fee will not be waived or reduced unless the application filed before the due date of the fee contains all the information necessary to permit the department to complete the requested action

[5] Specific licenses for special nuclear material in quantities sufficient to form a critical mass may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

[6] Such radioactive material includes accelerator material, byproduct material, and naturally occurring material.

[7] Particle accelerators not capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 and radiation machines excluded from the particle accelerator definition by design and use are exempted from licensing under this part. However, such radiation machines are subject to registration under part 4. Particle accelerators licensed under this part are exempt from registration under part 4.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5145. Payment of fees.

Rule 145. (1) License fee payments shall be by check, draft or money order payable to the "State of Michigan".

(2) Fee payments shall be received by the Michigan Department of Public Health, Division of Radiological Health, Licensing & Compliance Control Section, 3500 North Logan Street, Lansing, Michigan 48914.

(3) In any case where the department finds that a licensee has failed to pay the applicable annual fee required in this part, the department may suspend or revoke the license or may

issue such order with respect to licensed activities as the department determines to be necessary to carry out the provisions of these rules and the act.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664, Lansing, Michigan 48909.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

SCHEDULES A TO D

R 325.5147 Schedule B - Exempt quantities.
Rule 147. See rule 74.

Radionuclide	Microcuries
Antimony 122 (Sb122)	100
Antimony 124 (Sb124)	10
Antimony 125 (Sb125)	10
Arsenic 73 (As73)	100
Arsenic 74 (As74)	10
Arsenic 76 (As76)	10
Arsenic 77 (As77)	100
Barium 131 (Ba131)	10
Barium 133 (Ba133)	10
Barium 140 (Ba140)	10
Bismuth 210 (Bi210)	1
Bromine 82 (Br82)	10
Cadmium 109 (Cd109)	10
Cadmium 115m (Cd115m)	10
Cadmium 115 (Cd115)	100
Calcium 45 (Ca45)	10
Calcium 47 (Ca47)	10
Carbon 14 (C14)	100
Cerium 141 (Ce141)	100
Cerium 143 (Ce143)	100
Cerium 144 (Ce144)	1
Cesium 131 (Cs131)	1,000
Cesium 134m (Cs134m)	100
Cesium 134 (Cs134)	1
Cesium 135 (Cs135)	10
Cesium 136 (Cs136)	10

Cesium 137 (Cs137) 10
Chlorine 36 (C136) 10
Chlorine 38 (Cl38) 10
Chromium 51 (Cr51).....1,000
Cobalt 58m (Co58m) 10
Cobalt 58 (Co58).....10
Cobalt 60 (Co60)..... 1
Copper 64 (Cu64) 100
Dysprosium 165 (Dy165) 10
Dysprosium 166 (Dy166) 100
Erbium 169 (Er 169).....100
Erbium 171 (Er 171).....100
Europium 152 (Eu152) 9.2 h 100
Europium 152 (Eu152) 13 yr. 1
Europium 154 (Eu154) 1
Europium 155 (Eu155) 10
Fluorine 18 (F18).....1,000
Gadolinium 153 (Gd153).....10
Gadolinium 159 (Gd159).....100
Gallium 72 (Ga72) 10
Germanium 71 (Ge71) 100
Gold 198 (Au198).....100
Gold 199 (Au199).....100
Hafnium 181 (Hf181) 10
Holmium 166 (Ho166).....100
Hydrogen 3 (H3) 1,000
Indium 113m (In113m).....100
Indium 114m (In114m).....10
Indium 115m (In115m).....100
Indium 115 (In115).....10
Iodine 125 (I125) 1
Iodine 126 (I126) 1
Iodine129 (I129) 0.1
Iodine131 (I131) 1
Iodine132 (I132) 10
Iodine133 (I133) 1
Iodine134 (I134) 10
Iodine135 (I135) 10
Iridium192 (Ir192) 10
Iridium194 (Ir194) 100
Iron 55 (Fe55) 100
Iron 59 (Fe59) 10
Krypton 85 (Kr85) 100
Krypton 87 (Kr87) 10
Lanthanum140 (La140) 10
Lutetium177 (Lu177).....100

Manganese 52 (Mn52) 10
Manganese 54 (Mn54) 10
Manganese 56 (Mn56) 10
Mercury197m (Hg197m) 100
Mercury197 (Hg197) 100
Mercury 203 (Hg203) 10
Molybdenum 99 (Mo99).....100
Neodymium147 (Nd147).....100
Neodymium149 (Nd149).....100
Nickel 59 (Ni59) 100
Nickel 63 (Ni63) 10
Nickel 65 (Ni65) 100
Niobium 93m (Nb93m).....10
Niobium 95 (Nb95).....10
Niobium 97 (Nb97).....10
Osmium185 (Os185).....10
Osmium191m (Os191m) 100
Osmium191 (Os191).....100
Osmium193 (Os193).....100
Palladium103 (Pd103) 100
Palladium109 (Pd109) 100
Phosphorus 32 (P32).....10
Platinum191 (Pt191) 100
Platinum193m (Pt193m).....100
Platinum193 (Pt193).....100
Platinum197m (Pt197m).....100
Platinum197 (Pt197).....100
Polonium 210 (Po210) 0.1
Potassium 42 (K42).....10
Praseodymium142 (Pr142) 100
Praseodymium143 (Pr143) 100
Promethium147 (Pm147).....10
Promethium149 (Pm149).....10
Rhenium186 (Re186).....100
Rhenium188 (Re188).....100
Rhodium103m (Rh103m) 100
Rhodium105 (Rh105) 100
Rubidium 86 (Rb86) 10
Rubidium 87 (Rb87) 10
Ruthenium 97 (Ru97) 100
Ruthenium103 (Ru103) 10
Ruthenium105 (Ru105) 10
Ruthenium106 (Ru106) 1
Samarium151 (Sm151).....10
Samarium153 (Sm153) 100
Scandium 46 (Sc46).....10

Scandium 47 (Sc47).....100
Scandium 48 (Sc48).....10
Selenium 75 (Se75).....10
Silicon 31 (Si31).....100
Silver105 (Ag105).....10
Silver100m (Ag110m).....1
Silver111 (Ag111).....100
Sodium 24 (Na24).....10
Strontium 85 (Sr85).....10
Strontium 89 (Sr89).....1
Strontium 90 (Sr90).....0.1
Strontium 91 (Sr91).....10
Strontium 92 (Sr92).....10
Sulphur 35 (S35).....100
Tantalum182 (Ta182).....10
Technetium 96 (Tc96).....10
Technetium 97m (Tc97m).....100
Technetium 97 (Tc97).....100
Technetium 99m (Tc99m).....100
Technetium 99 (Tc99).....10
Tellurium125m (Te125m).....10
Tellurium127m (Te127m).....10
Tellurium127 (Te127).....100
Tellurium129m (Te129m).....10
Tellurium129 (Te129).....100
Tellurium131m (Te131m).....10
Tellurium132 (Te132).....10
Terbium160 (Tb160).....10
Thallium 200 (Tl200).....100
Thallium 201 (Tl201).....100
Thallium 202 (Tl202).....100
Thallium 204 (Tl204).....10
Thulium170 (Tm170).....10
Thulium171 (Tm171).....10
Tin113 (Sn113).....10
Tin125 (Sn125).....10
Tungsten181 (W181).....10
Tungsten185 (W185).....10
Tungsten187 (W187).....100
Vanadium 48 (V48).....10
Xenon131m (Xe131m).....1,000
Xenon133 (Xe133).....100
Xenon135 (Xe135).....100
Ytterbium175 (Yb175).....100
Yttrium 90 (Y90).....10
Yttrium 91 (Y91).....10

Yttrium 92 (Y92) 100
Yttrium 93 (Y93) 100
Zinc 65 (Zn65) 10
Zinc 69m (Zn69m) 100
Zinc 69 (Zn69) 1,000
Zirconium 93 (Zr93) 10
Zirconium 95 (Zr95) 10
Zirconium 97 (Zr97) 10
Any radionuclide not listed above other than alpha emitting radioactive material 0.1

History: 1954 ACS 85, Eff. Dec. 3, 1975.

DEPARTMENT OF PUBLIC HEALTH

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 4. REGISTRATION OF RADIATION MACHINES

R 325.5181. Purpose and scope.

Rule 181. (1) This part provides for the registration of radiation machines. A person shall not manufacture, produce, transport, own, receive, acquire, possess, use or transfer any radiation machine unless registered or exempted under this part.

(2) In addition to the requirements of this part, a registrant is subject to the requirements of part 1 and the applicable provisions of parts 5 to 11 and 13.

History: 1979 AC.

R 325.5182. Exemptions.

Rule 182. (1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration requirements of this part if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of the equipment. The production testing, or factory servicing of the equipment is not exempt.

(2) Radiation machines which are electrically disconnected pending sale, transfer of ownership or destructive disposal while in such temporary storage condition are exempt from the registration requirements of this part.

(3) Particle accelerators or other sources licensed under part 2 are exempt from the registration requirements of this part.

History: 1979 AC.

R 325.5183. Responsibility for compliance with rules.

Rule 183. The owner and the person effectively in control of radiation machines not exempted under rule 182 shall each be individually, and both shall be jointly, responsible for full compliance with all provisions of these rules.

History: 1979 AC.

R 325.5184. Applications for registration.

Rule 184. (1) Each person having 1 or more radiation machines shall apply for registration of the machines with the department within 30 days after the effective date of these rules or thereafter before the operation of the machines.

(2) An application for registration shall be completed on forms furnished by the department and shall contain all the information required by the form and accompanying instructions. The application shall be accompanied by the appropriate registration fee as specified in rules 191 to 194.

(3) The registrant shall designate an individual to be responsible for radiation protection, and shall specify that the individual:

(a) Is knowledgeable concerning the hazards and precautions in the handling of the radiation machines for which he is responsible.

(b) Has read and understands the applicable requirements of these rules.

(c) Shall permit operation of the radiation machines only by individuals who have received proper instructions in their safe use.

(d) Shall conduct or cause to be conducted such adequate radiation surveys and other procedures as may be necessary to demonstrate compliance with these rules.

(e) Has the authority to make or cause to be made such changes of the machines, their operation or both as may be necessary to comply with these rules.

(4) The application shall be signed by the registrant or an individual authorized to act for and on his behalf.

(5) In his application, the registrant may incorporate by reference information contained in previous applications, statements or reports filed with the department if the references are clear and specific.

(6) The application and documents submitted to the department may be made available for public inspection except that the department may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

History: 1979 AC.

R 325.5185. Issuance of registration tags.

Rule 185. (1) The department shall initially issue a registration tag for each radiation machine when it is properly registered with the department. The tag shall include a machine registration number uniquely assigned to a specific machine.

(2) The registrant shall apply the registration tag to the control panel of the radiation machine specified according to instructions provided by the department.

(3) The registrant shall not permit removal of the registration tag from the radiation machine unless instructed by the department. If the tag is accidentally removed or defaced the registrant shall notify the department by specifying the tag number and machine description from the registration certificate and requesting a replacement.

(4) The registrant shall refer to a radiation machine in any correspondence with the department according to the registration number assigned to that machine if available.

History: 1979 AC.

R 325.5186. Issuance of certificates of registration.

Rule 186. (1) The department shall issue a certificate of registration if it determines that an application meets the requirements of these rules and receives the appropriate registration fee as specified in rules 191 to 194.

(2) The department may incorporate in the certificate of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary.

History: 1979 AC.

R 325.5187. Registrations; expirations; applications for renewal; filing before expiration.

Rule 187. (1) Except as provided in subrule (3) and rule 188 a registration expires at the end of the day in the month and year stated in the certificate of registration.

(2) An application for renewal of registration shall be filed in accordance with rule 184 and shall be accompanied by the appropriate registration fee as specified in rules 191 to 193.

(3) If a registrant has filed an application for renewal in proper form not less than 30 days before the expiration of his existing registration, the existing registration shall not expire until the application has been finally determined by the department.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5188. Registrations; notices of change; complete changes; partial changes.

Rule 188. (1) The registrant shall notify the department in writing before making any change that would render the information contained in the application for registration or the certificate of registration, or both, no longer accurate. In the case of sale, transfer, or disposal of radiation machines, the notification shall specify the proposed recipient of the machines, or the location and method of disposal.

(2) A complete change in ownership, possession or location of all machines listed on a certificate of registration terminates the certificate of record, and requires a new application for registration except as provided in subrule (4).

(3) In case of a partial change the department may terminate the certificate of registration of record and issue a new certificate pursuant to rule 194.

(4) Notwithstanding subrule (2), replacement of all machines listed on a certificate of registration shall be considered a partial change if the name and address of the registrant and the name and address of the facility are not changed.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5189. Approval not implied.

Rule 189. A person, in an advertisement, shall not refer to the fact that he or his facility is registered with the department pursuant to this part and a person shall not state or imply that an activity under such registration has been approved by the department.

History: 1979 AC.

REGISTRATION FEES

R 325.5191. Registration fee; minimum fee.

Rule 191. (1) An application for registration submitted in accordance with rule 184 shall be accompanied by the full registration fee determined from the schedule provided in rule 193.

(2) The minimum fee submitted with the application shall be $10.00.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5192. Registration fee; exemptions.

Rule 192. Application fees or annual fees are not required for registration certificates applied for by, or issued to the following:

(a) An agency of this state or any political subdivision thereof.

(b) A nonprofit charitable institution using a radiation machine primarily for services rendered on a charitable basis or in connection with a facility used primarily for charitable purposes.

(c) A nonprofit educational institution using a radiation machine exclusively for teaching or training purposes or in connection with a facility used exclusively for teaching or training purposes.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5193. Registration fee; schedule of fees.

Rule 193. Specific registration fees are dependent upon the number of x-ray or electron tubes included in the application for registration. The minimum fee shall be applied toward the total registration. The following schedule shall be used to determine the registration fee:

SCHEDULE OF RADIATION MACHINES REGISTRATION FEES

Type of Machine (design or use)	Each Individual X-ray Tube (or electron tube)
Dental	
(intra-oral)	$10.00
(panoramic)	10.00
(cephalometric)	10.00
(multi-purpose)	10.00
Medical	
(extremities only)	10.00
(radiographic)	10.00
(fluoroscopic)	10.00
(radiographic-fluoroscopic)	10.00
(single tube combination)	10.00
(therapy)	10.00
(other)	10.00
Industrial	
(radiographic)	10.00
(fluoroscopic)	10.00
(electron beam welder)	10.00
(other)	10.00
Analytical	
(diffraction)	10.00
(fluorescence)	10.00
(electron microscope)	10.00
(other)	10.00
Miscellaneous	
(film identification markers)	10.00
(cold cathode discharge tubes)	10.00
(other)	10.00

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5194. Registration fee; notice of change; additional tubes; notice of disposal; refunds; amendment expiration.

Rule 194. (1) A notice of change submitted in accordance with rule 188 may necessitate issuance of an amended certificate of registration and shall be accompanied by the minimum registration fee specified in rule 191(2). If additional tubes are added to the registration before the current registration expiration date, the notice shall be accompanied by a fee for each added

x-ray tube as provided in subrule (2). The minimum fee shall not be applied toward the addition of tubes to the certificate of registration.

(2) The fee for each additional x-ray tube or electron tube shall be $5.00. Only net increase in the number of tubes currently registered requires an additional fee.

(3) Notwithstanding subrule (1), notice of disposal without replacement of all registered machines covered by a single registration certificate shall void the certificate of record. Such notice shall not require issuance of an amended certificate and shall not require payment of the minimum fee.

(4) Refund of a registration fee shall not be made as a result of a notice of change resulting in the deletion of machines or in the termination of the certificate of registration before the expiration date of the registration.

(5) An amended certificate of registration issued as provided in this rule expires on the expiration date of the current registration.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5195. Vendor obligation; notification of transfer; duty to report; compliance with these rules.

Rule 195. (1) A person who sells, leases, transfers, lends, assembles, or installs a radiation machine in this state shall notify the department in writing within 15 days after the end of each calendar quarter of the following:

(a) The name and address of the person who has received the machine.

(b) For each radiation machine transferred all of the following:

(i) Date of transfer of possession or ownership.

(ii) Manufacturer.

(iii) Model.

(iv) Department registration number, if the machine was previously registered with the department and the registration tag is on the control panel.

(v) Number of x-ray tubes.

(vi) Type of machine as described in rule 193, schedule of fees.

(2) A person who notifies the department in accord with subrule (1) shall thereafter report on a quarterly basis even if no sales or installations are made in this state until written notice is submitted to the department of termination of business in Michigan.

(3) A person shall not make, sell, lease, transfer, lend, assemble, or install radiation machines, including x-ray equipment and supplies used in connection with the machines, unless the equipment and supplies, when properly placed in operation and properly used, meet the requirements of these rules.

History: 1979 AC; 1954 ACS 98, Eff. Mar. 9, 1979.

R 325.5196. Out-of-state radiation machines.

Rule 196. (1) Whenever a radiation machine is brought into this state, for purposes other than temporary storage as provided for in rule 182(2), the person proposing to bring the machine into the state shall give written notice to the department not less than 2 working days before the

machine enters the state. The notice shall include the radiographer's name; the type of radiation machine; the nature, duration and scope of use; and the exact locations where the radiation machine is to be used. If for a specific case the 2 working-day period would impose an undue hardship on the person, upon application to the department, he may arrange for other notification to comply with the intent of this rule.

(2) In addition, the out-of-state person shall comply with all applicable rules of the department and supply the department with such other information as the department may reasonably request.

History: 1979 AC.

DEPARTMENT OF CONSUMER & 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 5. STANDARDS FOR PROTECTION AGAINST RADIATION

R 325.5201. Purpose and scope.

Rule 201. (1) This part establishes standards for protection against radiation hazards. Except as otherwise specifically provided, this part applies to all licensees and registrants.

(2) In addition to complying with requirements set forth in this part, every reasonable effort should be made to maintain radiation levels in unrestricted areas and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in this part as practicable. The term "as far below the limits specified in this part as practicable" means as low as is practicably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and in relation to the utilization of sources of radiation in the public interest.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5202. Intentional exposure of humans.

Rule 202. (1) Nothing in these rules shall be construed as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis, medical therapy or medical research conducted by licensed members of the healing arts.

(2) Intentional exposure of individuals to radiation or concentrations of radioactive material for diagnostic or therapeutic purposes shall be limited to supervision or prescriptions by licensed members of the healing arts.

(3) Nothing in these rules shall be construed as authorization to conduct medical diagnosis, medical therapy or medical research which is not fully consistent with the standards of practice for licensed members of the healing arts.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

PERMISSIBLE DOSES, LEVELS AND CONCENTRATIONS

R 325.5203. Exposure of individuals to radiation.

Rule 203. (1) Except as provided in subrules (3),(4) and (6) a licensee or registrant shall not receive, possess, use or transfer sources of radiation in such a manner as to cause any individual to receive in any period from all sources of radiation in the licensee's or registrant's possession a dose in excess of the limits specified in table 1 of rule 205.A licensee or registrant shall not be held liable for meeting the dose limit
for fertile women (with respect to fetus) listed in table 1 until and unless the employee has submitted written notice to the licensee or registrant of the pregnant condition. Potential risk of exposure if any, to the fetus before the written notice is received shall be assumed by the employee as a condition of employment as a radiation worker. Following receipt of written notice, the employee's dosimeter record shall be reviewed immediately and necessary steps shall be taken to meet the dose limit specified in table 1 of rule 205.

(2) For determining the doses specified in rules 203 to 215, a dose from x- or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface of the region of the highest exposure rate.

(3) A licensee or registrant may permit an individual in a restricted area to receive a dose to the whole body greater than that permitted in subrule (1) if:

(a) The annual dose does not exceed 5 rems in any 1 year and during any calendar quarter the dose to the whole body from sources of radiation in the licensee's or registrant's possession does not exceed 3 rems.

(b) The dose to the whole body, when added to the accumulated occupational dose to the whole body, does not exceed 5 (N-18) rems where "N" equals the individual's age in years at his last birthday.

(c) The licensee or registrant has determined the individual's accumulated occupational dose to the whole body on Form RH-101, or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of rule 206.

(4) Upon application showing an operational need, the department may authorize radiation doses at a higher annual level than the limits set forth in subrule (1) provided that the dose does not exceed 3 rems per quarter and that, based on the determination of the individual's prior

radiation record, his accumulated occupational dose does not exceed 5 (N-18) rems where "N" equals the individual's age in years at his last birthday.

(5) As used in this part "dose to the whole body" includes any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of the eye.

(6) Nothing in this part shall be interpreted as limiting the exposure of members of emergency response teams to radiation under emergency circumstances for the purpose of minimizing danger to life or property. Such teams may include police, fire, ambulance and paramedical crews acting
in the course of their assigned duties.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. The Department of Consumer & Industry Services has renamed Form RH-101 to BHS-101.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5205 Dose limits.

Rule 205. Table 1

Maximum Permissible Dose Equivalent for Occupational Exposure	
Dose to the whole body*	1.25 rem per quarter
Skin of whole body	7.5 rems per quarter
Hands	18.75 rems per quarter
Fertile women (with respect to fetus)	0.5 rem in gestation period
Maximum Permissible Dose Equivalent for Non-Occupational Exposure	
Individual	0.5 rem in any one year
Population Dose Limits	
Genetic	0.17 rem average per year
Somatic	0.17 rem average per year

*If the dose distribution is not uniform the limiting dose shall be the highest dose received by any of the critical organs specified in subrule (5) of rule 203.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5206 Determination of accumulated dose.

Rule 206. (1) This rule contains requirements which shall be satisfied by licensees or registrants who propose, pursuant to rules 203 (3) or (4), to permit individuals in a restricted area

to receive radiation doses in excess of the limits specified in table 1 of rule 205.

(2) Before permitting an individual in a restricted area to be exposed to radiation in excess of the limits specified in table 1 of rule 205, each licensee or registrant shall:

(a) Obtain a certificate on Form RH-101, or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation.

(b) Calculate on Form RH-101, in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for the individual under rules 203 (3) or (4).

(3) In the preparation of Form RH-101, or on a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee or registrant obtains these reports, he shall use the dose shown in the report in preparing the form. Where a licensee or registrant is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns apply:

Part of Body	COLUMN 1 Assumed Dose in Rems for Calendar Quarters Before January 1, 1961	COLUMN 2 Assumed Dose in Rems For Calendar Quarters Beginning on or After January 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of the eye	3.75	1.25

(4) The licensee or registrant shall retain and preserve records used in preparing Form RH-101. If calculation of the individual's accumulated occupational dose for all periods before January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in rule 205, the excess may be disregarded.

[Note: As a result of Executive Order 2011-4, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Licensing and Regulatory Affairs. The Department of Licensing and Regulatory Affairs has renamed Form RH-101 to BHS/HFS-101.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5210. Exposure of minors.

Rule 210. (1) A licensee or registrant shall not receive, acquire, possess, use or transfer sources of radiation in such a manner as to cause an individual who is under 18 years of age, to receive in any period of 1 calendar quarter from all sources of radiation in the licensee's or registrant's possession a dose in excess of 10% of the quarterly occupational limit specified in rule 205 (e.g. 125 mrems whole body).

(2) A licensee shall not receive, acquire, possess, use or transfer radioactive material in such a manner as to cause any individual in a restricted area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in table II of appendix A in rules 261 to 270. For purposes of this subrule, concentrations may be averaged over periods not greater than 1 week (7 consecutive days).

(3) Rule 208 (1) shall apply where an individual is exposed subject to subrule (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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5211. Radiation levels from external sources in unrestricted areas.

Rule 211. (1) Except as authorized by the department pursuant to subrule (2), a licensee or registrant shall not receive, acquire, possess, use or transfer sources of radiation in such a manner as to result in an individual in an unrestricted area receiving a dose in excess of:

(a) Two millirems in any 1 hour.

(b) One hundred millirems in any 7 consecutive days.

(c) Five hundred millirems in any 1 year.

(2) A person may apply to the department of proposed limits upon levels of radiation in unrestricted areas in excess of those specified in subrule (1) resulting from the applicants possession or use of sources of radiation. The application shall include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The department shall approve the proposed limits if the applicant demonstrates to the satisfaction of the department that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of 1 calendar year in excess of 0.5 rem.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

R 325.5213. General Information.

Rule 213. Rule 214 to 220:

(a) Establish requirements for notices, instructions and reports by licensees or registrants to individuals engaged in work under a license or registration.

(b) Explain options available to such individuals in connection with department investigations of licensees or registrants to ascertain compliance with the provisions of the act, these rules or orders, licenses or registration certificates issued there under regarding radiological working conditions. Department investigations include investigations of complaints and routine inspections or compliance investigations.

(c) Apply to all persons who own, receive, acquire, possess, use or transfer sources licensed by or registered with the department pursuant to parts 2 and 4.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5214. Posting of notices to workers.

Rule 214. (1) A licensee or registrant shall post current copies of the following documents:

(a) The regulations in this part.

(b) The license, certificate of registration and conditions or documents incorporated by reference and amendments thereto.

(c) The operating procedures applicable to work under the license or registration.

(d) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to part 1 and any response from the licensee or registrant.

(2) If posting of a document specified in subrule (1)(a), (b) or (c) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(3) Form RH-100 "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area. Copies of Form RH-100 may be obtained by writing to the Michigan Department of Public Health, Division of Radiological Health, 3500
North Logan Street, Lansing, Michigan 48914.

(4) Documents, notices or forms posted pursuant to this rule shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(5) Department documents posted pursuant to subrule(1)(d) shall be posted within 2 working days after receipt of the documents from the department. The licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. The Department of Consumer & Industry Services has renamed Form RH-100 to BHS-100. Any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, 3423 N. Martin L. King Jr. Blvd., P.O. Box 30664, Lansing, Michigan 48909.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5215. Instructions to workers.

Rule 215. (1) A licensee or registrant shall:

(a) Inform individuals working in or frequenting any portion of a restricted area of the occurrence of radiation or sources of radiation in those portions of the restricted area.

(b) Instruct these workers in the following:

(i) The health protection problems associated with exposure to the sources of radiation and in precautions or procedures to minimize exposure.

(ii) The purposes and functions of protective devices employed.

(iii) Appropriate responses to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material.

(c) Instruct these workers to observe, to the extent within the workers' control, the applicable provisions of department rules and license or registration conditions for the protection of personnel from exposures to radiation or radioactive material.

(d) Advise these workers of reports of radiation dose which they may request pursuant to rule 216.

(e) Inform these workers of their responsibility to report promptly to licensee or registrant any condition which may lead to or cause:

(i) A violation of department rules, licenses or registration certificates.
(ii) Unnecessary exposure to radiation or radioactive material.
(2) The extent of instructions required by this rule shall be commensurate with potential radiological health protection problems in the restricted area.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5216. Notifications and reports to individuals.
Rule 216. (1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to department rules or orders, or license or registration conditions, as shown in records maintained by the licensee or registrant pursuant to department rules. Each notification and report shall:
(a) Be in writing.
(b) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number.
(c) Include the individual's exposure information.
(d) Contain the following statement:
"This report is furnished to you under the provisions of part 5 of the Michigan Department of Public Health rules entitled ‘Standards for Protection Against Radiation’. You should preserve this report for future reference."
(2) At the request of any worker, employed by or associated with him, a licensee or registrant shall advise the worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to rule 245.
(3) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, a licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. The report shall:
(a) Be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later.
(b) Cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the department.
(c) Include the dates and locations of work under the license or registration certificate in which the worker participated during this period.
(4) When a licensee or registrant is required pursuant to rule 250 to report to the department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to 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.]

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any reference in these rules to the Michigan Department of Public Health should now reference the Michigan Department of Consumer & Industry Services.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5217. Presence of representatives of licensees or registrants and workers during investigations.

Rule 217. (1) A licensee or registrant shall afford opportunity to a department representative, at all reasonable times, to inspect or investigate materials, machines, activities, facilities, premises, and records pursuant to these rules.

(2) A licensee or registrant or his authorized representative may accompany a department representative during all phases of an investigation except during consultation with workers as specified in rule 218.

(3) If, at the time of investigation, an individual has been authorized by the workers to represent them during department investigations, the licensee or registrant shall notify the department representative of such authorization and shall give the workers' representative an opportunity to accompany the department representative during the investigation of physical working conditions.

(4) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in rule 215.

(5) Different representatives of licensees or registrants and workers may accompany the department representative during different phases of an investigation if there is no resulting interference with the conduct of the investigation. However, only 1 workers' representative at a time may accompany the department representative.

(6) With the approval of the licensee or registrant and the workers' representative an individual who is not routinely engaged in work under control of the licensee or registrant, e.g. a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany the department representative during the investigation of physical working conditions.

(7) Notwithstanding the other provisions of this rule, a department representative may refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly investigation. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5218. Consultation with workers during investigations.

Rule 218. (1) A department representative may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of department rules and licenses to the extent the department representative deems necessary for the conduct of an effective and thorough investigation.

(2) During an investigation, a worker or authorized representative may bring privately to the attention of the department representative, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused:

(a) A violation of the act, these rules or license or registration conditions.

(b) An unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control.

(3) A written notice presented pursuant to subrule (2) shall comply with requirements of rule 219(1).

(4) The provisions of subrule (2) shall not be interpreted as authorization to disregard instructions provided pursuant to rule 215.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5219. Requests by workers for investigations.

Rule 219. (1) A worker or representative of workers who believes that a violation of the act, these rules or license or registration conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an investigation by giving notice of the alleged violation to the Michigan Department of Public Health, Division of Radiological Health, 3500 North Logan Street, Lansing, Michigan 48914. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the department no later than at the time of investigation except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the department, except for good cause shown.

(2) If, upon receipt of such notice, the department determines that the complaint meets the requirements set forth in subrule (1) and that there are reasonable grounds to believe that the alleged violations exists or has occurred, an investigation shall be made as soon as practicable, to determine if such alleged violation exists or has occurred. An investigation pursuant to this rule need not be limited to matters referred to in the complaint.

(3) A licensee or registrant shall not discharge or in any manner discriminate against a worker because a worker has filed a complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by a worker on behalf of himself or others of any option afforded by this part.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry

Services. With respect to machine sources of ionizing radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664, Lansing, Michigan 48909.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5220. Investigation not warranted; informal review.

Rule 220. (1) If the department determines, with respect to a complaint under rule 219, that an investigation is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the director of the department who shall provide the licensee or registrant with a copy of such statement by registered mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the director of the department who will provide the complainant with a copy of such statement by registered mail. Upon the request of the complainant, the department may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant shall be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the director of the department or his designated representative shall affirm, modify, or reverse the determination of the department and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

(2) If the department determines that an investigation is not warranted because the requirements of rule 219 (1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of rule 219 (1).

(3) If the decision resulting from informal review is contested, the department shall proceed pursuant to rule 2 (2).

History: 1954 ACS 85, Eff. Dec. 3, 1975.

PRECAUTIONARY PROCEDURES

R 325.5221. Surveys.

Rule 221. (1) As used in this rule "survey" means a critical evaluation of a facility or area incident to the production, use, release, disposal or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, the evaluation includes tests, physical examination, source inventory and accountability, and measurements of levels of radiation or concentration of radioactive material present.

(2) Each licensee or registrant shall make or cause to be made such surveys as may be necessary for him to establish compliance with these rules.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5222. Personnel monitoring.

Rule 222. (1) Each licensee or registrant shall supply appropriate personnel monitoring equipment to, shall require the use of such equipment by, and shall demonstrate compliance pursuant to this rule for:

(a) Each individual under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25% of the quarterly occupational limit specified in rule 205, (e.g. 300 mrems whole body).

(b) Each individual under 18 years of age under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5% of the quarterly occupational limit specified in rule 205, (e.g. 60 mrems whole body).

(c) Each individual except a patient being intentionally irradiated who enters a high radiation area.

(d) Each individual who is likely to receive a dose in excess of 100 millirems in any 5 consecutive days while in a room or area occupied by a patient while the patient is receiving therapy from any gamma-emitting radioactive material.

(e) Each individual for whom personnel monitoring is specifically required under other parts of these rules pertaining to specific uses of sources of radiation.

(2) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. The dosimeter assigned for monitoring the trunk of the body shall not be used for any other purposes. If monitoring of other areas of the body (e.g. lens of the eye, extremity) is required by these rules or requested by the radiation worker because of the nature of exposure a separate dosimeter shall be assigned for this purpose. The separate dosimeter shall be designated as an auxiliary dosimeter and the
radiation record shall specify the specific area monitored.

(3) If auxiliary dosimeters are assigned in accordance with subrule (2) the specific body area shall be monitored for a minimum 13 consecutive weeks. If this monitoring results in recorded exposures in excess of 25% of the applicable specified quarterly limit in rule 205 (e.g. 300 mrems lens of the eye, 6.25 rems hands), the auxiliary dosimeter shall be permanently assigned to monitor that area.

[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.]

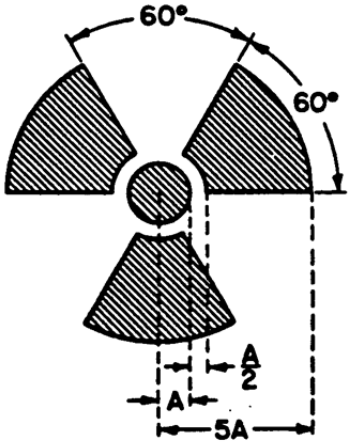
History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5224 Caution signs, labels, and signals.

Rule 224. (1) Except as otherwise authorized by the department, symbols prescribed by rules 224 to 232 shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed is the conventional three-bladed design:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.



(2) In addition to the contents of signs and labels prescribed in rules 224 to 232, a licensee or registrant may provide on or near these signs and labels any additional information which may be appropriate in aiding individuals to minimize being exposed to radiation.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5225. Radiation area signs.

Rule 225. Each radiation area shall be conspicuously posted with 1 or more signs bearing the radiation caution symbol and the words:

CAUTION: RADIATION AREA

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5226. High radiation area signs.

Rule 226. Each high radiation area shall be conspicuously posted with 1or more signs bearing the radiation caution symbol and the words:

CAUTION: HIGH RADIATION AREA

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5227. Controls for access to high radiation areas.

Rule 227. (1) Each entrance or access point to a high radiation area shall be equipped with a control device which complies with any 1 of the following:

(a) It causes that level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area.

(b) It energizes a conspicuous visible and audible alarm signal in such a manner that the individual entering the high radiation area and the licensee, registrant or a supervisor of the activity are made aware of the entry.

(c) It is locked except during periods when access to the area is required, with positive control over each individual entry.

(2) These controls shall be established in such a way that an individual will not be prevented from leaving a high radiation area.

(3) The controls required by subrule (1) (a) shall be constructed in such a manner that the primary radiation cannot be reactivated until all entrances have been secured, and the radiation on-off control is reset at the control panel.

(4) The controls required by subrule (1) (b) shall be constructed in such a manner that when the warning device is activated, it is necessary to shut off or secure the source of radiation and secure all tripped entrances before being able to inactivate the alarm system.

(5) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by this rule.

(6) A licensee, or registrant, or applicant for a license or registration, may apply to the department for approval of methods not included in subrules (1) and (5) for controlling access to high radiation areas. The department may approve the proposed alternatives if the licensee, registrant or applicant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of subrule (2) is met.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5231. Alternate wording for warning signs.

Rule 231. The word DANGER may be used instead of CAUTION in a warning sign required by rules 225, 226, 228, 229 and 230.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5232. Radiation machine labels.

Rule 232. All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5233. Exemptions from posting and labeling requirements.

Rule 233. Notwithstanding rules 225 to 230:

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, if the radiation level 30 centimeters (12 inches) from the surface of the source container or housing does not exceed 5 millirems per hour.

(b) A room or other area in a hospital is not required to be posted with a caution sign, and control of entrance or access thereto pursuant to rule 227 is not required, because of the presence of patients containing radioactive material provided the licensee or registrant has demonstrated by survey or monitoring that any individual who enters this area is not likely to receive a dose in excess of the applicable limit specified in rule 205.

(c) A room or other area containing radioactive material for periods of less than 8 hours is not required to be posted with a caution sign if:

(i) The material is constantly attended during these periods by an individual who shall take the precautions necessary to prevent any individual from being exposed to radiation or radioactive material in excess of the limits established in this part.

(ii) The room or area is subject to the licensee's or registrant's control.

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area, solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the United States department of transportation.

(e) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area, solely because of the operation of radiation machine during intentional irradiation of a patient if:

(i) The radiation machine is constantly attended during these periods by an individual who shall take the precautions necessary to prevent any individual from being exposed to radiation in excess of the limits established in this part.

(ii) The room or area is subject to licensee's or registrant's control.

[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.]

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. The Department of Consumer & Industry Services has renamed Form RH-102 to BHS-102.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5241. Use of safety equipment.

Rule 241. (1) The existence in these rules of requirements for safety interlocks, protective enclosures, protective clothing, precautionary labels, or any other safety equipment presumes the proper use of such equipment. Unauthorized override of safety interlocks or other intentional misuse or non-use of required safety equipment shall be considered willful violation of these rules.

(2) Authorized override of safety interlocks shall be requested by the radiation protection supervisor in writing from the department. The request shall include justification, precautionary procedures during override, and statement of immediate supervision by the radiation protection supervisor or his authorized representative. Prior approval by the department is required. Such approval may be granted by written condition on the specific license or registration certificate or by telephone followed by written confirmation from the department.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

RECORDS, REPORTS AND NOTIFICATION

R 325.5245. Records of surveys, radiation monitoring, disposal and tests.

Rules 245. (1) A licensee or registrant shall maintain records showing the radiation doses of all individuals for whom personnel monitoring is required under rule 222. These records shall be kept on department Form RH-102, in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by Form RH-102. The doses entered on the forms or records shall be for periods of time not exceeding 1 calendar quarter.

(2) A licensee or registrant shall maintain records in the same units used in this part, showing the results of surveys required in rule 221, disposals made under rules 238 to 240, and surveys required by other parts of these rules.

(3) Records of individual exposure to radiation and to radioactive material which shall be maintained pursuant to subrule (1) and records of bio-assays, including results of whole body counting examinations, made pursuant to rule 209 shall be preserved indefinitely or until the department authorizes their disposal.

(4) The discontinuance of or curtailment of activities, does not relieve the licensee or registrant of responsibility for retaining all records required by this rule. A licensee or registrant may, however, request the department to accept such records. The acceptance of the records by the department relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by this rule.

(5) Records which shall be maintained pursuant to this part may be maintained in the form of microfilms.

[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.]

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance

program were transferred to the Michigan Department of Consumer & Industry Services. The Department of Consumer & Industry Services has renamed Form RH-102 to BHS-102.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5246. Reports of theft or loss of sources of radiation.

Rule 246. A licensee or registrant shall report by telephone and telegraph to the department the theft or loss of any source of radiation immediately after such occurrence becomes known to the licensee or registrant.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5247. Notification of incidents.

Rule 247. (1) A licensee or registrant shall immediately notify the department by telephone and telegraph of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause any of the following:

(a) A dose to the whole body of any individual of 25 rems or more of radiation; a dose to the skin of the whole body of any individual of 150 rems or more of radiation; or a dose to the feet, ankles, hands or forearms of any individual of 375 rems or more of radiation.

(b) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in table II of rules 261 to 269.

(c) A loss of 1 working week or more of the operation of any facilities affected due to contamination or other potential hazard from radioactive material.

(d) Damage to property in excess of $100,000.

(e) Accidental administration of a radiopharmaceutical to a human patient in excess of the quantity established as appropriate for the procedure at hand.

(f) Accidental administration of a radiopharmaceutical to a human patient in chemical form different from that established as appropriate for the procedure at hand.

(2) A licensee or registrant shall within 24 hours notify the department by telephone and telegraph of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause any of the following:

(a) A dose to the whole body of any individual of 5 rems or more of radiation; a dose to the skin of the whole body of any individual of 30 rems or more of radiation; or a dose to the feet, ankles, hands or forearms of 75 rems or more of radiation.

(b) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in table II of rules 261 to 269.

(c) A loss of 1 day or more of the operation of any facilities affected or damage to property in excess of $1,000 due to contamination or other potential hazard from radioactive material.

(3) A report filed with the department pursuant to this rule shall be prepared in such a manner that names of individuals who have received exposure to radiation shall be stated in a separate part of the report.

[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: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5250. Reports of overdose and excessive levels and concentrations.

Rule 250. (1) In addition to any notification required by rule 247 a licensee or registrant shall report in writing within 30 days to the department:

(a) Each radiation dose received by an individual or concentrations of radioactive material in excess of any applicable limit as set forth in this part or as otherwise approved by the department.

(b) Each incident for which notification is required by rule 247.

(c) Levels of radiation or concentrations of radioactive material (not involving excessive exposure of any individual) in an unrestricted area in excess of 10 times any applicable limit as set forth in this part or as otherwise approved by the department.

(2) A report required in subrule (1) shall describe the extent of radiation dose received by individuals or exposure to radioactive material, including estimates of each individual's dose as required by subrule (3); levels of radiation and concentrations of radioactive material involved; the cause of exposure, levels or concentrations; and corrective steps taken or planned to assure against a recurrence.

(3) A report filed with the department pursuant to subrule (1) shall include for each individual exposed the name, social security number, and date of birth, and an estimate of the individual's dose. The report shall be prepared so that this information is stated in a separate part of the report.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

DEPARTMENT OF CONSUMER & 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 6. INDUSTRIAL RADIOGRAPHIC OPERATIONS AND INSTALLATIONS

R 325.5281. Purpose and scope.

Rule 281. (1) This part establishes radiation safety requirements for persons utilizing sources of radiation for industrial radiography and a classification system for industrial radiographic installations and use.

(2) This part applies to all licensees and registrants who use sources of radiation for industrial radiography; however, nothing in this part applies to the use of sources of radiation in the healing arts.

(3) Requirements of this part which refer to radiographic exposure devices or sealed sources apply to the use of radioactive material.Requirements which refer to sources of radiation apply to the use of radiation machines and radioactive material.

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

[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 325.5282. Definitions.

Rule 282. As used in this part:

(a) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.

(b) "Installation" means a location, having boundaries specified by the licensee or registrant, where for a period of more than 30 days 1 or more sources of radiation are used, operated or stored. A part of a building, an entire building, a plant or plant site may be designated as an installation.

(c) "Radiographer" means an individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all license or registration conditions.

(d) "Radiographer's assistant" means an individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in industrial radiography.

(e) "Radiographic exposure device" means an instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

(f) "Storage container" means a device in which sealed sources are transported or stored.

[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.

EQUIPMENT CONTROL

R 325.5286. Locking of sources of radiation.

Rule 286. (1) Each source of radiation shall be provided with a lock or outer-locked container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized by the department.

(2) Each storage container shall be provided with a lock and kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(3) Locked sources of radiation and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

[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 325.5287. Radiation survey instruments.

Rule 287. (1) A licensee or registrant shall maintain calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and part 5. Each radiation survey instrument shall be calibrated at intervals not to exceed 3 months and after each instrument servicing. A record of such calibration shall be maintained for examination by the department.

(2) Instrumentation required by this rule shall have a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured and shall be capable of measuring radiation of the energies and at the dose rates to be encountered.

(3) During repair or calibration of survey instruments required by this rule, spare operable and calibrated instruments shall be provided or radiographic operations shall be terminated pursuant to rule 307(1).

History: 1979 AC.

R 325.5289. Quarterly inventories.

Rule 289. A licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation received or possessed by him. The records of the inventories shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, the location of all sources of radiation, the date of the inventory, and the signature or initials of the individual certifying the accuracy of the inventory.

[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 325.5290. Utilization logs.

Rule 290. A licensee or registrant shall maintain for inspection by the department current logs, which show the following information for each source of radiation:

(a) A description, or make and model number, of each source of radiation or storage container in which the sealed source is located.

(b) The identity of the radiographer to whom assigned.

(c) Locations where used and dates of use.

(d) Signature or initials of the individual certifying each entry.

[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 325.5291. Inspection and maintenance.

Rule 291. (1) A licensee or registrant shall conduct a program for inspection and maintenance of sources of radiation and storage containers to assure proper functioning of components important to safety.

(2) A current checklist of inspection and maintenance of sources of radiation and storage containers indicating the date of the last inspection shall be maintained for inspection by the department.

History: 1979 AC.

CLASSIFICATION

R 325.5293. Class enumeration.

Rule 293. (1) For the purpose of licensing or registering and approving industrial radiographic 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 industrial radiography and sources of radiation intended for limited use at temporary job site locations this use shall be classified as class D operation.

History: 1979 AC.

R 325.5294. Class AA installations.

Rule 294. (1) In class AA installations the source of radiation and objects exposed thereto shall be contained within a permanent enclosure.

(2) The enclosure shall be constructed such that the radiation exposure rate as measured in air at a distance of 5 centimeters from any point on the external surface shall not exceed 2 milliroentgens per hour with the source of radiation placed in the shortest source-to-wall radiographically usable position under conditions of maximum radiation output permitted by the design or operating characteristics of the radiographic exposure device or radiation machine.

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

(4) A personnel barrier posted in accordance 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 radiation machine is on or the sealed source is unshielded, or which will terminate machine operation or automatically return the sealed source to a shielded position should anyone open the enclosure.

(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 radiation machine activation or exposure of the sealed source. Persons shall at all times be able to escape from within the enclosure.

(7) A person shall not be permitted to remain within the enclosure while the radiation machine is in operation or the sealed source is unshielded.

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

(9) Industrial fluoroscopy shall meet class AA requirements.

(10) Notwithstanding the provisions of subrule (2), the enclosure for industrial fluoroscopy shall be constructed such that the radiation exposure rate as measured in air at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 0.5 milliroentgens per hour under conditions of maximum radiation output permitted by the design or operating characteristics of the installation.

(11) Industrial cabinet radiography conducted in enclosures of insufficient size to permit human occupancy shall meet class AA requirements.

(12) Notwithstanding the provisions of subrule (2), the enclosure forindustrial cabinet radiography of insufficient size to permit human occupancy shall be constructed such that the radiation exposure rate as measured in air at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 0.5 milliroentgens per hour under conditions of maximum radiation output permitted by the design or operating characteristics of the installation.

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

[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 325.5296. Class A installations.

Rule 296. (1) Class A installations shall comply with all requirements of rule 294 except for a permissible exposure rate of 7 milliroentgens 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 for inspection by the department.

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

History: 1979 AC.

R 325.5297. Class B installations.

Rule 297. (1) Class B installations shall comply with all requirements of rule 296.

(2) Radiation machine current and potential controls shall be mechanically or electrically limited so as not to exceed the normal operating conditions as specified by the registrant at the time of application for registration.

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

History: 1979 AC.

R 325.5298. Class C installations.

Rule 298. (1) Class C installations shall comply with all requirements of rule 296 except for a permissible exposure rate of 50 milliroentgens per hour at any accessible external point.

(2) The maximum weekly exposure time of sources of radiation within the enclosure shall be established by the department under the conditions specified by the licensee or registrant at the time of application.

(3) Warning signs shall be posted in those areas outside the enclosure in which the radiation exposure rate in air at any accessible external point exceeds 2 milliroentgens per hour with the source of radiation placed in the shortest source-to-wall radiographically usable position under conditions of maximum radiation output permitted by the design or limited operating characteristics of the radiographic exposure device or radiation machine.

History: 1979 AC.

R 325.5299. Class D operations.

Rule 299. (1) Industrial radiography conducted under conditions not meeting the provisions and requirements of rules 294 to 298 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 may be granted by the department for class D operations longer than 30 days but not longer than 6 months when an undue and unnecessary hardship may result from the 30 day limitation. Written request by the licensee or registrant 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.

(3) Notwithstanding subrules (1) and (2) a person routinely engaged in providing industrial radiography services with mobile or portable sources of radiation at temporary job site locations may conduct such class D operations without time limitation subject to the following conditions:

(a) The person shall hold an unexpired certificate of registration from the department or specific license from the department, the NRC or an agreement state.

(b) The person shall give written notice to the department at least 2 working days before starting radiographic work at a job site. The notice shall include the radiographer's name; a description of each source of radiation; the nature, duration and scope of use; and the exact location of each job site. If for a specific case the 2 working-day period would impose an undue hardship on the person, upon application to the department, he may arrange for other notification to comply with the intent of this requirement.

(c) These class D operations shall be limited to locations and circumstances which cannot meet the provisions and requirements of permanent installation classification without undue and unnecessary hardship.

(d) A copy of written operating and emergency procedures shall be filed with and approved by the department.

(e) Upon reasonable notice from the department the person shall submit to the department or otherwise make available copies of specific records pertaining to radiographic operations and personnel conducting these operations within this state.

(4) A fence, rope or other suitable barrier shall be erected along the 5 mR/hr contour line during class D radiographic operations to exclude unauthorized persons from the radiation area.

(5) The radiation area and high radiation area shall be posted with caution signs as specified in rules 224 to 231.

(6) 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.

(7) Personnel exposure records shall be kept on permanent available file for examination by the department. A copy of the most recent record including current, quarterly, annual and lifetime cumulative totals for each monitored individual present at a temporary job site shall be available at the job site for examination by the department. A current supplemental daily dosimeter log shall also be available at the job site.

(8) The inside of the driver's compartment of the transport vehicle used to transport class D radiographic exposure devices shall be conspicuously posted with emergency instructions including the procedure for notifying the Michigan Department of Public Health, the Michigan Department of State Police, and other emergency agencies in event of accident or fire and the procedure for minimizing exposure to persons in the event of an accident.

(9) Written operating and emergency procedures shall be available at each class D radiographic operation.

[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.]

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any reference in these rules to the Michigan Department of Public Health should now reference the Michigan Department of Consumer & Industry Services.]

History: 1979 AC.

SAFETY FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANTS

R 325.5301. Limitations.

Rule 301. (1) A licensee or registrant shall not permit an individual to act as a radiographer until the individual:

(a) Has been instructed in the subjects outlined in rule 309 and has demonstrated understanding thereof.

(b) Has received copies of and instruction in the rules contained in this part and the applicable sections of part 5, 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 source of radiation, related handling tools, and survey instruments which will be employed in his assignment.

(2) A licensee or registrant shall not permit an individual to act as a radiographer's assistant until the individual:

(a) Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures, and has demonstrated understanding thereof.

(b) Has demonstrated competence to use under the personal supervision of the radiographer the sources of radiation, related handling tools and radiation survey instruments which will be employed in his assignment.

History: 1979 AC.

R 325.5302. Operating and emergency procedures.

Rule 302. A licensee's or registrant's written operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of sources or radiation to be employed such that an individual is not likely to be exposed to radiation doses in excess of the limits established in part 5.

(b) Methods and occasions for conducting radiation surveys.

(c) Methods for controlling access to radiographic areas.

(d) Methods and occasions for locking and securing sources of radiation.

(e) Personnel monitoring and the use of personnel monitoring equipment.

(f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation.

(g) Minimizing exposure of persons in the event of an accident.

(h) Procedure for notifying proper persons in the event of an accident.
(i) Maintenance of records.
(j) Inspection and maintenance of sources of radiation and storage containers.

History: 1979 AC.

R 325.5303. Personnel monitoring control.
Rule 303. (1) A licensee or registrant shall not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operation, the individual wears a long-term monitoring device such as a film badge or TLD and a short-term monitoring device such as a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers shall be capable of measuring doses from 0 to at least 200 milliroentgens. Each long-term monitoring device shall be assigned to and worn by only 1 individual.
(2) Pocket dosimeters and pocket chambers shall be read and doses recorded daily. A film badge or similar device shall be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range. All personnel exposure reports and records of pocket dosimeter and pocket chamber readings shall be maintained for inspection by the department.

History: 1979 AC.

PRECAUTIONARY PROCEDURES INRADIOGRAPHIC OPERATIONS

R 325.5305. Security.
Rule 305. (1) During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except where the high radiation area is equipped with interlocks as described in rule 294 (5), or where the high radiation area is locked to protect against unauthorized or accidental entry.
(2) A radiographer or radiographer's assistant shall not perform or permit radiographic operation unless all persons present in or entering the resulting radiation area are wearing film badges or thermoluminescent dosimeters. Radiographic operation shall cease if an unmonitored person enters the radiation area and shall not resume until the person is monitored or leaves the area.

History: 1979 AC.

R 325.5306. Posting.
Rule 306. Notwithstanding any provision in rule 233, areas in which radiography is being performed shall be conspicuously posted as required by rules 224 to 231.

History: 1979 AC.

R 325.5307. Radiation surveys and survey records.

Rule 307. (1) A radiographic operation shall not be conducted unless calibrated and operable radiation survey instrumentation as described in rule 287 is available and used at each site where radiographic exposures are made.

(2) A physical radiation survey shall be made after each radiographic exposure utilizing radiographic exposure devices or sealed sources of radioactive material to determine that the sealed source has been returned to its shielded condition.

(3) A physical radiation survey shall be made to determine that each sealed source is in its shielded condition before securing the radiographic exposure device or storage container as specified in rule 286. Records shall be kept of these surveys and maintained for inspection by the department.

(4) A physical radiation survey shall be conducted to determine that the radiation machine is off before each entry into the radiographic exposure area.

[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 325.5309. Appendix A - Instruction of radiographers.

Rule 309. See rule 301.

I. Fundamentals of Radiation Safety A. Characteristics of gamma and x-radiation B. Units of radiation dose (mrem) and quantity of radioactivity (curie) C. Hazards of excessive radiation exposure D. Levels of radiation from sources of radiation E. Methods of controlling radiation dose 1. Working time 2. Working distances 3. Shielding

II. Radiation Detection Instrumentation to be Used A. Use of radiation survey instruments 1. Operation 2. Calibration 3. Limitations B. Survey techniques C. Use of personnel monitoring equipment 1. Film badges, thermoluminescent dosimeters 2. Pocket dosimeters 3. Pocket chambers

III. Radiographic Equipment to be Used:

A. Remote handling equipment

B. Radiographic exposure devices and sealed sources

C. Storage containers

D. Operation and control of x-ray equipment

IV. The Requirements of Pertinent Federal and State Regulations

V. The Licensee's or Registrant's Written Operating and Emergency Procedures

VI. License or Registration Conditions

[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.

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 7. MEDICAL X-RAY INSTALLATIONS

R 325.5311. Purpose and scope.

Rule 311. (1) This part establishes requirements governing the use of x-radiation in medicine, osteopathy, chiropractic and podiatry.

(2) This part applies to all licensees and registrants who use x- radiation in these healing arts disciplines for the intentional exposure of humans.

(3) In addition to this part all licensees and registrants are subject to parts 1, 4 and 5 and all applicable provisions of the other parts.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

THERAPEUTIC MACHINES OPERATED ABOVE 85 KVP

R 325.5312. X-ray equipment.

Rule 312. (1) The tube housing shall be of the therapeutic type.

(2) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of attenuation as is required of the housing.

(3) Adjustable or removable beam-limiting devices shall transmit not more than 5% of the useful beam as determined at the maximum tube potential and with maximum treatment filter.

(4) Filters shall be so mounted as to prevent their movement during the treatment.

(5) The filter slot shall be so constructed that the radiation escaping through it does not produce an exposure rate exceeding 1 R/h at 1 meter, or if the patient is likely to be exposed to radiation escaping from the slot, 30 R/h at 5 centimeters (2 inches) from the external opening.

(6) A removable filter shall be permanently marked with its thickness and material.

(7) A filter indication system shall be used on therapy machines which use changeable filters and are manufactured after the effective date of these rules. It shall indicate, from the control panel, the presence or absence of any filter and it shall be designed to permit easy recognition of the filter in place.

(8) The x-ray tube shall be so mounted that it cannot turn or slide with respect to the housing aperture. A reproducible means of measuring the focal spot to patient distance shall be provided.

(9) Means to immobilize the tube housing during stationary portal treatment shall be provided.

(10) An easily discernible indicator which shows whether or not x-rays are being produced shall be on the control panel.

(11) On therapeutic machines manufactured after the effective date of these rules beam monitoring devices shall be fixed in the useful beam to indicate any error due to incorrect filter, tube current, or tube potential, unless the device introduces more filtration than is clinically acceptable.

(12) A suitable exposure control device (e.g. an automatic timer, exposure meter or dose meter) shall be provided to terminate the exposure after a preset time interval or preset exposure or dose limit. If a timer is used, it shall permit accurate presetting and determination of exposure times as short as 1 second. Means for the operator to terminate the exposure at any time shall be provided.

(13) Mechanical or electrical stops or both shall be provided to insure that the useful beam is oriented only toward primary barriers.

(14) Interlocks shall be provided so that, when any door to the treatment room is opened, the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 mR/h and a maximum of 10 mR/h at a distance of 1 meter in any direction from the source. After the shut-off or reduction in exposure rate, it shall be possible to restore the machine to full operation only from the control panel.

(15) The x-ray control circuit shall be so designed that it is not possible to energize the x-ray tube to produce x-rays without resetting the x-ray "ON-OFF" switch at the control panel.

(16) When the relationship between the beam interceptor (when present) and the useful beam is not permanently fixed, mechanical or electrical stops shall be provided to insure that the beam is oriented only toward primary barriers.

(17) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

(18) X-ray machines with electron beam extraction capability shall be provided with such additional safety devices as determined necessary and specified in writing by the department to prevent accidental electron beam exposure.

(19) To reduce the electron contamination of high energy treatment beams, shadow trays or other accessories placed in the primary beam shall be placed at a sufficient distance from the patient that the electron contamination contribution to the skin dose is minimal.

(20) X-ray machines capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 unless excluded from the particle accelerator definition in part 1 by design and use shall comply with the applicable requirements of part 11.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5315. Enclosures.

Rule 315. (1) An enclosure shall be a permanent part of the building or equipment. Portable protective barriers shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and shall be subject to design approval by the department.

(3) All wall, ceiling and floor areas that can be irradiated by the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier.

(4) For equipment capable of operating above 150 kVp the control station shall be outside of the therapy room.

(5) The enclosure shall be so constructed that persons may at all times be able to escape from within.

(6) If the radiation exposure rate within the therapy room is so high that a person who is accidentally in the treatment room when the machine is turned "ON" may receive as much as 1250 mR exposure during the time required to reach an access door, special cut-off or panic buttons shall be required. When pressed, these buttons, operable by open hand at appropriate positions about the treatment room, shall cause the irradiation to be terminated.

(7) Effective means shall be provided to prevent access to the treatment room during exposure. For equipment capable of operating above 150 kVp, each access door to the treatment room shall be provided with a fail-safe interlock. The interlock system shall be so designed that the failure of any 1 component will not jeopardize the safety of the system, (e.g., the use of series connected double switch assemblies at access doors, and dual interlock relays). If an access door is opened when the machine is "ON", the interlock shall cause termination or reduction of exposure as specified in rule 312 (14).

(8) Red warning signal lights, energized only when the useful beam in "ON", shall be located on the control panel and near each entrance to the therapy room. Under conditions as specified in subrule (6) a visible signal shall also be located within the therapy room. Depending upon control panel and door locations, a single warning signal light may be sufficient to comply with this subrule.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5317. Conditions of operation.

Rule 317. (1) An installation shall be operated in compliance with any limitations determined necessary and specified in writing by the department.

(2) The output of the x-ray generator shall be calibrated before use for the treatment of patients for each technique or condition of use. The department shall be informed by telephone or in writing of completion of initial calibration before patient treatment is initiated. A written report of this initial calibration only shall be submitted within 30 days to the department. Recalibration shall be required after each tube replacement and after any changes or replacement in the generating apparatus which could effect a change in the x-ray output.

Check calibrations shall be made on an annual basis and records of all calibration maintained for not less than 7 years.

(3) X-ray therapy equipment capable of operating above 150 kVp shall not be operated routinely until the radiation safety of the installation has been established by a protection survey conducted in accordance with rule 221. The department shall be informed by telephone or in writing of completion of the initial survey before patient treatment is initiated. A written report of this initial survey shall be submitted within 30 days to the department. All x-ray therapy equipment shall be operated in conformance with recommendations of the protection survey.

(4) Both the control panel and the patient shall be observable during exposure.

(5) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices should be used. If the patient must be held by an individual, upon approval by the radiologist in charge followed by written notice to the department, that individual shall be provided protection equivalent to 7 half-value layers and he shall be positioned so that no part of his body will be struck by the useful beam and so that his body is as far as possible from the edge of the useful beam. The exposure of any individual used for this purpose shall be monitored and a permanent record maintained. The individual selected for this purpose shall not otherwise be occupationally exposed to ionizing radiation.

(6) With the exception of subrule (5), a person other than the patient shall not be permitted in the treatment room when the tube is operated at potentials exceeding 85 kVp. At potentials of 85 kVp or below, other persons may be permitted in the treatment room by the radiologist in charge if essential to conduct the treatment, but only if they are protected as specified in subrule (5) and their radiation exposure is monitored and permanently recorded.

(7) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from therapeutic x-ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(9) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(10) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(11) Lead, lead rubber, lead foil and similar materials used for limiting the field shall not transmit more than 5% of the useful beam under the conditions at which the machine is operated for therapy. This subrule does not pertain to treatment blocks used to adjust or modify the intended radiation dose to the area of treatment.

(12) A therapeutic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

THERAPEUTIC MACHINES OPERATED AT OR BELOW 85 KVP

R 325.5321. X-ray equipment.

Rule 321. (1) The x-ray equipment shall comply with the general requirements of rule 312 excluding subrules (11), (14) and (16).

(2) Maximum potential shall be mechanically or electronically limited to 85 kVp.

(3) A contact therapy machine shall meet the additional requirement that the leakage radiation at 5 centimeters (2 inches) from the surface of the tube housing shall not exceed 0.1 R/h. As used in this subrule "contact therapy machine" means an x-ray therapy machine designed for source to skin treatment distances of 5 centimeters or less at tube potentials in the range of 20 to 50 kVp.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5322. Enclosures.

Rule 322. An enclosure shall comply with the general requirements of rules 315 (1) and (2).

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5323. Conditions of operation.

Rule 323. (1) Operation shall comply with the general requirements of rule 317.

(2) If the x-ray tube of a contact therapy machine as defined in rule 321 (3) is hand held during irradiation, the operator shall wear protective gloves and a protective apron. When practical, a cap of at least 0.5 millimeter lead equivalence should cover the aperture window of the tube housing of such apparatus when the apparatus is not being used. Because the exposure rate at the surface of the window of contact therapy and beryllium window machines may be more than 10,000 R per minute, extreme precautions are necessary to prevent accidental exposure to the useful beam.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

FIXED RADIOGRAPHIC INSTALLATIONS

R 325.5325 X-ray equipment.

Rule 325. (1) All x-ray tube housings in fixed radiographic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than the values shown in Table 1.

Table 1

Operating kVp	Minimum Total Filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(3) If the filter in the machine is not accessible for examination and the total filtration is not known subrule (2) may be assumed to have been met if the half-value layer is not less than

0.6 mm aluminum at 49 kVp
1.6 mm aluminum at 70 kVp
2.6 mm aluminum at 90 kVp

(4) Under conditions of subrule (3) for tube potentials above 90 kVp subrule (2) may be assumed to have been met if the half-value layer is not less than that specified in table 2.

(5) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in table 2.

Table 2

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (milli-meters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(6) If it is necessary to determine the half-value layer at an x-ray tube potential which is not listed in table 2, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve these beam quality

requirements is in the useful beam during each exposure.

(7) Machines equipped with beryllium window x-ray tubes with removable filters shall contain keyed filter interlock switches in the tube housing and suitable indication on the control panel of the added filter in the useful beam. The total filtration permanently in the useful beam shall not be less than 0.5 millimeter aluminum equivalent and shall be clearly indicated on the tube housing.

(8) Beryllium window x-ray tubes shall not be used routinely for general purpose diagnostic examinations. Such a tube may comprise an x-ray subsystem if needed for special soft tissue technique in accord with subrule (7).

(9) Beam-limiting devices (diaphragms, cones, adjustable collimators), capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(10) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-image distances (SID). This calibration shall be clearly and permanently recorded on the beam-limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(11) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID. However, for mammography the x-ray field need not be aligned with the center of the image receptor if the x-ray field does not extend beyond the edge of the image receptor.

(12) General purpose radiographic x-ray systems shall be equipped with adjustable beam-limiting devices containing light localizers that define the entire field. Rectangular beam-limiting devices are usually preferable.

(13) The size of the x-ray beam projected by fixed aperture beam-limiting devices, except those used for stereoradiography, shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(14) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable beam-limiting devices shall provide the same precision.

(15) For radiographic procedures resulting in multiple views on a single x-ray film the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation. This subrule does not apply to spotfilm devices manufactured before the effective date of these rules.

(16) After the effective date of these rules radiographic x-ray machines used for purposes other than mammography or extremity radiography only shall be capable of operation at not less than an average current of 100 milliamperes (mA) during any radiographic technique used. A machine not capable of sustained operation at not less than an average of 100 mA for the duration of a given technique shall not be used for that technique. As used in this subrule "extremity radiography" means radiography of the hand or arm excluding the shaft of the humerus or the foot or leg excluding the shaft of the femur.

(17) A device shall be provided which terminates the exposure at a preset time interval or

exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of any single exposure in progress.

(18) The exposure switch, except for those used in conjunction with spot film devices in fluoroscopy, shall be securely fixed so that the operator is required to be behind a fixed shield which will intercept the useful beam and any radiation which has been scattered only once.

(19) When 2 or more x-ray tube heads are operated from a single exposure switch (multiple tube units), there shall be indication at the control panel showing which tube is connected and ready to be energized, and means to prevent energizing more than 1 tube head at the same time unintentionally. Machines designed for simultaneous multiple tube operation shall have positive means for selecting single tube or multiple tube operation.

(20) The control panel shall provide positive visual identification of the production of x-rays whenever the x-ray tube is energized. A milliammeter may comply with this subrule.

(21) On radiographic machines manufactured after the effective date of these rules, a signal audible to the operator shall indicate that the exposure has ended.

(22) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set before the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

(23) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5331. Enclosures.

Rule 331. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject to design approval by the department. Recommended shielding appears in rule 357.

(3) Radiographic-room wall and floor areas exposed to the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors. All vertical primary protective barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(4) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers.

(5) Control apparatus for the radiographic equipment shall be shielded by a primary protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(6) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with subrule (5).

(7) Exposure switch location and control shield shall be oriented so that, at arm's length from the exposure switch, the operator shall not be exposed to the useful beam, leakage radiation or any radiation scattered only once.

(8) The operator shall be able to see and communicate with the patient from a shielded position at the control panel. When an observation window is provided, it shall be a lead equivalence at least equal to that required of the control barrier and shall be installed so that the attenuation effectiveness of the barrier is not impaired.

(9) At times it may be necessary for personnel to remain within operating room or special procedure installations during radiographic exposures. A primary protective barrier shall be provided for personnel protection under these circumstances unless necessary technique prevents use of such protection. This barrier may be movable if necessary. Movable barriers shall not be permitted in lieu of the provisions of subrules (3) and (5).

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5333. Conditions of operation.

Rule 333. (1) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(2) The operator shall insure the presence of adequate filtration before any radiographic procedure.

(3) Staff personnel routinely working with or around radiation sources shall not be required by the licensee or registrant to hold film or restrain patients during radiography. If such procedure is permitted personnel exposure shall not exceed rule 205 or the procedure shall be prohibited.

(4) When a patient must be held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and he shall be so positioned that no part of his body will be struck by the useful beam and that his body is as far as possible from the edge of the useful beam.

(5) Only individuals whose presence is necessary shall be permitted in the radiographic room during exposure. Each individual, except the patient, shall be protected by 0.5 millimeter minimum lead equivalent aprons unless protected by an approved primary barrier.

(6) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x- ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(8) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(9) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(10) The gonads of children and persons who have not passed the reproductive age shall be protected from the useful beam either by the use of shielding (0.5 mm lead equivalent), collimation, or special gonad shields when this will not interfere with the conditions or objectives of the examination.

(11) Intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image definition may reduce the clinical value of the examination. Film and screen speed combinations shall be carefully selected to produce the necessary clinical information with the least exposure to the patient consistent with current clinical judgement.

(12) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers unless otherwise tested to insure maximum information content of the developed film. Sight developing in not permitted except under extreme emergency conditions.

Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(13) A radiographic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

FIXED FLUOROSCOPIC INSTALLATIONS

R 325.5337. X-ray equipment.

Rule 337. (1) All x-ray tube housings of fixed fluoroscopic installations shall be of the diagnostic type.

(2) The aluminum equivalence of the total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum.

(3) Beam quality of fluoroscopic machines manufactured after the effective date of these rules shall comply with the provisions of rules 325 (5) and (6).

(4) The source-patient distance on fluoroscopic machines manufactured before the effective date of these rules should not be less than 45 centimeters (18 inches) and shall not be less than 30 centimeters (12 inches). Specific exemption may be granted in writing by the department for special purpose equipment such as heart catheterization machines.

(5) On fluoroscopic machines manufactured after the effective date of these rules, means shall be provided to limit the source-skin distance to not less than 38 centimeters. For image intensified fluoroscopes intended for specific surgical application that would be prohibited at this source- skin distance, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters.

(6) Provision shall be made to intercept the scattered x-rays from the undersurface of the table top and other structures under the fluoroscopic table if the tube is mounted under the

table. A cone or shield shall provide the same degree of attenuation as is required of the tube housing.

(7) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence for covering the bucky slot during fluoroscopy shall be provided.

(8) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence, such as overlapping protective drapes or hinged or sliding panels, shall be used to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

(9) The equipment shall be so constructed that, under conditions of normal use, the entire cross-section of the useful beam is attenuated by a primary protective barrier, permanently incorporated into the equipment. The exposure shall automatically terminate when the barrier is removed from the useful beam.

(10) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) The entrance exposure rate shall be measured in accordance with subrule (20). The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, if it is not closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of the entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(11) The lead equivalence of the barrier of conventional fluoroscopes shall be not less than 1.5 millimeters at 100 kVp, 1.8 millimeters at 125 kVp, and 2.0 millimeters at potentials greater than 125 kVp.

(12) A beam-limiting device shall be provided to restrict the size of the useful beam to less than the area of the barrier. The x-ray tube and beam-limiting system shall be linked with the fluorescent screen assembly so that the useful beam at the fluorescent screen is confined within the barrier irrespective of the panel-screen distance. For image intensifiers, the useful beam shall be centered on the input phosphor. It should not exceed the diameter of the input phosphor during fluoroscopy or cine- recording.

Ideally, for spot film radiography with image intensifier equipment, the shutters should automatically open to the required field size before such exposure.

(13) Beam-limiting devices (collimators, adjustable diaphragms or shutters) shall provide the same degree of attenuation as is required of the tube housing.

(14) When the beam-limiting device is opened to its fullest extent, a minimum ¼ inch unilluminated margin shall exist at all edges of the fluorescent screen when the screen is 35 centimeters (14 inches) from the panel surface or table top, or at the fixed screen position in equipment such as an orthodiascope. In equipment used solely for image intensified fluoroscopy, the x-ray beam shall not have dimensions greater than the diameter of the input phosphor.

(15) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5 centimeters.

(b) For image-intensified fluoroscopic equipment the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3% of the SID.The sum, without regard to sign, of the misalignment along any 2 orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4% of the SID. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(16) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in progress.

(17) When the fluoroscope is operated at 80 kVp, the exposure rate at the position where the beam enters the patient shall not exceed 3.2 R/mA-min and should not exceed 2.1 R/mA-min.

(18) The entrance exposure rate at the position where the center of the useful beam enters the patient should be as low as is consistent with the fluoroscopic requirements and shall not normally exceed 10 R/min. With modern equipment, most fluoroscopy can be carried out with entrance exposure rates of less than 5 R/min.

(19) Entrance exposure rate limits for fluoroscopic equipment manufactured after the effective date of these rules shall be as follows:

(a) Machines with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an a exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of

fluoroscopic images or when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of

activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) Machines without automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when a optional high level control is activated.Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(20) Compliance with subrules (18) and (19) shall be determined as follows:

(a) If the source is below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(b) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(c) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(21) A cumulative timing device, activated by the fluoroscope exposure switch, shall be provided. It shall indicate the passage of a predetermined period if irradiation either by an audible signal or by temporary interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(22) On fluoroscopic machines manufactured after the effective date of these rules means shall be provided to present the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on- time. This signal shall continue to sound while x-rays are produced until the timing device is reset.

(23) Devices which indicate the x-ray tube potential and current shall be provided. On image intensified fluoroscopic equipment, these devices should be located in such a manner that the operator may monitor the tube potential and current during fluoroscopy.

(24) X-ray equipment shall be installed and used in accord with article 660 of the national electrical code which is reproduced in rule 359.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5347. Enclosures.

Rule 347. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject to design approval by the department. Recommended shielding appears in rule 357.

(3) For conventional fluoroscopy extraneous light that interferes with the fluoroscopic examination shall be eliminated. Dark adaptation normally is not necessary when using image intensifiers.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5348. Conditions of operation.

Rule 348. (1) Each individual present in a fluoroscopic room, except the patient, shall wear a protective apron of at least 0.5 millimeter lead equivalence.

(2) Only individuals whose presence is needed to conduct the examination, to conduct radiation protection surveys or undergoing specific training shall be permitted in the fluoroscopy room during x-ray exposures.

(3) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x- ray equipment. Personnel monitoring devices, such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(5) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring or any other body part shall comply with rule 222. Since employees involved in fluoroscopic procedures are required to wear protective aprons and may be subjected to non-uniform radiation fields, a dosimeter assigned to monitor whole body exposure will not necessarily record the dose most representative of exposure to the lens of the eye. To monitor this critical area for which the exposure limit is the same as for whole body, active blood-forming organs, or gonads, an auxiliary dosimeter shall be provided in accordance with rule 222.

(6) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(7) The fluoroscopist's eyes should be sufficiently dark-adapted for the visual task required before commencing conventional fluoroscopy. Under no circumstances shall he attempt to compensate for inadequate adaptation by increasing exposure factors employed or by prolonging the fluoroscopic examination.

(8) Special precautions, consistent with clinical needs, shall be taken to minimize exposure of the gonads of potentially procreative patients and exposure of the embryo or fetus in patients known to be or suspected of being pregnant. Gonadal shielding is advised whenever it will not interfere with the conditions or objectives of the examination.

(9) In cineradiography, special care shall be taken to limit patient exposure when, as is often the case, tube currents and potentials employed are higher than those normally used in fluoroscopy. The exposure rates to which patients are normally subjected shall be determined quarterly and records of the surveys maintained.

(10) A fluoroscopic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

MOBILE OR PORTABLE DIAGNOSTIC X-RAY EQUIPMENT

R 325.5351. X-ray equipment.

Rule 351. (1) Radiographic x-ray equipment shall comply with the general requirements of rule 325 excluding subrules (11) and (18).

(2) Fluoroscopic x-ray equipment shall comply with the general requirements of rule 337 excluding subrules (5), (6), (7), (8) and (11).

(3) The radiographic exposure control switch shall be located on the machine where adequate personnel protection is provided to attenuate the direct and scatter radiation, or the length of switch cord shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) from the patient, the x-ray tube, and out of useful beam. A coil type extension switch cord capable of providing more than 1.8 meters (6 feet) of distance protection is recommended.

(4) Hand-held fluoroscopic screens and others not attached to a diagnostic source assembly with stable mounting shall not be used.

(5) Image intensification shall always be provided on mobile fluoroscopic equipment. It shall be impossible to operate mobile fluoroscopic equipment unless the useful beam is intercepted by the image intensifier. Means shall be provided to limit the source-skin distance to not less than 30 centimeters (12 inches). For fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subrule, provisions may be made for operation at shorter source- skin distances but in no case less than 20 centimeters.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5352. Shielding.

Rule 352. (1) Portable shielding shall be used by the operator and others in the room when possible, 1.6 millimeter (1/16 inch) lead equivalent.

(2) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the general requirements of rules 325 and 331 or rules 337 and 347 or both.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5353. Conditions of operation.

Rule 353. (1) Operation shall comply with the general requirements of rules 333 and 348.

(2) Individuals operating mobile or portable diagnostic x-ray equipment shall wear a protective apron of minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in rule 352 (1).

(3) Mobile or portable diagnostic x-ray equipment shall not be used for routine radiography or fluoroscopy in hospitals or private offices of practitioners of the healing arts. This equipment shall only be used when it is medically inadvisable to move a patient to a fixed radiographic or fixed fluoroscopic installation.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

MISCELLANEOUS AND SPECIAL INSTALLATIONS

R 325.5355. General provisions.

Rule 355. (1) Types of x-ray sources and uses not specifically covered by this part and not exempted in rule 182, shall comply with parts 1, 4 and 5.

(2) For the purpose of registering and approving medical x-ray producing equipment and devices not specifically covered by this part (e.g. therapy simulators) the protective design, the workload, the use factor and the occupancy factor shall be considered.

(3) Therapy simulators are considered special installations not specifically covered by this part and shall be subject to specific requirements designated by the department in the form of registration conditions for the protection of public health and safety until these rules are amended to specifically cover such sources and uses.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5357 Appendix A. Table 1.

Rule 357. Recommended shielding for medical diagnostic x-ray installations.*

	HIGH WORKLOAD HOSPITALS RADIOLOGY OFFICES		MODERATE WORKLOAD CLINICS		LOW WORKLOAD OFFICES	
Anticipated Workload	250-1000 mA-min/wk		15-250 mA-min/wk		0-15 mA-min/wk	
Thickness of shielding material or equivalent protection	Lead† (inches)	Concrete†† (inches)	Lead† (inches)	Concrete†† (inches)	Lead† (inches)	Concrete†† (inches)
OPERATOR SHIELDS	1/16 - 1/8	5 - 9	1/16	5	1/16	5
PRIMARY BEAMS						
Walls	1/16 - 1/8	5 - 9	1/16	5	1/16	5
Doors	1/16 - 1/8	- - -	1/16	- - -	1/16	- - -
Floors	3/32 - 1/8	6 ½ - 9	1/16 - 3/32	5 - 6 ½	1/16	5
SECONDARY RADIATION						
Walls	1/16	5	1/32 - 1/16	2 ½ - 5	0 - 1/32	0 - 2 ½
Doors	1/16	5	1/32 - 1/16	- - -	0 - 1/32	0 - 2 ½
Floors	1/16	5	1/32 - 1/16	2 ½ - 5	0 - 1/32	0 - 2 ½

Ceilings	1/16	2.5	1/32	2 ½	0 - 1/32	0 - 2 ½

* This table is provided only as a guideline for optimum shielding protection for a few typical radiographic workloads and conditions encountered in hospital, clinic and office situations. More or less shielding may be required in any specific case depending upon many variable factors. Shielding listed is that generally approved by the division of radiological health.

† Thickness ranging from 1/32-1/8 inch based on commercial lead sheets ranging from 2-8 pounds per square foot nominal weight.

†† Thickness based on concrete density of 2.35 grams per cubic centimeter (147 pounds per cubic foot).

[Note: As a result of Executive Order 2011-4, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Licensing and Regulatory Affairs. The reference in these rules to the Division of Radiological Health should now reference the Radiation Safety Section.]

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5358 Appendix A. Table 2.

Rule 358. Distances at which shielding may not be required for medical radiographic installations.*

	HIGH WORKLOAD HOSPITALS RADIOLOGY OFFICES	MODERATE WORKLOAD CLINICS	LOW WORKLOAD OFFICES
Anticipated Workload	250-1000 mA-min/wk	15-250 mA-min/wk	0-15 mA-min/wk
	DISTANCE IN FEET FROM X-RAY TUBE TO NEAREST OCCUPIED AREA		
PRIMARY BEAMS			
Area controlled	25 - 200	10 - 50	6 - 25
Area non-controlled	80 - 300	25 - 150	15 - 50
SECONDARY RADIATION			
Area controlled	10 - 25	3 - 15	0 - 10
Area non-controlled	30 - 80	10 - 40	15 - 15

* This table is provided only as a guideline to emphasize the need for protective shielding under most circumstances in typical installations. Distances may vary considerably depending upon many uncontrollable factors. Shielding is the preferred method of radiation protection because it can be precisely calculated and controlled.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5359. Appendix B. National Electrical Code
Rule 359. Excerpts from Articles 100, 500, 517 and 660.

ARTICLE 100 - DEFINITIONS

Approved: Acceptable to the authority having jurisdiction.

Approved for the Purpose: Approved for a specific purpose, environment, or application described in a particular Code requirement.

Ground: A conducting connection, whether intentional or accidental, between an electrical circuit or equipment and the earth, or to some conducting body that serves in place of the earth.

Grounded: Connected to earth or to some conducting body that serves in place of the earth.

Grounded Conductor: A system or circuit conductor that is intentionally grounded.

Grounding Conductor: A conductor used to connect equipment or the grounded circuit of a wiring system to a grounding electrode or electrodes.

Grounding Conductor Equipment: The conductor used to connect noncurrent- carrying metal parts of equipment, raceways, and other enclosures to the system grounded conductor at the service and/or the grounding electrode conductor.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

ARTICLE 500
HAZARDOUS (CLASSIFIED) LOCATIONS

500-4. Class I Locations. Class I locations are those in which flammable gases or vapors are or may be present in the air in quantities sufficient to produce explosive or ignitible mixtures. Class I locations shall include those specified in (a) and (b) below.

(a) Class I, Division 1. A Class I, Division 1 location is a location: (1) in which hazardous concentrations of flammable gases or vapors exist continuously, intermittently, or periodically under normal operating conditions; or (2) in which hazardous concentrations of such gases or vapors may exist frequently because of repair or maintenance operations or because of leakage; or (3) in which breakdown or faulty operation of equipment or processes that might release hazardous concentrations of flammable gases or vapors, and might also cause simultaneous failure of electric equipment.

ARTICLE 517 - HEALTH CARE FACILITIES

517-2. Definitions.

Anesthetizing Location. Any area in which it is intended to administer any flammable or nonflammable inhalation anesthetic agents in the course of examination or treatment and includes operating rooms, delivery rooms, emergency rooms, anesthetizing rooms, corridors, utility rooms and other areas when used for induction of anesthesia with flammable or nonflammable anesthetizing agents.

Critical Patient Care Area. A section (rooms, wards or portions of wards) designated for the treatment of critically ill patients.

Flammable Anesthetics. Gases or vapors such as fluroxene, cyclopropane, divinyl ether, ethyl chloride, ethyl ether, and ethylene, which may form flammable or explosive mixtures with air, oxygen, or reducing gases such as nitrous oxide.

Flammable Anesthetizing Location. Any operating room, delivery room, anesthetizing room, corridor, utility room, or any other area if used or intended for the application of flammable anesthetics.

Patient Grounding Point. A jack or terminal bus which serves as the collection point for redundant grounding of electric appliances serving a patient vicinity, and for grounding conductive furniture or nonelectric equipment within reach of a patient or a person who may touch him.

Patient Vicinity. The space with surfaces likely to be contacted by the patient or an attendant who can touch him. This represents a space 6 feet beyond the reach of the patient.

Reference Grounding Point. A terminal bus which is an extension of the equipment grounding bus and is a convenient collection point for grounding all electric appliances, equipment and exposed conductive surfaces in a patient vicinity.

Room Bonding Point. A grounding terminal bus which serves as a collection point for grounding exposed metal or conductive building surfaces in a room.

517-3. Grounding. In locations intended for occupancy by patients at any time, all noncurrent-carrying conductive surfaces of electrical equipment that are subject to personal contact shall be grounded by an insulated copper conductor, sized in accordance with Table 250-95, installed with the circuit conductors supplying these receptacles and equipment.

517-50. General.

(b) Patient Care areas shall be classified into one of the three following categories:
(1) General Care Area. Areas where patients ordinarily have only incidental contact with electrical devices.
(2) Critical Care Area, Controlled. Areas where patients ordinarily are intentionally exposed to electrical devices, and where the governing body requires protection (insulation) of

externalized cardiac conductors from contact with conductive surfaces other than those designed for connection to such cardiac conductors.

(3) Critical Care Area, Uncontrolled. Areas where patients ordinarily are intentionally exposed to electrical devices and where the governing body makes no requirements for protection of externalized cardiac conductors from contact with conductive surfaces other than those designed for the purpose.

517-51. Performance.

(a) Any two exposed conductive surfaces in the patient vicinity shall not exceed the following potential differences at frequencies of 1000 Hertz or less measured across a 1000 ohm resistance. Exception: Permanently installed x-ray equipment.

(1) General Care Areas. 500 mv under normal operation.

(2) Critical Care Areas, Controlled. 100 mv under normal operation.

(3) Critical Care Areas, Uncontrolled. 100 mv under normal operation or under conditions of line-to-ground fault.

(b) Special Requirements. The following requirements in both categories shall not apply to small portable nonelectric devices such as bed pans, chairs, and the like.

(1) General Care Areas. Each patient bed location shall be provided with a minimum of four single or two duplex receptacles, each receptacle shall be grounded by means of an insulated copper conductor sized in accordance with Table 250-95.

(2) Critical Care Areas. Each patient bed location shall be provided with a minimum of six single or three duplex receptacles, and grounded to the reference grounding point by means of an insulated copper equipment grounding conductor. Each patient bed location shall be provided with a patient
grounding point, grounded to the reference grounding point by means of an insulated continuous, stranded copper conductor, not smaller than No.10. All exposed conductive surfaces of portable equipment used in the patient vicinity, including those on double-insulated and nonelectric beds shall be grounded to the reference grounding point. One patient bed location shall not be served by more than one reference grounding point.

(7) The equipment grounding conductor for special purpose receptacles such as the operation of mobile x-ray equipment shall be extended to the reference grounding points for all locations likely to be served from such receptacles. When such a circuit is served from an isolated ungrounded system, the
grounding conductor need not be run with power conductors; however, the equipment grounding terminal of the special purpose receptacle shall be connected to the reference grounding point.

(c) Permanently Installed X-Ray Equipment.

(1) In addition to the grounding requirements of Article 660, permanently installed X-ray systems shall have a patient grounding point as described in
(b) above, located as close as possible to the patient support, and be connected to the metal frame of the patient support by a separate, insulated, continuous, stranded, copper conductor, not smaller than No. 4.

(2) The patient grounding point shall be connected to the ground conductor serving the X-ray equipment by an insulated, stranded, copper conductor not smaller than No. 10.

(3) The permanently installed X-ray system including all equipment powered from the X-ray generator power supply shall not be required to be powered by an isolated system. The equipment grounding conductors associated with the equipment shall have a maximum DC resistance of 0.025 ohms, as measured between the chassis and the patient ground point.

517-60. Anesthetizing Locations Classifications.

(a) Hazardous Location.
(1) Any room or space in which flammable anesthetics or volatile flammable disinfecting agents are stored shall be considered to be a Class I, Division 1 location throughout.
(2) In a flammable anesthetizing location, the entire area shall be considered to be a Class I, Division 1 location which shall extend upward to a level 5 feet above the floor.
(b) Other Than Hazardous Locations. The term "other than hazardous locations" shall apply to any operating rooms, delivery rooms, anesthesia rooms, corridors, utility rooms, and other areas permanently used for or intended for the exclusive use of nonflammable anesthetizing agents. Confirmation of other than hazardous locations shall be accomplished by a written policy by the hospital administration prohibiting the use of flammable anesthetics and posting of rooms. In such cases, the rooms are excluded from the requirements of Section 517-61, 517-62, 517-63(f) (2), and 517-63(f) (3) as applied to X-ray systems only.

517-61. Wiring and Equipment Within Hazardous Areas.

(a) In hazardous areas referred to in Section 517-60, all fixed wiring and equipment, and all portable equipment, including lamps and other utilization equipment, operating at more than 8 volts between conductors, shall conform to the requirements of Section 501-1 through 501-15 and Sections 501-16(a) and (b) for Class I, Division 1 locations. All such equipment shall be specifically approved for the hazardous atmospheres involved.
(b) Where a box, fitting or enclosure is partially, but not entirely, within a hazardous area, the hazardous area shall be considered to be extended to include the entire box, fitting or enclosure.
(c) Flexible cords, which are or may be used in hazardous areas for connection to portable utilization equipment, including lamps operating at more than 8 volts between conductors, shall be of a type approved for extra-hard usage, shall be of ample length, and shall include an additional conductor for grounding. A storage device for the flexible cord shall be provided, and shall not subject the cord to bending at a radius of less than 3 inches.
(d) Receptacles and attachment plugs in hazardous areas shall be listed for use in Class I, Group C hazardous locations, and shall have provision for the connection of a grounding conductor.

517-62. Wiring and Equipment in Nonhazardous or Above Hazardous Anesthetizing Areas.

(a) Wiring above a hazardous area as referred to in Section 517-60 or in a nonflammable anesthetizing area shall be installed in rigid raceways or shall be Type MI cable, Type ALS cable, Type CS cable, or Type MC cable which employs a continuous, impervious metallic sheath.

(b) Equipment which may produce arcs, sparks or particles of hot metal, such as lamps and lampholders for fixed lighting, cutouts, switches, receptacles, generators, motors, or other equipment having make-and-break or sliding contacts, shall be of the totally enclosed type or so constructed as to prevent escape of sparks or hot metal particles.

(f) Plugs and receptacles for connection of 250V, 50-ampere and 60-ampere AC medical equipment for use in nonhazardous areas of flammable anesthetic Anesthetizing Locations and in nonflammable Anesthetizing Locations shall be so arranged that the 60-ampere receptacle will accept either the 50- ampere or the 60-ampere plug. 50-ampere receptacles shall be designed so as not to accept the 60-ampere attachment plug. The plugs shall be of the two-pole, 3-wire design with a third contact connecting to the (green or green with yellow stripe) equipment grounding conductor of the electrical system.

517-63. Circuits in Anesthetizing Locations.

(a) Except as provided in Section 517-63(f) and (g), each circuit within, or partially within, an anesthetizing location as referred to in Section 517-60 shall be controlled by a switch having a disconnecting pole in each circuit conductor, and shall be isolated from any distribution system supplying areas other than anesthetizing locations. Such isolation shall be acceptable by means of one or more transformers having no electrical connection between primary and secondary windings, by means of motor- generator sets, or by means of suitable isolated batteries.

(f) Branch circuits supplying only fixed lighting fixtures in nonhazardous areas of anesthetizing locations other than surgical lighting fixtures, or supplying only approved permanently installed X-ray equipment shall be permitted to be supplied by a conventional grounded system, provided: (1) wiring for grounded and ungrounded circuits does not occupy the same raceways: (2) the lighting fixtures and the X-ray equipment (except the enclosed X-ray tube and the metal-enclosed high-voltage leads to the tube) are located at least 8 feet above the floor or outside the anesthetizing location; and (3) switches for the grounded circuits are located outside of the anesthetizing location.

(g) Components of an isolated power center approved for the purpose and its grounded primary feeder shall be permitted to be located in an anesthetizing location provided it is located in an other than hazardous area.

Note 1: For a description of approved permanently installed X-ray equipment, see Sections 3384, 3385, 3432, 3433, 4435, and 4437 of the Inhalation Anesthetics Standard, NFPA No. 56A-1973.

Note 2: Remote-control stations for remote-control switches shall be permitted in the anesthetizing location if the remote-control circuit is energized from the ungrounded distribution system.

517-65. Other Equipment.

(b) X-ray equipment installed or operated in an anesthetizing location as defined in Section 517-2 shall be provided with approved means for preventing accumulation of electrostatic charges. All X-ray control devices, switches, relays, meters, and transformers shall be totally

enclosed, and where installed or operated within a hazardous area, shall be approved for Class I, Group C locations. High-voltage wiring shall be effectively insulated from ground and adequately guarded against accidental contact. The entire installation shall comply with Article 660.

517-66. Grounding. In any anesthetizing area, all metallic raceways, and all noncurrent-carrying conductive portions of fixed or portable equipment including the conductive floor shall be grounded.

Exception: Equipment operating at not more than 8 volts between conductors shall not be required to be grounded.

ARTICLE 660 - X-RAY EQUIPMENT

660-2. Definitions.

Portable: X-ray equipment designed to be hand-carried.

Mobile: X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Transportable: X-ray equipment to be installed in a vehicle or that may be readily disassembled for transport in a vehicle.

Long-Time Rating: A rating based on an operating interval of five minutes or longer.

Momentary Rating: A rating based on an operating interval that does not exceed five seconds.

660-3. Hazardous Locations. Unless approved for the location, X-ray and related equipment shall not be installed or operated in hazardous locations. See Article 517, Part E.

660-4. Connection to Supply Circuit.
(a) Fixed and Stationary Equipment. Fixed and stationary X-ray equipment shall be connected to the power supply by means of a wiring method meeting the general requirements of this Code.

Exception: Equipment properly supplied by a branch circuit rated at not over 30 amperes shall be permitted to be supplied through a suitable attachment plug cap and hard-service cable or cord.

(b) Portable, Mobile, and Transportable Equipment. Individual branch circuits shall not be required for portable, mobile, and transportable medical X-ray equipment requiring a capacity of not over 60 amperes. Portable and mobile types of X-ray equipment of any capacity shall be supplied through a suitable hard-service cable or cord. Transportable X-ray equipment of

any capacity shall be permitted to be connected to its power supply by suitable connections and hard-service cable or cord.

(c) Over 600-Volt Supply. Circuits and equipment operated on a supply circuit of over 600 volts shall comply with Article 710.

660-5. Disconnecting Means. A disconnecting means of adequate capacity for at least 50 percent of the input required for the momentary rating or 100 percent of the input required for the long-time rating of the X-ray equipment, whichever is greater, shall be provided in the supply circuit. The disconnecting means shall be operable from a location readily accessible from the X-ray control. For equipment connected to a 120-volt branch circuit of 30 amperes or less, a grounding-type attachment plug cap and receptacle of proper rating shall be permitted to serve as a disconnecting means.

660-9. Minimum Size of Conductors. Sizes No. 18 or 16 fixture wires as specified in Section 725-16 and flexible cords shall be permitted for the control and operating circuits of X-ray and auxiliary equipment where protected by not larger than 20-ampere overcurrent devices.

D. Guarding and Grounding.

660-47. General.

(a) High-Voltage Parts. All high-voltage parts, including X-ray tubes, shall be mounted within grounded enclosures. Air, oil, gas, or other suitable insulating media shall be used to insulate the high voltage from the grounded enclosure. The connection from the high-voltage components shall be made with high-voltage shielded cables.

(b) Low-Voltage Cables. Low-voltage cables connecting to oil-filled units that are not completely sealed, such as transformers, condensers, oil coolers, and high-voltage switches, shall have insulation of the oil- resistance type.

660-48. Grounding.

Noncurrent-carrying metal parts of X-ray and associated equipment (controls, tables, X-ray tube supports, transformer tanks, shielded cables, X-ray tube head, etc.) shall be grounded in the manner specified in Article 250. Portable and mobile equipment shall be provided with an approved grounding-type attachment plug cap. In areas designated as critical care areas, X-ray equipment shall be grounded in the manner prescribed in Section 517-51.

Exception: Battery-operated equipment.

(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 8. MEDICAL EXTREMITY X-RAY INSTALLATIONS

R 325.5361. Purpose and scope.

Rule 361. (1) This part establishes requirements governing the use of x-radiation in any healing arts discipline for human extremity radiography only. As used in this part "extremity radiography" means radiography of the hand or arm excluding the shaft of the humerus or the foot or leg excluding the shaft of the femur.

(2) This part applies to all registrants who use x-radiation for the intentional exposure of human extremities only.

(3) In addition to the requirements of this part all registrants are subject to parts 1, 4 and 5 and all applicable provisions of the other parts. Registrants using x-radiation for intentional human exposure other than or in addition to extremity radiography are subject to part 7.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

FIXED RADIOGRAPHIC INSTALLATIONS

R 325.5362. X-ray equipment.

Rule 362. (1) All x-ray tube housings in fixed radiographic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in table I.

TABLE I

Operating kVp (Inherent plus added)	Minimum Total Filter
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(3) If the filter in the machine is not accessible for examination and the total filtration is not known subrule (2) may be assumed to have been met if the half-value layer is not less than

0.6 mm aluminum at 49 kVp
1.6 mm aluminum at 70 kVp
2.6 mm aluminum at 90 kVp

(4) Under conditions of subrule (3) for tube potentials above 90 kVp subrule

(2) may be assumed to have been met if the half-value layer is not less than that specified in table 2 in rule 325 (5).

(5) Beam-limiting devices (diaphragms, cones, adjustable collimators),capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(6) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-image distances (SID). The calibration shall be clearly and permanently recorded on the beam-limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(7) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(8) The size of the x-ray beam projected by fixed aperture beam-limiting devices, except those used for stereoradiography, shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(9) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable collimators shall provide the same precision.

(10) For radiographic procedures resulting in multiple views on a single x-ray film the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation.

(11) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch.

(12) Unless protective shielding is provided for the operator, the length of the exposure control switch cord or remote control location shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) away from the patient and the x-ray tube and out of the useful beam. When protective shielding is provided, the operator shall always be entirely behind the shield during the exposure.

(13) The control panel shall provide positive identification of the production of x-rays whenever the x-ray tube is energized. A milliammeter may comply with this subrule.

(14) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

(15) On radiographic x-ray machines manufactured after the effective date of these rules a signal audible to the operator shall indicate that the exposure has ended.

(16) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective

date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5365. Enclosures.

Rule 365. (1) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject to design approval by the department.

(2) Radiographic-room wall and floor areas exposed to the useful beam plus an area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors.

(3) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers. Common building materials often fulfill this requirement.

(4) A fixed barrier of 1.6 millimeters (1/16 inch) lead equivalence, such as a shielded wall partition or immobilized portable shield, is recommended for operator protection. When this protection is provided the operator shall be able to see and communicate with the patient from a shielded position.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

R 325.5366. Conditions of operation.

Rule 366. (1) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(2) The operator shall insure the presence of adequate filtration before any radiographic procedure.

(3) Staff personnel routinely working with or around radiation sources shall not be required by the licensee or registrant to hold film or restrain patients during radiography. If such procedure is permitted personnel exposure shall not exceed rule 205 or the procedure shall be prohibited.

(4) When a patient must be held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and he shall be so positioned that no part of his body will be struck by the useful beam and that his body is as far as possible from the edge of the useful beam.

(5) During each exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and the x-ray tube and outside the useful beam or behind a suitable barrier.

(6) Only individuals whose presence is necessary shall be permitted in the radiographic room during exposure. Each individual, except the patient, shall be protected by 0.5 millimeter minimum lead equivalent aprons unless protected by an approved primary barrier.

(7) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Personnel monitoring devices, such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(9) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(10) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(11) The gonads of children and persons who have not passed the reproductive age shall be protected from the useful beam either by the use of shielding (0.5 mm lead equivalent), collimation, or special gonad shields. Special gonadal aprons (0.25 mm lead equivalent) are commercially available and recommended for patient protection from secondary radiation.

(12) Intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image definition may reduce the clinical value of the examination. Film and screen speed combinations shall be carefully selected to produce the necessary clinical information with the least exposure to the patient consistent with current clinical judgment.

(13) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers unless otherwise tested to insure maximum information content of the developed film. Sight developing shall not be permitted except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(14) A radiographic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

MOBILE OR PORTABLE RADIOGRAPHIC EQUIPMENT

R 325.5368. General provisions.

Rule 368. (1) Radiographic x-ray equipment shall comply with the general requirements of rule 362.

(2) Mobile or portable radiographic x-ray equipment used routinely in 1 location shall be considered a fixed installation and enclosures shall comply with the general requirements of rule 365.

(3) Operation shall comply with the general requirements of rule 366.

History: 1954 ACS 85, Eff. Dec. 3, 1975.

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 9. DENTAL X-RAY INSTALLATIONS

R 325.5371. Purpose and scope.

Rule 371. (1) This part establishes requirements governing the use of x-radiation in dentistry.

(2) This part applies to all registrants who use x-radiation in dentistry for the intentional exposure of humans.

(3) In addition to the requirements of this part all registrants are subject to parts 1, 4 and 5 and all applicable provisions of the other parts.

(4) The dentist should be aware of the requirements of the Michigan department of labor with regard to the employment of persons under 18 in occupations involving x-ray equipment.

History: 1979 AC.

CONVENTIONAL (SINGLE TUBE) INSTALLATIONS

R 325.5372. Scope.

Rule 372. Rules 373 to 376 apply to installations consisting of a single x-ray source, its individual control unit, and protective enclosure used for the production of intra-oral radiographs.

History: 1979 AC.

R 325.5373 X-ray equipment.

Rule 373. (1) The tube housing shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than 2.0 millimeter aluminum for equipment capable of operating at potentials up to 70 kVp and shall not be less than 2.5 millimeter aluminum for equipment capable of operating at potentials greater than 70 kVp. The filter shall be located as near the window of the tube housing as possible.

(3) For diagnostic x-ray machines manufactured after the effective date of these rules the aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in table 1.

TABLE 1

Operating kVp	Minimum Total Filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50 - 70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(4) If the filter in the machine is not accessible for examination and the total filtration is not known subrule (3) may be assumed to have been met if the half-value layer is not less than
0.6 mm aluminum at 49 kVp
1.6 mm aluminum at 70 kVp
2.6 mm aluminum at 90 kVp
(5) Under conditions of subrule (4) for tube potentials above 90 kVp subrule (3) may be assumed to have been met if the half-value layer is not less than that specified in table 2.
(6) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in table 2.

TABLE 2

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (milli-meters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(7) If it is necessary to determine the half-value layer at an x-ray tube potential which is not listed in table 2, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve these beam quality requirements is in the useful beam during each exposure.
(8) Diaphragms or cones shall be provided for collimating the useful beam to a size no larger than clinically necessary and shall provide the same degree of protection as required of the tube housing. The diameter of the useful beam at the cone tip shall not be greater than 3 inches.

(9) Radiographic equipment manufactured after the effective date of these rules and designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam so that:

(a) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of not more than 7 centimeters.

(b) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of not more than 6 centimeters.

(10) For intra-oral film exposures, means (e.g. cones) shall be provided to limit the source-to-skin distance (SSD) to not less than 18 centimeters with apparatus operable above 50 kVp, and not less than 10 centimeters with apparatus not operable above 50 kVp. Open-ended cones are recommended to reduce scattered radiation.

(11) Mechanical support of the tube head and pointer cone shall maintain the exposure position without drift or vibration of sufficient magnitude to cause the need for manually restraining the tube or retaking the x-ray.

(12) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of any single exposure of the series in progress.

(13) If a recycling timer is employed, it shall not be possible to make a repeat exposure without release of the exposure switch to reset the timer.

(14) The exposure control switch shall have a circuit-closing contact which can be maintained only by continuous pressure on the switch by the operator.

(15) Unless protective shielding is provided for the operator, the length of the exposure control switch cord or remote control location shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) away from the patient and the x-ray tube and out of the useful beam.

(17) The control panel shall provide positive visual identification of the production of x-rays whenever the x-ray tube is energized. A milliammeter may comply with this subrule.

(18) On all diagnostic machines manufactured after the effective date of these rules a signal audible to the operator shall indicate that the exposure has ended.

(19) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set before the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

(20) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1979 AC.

R 325.5375. Shielding.

Rule 375. Conventional building materials in partitions, floors and ceilings may provide adequate radiation shielding for dental installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel or other suitable materials to the walls, floor and ceiling of an existing room. Shielding shall be subject to approval by the department.

History: 1979 AC.

R 325.5376. Conditions of operation.

Rule 376. (1) Deliberate exposure of an individual to the useful beam for training or demonstration purposes shall not be permitted unless there is a diagnostic need for the exposure and the exposure is prescribed by a dentist or physician.

(2) The operator or the assistant shall not hold the film in place for the patient during the exposure.

(3) During the exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and the x-ray tube and outside the useful beam or behind a suitable barrier.

(4) Only persons whose presence is necessary to conduct the radiographic examination shall be permitted in the radiographic room during exposure.

(5) The operator shall direct the x-ray tube such that the useful beam strikes a primary barrier or unoccupied area after emerging from the patient.

(6) Neither the tube housing nor the cone shall be hand-held during the exposure.

(7) Fluoroscopy shall not be used in dental examinations.

(8) The exposure to the patient shall be kept to the practical minimum consistent with clinical objectives.

(9) X-ray film with a minimum sensitivity of 12.0 to 24.0 reciprocal roentgens as specified in American standards association speed group D (A.S.A. PH 6.1-1961) shall be used for routine dental radiography.

(10) The x-ray beam and the film shall be aligned very carefully with the area to be radiographed.

(11) Film processing materials and techniques shall be those recommended by the x-ray film manufacturer unless otherwise tested to insure maximum information content of the developed film. Sight developing is not permitted except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(12) A variable intensity light source should be used for viewing the finished radiograph.

(13) A radiographic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1979 AC.

MULTIPLE TUBE INSTALLATIONS

R 325.5378. Scope.

Rule 378. Rules 379 to 381 apply to installations consisting of more than 1 x-ray source in the same room or of sources located in separate rooms. These installations may include 2 or more complete x-ray units (single tube units) or a combination of 2 or more tube heads operable from a single control panel (multiple tube units).

History: 1979 AC.

R 325.5379. X-ray equipment.

Rule 379. (1) X-ray equipment in multiple tube installations shall comply with the general requirements of rule 373 with regard to each tube housing assembly and each complete x-ray unit.

(2) When 2 or more x-ray tube heads are operated from a single exposure switch (multiple tube units), there shall be indication at the control panel showing which tube is connected and ready to be energized, and means to prevent energizing more than 1 tube head at the same time.

(3) For multiple tube units there shall be indication at the tube housing assembly when it is connected and ready to be energized.

History: 1979 AC.

R 325.5380. Shielding.

Rule 380. Conventional building materials in partitions, floors and ceilings may provide adequate radiation shielding for dental installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel or other suitable materials to the walls, floor and ceiling of an existing room. In multiple tube installations the possibility of exposure from multiple sources shall be considered. Shielding shall be subject to approval by the department.

History: 1979 AC.

R 325.5381. Conditions of operation.

Rule 381. Operation shall comply with the general requirements of rule 376.

History: 1979 AC.

PANORAMIC INSTALLATIONS

R 325.5383. Scope.

Rule 383. Rules 384 to 386 apply to panoramic installations and protective enclosures.

History: 1979 AC.

R 325.5384. X-ray equipment.

Rule 384 (1) X-ray equipment in panoramic installations shall comply with the general requirements of rule 373 excluding subrules (8) to (13).

(2) For purposes of this rule, "image receptor" means that portion of the x-ray film instantaneously exposed by the x-ray beam subtended by a beam- limiting diaphragm immediately adjacent to the front of the radiographic film, if the panoramic technique requires such a diaphragm.

(3) The x-ray tube housing shall be provided with a beam-limiting diaphragm which shall limit the field at the plane of the image receptor to dimensions not exceeding the dimensions of the image receptor, and shall align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(4) Mechanical support of the tube head and image receptor shall maintain beam alignment without drift or vibration of sufficient magnitude to cause the need for manually restraining the tube or retaking the x-ray.

(5) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch.

History: 1979 AC.

R 325.5385. Shielding.

Rule 385. Conventional building materials in partitions, floors and ceilings may provide adequate radiation shielding for panoramic installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel or other suitable materials to the walls, floor and ceiling of an existing room. Shielding shall be subject to approval by the department.

History: 1979 AC.

R 325.5386. Conditions of operation.

Rule 386. Operation shall comply with the general requirements of rule 376.

History: 1979 AC.

CEPHALOMETRIC INSTALLATIONS

R 325.5388. Scope.

Rule 388. Rules 389 to 391 apply to installations consisting of an x-ray source used for the production of radiographs of the skull or related extra- oral radiographs, its individual control unit, and protective enclosure.

History: 1979 AC.

R 325.5389. X-ray equipment.

Rule 389. (1) X-ray equipment in cephalometric installations shall comply with the general requirements of rule 373 excluding subrules (8), (9), (10), (11), and (15).

(2) Beam-limiting devices (diaphragms, cones, adjustable collimators), capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(3) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-film distances. This calibration shall be clearly and permanently recorded on the beam limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(4) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions not exceeding those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(5) The size of the x-ray beam projected by fixed aperture beam-limiting devices (except those used for stereoradiography) shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(6) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable beam-limiting devices shall provide the same precision.

(7) For radiographic procedures resulting in multiple views on a single x-ray film the beam-limiting device shall limit the x-ray field size to the recorded radiographic image within 2% of the SID. Covering a portion of the radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation.

History: 1979 AC.

R 325.5390. Shielding.

Rule 390. (1) The degree of protection required shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and shall be subject to design approval by the department.

(2) Radiographic-room wall and floor areas exposed to the useful beam plus an area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors. All vertical primary protective

barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(3) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers.

(4) Control apparatus for the radiographic equipment shall be shielded by a non-removable primary protective barrier extending to a minimum height of 2.1 meters (7 feet).

(5) Exposure switch location and control shield shall be oriented such that, at arm's length from the exposure switch, the operator shall not be exposed to the useful beam, leakage radiation or any radiation which has been scattered only once.

(6) The operator shall be able to see and communicate with the patient from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier and shall be installed such that the attenuation effectiveness of the barrier is not impaired.

History: 1979 AC.

R 325.5391. Conditions of operation.

Rule 391. Operation shall comply with the general requirements of rule 376 excluding subrule (3).

History: 1979 AC.

MULTIPLE PURPOSE INSTALLATIONS

R 325.5395. General provisions.

Rule 395. (1) This rule applies to installations consisting of an x-ray source or sources used for 2 or more purposes described and provided for in rules 372 to 391.

(2) X-ray equipment in multiple purpose installations shall comply with the applicable requirements of rules 373, 379, 384 and 389 for each mode of operation permitted by the design of the equipment.

(3) Shielding in multiple purpose installations shall comply with the applicable requirements of rules 375, 380, 385 and 390 for each mode of operation permitted by the design of the equipment.

(4) Operation in multiple purpose installations shall comply with the applicable requirements of rules 376, 381, 386 and 391 for each mode of operation permitted by the design of the equipment.

History: 1979 AC.

R 325.5396. Hand-held portable dental x-ray systems.

Rule 396. (1) X-ray equipment designed to be hand-held shall comply with the general requirements of R 325.5373, excluding subrules (11) and (15).

(2) The x-ray tube housing for tubes designed to be hand-held shall be constructed such that the leakage radiation measured in air at a distance 5 centimeters from any point on the external surface shall not exceed 0.02 mGy (2 milliroentgens) in 1 hour when operated under conditions of maximum
radiation output permitted by the design or operating characteristics of the radiation machine.

(3) Operation of a hand-held portable x-ray system shall comply with the general requirements of R 325.5376, excluding subrules (3) and (6).

(4) Protective shielding of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso, hands, face, and gonads from backscattered radiation. If the protective shielding is a backscatter shield attached to the unit, the shield shall be positioned as close to the patient as possible and the operator shall take care to remain in a protective position.

(5) Each operator shall complete the training program supplied by the manufacturer and approved by the department prior to using the x-ray unit. Records of the training shall be maintained on file for examination by the department.

(6) Hand-held dental x-ray systems shall not be used for routine dental radiography in dental offices. This equipment shall only be used for portable use including use in nursing homes, home health care, or for use on special needs patients.

History: 2007 AACS.

OTHER TYPES OF INSTALLATIONS

R 325.5397. General provisions.

Rule 397. (1) This rule applies to dental x-ray producing equipment and devices not specifically covered elsewhere by this part.

(2) Types of dental x-ray sources and uses not specifically covered by this part and not exempted under rule 182 shall comply with parts 1, 4 and 5.

History: 1979 AC.

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 10. VETERINARY X-RAY INSTALLATIONS

R 325.5401. Purpose and scope.

Rule 401. (1) This part establishes requirements governing the use of x-radiation in veterinary medicine.

(2) This part applies to all registrants who use x-radiation in veterinary medicine or research for the intentional exposure of animals.

(3) In addition to the requirements of this part all registrants are subject to parts 1, 4 and 5 and all applicable provisions of the other parts.

(4) The veterinarian should be aware of the requirements of the Michigan department of labor with regard to the employment of persons under 18 in occupations involving x-ray equipment.

History: 1979 AC.

THERAPEUTIC MACHINES USED FOR VETERINARY X-RAY TREATMENT

R 325.5402. X-ray equipment.

Rule 402. The x-ray equipment shall comply with the general requirements of rules 312 and 321.

History: 1979 AC.

R 325.5403. Enclosures.

Rule 403. The enclosure shall comply with the general requirements of rules 315 and 322.

History: 1979 AC.

R 325.5404. Conditions of operation.

Rule 404. (1) Operation shall comply with the general requirements of rule 317 excluding (2), (5), (6), and (11).

(2) The output of the x-ray generator should be calibrated initially before use for the treatment of animals. It should also be recalibrated after each tube replacement and after any changes or replacement in the generating apparatus which could effect a change in the x-ray output. Check calibrations should be made on an annual basis and records of all calibration maintained for not less than 5 years.

(3) Patients shall not be hand-held in position for radiation therapy. Mechanical supporting or restraining devices shall be used if restraint is required.

(4) A person shall not be permitted in the treatment room when the tube is operated at any potential.

(5) The x-ray tube of a contact therapy machine as defined in rule 321 (3) shall not be hand-held during irradiation. When practical, a cap of at least 0.5 millimeter lead equivalence should cover the aperture window of the tube housing of such apparatus when the apparatus is not being used. Because the exposure rate at the surface of the window of contact therapy and

beryllium window machines may be more than 10,000 R per minute, extreme precautions are necessary to prevent accidental exposure to the useful beam.

(6) Lead, lead rubber, lead foil and similar materials used for limiting the field, should not transmit more than 5% of the useful beam under the conditions at which the machine is operated for therapy.

History: 1979 AC.

FIXED RADIOGRAPHIC INSTALLATIONS

R 325.5405. X-ray equipment.

Rule 405. (1) All x-ray tube housings in fixed radiographic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than the values shown in table 1.

TABLE 1

Operating kVp (Inherent plus added)	Minimum Total Filter
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(3) Beam-limiting devices (diaphragms, cones, adjustable collimators) capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(4) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-image distances (SID). This calibration shall be clearly and permanently recorded on the beam-limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(5) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions not greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(6) General purpose radiographic x-ray systems should be equipped with adjustable beam-limiting devices containing light localizers that define the entire field. Rectangular beam-limiting devices are usually preferable.

(7) The size of the x-ray beam projected by fixed aperture beam-limiting devices, except those used for stereoradiography, shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(8) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable beam-limiting devices shall provide the same precision.

(9) For radiographic procedures resulting in multiple views on a single x-ray film the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation. This subrule does not apply to spotfilm devices manufactured before the effective date of these rules.

(10) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at any time by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of any single exposure of the series in progress.

(11) A primary radiographic exposure switch shall be provided which shall be securely fixed such that the operator is required to be behind a fixed shield which will intercept the useful beam and any radiation which has been scattered only once.

(12) An auxiliary foot switch may be provided to activate the radiographic tube in addition to but not in substitution of the requirement of subrule (11). This auxiliary switch need not be fastened behind a fixed shield.

(13) The control panel shall provide positive visual identification of the production of x-rays whenever the x-ray tube is energized. A milliammeter may comply with this subrule.

(14) On diagnostic x-ray systems manufactured after the effective date of these rules, a signal audible to the operator shall indicate that the exposure has ended.

(15) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set before the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

(16) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1979 AC.

R 325.5407. Enclosures.

Rule 407 (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and shall be subject to design approval by the department.

(3) Radiographic-room wall and floor areas exposed to the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary as determined by workload, use, occupancy and distance factors.

All vertical primary protective barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(4) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers.

(5) Control apparatus for the radiographic equipment shall be shielded by a primary protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(6) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with subrule (5).

(7) The primary exposure switch location and control shield shall be oriented so that, at arm's length from the exposure switch, the operator shall not be exposed to the useful beam, leakage radiation or any radiation which has been scattered only once.

(8) The operator shall be able to see and communicate with personnel within the room from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier and shall be installed so that the attenuation effectiveness of the barrier is not impaired.

(9) At times it may be necessary for personnel to remain within operating room or special procedure installations during radiographic exposures. A primary protective barrier shall be provided for personnel protection under these circumstances unless necessary technique prevents use of such protection. This barrier may be movable if necessary. Movable barriers shall not be permitted in lieu of the provisions of subrules (3) and (5).

History: 1979 AC.

R 325.5409. Conditions of operation.

Rule 409. (1) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(2) The operator shall insure the presence of adequate filtration before any radiographic procedure. See rule 405 (2).

(3) When a patient or film must be held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. Proper use of these devices shall permit the operator to stand behind the primary control shield during most radiographic procedures.

(4) If the patient or film must be held by 1 or more individuals, each individual shall wear protective gloves and body aprons of 0.5 millimeter minimum lead equivalence as well as head and neck protection of 0.25 millimeter minimum lead equivalence. Each person shall be so positioned that no part of his body will be struck by the useful beam and that his body is as far as possible from the edge of the useful beam.

(5) Only individuals whose presence is necessary shall be permitted in the radiographic room during exposure. These individuals shall be protected as specified in subrule (4) unless protected by an approved primary barrier.

(6) If an auxiliary foot switch is provided as specified in rule 405 (12), it shall be used only be a licensed veterinarian and only at times when sufficient personnel are not available to permit use of the primary exposureswitch specified in rule 405 (11).

(7) To protect the feet of the veterinarian or his assistant from the primary beam while restraining patients, the underside of the radiographic table shall be protected by at least 1.6 millimeter (1/16 inch) lead or equivalent protection approved by the department.

(8) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(10) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222.

(11) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(12) Medical x-ray screen type films and intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image definition resulting from increased sensitivity may reduce the clinical value of the examination.

(13) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers unless otherwise tested to insure maximum information content of the developed film. Sight developing is not permitted except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(14) A radiographic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1979 AC.

FIXED FLUOROSCOPIC INSTALLATIONS

R 325.5411. X-ray equipment.

Rule 411. (1) All x-ray tube housings in fixed fluoroscopic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum.

(3) The source-patient distance on fluoroscopic machines manufactured before the effective date of these rules should not be less than 45 centimeters (18 inches) and shall not be less than 30 centimeters (12 inches).

(4) Provision shall be made to intercept the scattered x-rays from the undersurface of the table top and other structures under the fluoroscopic table if the tube is mounted under the

table. A cone or shield shall provide the same degree of attenuation as is required of the tube housing.

(5) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence for covering the bucky slot during fluoroscopy shall be provided.

(6) On fluoroscopic machines manufactured after the effective date of these rules a shielding device of at least 0.25 millimeter lead equivalence, such as overlapping protective drapes or hinged or sliding panels, shall be used to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.

(7) The equipment shall be so constructed that, under conditions of normal use, the entire cross-section of the useful beam is attenuated by a primary protective barrier, permanently incorporated into the equipment. The exposure shall automatically terminate when the barrier is removed from the useful beam.

(8) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) The entrance exposure rate shall be measured in accordance with subrule (18). The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by
measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, if it is not closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of the entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(9) The lead equivalence of the barrier of conventional fluoroscopes shall be not less than 1.5 millimeters at 100 kVp, 1.8 millimeters at 125 kVp, and 2.0 millimeters at potentials greater than 125 kVp.

(10) A beam-limiting device shall be provided to restrict the size of the useful beam to less than the area of the barrier. The x-ray tube and beam- limiting system shall be linked with the fluorescent screen assembly so that the useful beam at the fluorescent screen is confined within the barrier irrespective of the panel-screen distance. For image intensifiers, the useful beam shall be centered on the input phosphor. It should not exceed the diameter of the input phosphor during fluoroscopy or cine- recording. Ideally, for spot film radiography with image intensifier equipment, the shutters should automatically open to the required field size before such exposure.

(11) Beam-limiting devices (collimators, adjustable diaphragms or shutters) shall provide the same degree of attenuation as is required of the tube housing.

(12) When the beam-limiting device is opened to its fullest extent, a minimum 1/4 inch unilluminated margin shall exist at all edges of the fluorescent screen when the screen is 35 centimeters (14 inches) from the panel surface or table top, or at the fixed screen position in equipment such
as an orthodiascope. In equipment used solely for image intensified fluoroscopy, the x-ray beam shall not have dimensions greater than the diameter of the input phosphor.

(13) On fluoroscopic machines manufactured after the effective date of these rules:

(a) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5
centimeters.

(b) For image-intensified fluoroscopic equipment, the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3% of the SID.The sum, without regard to sign, of the misalignment along any 2 orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4% of the SID. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(14) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in progress.

(15) When the fluoroscope is operated at 80 kVp, the exposure rate at the position where the beam enters the patient shall not exceed 3.2 R/mA-min and should not exceed 2.1 R/mA-min.

(16) The entrance exposure rate at the position where the center of the useful beam enters the patient should be as low as is consistent with the fluoroscopic requirements and shall not normally exceed 10 R/min. With modern equipment, most fluoroscopy can be carried out with entrance exposure rates of less than 5 R/min.

(17) Entrance exposure rate limits for fluoroscopic machines manufactured after the effective date of these rules shall be as follows:

(a) Machines with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A

continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) Machines without automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(18) Compliance with subrules (16) and (17) shall be determined as follows:

(a) If the source is below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(b) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(c) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(19) A cumulative timing device, activated by the fluoroscope exposure switch, shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(20) On fluoroscopic machines manufactured after the effective date of these rules means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on- time. This signal shall continue to sound while x-rays are produced until the timing device is reset.

(21) Devices which indicate the x-ray tube potential and current shall be provided. On image intensified fluoroscopic equipment, these devices should be located in such a manner that the operator may monitor the tube potential and current during fluoroscopy.

(22) All x-ray equipment shall be installed and used in accord with article 660 of the national electrical code which is reproduced in rule 359.

History: 1979 AC.

R 325.5417. Enclosures.

Rule 417. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement and distance factor, and shall be subject
to design approval by the department.

(3) For conventional fluoroscopy extraneous light that interferes with the fluoroscopic examination shall be eliminated. Dark adaptation normally is not necessary when using image intensifiers.

History: 1979 AC.

R 325.5418. Conditions of operation.

Rule 418. (1) Each individual present in a fluoroscopic room shall wear a protective apron of at least 0.5 millimeter lead equivalence.

(2) Only individuals whose presence is needed to conduct the examination, to conduct radiation protection surveys or undergoing specific training shall be permitted in the fluoroscopy room during x-ray exposures.

(3) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Personnel monitoring devices such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(5) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with rule 222. Since employees involved in fluoroscopic procedures are required to wear protective aprons and may be subjected to non-uniform radiation fields, a dosimeter assigned to monitor whole body exposure will not necessarily record the dose most representative of exposure to the lens of the eye. To monitor this critical area for which the exposure limit is the same as for whole body, active blood-forming organs, or gonads, an auxiliary dosimeter shall be provided in accord with rule 222.

(6) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he is exposed as a patient for any medical or dental reason.

(7) The fluoroscopist's eyes should be sufficiently dark-adapted for the visual task required before commencing conventional fluoroscopy. Under no circumstances shall he attempt to compensate for inadequate adaptation by increasing exposure factors employed or by prolonging the fluoroscopic examination.

(8) A fluoroscopic x-ray system shall not be left unattended without locking the apparatus, room or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 1979 AC.

MOBILE OR PORTABLE DIAGNOSTIC X-RAY EQUIPMENT

R 325.5421. X-ray equipment.

Rule 421. (1) Radiographic x-ray equipment shall comply with the general requirements of rule 405 excluding subrules (5) and (11).

(2) Fluoroscopic x-ray equipment shall comply with the general requirements of rule 411 excluding subrules (4), (5), (6) and (9).

(3) The radiographic exposure control switch shall be located on the machine where adequate personnel protection is provided to attenuate the direct and scatter radiation, or the length of switch cord shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) from the patient, the x-ray tube, and out of the useful beam. A coil type extension switch cord capable of providing more than 1.8 meters (6 feet) of distance protection is recommended.

(4) Hand-held fluoroscopic screens and others not attached to a diagnostic source assembly with stable mounting shall not be used.

(5) Image intensification shall always be provided on mobile fluoroscopic equipment. It shall be impossible to operate mobile fluoroscopic equipment unless the useful beam is intercepted by the image intensifier. Means shall be provided to limit the source-skin distance to not less than 30 centimeters (12 inches). For fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subrule, provisions may be made for operation at shorter source- skin distances but in no case less than 20 centimeters.

History: 1979 AC.

R 325.5422. Shielding.

Rule 422. (1) Portable shielding shall be used by the operator and others nearby when possible, 1.6 millimeter (1/16 inch) lead equivalent.

(2) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the general requirements of rules 405 and 407 or rules 411 and 417 or both.

History: 1979 AC.

R 325.5423. Conditions of operation.

Rule 423. (1) Operation shall comply with the general requirements of rules 409 and 418.

(2) Individuals operating mobile or portable diagnostic x-ray equipment shall wear a protective apron of minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in subrule (1) of rule 422.

History: 1979 AC.

MISCELLANEOUS AND SPECIAL INSTALLATIONS

R 325.5425. General provisions.

Rule 425. (1) Types of x-ray sources and uses not specifically covered by this part and not exempted in rule 182, shall comply with parts 1, 4 and 5.

(2) For the purpose of registering and approving veterinary x-ray producing equipment and devices not specifically covered by this part the protective design, the workload, the use factor and the occupancy factor shall be considered.

History: 1979 AC.

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.

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 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.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

BUREAU OF HEALTH CARE SERVICES - RADIATION SAFETY SECTION

IONIZING RADIATION RULES – PART 14. MAMMOGRAPHY

(By authority conferred on the director of the department of licensing and regulatory affairs by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, and 2011-4 being MCL 330.3101, 445.2001, 445.2011, and 445.2030)

GENERAL PROVISIONS

R 325.5601 Purpose and scope.

Rule 601. (1) This part establishes requirements governing the use of x-radiation for mammography and applies to all persons who use x-radiation for mammography for the intentional exposure of humans. A person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department pursuant to R 325.5181 to R 325.5196 and is specifically authorized to perform mammography pursuant to the act.

(2) In addition to the requirements of this part, all persons are subject to all applicable provisions of R 325.5001 to R 325.5721.

(3) A facility shall not misrepresent to its employees, to the public, or to the department its status with respect to accreditation of the mammography equipment by the American college of radiology, department authorization to perform mammography, or compliance with department rules.

History: 1993 AACS; 2013 AACS.

R 325.5601a Adoption by reference.

Rule 601a. Some of these rules refer to all or parts of the following nationally recognized standards, which are adopted by reference and identified by date:

(a) Standards of the United States department of health & human services, title 21 - food and drugs, part 900 - mammography. These standards are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety

section at http://www.michigan.gov/rss

(ii) The website of the United States department of health & human services, mammography quality standards act and program at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm

(b) The regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (April 2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (June 2005). These regulations are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss

(ii) The website of the United States department of health & human services, U.S. Food and Drug Administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

(c) Criteria of the American college of radiology, "Mammography Accreditation Program Requirements" (May 2012), and "Stereotactic Breast Biopsy Accreditation Program Requirements" (May 2012). These criteria are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(ii) The website of the American college of radiology at http://www.acr.org.

History: 2013 AACS.

R 325.5602 Definitions.

Rule 602. (1) As used in this part the definitions in 21 C.F.R. 900.2, "Definitions" (2002), are adopted by reference with the exception of the definition of "mammography."

(2) As used in this part the following definitions apply:

(a) "Act" means 1978 PA 368, as amended, MCL 333.1101 to 333.25211.

(b) "Annual" means a period of 12 consecutive months.

(c) "Interpreting physician" means a physician who interprets mammograms and who meets the requirements of R 325.5627 to R 325.5629.

(d) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast. Mammography includes interventional mammography.

(e) "Stereotactic breast biopsy" means the imaging of a breast performed in at least 2 planes to localize a target lesion during invasive interventions for biopsy procedures.

(f) "Stereotactic breast biopsy physician" means a physician licensed under article 15 of the act who conducts stereotactic breast biopsy.

(3) The terms defined in the act shall have the same meanings when used in these rules.

History: 1993 AACS; 2013 AACS.

R 325.5603 Department inspections.

Rule 603. (1) The department shall inspect a mammography machine and system not later than 60 days after initial mammography authorization is issued. After that initial inspection, the department shall annually inspect the mammography machine and system. The department may

inspect more frequently than annually.

(2) After each satisfactory inspection by the department, the department shall issue a certificate of radiation machine inspection which identifies the facility and the machine inspected and which provides a record of the date that the machine was inspected. The facility shall conspicuously post the certificate on or near the inspected machine and in a location that is observable by patients.

(3) The department may issue a notice of violations certificate if violations found during an inspection are not corrected within the specified time limit or if the department has not received written verification of corrections within the specified time limit. The notice of violations certificate shall be conspicuously posted on or near the inspected machine and in a location observable by patients.

(4) A facility shall remove the certificate of radiation machine inspection if directed by the department due to subsequent failure to comply with this part and applicable provisions of R 325.5001 to R 325.5721 as determined by follow-up inspections by the department.

(5) In conducting inspections, the department shall have access to all equipment, materials, records, personnel, and information that the department considers necessary to determine compliance with these rules. The department may copy, or require the facility to submit to the department, any of the materials, records, or information considered necessary to determine compliance with these rules.

(6) The department shall designate department employees to conduct regulatory inspections.

(7) The department may conduct tests and evaluations as the department deems appropriate to determine compliance with all of the provisions of this part and the provisions of R 325.5001 to R 325.5721.

History: 1993 AACS; 2013 AACS.

MAMMOGRAPHY AUTHORIZATION

R 325.5605 Standards for authorization.

Rule 605. The department shall issue a 3-year mammography authorization if the mammography facility is in compliance with all of the following standards:

(a) The radiation machine meets any of the following requirements:

(i) The machine and the facility in which the machine is used meet the criteria for the American college of radiology mammography accreditation program dated May 2012, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only.

(ii) A machine used for stereotactic breast biopsy and the facility in which the machine is used meet the criteria of the American college of radiology stereotactic breast biopsy accreditation program dated May 2012, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only. A mammography machine that uses a specially designed add-on device for breast biopsy shall be authorized for both mammography and stereotactic breast biopsy.

(iii) The machine is used in a facility that has successfully completed the department's evaluation of the items described in R 325.5610.

(b) The radiation machine, the film or other image receptor that is used with the machine, and the facility where the machine is used comply with the requirements of this part and applicable provisions of R 325.5001 to R 325.5721.

(c) The radiation machine is specifically designed to perform mammography.

(d) The radiation machine is used exclusively to perform mammography.

(e) The radiation machine is used in a facility that, before the machine is used on patients and at least annually thereafter, has a qualified medical physicist provide on-site consultation to the facility as described in these rules. Records and findings of on-site consultations shall be maintained for not less than 7 years.

(f) The radiation machine is used according to R 325.5667 of this part or R 325.5690 for stereotactic breast biopsy.

(g) The radiation machine is operated only by an individual who can demonstrate to the department that he or she meets the standards described in this part.

History: 1993 AACS; 2013 AACS.

R 325.5606 Temporary mammography authorization.

Rule 606. (1) The department may issue a nonrenewable temporary mammography authorization. A temporary authorization may only be issued if additional time is needed to allow the submission of evidence that is satisfactory to the department to demonstrate compliance with the provisions of R 325.5605.

(2) The department may withdraw a temporary authorization before its expiration if the radiation machine does not meet 1 or more of the criteria specified in R 325.5605.

History: 1993 AACS.

R 325.5607 Application.

Rule 607. (1) An applicant who seeks mammography authorization shall apply to the department using an application form that is supplied by the department. If mammography is performed at more than 1 address, a separate application shall be used for each address. An applicant shall accurately provide all information that is requested on the form. The information submitted as part of the application shall be sufficient, as determined by the department, to address all of the standards for authorization. Applications that do not provide sufficient information shall be returned to the applicant for completion and resubmission. Applications shall include all of the following information:

(a) Information about the facility, including all of the following:

(i) Mammography facility name, address, and telephone number.

(ii) Type of practice.

(iii) The facility registration number, if currently registered.

(iv) A contact person’s name and telephone number.

(b) Personnel information, including the education, training, experience, and certification of the lead interpreting physician, any qualified medical physicist who provides on-site consultation,

and any radiologic technologist who performs mammography.

(c) Mammography machine technical information, including all of the following:

(i) Machine registration number, if currently registered.

(ii) Manufacturer.

(iii) Model.

(iv) Target material.

(v) Filter material.

(d) Imaging system information, including all of the following:

(i) The type of imaging system being used.

(ii) Review workstation monitor information, if the machine uses digital imaging.

(iii) Laser printer information, as applicable, for machines using digital imaging.

(iv) Film and screen information, if the machine uses screen-film imaging.

(v) Film processor information, if the machine uses screen-film imaging.

(e) The date of the most recent medical physicist survey.

(2) The department shall respond to an application within 30 days after the date of receipt of the application.

History: 1993 AACS; 2013 AACS.

R 325.5608 Application fee schedule; waiver.

Rule 608. (1) An application form for mammography authorization shall be accompanied by a nonrefundable payment, in full, by the applicant, for department evaluation of compliance with the provisions of R 325.5605 (a). The fee schedule is specified in the act.

(2) If an applicant for mammography authorization submits an evaluation report which is issued by the American college of radiology and which demonstrates compliance with the provisions of R 325.5605 (a), then the fee for department evaluation of compliance with the provisions of R 325.5605 (a) shall be waived.

History: 1993 AACS; 2013 AACS.

R 325.5609 Application expiration.

Rule 609. An application for mammography authorization submitted to the department shall expire 6 months from the date of the department's receipt of the completed application unless the time limit is extended by the department.

History: 1993 AACS.

R 325.5610 Supplemental machine information; effect of failure to submit information.

Rule 610. (1) Upon notice from the department that an application for mammography authorization is complete and complies with these rules and at the specific request of the department, the applicant shall, within 45 days of the department's request, provide all of the following information for each radiation machine for which mammography authorization is being sought:

(a) Confirmation that a department-approved mammography phantom is on-site when mammography is performed and is used in the facility's ongoing quality control program.

(b) Processor or laser film printer quality control data and corrective actions, if any, taken as a result of that data for a 30-day period beginning after the date the application was sent to the department.

(c) An x-ray image of a department-approved mammography phantom which is taken during the 30-day period for which processor quality control data is required under subdivision (b) of this subrule. The phantom image shall be taken using routine machine settings being used by the facility for that mammography machine for a 4.2-centimeter compressed breast of average density. The phantom image shall be accompanied by documentation of the date that the image was taken and the machine settings that were used.

(d) Determinations of the half-value layer, radiation exposure at skin entrance, and mean glandular dose that are made with the use of a department-approved dosimetry device exposed on the phantom during the same exposure of the phantom that is used to produce an x-ray image to be submitted under subdivision (c) of this subrule or that are made by other methods as specified or approved by the department.

(e) A set of clinical images produced on or after the date that the application was sent to the department. Mammography images shall be without pathology for each of 2 representative patients, 1 with dense breasts and 1 with fatty breasts. Stereotactic breast biopsy images shall be from 1 calcification biopsy case that demonstrates accurate needle location and includes the case's corresponding mammograms. The submitted images shall meet all of the following:

(i) The cases are examples of the facility's best work.

(ii) The images are from actual patients.

(iii) Both screen-film and digital images are labeled with the identification information required in R 325.5657 for mammography images or R 325.5683 for stereotactic breast biopsy images.

(iv) The lead interpreting physician reviews and approves the clinical images.

(2) The department may waive the requirements of subrule (1) of this rule if the mammography machine is accredited, or is in the process of becoming accredited, by the American college of radiology. To have the requirements of subrule (1) of this rule waived, an applicant shall provide, to the department, within 45 days of the department's request, copies of the applicant's current accreditation application, current accreditation-related correspondence to and from the American college of radiology, or current accreditation certificate that is issued by the American college of radiology.

(3) Failure of an applicant to submit the information required by the provisions of either subrule (1) or (2) of this rule within 45 days of the department's request may be considered a basis for withdrawal or denial of the mammography authorization, unless the time limit is extended by the department for cause.

History: 1993 AACS; 2013 AACS.

R 325.5611 Contracts for technical evaluation.

Rule 611. (1) In evaluating clinical image quality and acceptability for mammography authorization, upon receipt of the information required in R 325.5610 (1) (e), the department may enter into any necessary contracts with mammography experts, submit the images to those experts for technical evaluation, and rely upon their expert evaluation in arriving at a department

conclusion regarding image quality and acceptability in terms of granting or not granting mammography authorization.

(2) Technical parameters that are used in evaluating clinical image quality and acceptability pursuant to subrule (1) of this rule shall include judgments of all of the following:

(a) Positioning.

(b) Compression.

(c) Radiation exposure and dose level.

(d) Sharpness.

(e) Contrast.

(f) Noise.

(g) Exam identification.

(h) Artifacts.

History: 1993 AACS; 2013 AACS.

R 325.5612 Notice of change in application information; authorization not transferable.

Rule 612. (1) A facility that is authorized to perform mammography shall notify the department, in writing, of any change in the information contained in the application or supporting material upon which authorization was granted or any change that affects the accuracy of information which is provided or obtained during the application and evaluation process for authorization. Changes that shall be reported include changes in any of the following:

(a) Facility ownership.

(b) Facility location.

(c) Mammography machine.

(d) Image modality.

(e) American college of radiology accreditation status.

(2) Upon receipt of a notice of change, the department shall advise the facility if reapplication for mammography authorization, resubmittal of phantom or clinical images, or other actions are deemed by the department to be necessary to establish that the facility, machine, system, and personnel remain in compliance with the requirements of these rules. Upon department request, a facility shall provide any requested information or materials within 45 days after the request is made.

(3) If changes in information are deemed to require reapplication for mammography authorization, the application shall be filed and processed in the same manner as set forth in R 325.5607 and R 325.5608.

(4) Mammography authorization that is issued by the department is not transferable between machines or between persons who own or lease a radiation machine.

History: 1993 AACS; 2013 AACS.

R 325.5613 Authorization withdrawal; reinstatement.

Rule 613. (1) Three-year mammography authorization is subject to continued compliance with this part and the provisions of R 325.5001 to R 325.5721. Authorization may be withdrawn

based on evidence of noncompliance with this part and the provisions of R 325.5001 to R 325.5721 in accordance with the provisions of 1969 PA 306, MCL 24.201 to 24.328.

(2) If the department withdraws the mammography authorization of a machine, the machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization under R 325.5607 and R 325.5608.

(3) The department shall not issue a reinstated mammography authorization until the department receives the reinspection fee, inspects the machine, and determines that the facility meets the standards in R 325.5605.

History: 1993 AACS; 2013 AACS.

MAMMOGRAPHY SUPERVISOR

R 325.5617 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5618 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5619 Rescinded.

History: 1993 AACS; 2013 AACS.

OPERATORS OF MAMMOGRAPHY EQUIPMENT

R 325.5621 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5622 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5623 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5624 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5625 Rescinded.

History: 1993 AACS; 2013 AACS.

PERSONNEL

R 325.5626 Scope of personnel requirements.
Rule 626. The requirements of R 325.5627 to R 325.5634 apply to all personnel involved in any aspect of mammography, including but not limited to, the production, processing, and interpretation of mammograms and related quality assurance activities.

History: 2013 AACS.

R 325.5627 Interpreting physician initial qualifications.
Rule 627. Before beginning to interpret mammograms independently, an interpreting physician shall meet all of the following requirements:

(a) Be licensed as a physician or osteopathic physician under article 15 of the act to practice medicine.

(b) Meet either of the following requirements:

(i) Be certified in radiology or diagnostic radiology by the American board of radiology, the American osteopathic board of radiology, or the royal college of physicians and surgeons of Canada; have been eligible for certification in radiology or diagnostic radiology for not more than 2 years; or, be certified or determined to be qualified in radiology or diagnostic radiology by another professional organization determined by the department to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography.

(ii) If the physician has been eligible for certification in radiology or diagnostic radiology for less than 2 years, he or she shall have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component of the training shall be under the direct supervision of a physician who meets the requirements of this rule.

(c) Have a minimum of 60 hours of documented medical education in mammography, including instruction in the interpretation of mammograms and education in basic breast anatomy,

pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category 1 and at least 15 of the category 1 hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography are considered as equivalent to category 1 continuing education credits and shall be accepted if documented in writing by the appropriate representative of the training institution. A physician who meets the board certification requirements of subdivision (b) (i) of this rule is deemed to have met this requirement.

(d) Have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualified as an interpreting physician. The interpretation or multi-reading shall be under the direct supervision of an interpreting physician. A physician who becomes appropriately board certified at the first allowable time, as defined by an eligible certifying body, shall have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency. A physician who was qualified to interpret mammograms prior to the effective date of this rule is considered to have met the requirements of this subdivision.

History: 2013 AACS.

R 325.5628 Interpreting physician continuing experience and education.

Rule 628. An interpreting physician shall maintain his or her qualifications by meeting the continuing experience and education requirements of 21 C.F.R. 900.12 (a) (1) (ii), "Personnel – Interpreting physicians – Continuing experience and education" (2000).

History: 2013 AACS.

R 325.5629 Interpreting physician reestablishment of qualifications.

Rule 629. An interpreting physician who failed to maintain the required continuing experience or continuing education requirements of R 325.5628 shall reestablish his or her qualifications before resuming the independent interpretation of mammograms by meeting the reestablishing qualifications requirements of 21 C.F.R. 900.12 (a) (1) (iv), "Personnel – Interpreting physicians – Reestablishing qualifications" (2000).

History: 2013 AACS.

R 325.5630 Radiologic technologists.

Rule 630. All mammographic examinations shall be performed by a radiologic technologist who meets the general requirements, mammography requirements, continuing education requirements, and continuing experience requirements of 21 C.F.R. 900.12 (a) (2), "Radiologic technologists" (2000), with the exception of 21 C.F.R. 900.12 (a) (2) (i) (A).

History: 2013 AACS.

RADIATION PHYSICIST

R 325.5631 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5632 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5633 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5634 Medical physicists.

Rule 634. A medical physicist who conducts surveys of mammography facilities and provides oversight of a facility's quality assurance program shall meet the initial qualifications, continuing qualifications and reestablishing qualification requirements of 21 C.F.R. 900.12 (a) (3), "Medical physicists" (2000).

History: 2013 AACS.

R 325.5635 Retention of personnel records.

Rule 635. A mammography facility shall maintain records to document the qualifications of all personnel who work at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records shall be made available for review during department inspections. Records of personnel no longer employed by the mammography facility shall be kept on file until the next inspection following the employee's termination has been completed, and the department determines that the facility complies with the personnel requirements.

History: 2013 AACS.

X-RAY EQUIPMENT

R 325.5637 X-ray equipment; requirements.

Rule 637. (1) The mammographic x-ray equipment shall be maintained in compliance with the applicable regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major

components" (2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (2005).

(2) The mammography machine, x-ray film, intensifying screens, film processing solutions, film illumination, and film masking devices shall meet the requirements of 21 C.F.R. 900.12 (b), "Equipment" (2000).

History: 1993 AACS; 2013 AACS.

R 325.5638 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5639 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5640 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5641 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5642 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5643 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5644 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5645 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5646 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5647 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5648 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5649 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5650 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5651 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5652 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5655 Enclosure requirements; use of mobile equipment.

Rule 655. (1) A fixed x-ray equipment enclosure shall comply with the requirements of R 325.5331.

(2) For mammography, the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater than 35 kilovolts.

(3) An individual operating a mobile or portable mammography machine shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless shielding is provided as

specified in subrule (2) of this rule.

(4) Mobile or portable mammography equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of R 325.5331.

(5) Mobile or portable mammography equipment shall not be used for routine mammography in hospitals or private offices of practitioners of the healing arts. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

History: 1993 AACS; 2013 AACS.

R 325.5656 Conditions of operation.

Rule 656. The operation of each mammography x-ray machine shall comply with R 325.5333.

History: 1993 AACS; 2013 AACS.

MEDICAL RECORDS AND MAMMOGRAPHY REPORTS

R 325.5657 Medical records and mammography reports.

Rule 657. A mammography facility shall comply with 21 C.F.R. 900.12 (c), "Medical records and mammography reports" (2000), except that the reference to retention of records in 21 C.F.R. 900.12 (c) (4) (i) is changed from "not less than 5 years" to "not less than 7 years" in accordance with MCL 333.20175.

History: 2013 AACS.

QUALITY ASSURANCE

R 325.5658 Quality assurance - general.

Rule 658. A mammography facility shall comply with 21 C.F.R. 900.12 (d), "Quality assurance general" (2000).

History: 2013 AACS.

QUALITY CONTROL

R 325.5659 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5660 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5661 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5662 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5663 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5664 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5665 Rescinded.

History: 1993 AACS; 2013 AACS.

R 325.5667 Quality assurance – equipment.
Rule 667. A mammography facility shall comply with 21 C.F.R. 900.12 (e), "Quality assurance – equipment" (2000).

History: 2013 AACS.

R 325.5668 Quality assurance - mammography medical outcomes audit; mammographic procedure and techniques for mammography of patients with breast implants; consumer complaint mechanism; and clinical image quality.
Rule 668. A mammography facility shall comply with 21 C.F.R. 900.12 (f), "Quality assurance – mammography medical outcomes audit" (2000); 21 C.F.R. 900.12 (g), "Mammographic procedure and techniques for mammography of patients with breast implants" (2000); 21 C.F.R. 900.12 (h), "Consumer complaint mechanism" (2000) and 21 C.F.R. 900.12 (i), "Clinical image quality" (2000).

History: 2013 AACS.

R 325.5669 Alternative requirements for personnel, x-ray equipment, medical records and mammography reports, and quality assurance.
Rule 669. The department may accept alternatives to a quality standard under 21 CFR 900.12 that have been approved by the U.S. Food and Drug Administration under 21 CFR 900.18, "Alternative requirements for § 900.12 quality standards" (2000).

History: 2013 AACS.

STEREOTACTIC BREAST BIOPSY

PERSONNEL

R 325.5674 Radiologic technologists.
Rule 674. All stereotactic breast biopsy procedures shall be performed by a radiologic technologist who meets all of the following requirements:
(a) Initial qualifications. Before beginning to perform stereotactic breast biopsy procedures independently, a technologist shall do all of the following:
(i) Meet the requirements of R 325.5630.
(ii) Have 3 hours of category A continuing education units in stereotactic breast biopsy.
(iii) Have performed 5 stereotactic breast biopsy procedures under supervision of a stereotactic breast biopsy physician or a qualified stereotactic breast biopsy technologist.
(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy technologist shall have performed at least 24 stereotactic breast biopsy procedures during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 24-month period.
(c) Continuing education. A technologist shall comply with the American registry of radiologic technologist's requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to stereotactic breast biopsy.

History: 2013 AACS.

R 325.5675 Medical physicists.
Rule 675. A stereotactic breast biopsy medical physicist shall meet all of the following requirements:
(a) Initial qualifications. Before independently performing surveys of stereotactic breast biopsy facilities a medical physicist shall have complied with all of the following:
(i) Met the requirements of R 325.5634.
(ii) Have performed 1 hands-on stereotactic breast biopsy physics survey under a qualified

stereotactic breast biopsy medical physicist or 3 independent stereotactic breast biopsy surveys before the effective date of this rule.

(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have performed at least 2 stereotactic breast biopsy physics surveys during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 24-month period.

(c) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have completed at least 3 continuing medical education credits in stereotactic breast biopsy during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 36-month period.

History: 2013 AACS.

X-RAY EQUIPMENT

R 325.5676 Equipment requirements.

Rule 676. (1) The stereotactic breast biopsy mammographic x-ray equipment shall comply with the requirements of R 325.5325 (1) and (17) to (23).

(2) A machine that is used for stereotactic breast biopsy shall be 1 of the following:

(i) A radiation machine that is specifically designed to perform stereotactic breast biopsy.

(ii) A mammography machine with a specially designed add-on device for breast biopsy.

(iii) A mammography machine that exclusively uses lateral arm devices if the needle can be seen in 2 ways in relation to the target lesion.

History: 2013 AACS.

R 325.5677 Enclosures; use of mobile equipment.

Rule 677. (1) A fixed x-ray equipment enclosure shall comply with R 325.5331.

(2) For stereotactic breast biopsy, the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater than than 35 kilovolts.

(3) An individual operating mobile or portable stereotactic breast biopsy equipment shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless shielding is provided as specified in subrule (2) of this rule.

(4) Mobile or portable stereotactic breast biopsy equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of R 325.5331.

(5) Mobile or portable stereotactic breast biopsy equipment shall not be used for routine

mammography in hospitals or private offices of physicians or osteopathic physicians. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

History: 2013 AACS.

R 325.5678 Conditions of operation.
Rule 678. The operation of a mammography x-ray machine shall comply with R 325.5333.

History: 2013 AACS.

MEDICAL RECORDS AND STEREOTACTIC BREAST BIOPSY REPORTS

R 325.5679 Report contents.
Rule 679. A stereotactic breast biopsy facility shall prepare a written report of the results of each stereotactic breast biopsy procedure. The stereotactic breast biopsy report shall include all of the following information:
(a) The name of the patient and an additional unique patient identifier.
(b) The date of the procedure.
(c) The name of the stereotactic breast biopsy physician who conducted the procedure.
(d) The procedure performed.
(e) Designation of the left or right breast.
(f) Description and location of the lesion.

History: 2013 AACS.

R 325.5681 Communication of stereotactic breast biopsy results to health care providers.
Rule 681. When a patient has a referring health care provider or a patient has named a health care provider, the stereotactic breast biopsy facility shall provide a written report of the stereotactic breast biopsy procedure, including the items listed in R 325.5679, to that health care provider not later than 30 days after the date that the stereotactic breast biopsy procedure was performed.

History: 2013 AACS.

R 325.5682 Record keeping.
Rule 682. (1) A facility that performs stereotactic breast biopsy procedures shall comply with both of the following:
(a) Maintain stereotactic breast biopsy images and reports in a permanent medical record of the patient for a period of not less than 7 years, or not less than 10 years if no additional stereotactic breast biopsy procedures of the patient are performed at the facility.

(b) Upon request by, or on behalf of, a patient, permanently or temporarily transfer the original stereotactic breast biopsy images and copies of the patient's reports to any of the following:

(i) A medical institution.

(ii) A patient's physician.

(iii) The patient directly.

(2) Any fee a facility charges a patient for providing the services specified in subrule (1) (b) of this rule shall not exceed the documented costs associated with this service.

History: 2013 AACS.

R 325.5683 Stereotactic breast biopsy image identification.

Rule 683. A stereotactic breast biopsy image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(a) Name of patient and an additional unique patient identifier.

(b) Date of the procedure.

(c) Designation of left or right breast.

(d) Cassette identification, if applicable.

(e) Stereotactic breast biopsy unit identification if there is more than 1 unit in the facility.

History: 2013 AACS.

QUALITY ASSURANCE

R 325.5684 Quality assurance – general.

Rule 684. A stereotactic breast biopsy facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of stereotactic breast biopsy services performed at the facility.

History: 2013 AACS.

R 325.5685 Responsible individuals.

Rule 685. Responsibility for the quality assurance program and for each of its elements shall be assigned to the following individuals who are qualified for their assignments:

(a) Lead stereotactic breast biopsy physician. The facility shall identify a lead stereotactic breast biopsy physician who shall be responsible for ensuring that the quality assurance program meets all requirements of R 325.5684 to R 325.5698. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead stereotactic breast biopsy physician has determined that the individual is qualified to perform the assignment.

(b) Stereotactic breast biopsy physicians. All stereotactic breast biopsy physicians conducting stereotactic breast biopsy procedures for the facility shall do both of the following:

(i) Follow the facility's procedures for corrective action when the images they are asked to

interpret are of poor quality.

(ii) Participate in the facility's medical outcomes audit program.

(c) Medical physicist. The facility shall have the services of a medical physicist available to survey stereotactic breast biopsy equipment and oversee the equipment-related quality assurance practices of the facility. The medical physicist shall be responsible for performing the surveys and stereotactic breast biopsy equipment evaluations and providing the facility with the reports described in R 325.5693 and R 325.5694.

(d) Quality control technologist. Responsibility for tasks within the quality assurance program not assigned to the lead stereotactic breast biopsy physician or the medical physicist shall be assigned to a quality control technologist. The tasks are to be performed by the quality control technologist, but may be delegated to other qualified personnel by the quality control technologist. When other personnel are utilized for these tasks, the quality control technologist shall ensure that they were completed in compliance with R 325.5687.

History: 2013 AACS.

R 325.5686 Quality assurance records.

Rule 686. (1) The lead stereotactic breast biopsy physician, quality control technologist, and medical physicist shall ensure that records concerning the following items are properly maintained and updated:

(a) Stereotactic breast biopsy techniques and procedures.

(b) Quality control, including monitoring data and corrective actions taken.

(c) Safety.

(d) Employee qualifications to meet assigned quality assurance tasks.

(2) The quality assurance records specified in subrule (1) of this rule shall be kept for each test specified in R 325.5684 to R 325.5698 until the next annual inspection has been completed and the department has determined that the facility is in compliance with the quality assurance requirements, or until the test has been performed 2 additional times at the required frequency, whichever is longer.

History: 2013 AACS.

R 325.5687 Radiologic technologist quality control tests.

Rule 687. A stereotactic breast biopsy facility shall have a radiologic technologist perform the following quality control tests at the intervals specified in this rule:

(a) A localization accuracy test shall be performed daily before the equipment is used on patients. Each of the indicated needle tip coordinates shall be within 1 millimeter of the actual preset needle tip location.

(b) A phantom image evaluation shall be performed at least weekly. The phantom image shall achieve at least the minimum score established in R 325.5689.

(c) A hard copy output quality test shall be performed at least monthly, if hard copies are produced from digital data.

(d) A compression test shall be performed at least semiannually. The maximum compression force for the power drive mode shall be between 25 pounds and 45 pounds.

(e) A repeat analysis shall be performed at least semiannually. If the overall repeat or reject rate exceeds 20% based on an image volume of not less than 150 patients, the reason for the change shall be determined. A repeat analysis shall be assessed semiannually even if fewer than 150 patients are examined during that period.

(f) If stereotactic breast biopsy is performed using a screen-film system, the following tests shall be required:

(i) A processor quality control test shall be performed at least daily. Film processors used to develop stereotactic breast biopsy films shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed at the beginning of each operational day before processing any clinical images. The test shall use the mammography film used clinically at the facility and shall include an assessment of base plus fog density, mid-density, and density difference as follows:

(A) The base plus fog density shall be within 0.03 of the established operating level.

(B) The mid-density shall be within plus or minus 0.15 of the established operating level.

(C) The density difference shall be within plus or minus 0.15 of the established operating level.

(ii) An analysis of fixer retention in film assessed at least quarterly. The residual fixer shall be not more than 5 micrograms per square centimeter.

(iii) A screen-film contact test shall be performed at least semiannually. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for stereotactic breast biopsy shall be tested.

(iv) A test of darkroom fog shall be performed at least semiannually. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of not less than 1.2 optical density, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up.

History: 2013 AACS.

R 325.5688 Annual medical physicist's quality control tests.

Rule 688. A stereotactic breast biopsy facility shall have the medical physicist perform the following quality control tests at least annually after equipment installation:

(a) Collimation assessment that meets either of the following:

(i) For screen-film systems, the x-ray field shall be contained within the image receptor on all 3 sides except the chest wall edge. The x-ray field shall not extend beyond the chest wall edge of the image receptor by more than 2% of the source-to-image receptor distance.

(ii) For digital image receptors, the x-ray field may extend beyond the edge of the image receptor on all 4 sides, but no edge of the x-ray field shall extend beyond the image receptor by more than 5 millimeters on any side. Distances shall be measured in, or referred to, the plane of the digital image receptor.

(b) Focal spot performance and system limiting spatial resolution. Assess consistency of system-limiting resolution over time and in comparison to acceptance testing results using a line pair test pattern.

(c) Kilovoltage peak (kVp) accuracy and reproducibility. The kVp shall be accurate to within plus or minus 5% of the indicated or selected kVp. The coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02 at the most commonly used clinical settings of kVp.

(d) Beam quality assessment. The half-value layer (HVL) shall be equal to or greater than the value kVp/100 in units of millimeter of aluminum.

(e) Automatic exposure control system or manual exposure performance assessment that meets either of the following:

(i) For screen-film systems, the image optical density shall be within plus or minus 0.15 of the mean optical density when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the optical densities do not meet this criterion, the medical physicist shall develop a technique chart which meets this criterion.

(ii) For digital systems, the signal value at the center of the digital field of view shall remain within 20% of the signal obtained for the 4 centimeter phantom when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the signal values do not meet this criterion, the medical physicist shall develop technique chart which meets this criterion.

(f) Image receptor speed uniformity that meets either of the following:

(i) For screen-film systems, the difference between the maximum and minimum optical densities of all the cassettes in the facility shall not exceed 0.30.

(ii) For digital systems, the signal-to-noise ratios (SNR) measured in each corner of the image shall be within plus or minus 15% of the SNR measured at the center of the field of view.

(iii) For digital systems that are not equipped with region of interest signal measurements, the machine will meet the receptor uniformity requirements specified by the manufacturer.

(g) Breast entrance exposure, average glandular dose, and exposure reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligray (300 millirad) per exposure.

(h) Image quality evaluation. An image of a department-approved phantom shall achieve at least the minimum score established in R 325.5689.

(i) Artifact evaluation. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the full area of the exposed image receptor on the breast support assembly.

(j) Localization accuracy test. Using a phantom made of gelatin or similar material, the biopsy needle shall capture the intended object in the phantom.

History: 2013 AACS.

R 325.5689 Phantom image scores.

Rule 689. A stereotactic breast biopsy phantom image score for the tests required in rules R 325.5687 (b) and R 325.5688 (h) shall be not less than the values specified in table 689:

TABLE 689

Image System	Standard Mammography Phantom			Mini Stereotactic Phantom		
	Fibers	Speck Groups	Masses	Fibers	Speck Groups	Masses
Screen-film	4.0	3.0	3.0	2.0	2.0	2.0
Digital	5.0	4.0	3.5	3.0	3.0	2.5

History: 2013 AACS.

R 325.5690 Dosimetry.

Rule 690. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligray (300 millirad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

History: 2013 AACS.

R 325.5691 Quality assurance for mobile units.

Rule 691. A stereotactic breast biopsy facility shall verify that mammography units used to produce interventional mammograms at more than 1 location meet the requirements in R 325.5687 to R 325.5690. At each examination location and before any examinations are conducted, the facility shall verify satisfactory performance of these units by using a test method that establishes the adequacy of the image quality produced by the unit.

History: 2013 AACS.

R 325.5692 Use of quality assurance test results.

Rule 692. (1) After completion of tests specified in R 325.5687 to R 325.5691, the facility shall compare the test results to the corresponding specified action limits or the limits established by the facility to verify the image quality of mobile units following a move.

(2) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken within the following time frames:

(a) Before any further examinations are performed or any films are processed using a component of the mammography system that failed any of the tests described in R 325.5687 (a), (b), (d), (f) (i), (f) (iii), (f) (iv); R 325.5688 (g) and (h); or R 325.5691.

(b) Within 30 days of the test date for all other tests described in R 325.5687 to R 325.5691.

History: 2013 AACS.

R 325.5693 Medical physicist surveys.

Rule 693. (1) A stereotactic breast biopsy facility shall annually undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. The survey shall include, at a minimum, the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in R 325.5688 and the weekly phantom image quality test as provided in R 325.5687 (b).

(2) The results of all tests conducted by the facility in accordance with R 325.5687 to R 325.5691 and written documentation of any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

(3) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(4) The survey report shall be provided to the facility within 30 days of the date of the survey.

(5) The survey report shall be dated and signed by the medical physicist who performed or supervised the survey. If the survey was performed entirely or in part by an individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall be identified in the survey report.

History: 2013 AACS.

R 325.5694 Mammography equipment evaluations.

Rule 694. (1) Additional evaluations of stereotactic breast biopsy units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a stereotactic breast biopsy unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of R 325.5676 to R 325.5678 and R 325.5687 to R 325.5691, as applicable. Problems revealed by the evaluation shall be corrected before the new or changed equipment is put into service for procedures or film processing.

(2) The equipment evaluations specified in subrule (1) of this rule shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

History: 2013 AACS.

R 325.5695 Cleanliness in facilities using screen-film systems.

Rule 695. (1) A stereotactic breast biopsy facility shall establish and implement protocols for maintaining darkroom, screen, and view box cleanliness.

(2) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

History: 2013 AACS.

R 325.5696 Calibration of air kerma measuring instruments.

Rule 696. Instruments used by a medical physicist in his or her annual survey to measure the air kerma or air kerma rate from a stereotactic breast biopsy unit shall be calibrated once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

R 325.5697 Infection control.

Rule 697. A stereotactic breast biopsy facility shall establish and comply with procedures to be followed for cleaning and disinfecting stereotactic breast biopsy equipment after contact with blood or other potentially infectious materials. The procedures shall include methods for

documenting facility compliance with the infection control procedures.

History: 2013 AACS.

R 325.5698 Medical outcomes audit.

Rule 698. A stereotactic breast biopsy facility shall establish and maintain a stereotactic breast biopsy medical outcomes audit program that complies with the following:

(a) General requirements. A stereotactic breast biopsy facility shall establish a system to collect and review all of the following data:

(i) Total number of procedures.

(ii) Total number of cancers found.

(iii) Total number of benign lesions.

(iv) Total number of stereotactic breast biopsy needing repeat biopsy.

(v) Total number of complications.

(b) Frequency of audit analysis. The facility's first audit analysis shall be initiated not later than 12 months after the date the facility becomes registered with the department, or 12 months after the effective date of this rule, whichever date is later. The audit analysis shall be completed within an additional 12 months to permit completion of procedures and data collection. Subsequent audit analyses shall be conducted at least once every 12 months.

(c) Audit stereotactic breast biopsy physician. A stereotactic breast biopsy facility shall designate at least 1 stereotactic breast biopsy physician to review the medical outcomes audit data at least once every 12 months. This physician shall record the dates of the audit period; analyze results based on the audit; document the results; and notify other stereotactic breast biopsy physicians of the results and the facility’s aggregate results. The audit stereotactic breast biopsy physician shall ensure that any follow-up actions are documented.

History: 2013 AACS.

DEPARTMENT OF COMMUNITY HEALTH

DIRECTOR'S OFFICE

BUREAU OF HEALTH SYSTEMS - RADIATION SAFETY SECTION

IONIZING RADIATION RULES PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

(By authority conferred on the director of the department of community health by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, and 2003-01, MCL 330.3101, 445.2001, and 445.2011)

R 325.5701 Purpose and scope.

Rule 701. (1) This part establishes requirements governing the use of computed tomography (CT) scanners in the healing arts.

(2) This part applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.

(3) A CT scanner is exempt from this part if the scanner meets 1 of the following:

(a) Generates a peak power of 5 kilowatts or less as certified by the manufacturer.

(b) Is used only for attenuation corrections and anatomical markers as part of a positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) study.

(c) Is used as a simulator solely for treatment planning purposes in conjunction with a megavoltage radiation therapy unit.

(d) Is used solely for intra-operative guidance tomography.

(4) In addition to the requirements of this part, all registrants are subject to R 325.5001 to R 325.5665 and the certificate of need review standards for computed tomography scanner services.

History: 2011 AACS.

R 325.5703 Definitions.

Rule 703. (1) As used in this part the definitions in 21 C.F.R. 1020.33, "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(2) As used in this part the following definitions apply:

(a) "Annual" means a period of 12 consecutive months.

(b) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms.

(c) "CT medical event" means an unintended event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual due to or suspected to be due to exposure to diagnostic radiation from a CT scanner.

(d) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT scanner hybrids if used for CT only procedures.

(e) "Medical physicist" means a person trained in evaluating the performance of CT scanners, related equipment, and facility quality assurance programs and who meets the requirements in R 325.5707.

(f) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.

(g) "Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in R 325.5705.

(h) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimentional images of functional processes in the body.

(i) "Tomogram" means the depiction of the attenuation properties of a section through a body.

(j) "Traceable to a national standard" means an instrument is calibrated at either the national institute of standards and technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3% of the national standard in the appropriate energy range.

History: 2011 AACS.

R 325.5705 CT operators.

Rule 705. Six months after the effective date of these rules, all CT examinations shall be performed by a radiologic technologist who meets all of the following requirements or by a physician or osteopathic physician licensed under article 15 of the act.

(a) Initial qualifications. Before beginning to perform CT examinations independently, a technologist shall meet both of the following:

(i) Be currently registered by the American registry of radiologic technologists (ARRT) or by the Canadian association of medical radiation technologists (CAMRT).

(ii) Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection or have the advanced certification in computed tomography from the ARRT.

(b) Continuing education. A technologist shall be in compliance with the ARRT requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to CT.

History: 2011 AACS.

R 325.5707 Medical physicist.

Rule 707. Each registrant with 1 or more CT scanners shall employ or contract with a medical physicist to review the quality and safety of the operation of the CT scanner. The medical physicist shall meet all of the following:

(a) Initial qualifications. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet 1 of the following:

(i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology, or in diagnostic imaging physics by the American board of medical physics, or in diagnostic radiology physics by the Canadian college of physicists in medicine.

(ii) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal

coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the U.S.

(iii) During the 3 years immediately following the effective date of this part, a medical physicist that does not meet the requirements of paragraph (i) or (ii) of this subdivision shall be considered qualified if the physicist conducted evaluations of at least 3 CT scanners between January 1, 2007 and January 1, 2010. Three years after the effective date of this part, a medical physicist shall meet the requirements of paragraph (i) or (ii) of this subdivision.

(b) Continuing experience. After the second anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT scanners in the prior 24-month period.

(c) Continuing education. After the third anniversary of the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units, at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.

(d) Reestablishing qualifications. A medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(i) A medical physicist who fails to meet the continuing experience requirements of subdivision (b) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist, to meet the requirements of subdivision (b) of this rule.

(ii) A medical physicist who fails to meet the continuing education requirements of subdivision (c) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (c) of this rule.

History: 2011 AACS.

R 325.5709 Equipment requirements.

Rule 709. (1) The regulations in 21 C.F.R. 1020.33(c), (d), (f), (g), (h), (i), and (j), "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664, Lansing, Michigan 48909 or via the internet at website: www.michigan.gov/rss and from the Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903
New Hampshire Avenue, Silver Spring, Maryland 20993 or via the internet at website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(2) CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.

History: 2011 AACS.

R 325.5711 Enclosures

Rule 711. (1) A fixed CT scanner enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for a CT scanner enclosure shall be determined by the workload, use, and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and is subject to design approval by the department.

(3) Protective barriers shall be provided in the ceiling, floor, and walls of a fixed CT scanner enclosure.

(4) The control panel for a fixed CT scanner shall be shielded by a protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(5) Movable barriers with electrical interlocks shall not be approved in lieu of compliance with subrule (4) of this rule.

(6) The operator of a fixed CT scanner shall be able to see and communicate with the patient from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.

(7) Mobile or portable CT scanners used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of subrules (1) to (6) of this rule.

History: 2011 AACS.

R 325.5713 Conditions of operation

Rule 713. (1) Six months after the effective date of these rules, the CT facility shall establish scanning protocols in consultation with the medical physicist.

(2) The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the technique and individual patient. This may be accomplished by reviewing dose indicator devices if available or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist.

(3) A fixed CT scanner shall be operated from a shielded position behind a protective barrier pursuant to R 325.5711(4).

(4) Staff personnel routinely working with or around radiation sources shall not be required by the licensee or registrant to restrain patients during CT examinations. If such procedure is permitted personnel exposure shall not exceed the limits in R 325.5205 or the procedure is prohibited.

(5) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead

equivalence and be so positioned that no part of his or her body will be struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam.

(6) Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(7) Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Personnel monitoring devices shall be permanently assigned to each occupationally exposed individual. Monitoring shall be continuous during employment as a radiation worker.

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

(9) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of any other body part shall comply with R 325.5222.

(10) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for any medical or dental reason.

(11) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which will prevent use of the apparatus by unauthorized persons.

History: 2011 AACS.

R 325.5715 Report and notification of a CT medical event.

Rule 715. (1) A CT facility shall report any CT medical event.

(2) The registrant shall submit a written report to the department within 15 days after a physician of the CT facility discovers the CT medical event or within 15 days after the CT facility is notified of the CT medical event by another physician, whichever comes first.

(3) The written report shall include all of the following:

(a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate.

(b) The name of the physician who determined a CT medical event occurred.

(c) The dates of occurrence and discovery of the CT medical event.

(d) A narrative description of the CT medical event.

(e) The cause of the CT medical event.

(f) The effect on the individual who received the exposure.

(g) A narrative detailing corrective action taken or planned to prevent a recurrence.

(h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not.

(i) The name and signature of the person preparing the report.

(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the CT medical event to the referring physician and shall notify the individual who is the subject of the CT medical event not later than 1 week after its discovery, unless the referring physician personally informs the registrant that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot

be reached within 1 week, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the CT medical event, because of any delay in notification. The notification of the individual who is the subject of the CT medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the CT medical event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

History: 2011 AACS.

R 325.5717 Quality control program.

Rule 717. (1) Six months after the effective date of these rules, a CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following:

(a) Image quality.

(b) Patient radiation dose.

(c) Personnel radiation protection.

(d) Compliance with the provisions of this part.

(e) Ongoing quality control.

(2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits.

(3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule.

(4) The ongoing quality control evaluation should include the following:

(a) Image quality, including the following:

(i) High-contrast resolution.

(ii) Low-contrast resolution.

(iii) Image uniformity.

(iv) Noise.

(v) Artifact evaluation.

(b) Alignment light accuracy.

(c) Slice thickness.

(d) CT number accuracy.

(e) Dose display devices.

History: 2011 AACS.

R 325.5719 Initial and annual medical physicist performance evaluations.

Rule 719. (1) A medical physicist shall complete an initial performance evaluation of the CT scanner before use on human patients and annually thereafter.

(2) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months and shall be traceable to a national standard as specified in R 325.5703(2)(j).

(3) A performance evaluation should include the following:

(a) Alignment light accuracy.

(b) Alignment of table to gantry.

(c) Table and gantry tilt.

(d) Slice localization from scanned projection radiograph.

(e) Table increment accuracy.

(f) Slice thickness.

(g) Image quality, including the following:

(i) High-contrast resolution.

(ii) Low-contrast resolution.

(iii) Image uniformity.

(iv) Noise.

(v) Artifact evaluation.

(h) CT number accuracy and linearity.

(i) Dosimetry, including the following:

(i) Dose indicator such as computed tomography dose index (CTDI).

(ii) Patient radiation dose for representative examinations.

(j) Safety evaluation, including the following:

(i) Visual inspection.

(ii) Audible and visual signals.

(iii) Posting requirements.

(iv) Scattered radiation measurements.

(k) Review of the ongoing quality control program, including test results and corrective action.

(4) The medical physicist shall prepare a report that includes all of the following:

(a) A summary of the performance evaluation required under subrule (1) of this rule.

(b) Recommendations for necessary improvements, if any.

(c) Type of dosimetry system used, including the date of the last calibration.

(5) The report required under subrule (4) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation.

History: 2011 AACS.

R 325.5721 Records and report retention.

Rule 721. A CT facility shall maintain records and reports on file and shall make the records and reports available for review by the department as follows:

(a) Records documenting the qualifications of all personnel who worked at the facility as an operator or medical physicist. Records of personnel no longer employed by the CT facility shall be kept on file until the next inspection following the employee's termination has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.

(b) A report of a CT medical event required under R 325.5715 shall be maintained on file for at least 7 years.

(c) Initial and annual medical physicist performance evaluation reports required under R 325.5719(4) shall be maintained on file for at least 5 years.

(d) Records of the results from the ongoing quality control evaluation required under R 325.5717 shall be maintained on file for at least 2 years.

History: 2011 AACS.