

**MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
RADIATION SAFETY SECTION
IONIZING RADIATION RULES GOVERNING THE USE OF RADIATION
MACHINES**

DETAILED TABLE OF CONTENTS

**PART 3. STANDARDS FOR PROTECTION AGAINST RADIATION FOR USERS OF
RADIATION MACHINES**

	PAGE
GENERAL PROVISIONS.....	1
R 333.5051 Purpose.	1
R 333.5052 Scope.	1
R 333.5053 Definitions.	1
R 333.5055 Intentional exposure of humans.	1
OCCUPATIONAL DOSE LIMITS	1
R 333.5057 Occupational dose limits for adults.	1
R 333.5058 Occupational dose limits for minors.	2
R 333.5059 Dose equivalent to embryo or fetus.	2
RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC	2
R 333.5060 Dose limits for individual members of the public.	2
R 333.5061 Compliance with dose limits for individual members of the public.	2
SURVEYS AND MONITORING.....	3
R 333.5063 General.....	3
R 333.5064 Conditions requiring individual monitoring of occupational dose.	3
R 333.5065 Location of individual monitoring devices.	3
CONTROL OF EXPOSURE IN RESTRICTED AREAS	3
R 333.5067 Control of access to high radiation areas.	3
R 333.5068 Control of access to very high radiation areas.	4
R 333.5069 Security and control of sources of radiation.	4
PRECAUTIONARY PROCEDURES	4
R 333.5071 Caution signs.	4
R 333.5072 Posting requirements.	4
R 333.5073 Exceptions to posting requirements.	5

R 333.5074	Labeling radiation machines.....	5
R 333.5075	Use of safety equipment.	5
RECORDS.....		5
R 333.5077	General provisions for records.....	5
R 333.5079	Records of surveys and calibrations.	5
R 333.5080	Determination and records of prior occupational dose.	5
R 333.5081	Records of individual monitoring results.....	6
R 333.5082	Records of dose to individual members of the public.....	6
R 333.5083	Records of testing entry control devices for very high radiation areas.....	6
R 333.5084	Form of records.....	6
NOTIFICATIONS AND REPORTS		7
R 333.5086	Notifications and reports of theft or loss of registered radiation machines.	7
R 333.5087	Notification of incidents.	7
R 333.5088	Reports of exposures and radiation levels exceeding limits.	7
R 333.5089	Reports to individuals of exceeding dose limits.	8

PART 3. STANDARDS FOR PROTECTION AGAINST RADIATION FOR USERS OF RADIATION MACHINES

GENERAL PROVISIONS

R 333.5051 Purpose.

Rule 51. (1) This part establishes standards for protection against ionizing radiation resulting from activities conducted under registrations of radiation machines issued by the department.

(2) The requirements of this part are designed to control the receipt, possession, use, and transfer of radiation machines by a registrant so that the total dose to an individual, including doses resulting from all radiation machines, does not exceed the standards for protection against radiation prescribed in this part. Nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5052 Scope.

Rule 52. This part applies to radiation machine registrants of the department. The limits in this part do not apply to doses due to background radiation, exposure of patients to radiation for medical diagnosis or therapy, exposure from individuals administered radioactive material, or exposure from voluntary participation in medical research programs.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5053 Definitions.

Rule 53. As used in these rules, the following definitions apply:

(1) "Declared pregnant woman" means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(2) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment to determine the radiation dose delivered to the monitoring equipment.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5055 Intentional exposure of humans.

Rule 55. (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 a health practitioner

licensed under article 15 of the act, MCL 333.1101 to 333.25211.

(2) Intentional exposure of individuals to radiation for diagnostic or therapeutic purposes shall be limited to supervision or prescriptions by a person licensed under article 15 of the act to provide such.

(3) Nothing in these rules shall be construed as authorization to conduct medical diagnosis, medical therapy, or medical research that is not fully consistent with the standards of practice for a health practitioner licensed under article 15 of the act.

History: 2016 MR 10, Eff. May 25, 2016

OCCUPATIONAL DOSE LIMITS

R 333.5057 Occupational dose limits for adults.

Rule 57. (1) A registrant shall control the occupational dose to individual adults, to the following dose limits:

- (a) An annual limit, which is the more limiting of the following:
 - (i) The effective dose equivalent of 0.05 sievert (5 rem).
 - (ii) The dose equivalent to an individual organ or tissue other than the lens of the eye of 0.5 sievert (50 rem).
- (b) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are the following:
 - (i) A lens dose equivalent of 0.15 sieverts (15 rem).
 - (ii) A shallow dose equivalent of 0.5 sievert (50 rem) to the skin of the whole body or to the skin of an extremity.

(2) For exposure determined by measurement with an external individual monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.

(3) The assigned deep dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

- (a) If the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable, the deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation

measurements to demonstrate compliance with the occupational dose limits.

- (b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in R 333.5065, the effective dose equivalent shall be determined by any of the following:
- (i) When only 1 individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.
 - (ii) When only 1 individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in subrule (1) of this rule, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation.
 - (iii) When 2 individual monitoring devices are worn, 1 under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by another person during the current year. Requirements for determining prior occupational exposure are provided in R 333.5080.

History: 2016 MR 10, Eff. May 25, 2016

Editor's Note: An obvious error in R 333.5057 was corrected at the request of the promulgating agency, pursuant to Section 56 of 1969 PA 306, as amended by 2000 PA 262, MCL 24.256. The rule containing the error was published in Michigan Register, 2016 MR 10. The memorandum requesting the correction was published in Michigan Register, 2016 MR 16.

R 333.5058 Occupational dose limits for minors.

Rule 58. The annual occupational dose limits for a minor are 10% of the annual occupational dose limits specified for an adult worker in R 333.5057.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5059 Dose equivalent to embryo or fetus.

Rule 59. (1) The registrant shall ensure that the dose

equivalent to the embryo or fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 millisieverts (500 mrem). Records for doses to the embryo or fetus shall be kept according to R 333.5081(4).

(2) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in subrule (1) of this rule.

(3) The dose equivalent to the embryo or fetus is the deep dose equivalent to the declared pregnant woman.

(4) If the dose equivalent to the embryo or fetus has exceeded 4.5 millisieverts (450 mrem), when the woman declares the pregnancy to the registrant, the registrant shall be considered in compliance with subrule (1) of this rule if the additional dose equivalent to the embryo or fetus does not exceed 0.5 millisievert (50 mrem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

R 333.5060 Dose limits for individual members of the public.

Rule 60. (1) A registrant shall conduct operations in compliance with both of the following:

- (a) The dose equivalent to a member of the public from the registered operation does not exceed 1 millisievert (100 mrem) in a year, excluding dose contributions from both of the following:
 - (i) Medical administrations the individual has received.
 - (ii) Voluntary participation in medical research programs.
- (b) The dose in an unrestricted area from radiation machines does not exceed 0.02 millisievert (2 mrem) in any 1 hour.

(2) If a registrant allows members of the public to have access to controlled areas, the dose limits for members of the public shall apply to those individuals.

(3) The department may impose additional restrictions on radiation levels in unrestricted areas to restrict the collective dose.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5061 Compliance with dose limits for individual members of the public.

Rule 61. A registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in R 333.5060.

History: 2016 MR 10, Eff. May 25, 2016

SURVEYS AND MONITORING

R 333.5063 General.

Rule 63. (1) A registrant shall make, or cause to be made, surveys that may be necessary to demonstrate compliance with the rules in this part and are reasonable under the circumstances to evaluate both of the following:

- (a) The magnitude and extent of radiation levels.
- (b) All potential radiological hazards.

(2) A registrant shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated annually for the radiation measured, except as otherwise specified in another part of these rules or in a registration condition.

(3) This subrule applies to personnel dosimeters, including dosimeters used to measure the dose to an extremity, that require processing to determine the radiation dose and that a registrant uses to comply with R 333.5057, with other applicable provisions of these rules, or with conditions specified in a registration. This subrule does not apply to direct and indirect reading pocket dosimeters and electronic personnel dosimeters. Personnel dosimeters shall be processed and evaluated by a dosimetry processor that meets both of the following:

- (a) Holds a current personnel dosimetry accreditation from the national voluntary laboratory accreditation program of the national institute of standards and technology.
- (b) Is approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5064 Conditions requiring individual monitoring of occupational dose.

Rule 64. A registrant shall monitor occupational exposure to radiation from radiation machines under the control of the registrant and shall supply and require the use of individual monitoring devices by all of the following:

- (a) An adult likely to receive in 1 year a dose greater than 10 % of the limits specified in R 333.5057(1).
- (b) A minor likely to receive in 1 year a deep dose equivalent greater than 1 millisievert (100 mrem), a lens dose equivalent greater than 1.5 millisieverts (150 mrem), or a shallow dose equivalent to the skin or to the extremities greater than 5 millisieverts (500 mrem).
- (c) A declared pregnant woman likely to receive during the entire pregnancy a deep dose equivalent greater than 1 millisievert (100 mrem).

- (d) An individual who enters a high or very high radiation area.
- (e) An individual for whom personnel monitoring is required under other parts of these rules pertaining to specific uses of radiation machines.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5065 Location of individual monitoring devices.

Rule 65. If R 333.5064 or other parts of these rules require occupational dose monitoring for an individual, the registrant shall ensure that the individual wears an individual monitoring device or devices according to 1 of the following:

- (a) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck as described in R 333.3057(3)(b)(i).
- (b) An individual monitoring device used to monitor the dose to an embryo or fetus of a declared pregnant woman, pursuant to R 333.5059(1), shall be worn at the waist under any protective apron being worn by the woman.
- (c) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with R 333.5057(1)(b)(i), shall be worn at the neck, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.
- (d) An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with R 333.5057(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. The individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

History: 2016 MR 10, Eff. May 25, 2016

CONTROL OF EXPOSURE IN RESTRICTED AREAS

R 333.5067 Control of access to high radiation areas.

Rule 67. (1) A registrant shall ensure that each entrance or access point to a high radiation area has 1 or more of the following control features:

- (a) A device that, upon entry into the area, causes the radiation level to be reduced below the level where an individual could receive a deep dose equivalent of 1 millisievert (100 mrem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

- (b) A device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry.
- (c) Locked entryways, except when access to the area is required, with positive control over each individual entry.

(2) In place of the controls required for a high radiation area by subrule (1) of this rule, a registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) A registrant or applicant for a registration may apply to the department for approval of alternative methods for controlling access to high radiation areas.

(4) A registrant shall establish the controls required by subrules (1) and (3) of this rule in a way that does not prevent individuals from leaving a high radiation area.

(5) The registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a high radiation area as described in subrule (1) of this rule if the registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5068 Control of access to very high radiation areas.

Rule 68. (1) In addition to the requirements in R 333.5067, a registrant shall institute additional measures to ensure that an individual cannot gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 grays (500 rads) or more in 1 hour at 1 meter from a radiation machine or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

(2) A registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a very high radiation area as described in subrule (1) of this rule if the registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5069 Security and control of sources of radiation.

Rule 69. A registrant shall use devices or administrative procedures, or both, to prevent unauthorized use or removal of radiation machines.

History: 2016 MR 10, Eff. May 25, 2016

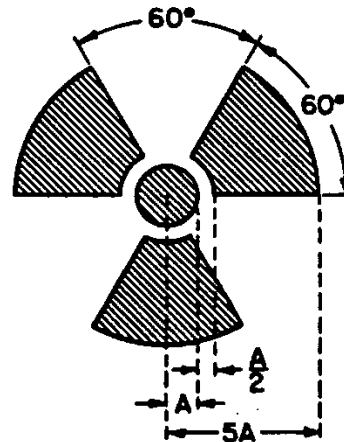
PRECAUTIONARY PROCEDURES

R 333.5071 Caution signs.

Rule 71. (1) Except as otherwise authorized by the department, symbols prescribed by R 333.5072 shall use the conventional 3-bladed design as follows:

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 required in this part, a registrant may provide, on or near the required signs and labels, additional information to make individuals aware of potential radiation exposures and to minimize those exposures.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5072 Posting requirements.

Rule 72. (1) The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

(2) The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

(3) The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "GRAVE DANGER, VERY HIGH RADIATION AREA".

(4) The registrant shall post access openings to manufacturing or process equipment such as tanks and vessels on or in which radiation machines are mounted, if an individual can gain access to the radiation beam and receive a dose to any part of his or her body greater than

the applicable limits for individuals in R 333.5057 to R 333.5061. The posting shall include a conspicuous sign or signs bearing the radiation symbol and warning of the hazard.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5073 Exceptions to posting requirements.

Rule 73. A registrant is not required to post caution signs pursuant to R 333.5072 in areas or rooms in any of the following situations:

- (a) The radiation machines are in the room for periods of less than 8 hours and constantly attended by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation above the limits specified in this part. The area or room shall be under the registrant's control.
- (b) The room is used for teletherapy and access is controlled pursuant to the applicable radiation therapy rules. Attending personnel shall take the necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation above the limits specified in this part.
- (c) The area or room contains radiation machines used for diagnosis by, or on behalf of, health practitioners licensed under article 15 of the act, MCL 333.1011 to 333.25211.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5074 Labeling radiation machines.

Rule 74. A registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when the machine is energized.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5075 Use of safety equipment.

Rule 75. (1) The requirements for safety interlocks, protective enclosures, protective clothing, precautionary labels, or other safety equipment presume the proper use of this 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 or her authorized representative. Prior approval by the department is required. The approval may be granted by written condition on the registration certificate or by telephone followed by written confirmation from the department.

History: 2016 MR 10, Eff. May 25, 2016

RECORDS

R 333.5077 General provisions for records.

Rule 77. (1) A registrant shall use either the international system of units (SI) gray, sievert, and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(2) The registrant shall make a clear distinction among the quantities entered on the records required by these rules. The dose to an individual shall be specified in quantities such as the effective dose equivalent, shallow dose equivalent, lens dose equivalent, or deep dose equivalent.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5079 Records of surveys and calibrations.

Rule 79. (1) A registrant shall retain records of the results of surveys and calibrations required by R 333.5063 for 3 years after the record is made.

(2) A registrant shall maintain records of the results of surveys used to determine exposures, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. A registrant shall retain these records until the department terminates the registration requiring the record.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5080 Determination and records of prior occupational dose.

Rule 80. (1) For each individual likely to receive an annual occupational dose requiring monitoring under R 333.5064, the registrant shall determine the occupational radiation dose received during the current year. To comply, a registrant may do any of the following:

- (a) Accept, as a record of an individual's occupational dose, a written and signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that documents the nature and the amount of occupational dose the individual may have received during the current year.
- (b) Accept, as the record of cumulative radiation dose, an up-to-date department Form MIOSHA-RSS-101, or equivalent, signed by the individual and countersigned by either an appropriate official of the most recent employer for work involving radiation exposure, or by the individual's current employer if the

- individual is not employed by the registrant.
- (c) Obtain reports of the individual's dose equivalents from the most recent employer for work involving radiation exposure, or the individual's current employer if the individual is not employed by the registrant, by telephone, telegram, facsimile, other electronic media, or letter. The registrant shall request a written verification of the dose data if the authenticity of the reports cannot be established.

(2) The registrant shall record the exposure history of each individual, as required by subrule (1) of this rule, on department Form MIOSHA-RSS-101, or other clear and legible record, that includes all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing department Form MIOSHA-RSS-101 or equivalent. For a period in which the registrant does not obtain a report, the registrant shall place a notation on department Form MIOSHA-RSS-101, or equivalent, indicating the periods for which data are not available.

(3) If the registrant cannot obtain a complete record of an individual's occupational dose for the current year, the registrant shall assume, in establishing administrative controls pursuant to R 333.5057(4) for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisieverts (1,250 mrem) for each calendar quarter for which records are unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(4) The registrant shall retain the records on department Form MIOSHA-RSS-101, or equivalent, until the department terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing department Form MIOSHA-RSS-101, or equivalent, for 3 years after the record is made.

History: 2016 MR 10, Eff. May 25, 2016

Editor's Note: An obvious error in R 333.5080 was corrected at the request of the promulgating agency, pursuant to Section 56 of 1969 PA 306, as amended by 2000 PA 262, MCL 24.256. The rule containing the error was published in Michigan Register, 2016 MR 10. The memorandum requesting the correction was published in Michigan Register, 2016 MR 16.

R 333.5081 Records of individual monitoring results.

Rule 81. (1) A registrant shall maintain records of doses received by all individuals for whom monitoring is required pursuant to R 333.5064. When applicable, these records shall include the deep-dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

(2) The registrant shall make entries of the records specified in subrule (1) of this rule at least annually.

(3) The registrant shall maintain the records specified in subrule (1) of this rule on department Form MIOSHA-RSS-102, pursuant to the instructions for department Form MIOSHA-RSS-102, or in clear and legible records containing all the information required by department Form MIOSHA-RSS-102.

(4) The registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(5) The registrant shall retain the required form or record until the department terminates each pertinent registration requiring the record.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5082 Records of dose to individual members of the public.

Rule 82. (1) A registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public as required by R 333.5060.

(2) A registrant shall retain the records required by subrule (1) of this rule until the department terminates each pertinent registration requiring the record.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5083 Records of testing entry control devices for very high radiation areas.

Rule 83. (1) A registrant shall maintain records of tests performed on entry control devices for very high radiation areas. These records shall include the date, time, and results of each test.

(2) The registrant shall retain the records required by subrule (1) of this rule for 3 years after the record is made.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5084 Form of records.

Rule 84. (1) A record required by these rules shall be legible, readily identifiable, and retrievable throughout the specified retention period. The record shall be 1 of the following:

- (a) The original.
- (b) A reproduced copy.
- (c) An electronic copy stored in an electronic recordkeeping system.
- (d) A microform if it is authenticated by authorized personnel and is capable of producing a clear copy throughout the required retention period.

(2) Records, such as letters, drawings, and specifications, shall include all pertinent information, such

as stamps, initials, and signatures.

(3) The registrant shall maintain adequate safeguards against tampering with and loss of records.

History: 2016 MR 10, Eff. May 25, 2016

NOTIFICATIONS AND REPORTS

R 333.5086 Notifications and reports of theft or loss of registered radiation machines.

Rule 86. (1) A registrant shall notify the department by telephone of a stolen, lost, or missing radiation machine within 10 days after its absence becomes known.

(2) A registrant required to notify the department under subrule (1) of this rule shall, within 30 days after making the telephone notification, make a written report to the department containing all of the following information:

- (a) A description of the radiation machine involved, including the manufacturer and model, and the registration tag number of the radiation machine.
- (b) A description of the circumstances under which the loss or theft occurred.
- (c) A statement of disposition, or probable disposition, of the radiation machine involved.
- (d) Exposures of individuals to radiation, the circumstances under which the exposures occurred, and the possible total effective dose equivalent to individuals in unrestricted areas.
- (e) Actions that have been taken, or will be taken, to recover the radiation machine.
- (f) Actions taken or planned to prevent a recurrence of the loss or theft of the radiation machine.

(3) After filing the written report, the registrant shall make an additional written report to the department containing any additional substantive information regarding the loss or theft within 30 days after the registrant learns of the new information.

(4) The registrant shall prepare a report filed with the department pursuant to this rule so that the names of individuals who may have received exposure to radiation are contained in a separate and detachable part of the report.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5087 Notification of incidents.

Rule 87. (1) In addition to any other requirements for notification, a registrant shall immediately notify the department of an event involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual to receive any of the following:

- (a) An effective dose equivalent of 0.25 sievert (25

rem) or more.

- (b) A lens dose equivalent of 0.75 sievert (75 rem) or more.
- (c) A shallow dose equivalent to the skin or extremities of 2.5 grays (250 rads) or more.

(2) Within 24 hours of discovery of the event, a registrant shall notify the department of an event involving a registered radiation machine possessed by the registrant that may have caused, or threatens to cause, an individual to receive, in a period of 24 hours, any of the following:

- (a) An effective dose equivalent exceeding 0.05 sievert (5 rem).
- (b) A lens dose equivalent exceeding 0.15 sievert (15 rem).
- (c) A shallow dose equivalent to the skin or extremities exceeding 0.5 sievert (50 rem).

(3) Registrants shall make the notifications required by subrules (1) and (2) of this rule by telephone to the department and shall confirm the notification within 24 hours by e-mail, facsimile, or overnight mail to the department.

(4) The registrant shall prepare the written confirmation filed with the department pursuant to this rule so that the names of individuals who have received an exposure to radiation are contained in a separate and detachable part of the written confirmation.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5088 Reports of exposures and radiation levels exceeding limits.

Rule 88. (1) In addition to the notification required by R 333.5087, a registrant shall submit a written report to the department within 30 days after learning of any of the following occurrences:

- (a) An event requiring notification under R 333.5087.
- (b) A dose exceeding any of the following:
 - (i) The occupational dose limits for adults in R 333.5057.
 - (ii) The occupational dose limits for a minor in R 333.5058.
 - (iii) The limit for an embryo or fetus of a declared pregnant woman in R 333.5059.
 - (iv) The limits for a member of the public in R 333.5060.
 - (v) Any applicable limit in the registration.
- (c) Levels of radiation in either of the following conditions:
 - (i) A restricted area exceeding an applicable limit in the registration.
 - (ii) An unrestricted area exceeding 10 times an applicable limit in this part or in the registration, whether or not this involves a dose to an individual in excess of the limits in R 333.5060.

(2) A written report required by subrule (1) of this rule

shall include, as appropriate, all of the following:

- (a) The registrant's name, address, and facility registration number.
- (b) A description of the event, including the possible cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned.
- (c) The location of the event.
- (d) The date and time of the event.
- (e) The results of any evaluations or assessments, including an estimate of each individual's dose and the levels of radiation involved.
- (f) Actions taken or planned to prevent a recurrence, including the schedule for achieving conformance with applicable limits and applicable registration conditions.

(3) After filing a report required by this rule, the registrant shall make an additional written report to the department containing any additional substantive information regarding the event within 30 days after the registrant learns of the new information.

(4) A report filed with the department under this rule shall include the name, a unique identification number or social security number as appropriate, and the date of birth of each overexposed individual. The report shall be prepared so that the information is contained in a separate and detachable part of the report and shall be clearly labeled "Protected Information: Not for Public Disclosure."

History: 2016 MR 10, Eff. May 25, 2016

R 333.5089 Reports to individuals of exceeding dose limits.

Rule 89. When R 333.5088 requires a registrant to report to the department, the registrant shall also provide to any affected individual a report on his or her exposure data included in the report submitted to the department. This report shall be transmitted no later than the transmittal to the department.

History: 2016 MR 10, Eff. May 25, 2016