

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
RADIATION SAFETY SECTION
IONIZING RADIATION RULES**

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PART 2. REGISTRATION OF RADIATION MACHINES AND SERVICES

R325.5181. Purpose and scope.

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

This wording change is to simplify the list of actions considered significant for registration purposes.

(2) In addition to the requirements of this part, a registrant is subject to the requirements of part 4 and the applicable provisions of parts 5 to 11 and 13 applicable provisions of other parts of these rules.

This wording change is to simplify the rule.

R325.5XXX. Definitions.

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

(a) "Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located and/or used.

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

R325.5182. Exemptions.

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

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58 | The possession or use of television receivers and video display terminals are considered exempt from the
59 | requirements of these rules.

60

The phrase "the production, testing, or factory servicing of the equipment is not exempt" is deleted because it is unnecessary as these hazards are covered by the qualifier in the first sentence.

61

"Television receivers and video display terminals are exempt from the requirements of these rules" is from Texas rules Part 42.2(c). The Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors also exempts domestic television receivers.

62

63 | **(2)** Radiation machines ~~which that~~ are electrically disconnected pending sale, transfer of ownership,
64 | or destructive disposal while in such temporary storage condition or are otherwise rendered inoperable
65 | are exempt from the registration requirements of this part.

66

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

69

A particle accelerator should be registered (not licensed) as a radiation machine. Deletion of this rule would eliminate current confusion and the unnecessary requirement for machine licensing, such as licensing by MDEQ, in certain circumstances. The radioactive material produced by a particle accelerator could be subject to licensing.

70

71 | **R325.5183. Responsibility for compliance with rules.**

72

73 | **Rule 183. (1)** The owner or registrant, ~~and~~ the person effectively in control of radiation machines not
74 | exempt under rule 182, and the person who, pursuant to rule 184(3), is designated to be responsible for
75 | radiation protection shall ~~each be individually, and both shall be jointly,~~ responsible for full compliance
76 | with all provisions of these rules.

77

This wording change is to clarify the intent of the rule and to simplify its application.

78

79 | **R325.5XXX. Shielding plan review.**

80

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81 **Rule XXX. (1)** Prior to construction, the floor plans, shielding specifications and equipment
82 arrangement of new installations, or modifications of existing installations, utilizing ionizing radiation
83 machines shall be submitted to the department for review and approval. The required information is
84 denoted in appendix a of this part. Facilities that should normally submit radiation-shielding plans prior to
85 x-ray room construction are as follows:

- 86 (a) Hospitals
- 87 (b) Radiology practices
- 88 (c) Medical clinics, including medical clinics in industrial or educational facilities
- 89 (d) Offices of MD, DO, DC, DPM, or DVM practitioners
- 90 (e) Offices of DDS practitioners who will use dental cephalographic or tomographic x-ray equipment.
91 Plan submittal and prior shielding approval are not normally required for dental clinical facilities with
92 only dental intraoral machines or dental panoramic machines.
- 93 (f) Teaching or training facilities that are intended for training x-ray machine operators, including
94 operators of medical x-ray equipment or any type of dental x-ray equipment
- 95 (g) Industrial or educational facilities, except for those using only FDA-certified cabinet x-ray
96 systems, analytical systems, electron microscopes, process or control gauges, or cold-cathode gas
97 discharge tubes.

98

99 **(2)** The department may require the applicant to utilize the services of a qualified expert to determine
100 the shielding requirements prior to the plan review and approval.

101

102 **(3)** The approval of such plans shall not preclude the requirement of additional modifications should
103 a subsequent analysis of operating conditions, shielding, or other factors indicate the possibility of an
104 individual receiving a dose in excess of the limits prescribed in part 5 of these regulations.

105

106 **(4)** After installation of a radiation machine, the registrant shall maintain for inspection by the
107 department:

- 108 (a) The maximum rated technique factors of each machine.

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109 (b) A scale drawing of the room in which a stationary radiation machine system is located with such
110 drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy
111 by an individual in such areas. In addition, the drawing shall include either:

112 (i) _____ The results of a survey for radiation levels present at the operator's position and at
113 pertinent points outside the room at specified test conditions.

114 (ii) _____ The type and thickness of materials, or lead equivalency, of each protective barrier.

115
116 (5) The department may temporarily withhold initial registration of a radiation machine pending (a)
117 receipt of plans and specifications for room design and shielding and approval of those plans and
118 specifications, or (b) receipt of evidence from a facility that, for any machine that is subject to certificate of
119 need (CON) standards, a CON approving the purchase, installation and use of that machine has been
120 issued by the certificate of need section of this department.

121
122 (6) To insure future compliance with rule 210 of part 4, new construction shall be designed using an
123 annual dose constraint (p) of 1 mSv (100 mrem) for uncontrolled areas and 5 mSv (500 mrem) for
124 controlled areas

125
126

Shielding plan review requirements inserted from Suggested State Regulations Part B. Subrules (5) and (6) added.
--

127 **R325.5184. Applications for registration.**

128
129 **Rule 184. (1)** Each person ~~having with~~ 1 or more radiation machines shall apply for registration of the
130 machines with the department ~~within 30 days after the effective date of these rules or thereafter before~~
131 ~~the~~ operation of the machines.

132
133

A 30-day grace period is no longer necessary because the registration rules took effect in 1975.
--

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

137

Public Act 368, PA 1978, as amended, supersedes the original language concerning fees.

138

139 | **(3)** The ~~registrant~~applicant shall designate an individual to be responsible for radiation protection,
140 | and shall specify that the individual:

141 | **(a)** Is knowledgeable concerning the hazards and precautions in the handling of the radiation
142 | machines for which ~~he~~this individual is responsible.

143 | **(b)** Has read and ~~understands~~has an adequate understanding of the applicable requirements of
144 | these rules and has a copy of these rules available for reference.

These wording changes are to clarify the rule.

The individual responsible for radiation protection should have a copy of the rules.

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

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

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

151

152 | **(4)** The application shall be signed by the ~~registrant~~applicant or an individual authorized to act for
153 | and on ~~his~~the applicant's behalf.

154

This wording change is to clarify the rule.

155

156 | **(5)** In ~~his~~the application, ~~the registrant may incorporate by reference~~ information contained in
157 | previous applications, statements, or reports filed with the department may be incorporated by reference
158 | if the references are clear and specific.

159

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This wording change is to clarify and simplify the rule.

160

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

165

This wording change is to clarify specific intent of the rule.

166

167 **R325.5185. Issuance of registration tags.**

168

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

172

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

175

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

180

This wording change is to clarify the rule.

181

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

184

Section experience has shown no significant need for this requirement to continue.

185

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186 | **R325.5186. Issuance of radiation machine registration certificates of registration.**
187

This wording change is to accurately cite the title of the registration document. This change appears in several places throughout this part.

188
189 | **Rule 186. (1)** The department shall issue a radiation machine registration certificate ~~of registration~~ if it
190 determines that an application contains the information required by the department, meets the
191 requirements of these rules, ~~and~~ receives the appropriate registration fee as specified in ~~rules 191 to 194~~
192 the Act, and has not concluded that use of the machine would pose a likely violation of these rules.

This wording change is to clarify the intent of the rule and to refer to the correct citation for fees.

193
194 | **(2)** The department may incorporate in the radiation machine registration certificate ~~of registration~~ ~~at~~
195 ~~the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements~~
196 ~~and~~ in the form of registration conditions with respect to the registrant's receipt, possession, and use ~~and~~
197 ~~transfer~~ of radiation machines as it deems appropriate or necessary for the protection of public health.
198 The registrant shall comply with all registration conditions.
199

The old wording was confusing and cumbersome to implement. This wording change is to simplify the application and to clarify the intent of the rule.

200
201 | **R325.5187. Registrations; expirations; applications for renewal; filing before expiration;**
202 **refunds; amendments.**
203

204 | **Rule 187. (1)** Except as provided in subrule (3) and rule 188, registration expires at the end of the
205 specified day in the month and year stated in the radiation machine registration certificate ~~of registration~~.
206

207 | **(2)** An application for renewal of registration shall be filed annually in accordance with rule 184 and
208 shall be accompanied by the appropriate registration fee as specified in ~~rules 191 to 193~~ the Act.
209

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

213

214 **Rule 194(4)(4)** A refund of any portion of a registration fee shall not be made as a result of a
215 notice of change resulting in the deletion of machines or in the termination of the radiation machine
216 registration certificate of registration before the expiration date of the registration.

217

These wording changes are to clarify the intent of the rule.

218

219 ~~**Rule 194(5)(5)** An amended radiation machine registration certificate of registration issued as provided~~
220 ~~in this rule~~ expires on the expiration date of the current registration.

221

222 **R325.5188. ~~Registration; notices~~ Notices of change; complete changes; partial changes;**
223 **amendments; notices of disposal.**

224

225 **Rule 188. (1)** The registrant shall notify the department in writing before making any change that would
226 render the information contained in the application for registration or the ~~certificate of radiation machine~~
227 ~~registration~~ or both, no longer accurate. ~~In the case of sale, transfer, or disposal of radiation machines,~~
228 ~~the notification shall specify the proposed recipient of the machines, or the location and method of~~
229 ~~disposal.~~ Changes that shall be reported include changes in any of the following:

230

(a) Registrant name or address.

231

(b) Facility name or address.

232

(c) Designated radiation protection supervisor.

233

(d) Additions or deletions of radiation machines.

234

(e) Additions or deletions of tubes on a radiation machine.

235

(f) Authorized use of a machine as designated on the radiation machine registration certificate.

236

Items requiring a notice of change are specified to simplify the application and to clarify the rule.

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(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.

R325.5189. Approval not implied.

Rule 189. (1) A person, in an advertisement, shall not refer to the fact that he or his the facility is registered with the department pursuant to this part and a person shall not state or imply that an activity under such the registration has been approved by the department.

These wording changes are for improved rule clarity.

REGISTRATION FEES

~~**R325.5191. 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.~~

Registration fees are now specified in the statute with no need for repetition in the rules. Also, they are adjusted annually according to the consumer price index.

~~**R325.5192. 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 Department of this state or any political subdivision thereof.~~

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- 271 ~~(b) A nonprofit charitable institution using a radiation machine primarily for services rendered on a~~
- 272 ~~charitable basis or in connection with a facility used primarily for charitable purposes.~~
- 273 ~~(c) A nonprofit educational institution using a radiation machine exclusively for teaching or training~~
- 274 ~~purposes or in connection with a facility used exclusively for teaching or training purposes.~~
- 275

Registration fee exemptions are now limited in the statute.

276

277 **R325.5193. — Registration fee; schedule of fees.**

278

279 ~~**Rule 193.** — Specific registration fees are dependent upon the number of x-ray or electron tubes~~

280 ~~included in the application for registration. The minimum fee shall be applied toward the total registration.~~

281 ~~The following schedule shall be used to determine the registration fee:~~

282

283 **SCHEDULE OF RADIATION MACHINES**

284 **REGISTRATION FEES**

285

286 _____ Each Individual

287 Type of Machine _____ X-ray Tube

288 (design or use) (or electron tube)

289

290 **Dental**

291 _____ (intra-oral) _____ \$10.00

292 _____ (panoramic) _____ 10.00

293 _____ (cephalometric) _____ 10.00

294 _____ (multiple purpose) _____ 10.00

295 **Medical**

296 _____ (extremities only) _____ 10.00

297 _____ (radiographic) _____ 10.00

298 _____ (fluoroscopic) _____ 10.00

299 _____ (radiographic-fluoroscopic) _____ 10.00

300 _____ (single tube combination) _____ 10.00

301 _____ (therapy) _____ 10.00

302 _____ (other) _____ 10.00

303 **Industrial**

304 _____ (radiographic) _____ 10.00

305 _____ (fluoroscopic) _____ 10.00

306 _____ (electron beam welder) _____ 10.00

307 _____ (other) _____ 10.00

308 **Analytical**

309 _____ (diffraction) _____ 10.00

310 _____ (fluorescence) _____ 10.00

311 _____ (electron microscope) _____ 10.00

312 _____ (other) _____ 10.00

313 **Miscellaneous**

314 _____ (firm identification markers) _____ 10.00

315 _____ (cold cathode discharge tubes) _____ 10.00

316 _____ (other) _____ 10.00

317

Registration fees are now specified in the statute.

318

319 ~~**R325.5194 — Registration fee; notice of change; additional tubes; notice of disposal; refunds;**~~

320 ~~**amendment expiration.**~~

321

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322 ~~**Rule 194.(1)** A notice of change submitted in accordance with rule 188 may necessitate issuance of an~~
323 ~~amended certificate of registration and shall be accompanied by the minimum registration fee specified in~~
324 ~~194(2). If additional tubes are added to the registration before the current registration expiration date, the~~
325 ~~notice shall be accompanied by a fee for each added x ray tube as provided in subrule (2). The minimum~~
326 ~~fee shall not be applied toward the addition of tubes to the certificate of registration.~~

327
328 ~~**(2)** The fee for each additional x ray tube or electron tube shall be \$5.00. Only a net increase in the~~
329 ~~number of tubes currently registered requires an additional fee.~~

330
331 ~~**(3)** Notwithstanding subrule (1), notice of disposal without replacement of all registered machines~~
332 ~~covered by a single registration certificate shall void the certificate of record. Such notice shall not require~~
333 ~~issuance of an amended certificate and shall not require payment of the minimum fee.~~

334

Registration fees are now specified in the statute. The notice-of-change fee, or amendment fee, is prohibited by the current statute.

335
336 ~~**(4)** Refund of a registration fee shall not be made as a result of a notice of change resulting in the~~
337 ~~deletion of machines or in the termination of the certificate of registration before the expiration date of the~~
338 ~~registration.~~

339

Rule 194(4) is transferred to Rule 187.

340
341 ~~**(5)** An amended certificate of registration issued as provided in this rule expires on the expiration~~
342 ~~date of the current registration.~~

343

Rule 194(5) is transferred to Rule 187.

344
345 **R325.5195 Vendor obligation; notification of transfer; duty to report; compliance with these**
346 **rules.**

347
348 **Rule 195. (1)** A person who sells, leases, transfers, lends, assembles, or installs a radiation machine in
349 this state shall notify the department in writing within 15 days after the end of each calendar quarter of the
350 following:

- 351 **(a)** The name and address of the person who has received the machine.
- 352 **(b)** For each radiation machine transferred all of the following:
 - 353 **(i)** Date of transfer of possession or ownership.
 - 354 **(ii)** Manufacturer.
 - 355 **(iii)** Model.
 - 356 **(iv)** Department registration number, if the machine was previously registered with the
357 department and the registration tag is on the control panel.
 - 358 **(v)** Number of x-ray tubes.

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

360

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

364

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

368

369 | **R325.5196. Out-of-state radiation machines.**

370

371 | **Rule 196. (1)** ~~Whenever~~When a radiation machine is brought into this state, for purposes other than
372 | temporary storage as provided for in rule 182(2), the person proposing to bring the machine into the state
373 | shall give written notice to the department not less than ~~23~~ working days before the machine enters the
374 | state. The notice shall include the radiographer's name; the type of radiation machine; the nature,
375 | duration, and scope of use; and the exact locations where the radiation machine is to be used. If, for a
376 | specific case, the ~~2–3~~ working-day period would impose an undue hardship on the person, upon
377 | application to the department, he may arrange for other notification to comply with the intent of this rule.

378

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

381

A 3-day notice would allow staff more time to schedule an inspection. Texas has a 3-day notice requirement. Other wording changes are to clarify the intent of the rule.
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382

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Appendix A - Information on radiation shielding required for plan reviews

Facility Identifying Information

1. Provide the facility name and address, facility type and machine type, for the proposed installation.

Architectural Information

1. Provide plans or blueprints of rooms and adjacent areas (to scale). Scale must be 1/4 inch per foot or greater for the x-ray room and accessories. Indicate position of doors, windows, operator's barrier, patient viewing window, and all the proposed shielding. Show compass directions.

2. Indicate location of x-ray machine and accessories (control panel, table, exposure switch, wall cassette holder, etc.) on the plans or blueprints.

3. Describe occupancy and control of adjoining areas including above and below x-ray room. Describe any area beyond an outside wall, such as lawn, parking lot, sidewalk, etc.

4. For exterior walls, show distance to property line and to closest area where individuals may be present.

5. Indicate floor and ceiling construction, such as poured concrete on a corrugated metal pan or wood framing, and the floor-to-floor distance when applicable. If concrete is used, specify minimum thickness and density.

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409 6. Specify proposed shielding, such as lead (note thickness), brick veneer, solid or hollow-core
410 concrete block, cinder block, poured concrete, etc. Indicate the thickness and density of concrete and
411 masonry materials.

412
413 **For assistance in proposing shielding, some general shielding guidance is available on our web**
414 **site at www.michigan.gov/rss under Radiation Shielding Information.**

415
416 **Equipment Information**

417
418 1. Indicate maximum kilovoltage and milliamperage rating of the x-ray machine to be installed.

419
420 2. Describe restrictions in direction of primary beam and limits of x-ray tube travel.

421
422 3. Specify limits of travel of movable image receptors, tilt tables, table tops, etc. Specify the location
423 of the exposure switch(es) on the plans or blueprints. If the controls or exposure switches are movable,
424 indicate the limits of travel.

425
426 4. For CT scanners, include a copy of the iso-exposure curves normally provided by the
427 manufacturer.

428
429 5. Estimate the anticipated maximum workload in milliampere-minutes per week. For an
430 accelerator, specify rads per week at 1 meter for photon treatment beams or specify other dose unit at 1
431 meter for other than photon beams.

432
433 6. For accelerator facilities, include all assumptions and calculations upon which the proposed
434 shielding is based. Such calculations should address instantaneous dose equivalent rates, as would be
435 measured with a rate-type survey meter, and integrated weekly doses to adjacent areas for worst-case

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436 | operating conditions. Specify neutron shielding methods for duct work and for other room penetrations,
437 | such as the use of borated polyethylene on doors.

438