

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

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

DETAILED TABLE OF CONTENTS

	PAGE
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
29	
30	
31	
32	
33	
34	
35	
36	
37	
38	
39	
40	
41	
42	
43	
PART 1. GENERAL PROVISIONS	1-1
R325.5001. Purpose and scope.....	1-1
R325.5002. Hearing procedure.....	1-1
R325.5003. Definitions Ab to Ai.....	1-1
R325.5004. Definitions Al to Au.....	1-3
R325.5005. Definitions B.....	1-5
R325.5006. Definitions C.....	1-6
R325.5007. Definitions D.....	1-8
R325.5008. Definitions E and F.....	1-9
R325.5009. Definitions G and H.....	1-11
R325.5010. Definitions I.....	1-13
R325.5011. Definitions L.....	1-14
R325.5012. Definitions M to O.....	1-16
R325.5013. Definitions P. TO Q.....	1-18
R325.5014. Definitions Ra.....	1-20
R325.5016. Definitions Re to Ro.....	1-22
R325.5017. Definitions Se to So.....	1-25
R325.5018. Definitions Sp to Su.....	1-27
R325.5019. Definitions T.....	1-29
R325.5020. Definitions U and V. TO W.....	1-30
R325.5021. Definitions X-ray.....	1-32
R325.5025. Prefixes.....	1-33
EXEMPTIONS.....	1-34
R325.5031. Departmental action.....	1-34
RECORDS, INSPECTIONS, TESTS AND ENFORCEMENT.....	1-35
R325.5041. Records.....	1-35
R325.5042. Inspections.....	1-35
R325.5043. Impounding.....	1-35
R325.5044. Tests.....	1-35
R325.5045. Additional requirements.....	1-36
R325.5046. Violations.....	1-36
R325.5047. Communications.....	1-36

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

PART 1. GENERAL PROVISIONS

44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69

R325.5001. 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~~ machine 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.~~

~~[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.]~~

R325.5002. 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.

R325.5003. Definitions ~~Ab~~ to ~~Aik~~.

Definitions that apply to radioactive materials regulation have been deleted. Added and amended definitions are from SSRCR parts that have been used to update the Michigan rules.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

70 **Rule 3. (1)** "Absorbed dose" means ~~the energy imparted to matter by radiation per unit mass of irradiated~~
71 ~~material at the place of interest. The special unit of absorbed dose is the rad. the energy imparted by ionizing~~
72 ~~radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.~~

73
74 **(2)** "Accelerator" or "particle accelerator" means a radiation machine designed for or capable of
75 accelerating electrically charged particles such as electrons, protons, ~~or deuterons,~~ or heavy ions with an
76 electrical potential in excess of 1 MeV. ~~Radiation machines designed and used exclusively for the production~~
77 ~~of electron beams or x-radiation for any of the following purposes except those capable of producing~~
78 ~~radioactive material in excess of exempt quantities listed in schedule B of Rule 147 are excluded from this~~
79 ~~definition:~~

80 ~~(A) The diagnosis or treatment of patients.~~

81 ~~(B) Industrial radiography.~~

82 ~~(C) Examination of the microscopic structure of materials.~~

83 ~~(D) Manufacturing process control.~~

84 ~~(E) Research and development.~~

85 ~~(F) Demonstration of scientific principles for educational purposes.~~

86
87 ~~(3)~~ "Accelerator material" means ~~any material made radioactive by exposing it in a particle accelerator.~~

88
89 ~~(4)(3)~~ "Act" means Act No. 305-368 of the Public Acts of 1972-1978 being ~~"325.451 (333.13501?)~~ et. Seq. of
90 the Michigan Compiled Laws. The terms defined in the Act have the same meanings when used in these
91 rules.

92
93 ~~(5)~~ "Agreement material" means ~~"byproduct material", "source material", or "special nuclear material in~~
94 ~~quantities not sufficient to form a critical mass" which is subject to regulation by this state under an agreement~~
95 ~~between the NRC and this state pursuant to section 274 of the federal atomic energy act of 1954,~~
96 ~~as amended, being 42. U.S.C. '2021 (Supp. 1973).~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

98 | (4) “Adult” means an individual 18 or more years of age.

99

100 | ~~(6) “Agreement state” means a state with which the NRC has entered into an effective agreement~~
101 | ~~pursuant to section 274b of the federal atomic energy act of 1954, as amended, being 42 U.S.C. ‘2021 (Supp.~~
102 | ~~1973).~~

103

104 | (5) “Air kerma” means kerma in air (see kerma).

105

106 | ~~(7) “Airborne radioactive material” means any radioactive material dispersed in the air in the form of dusts,~~
107 | ~~fumes, mists, vapors or gases.~~

108

109 | (6) “AKR” means air kerma rate (see kerma)

110

111 | ~~(8) “Airborne radioactivity area” means a room, enclosure or operating area in which airborne radioactive~~
112 | ~~material exists in concentrations in excess of the amounts specified in column 1, table I of rules 261 to 269 or~~
113 | ~~a room, enclosure or operating area in which airborne radioactive material exists in concentrations which,~~
114 | ~~averaged over the number of hours in any week during which individuals are in the area, exceed 25% of the~~
115 | ~~amounts specified in column 1, table I of rules 261 to 269.~~

116

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

119

120 | **R325.5004. Definitions Al to Au.**

121

122 | **Rule 4.** ~~(1) “Aluminum equivalent” means the thickness of type 1100 aluminum alloy with nominal~~
123 | ~~chemical composition of 99.00% minimum aluminum and 0.12% copper which will provide the same~~
124 | ~~attenuation, under specified conditions, as the material in question. “Aluminum equivalent” means the~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

125 thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions as the
126 material in question.

127
128
129 ~~(2) “Atomic Energy Commission” or “AEC” means the United States atomic energy commission, which~~
130 ~~was abolished by Section 104 of the federal energy reorganization act of 1974, being Public Law 93-438. See~~
131 ~~nuclear regulatory commission.~~

132
133 (2) “As low as is reasonably achievable” (ALARA) means making every reasonable effort to maintain
134 exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the
135 purpose for which the registered activity is undertaken, taking into account the state of technology, the
136 economics of improvements in relation to state of technology, the economics of improvements in relation to
137 benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation
138 to registered sources of radiation in the public interest.

139
140 (3) “Assembler” means any person engaged in the business of assembling, replacing, or installing one or
141 more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his
142 or her employee or agent who assembles components into an x-ray system that is subsequently used to
143 provide professional or commercial services.

144
145 ~~(3)(4) “Attenuation block” means a block or stack, having dimensions 20 centimeters by 20 centimeters by~~
146 ~~3.8 centimeters, of type 1100 aluminum alloy or other material with the same aluminum equivalent.~~
147 “Attenuation block” means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent
148 attenuation with dimensions 20 centimeters by 20 centimeters by 3.8 centimeters.

149
150

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

151 ~~(4) "Authorized recipient" means any person licensed or otherwise authorized in writing by the~~
152 ~~department, the federal government or any agency thereof, or an agreement state to possess radioactive~~
153 ~~material or as authorized to the extent permitted by exemption from these rules.~~

154
155 **(5)** "Automatic exposure control" (AEC) means a device which automatically controls ~~4~~one or more
156 technique factors in order to obtain at a preselected location(s) a required quantity of radiation. Automatic
157 exposure rate control (AERC) means a device which automatically controls one or more technique factors
158 in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

159
160 ~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance~~
161 ~~are under the purview of the Michigan Department of Consumer & Industry Services.]~~

162
163
164 **R325.5005. Definitions B.**

165
166 **Rule 5. (1)** "Barrier" includes a primary protective barrier, a secondary protective barrier or a personnel
167 barrier.

168
169 **(2)** "Beam axis" means a line from the source through the centers of the x-ray ~~or gamma-ray~~ fields.

170
171 **(3)** "Beam-limiting device" means a device, which provides a means to restrict the dimensions of the x-ray
172 ~~or gamma-ray~~ field.

173
174 ~~(4) "Byproduct material" means any radioactive material, except special nuclear material, yielded in or~~
175 ~~made radioactive by exposing it to the radiation incident to the process of producing or utilizing special nuclear~~
176 ~~material.~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

178 (4) "Bone densitometry system" means a medical device which uses electronically-produced ionizing
179 radiation to determine the density of bone structures of human patients.

180
181 ~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance~~
182 ~~are under the purview of the Michigan Department of Consumer & Industry Services~~

183
184 **R325.5006. Definitions C.**

185
186 **Rule 6. (1)** "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube
187 housing assembly are connected by a common mechanical support system in order to maintain a desired
188 spatial relationship. This system is designed to allow a change in the projection of the beam through the
189 patient without a change in the position of the patient.

190
191 (2) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure,
192 hereinafter termed a cabinet, that is independent of existing architectural structures except the floor on which it
193 may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being
194 irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation.
195 This definition includes x-ray systems designed for baggage inspection. An x-ray tube used within a shielded
196 part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not
197 considered a cabinet x-ray system.

198
199 ~~(1) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive~~
200 ~~weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters~~
201 ~~shall be arranged so that a day is not included in more than 1 calendar quarter nor is a day in any 1 year~~
202 ~~omitted from inclusion within a calendar quarter. A licensee or registrant shall not change the method~~
203 ~~observed by him of determining calendar quarters for purposes of these rules except at the beginning of a~~
204 ~~calendar year.~~

See "Quarter".

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

205
206 (3) "Calibration" means the determination of (1) the response or reading of an instrument relative to a
207 series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation
208 relative to a standard.

209
210 (4) "Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position
211 of an x-ray film cassette during an x-ray exposure.

212
213 (5) "Cephalometric device" means a device intended for the radiographic visualization and measurement
214 of the dimensions of the human head in dental radiography.

215
216 ~~(2)~~(6) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of
217 observations. It is estimated using the following equation:

218
219
$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{\frac{1}{2}}$$

- 220
221 **where: s = Estimated standard deviation of the population.**
222 **\bar{X} = Mean value of observations in sample.**
223 **X_i = i th observation in sample.**
224 **n = Number of observations in sample.**
225
226

227 (7) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer
228 processing of x-ray transmission data.

229
230 ~~(3)~~(8) "Controlled area" means a restricted area, an area, outside of a restricted area but inside
231 the site boundary, access to which can be limited by the registrant for any reason.

232
233 (9) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs,
234 pushbuttons, and other hardware necessary for manually setting the technique factors.

235

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

236 | ~~(4)(10)~~ "Cooling curve" means the graphical relationship between heat units stored and cooling time.

237

238 | ~~(5)~~ "Curie" means the quantity of radioactive material which decays at the rate of 3.7×10^{10}
239 | disintegrations per second (dps). Commonly used submultiples of the curie (Ci) are the millicurie (mCi), the
240 | microcurie (μ Ci) and the nanocurie (nCi). One millicurie = 0.001 curie = 3.7×10^7 dps. One microcurie =
241 | 0.000001 curie = 3.7×10^4 dps. One nanocurie = 0.000000001 curie = 37 dps. Curie is the special unit of
242 | measurement of radioactivity.

243

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

246

247 | **R325.5007. Definitions D.**

248

249 | **Rule 7. (1)** ~~"Department" means the department of public health.~~ "Deep-dose equivalent" means the dose
250 | equivalent at a tissue depth of 1 cm (1000 mg/cm²) and applies to whole-body exposure.

251

252 | **(2)** "Department" means the department of community health.

253

254 | ~~(2)(3)~~ "Diagnostic source assembly" means a diagnostic tube housing assembly with a beam-limiting device
255 | attached.

256

257 | ~~(3)(4)~~ "Diagnostic type tube housing" (see leakage technique factors) ~~means an x-ray tube housing~~
258 | ~~constructed so that the leakage radiation at a distance of 1 meter from the tube target does not exceed 0.10~~
259 | ~~roentgen per hour under the following conditions:~~

260 | ~~(A) For capacitor energy storage equipment when operated at its leakage technique factors.~~

261 | ~~(B) For field emission equipment rated for pulsed operation when operated at its leakage technique~~
262 | ~~factors.~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

263 | ~~(C)~~ For all other equipment when operated at 70 kVp and 10 milliamps or its calculated
264 | equivalent.

265 |
266 | ~~(4)(5)~~ "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or
267 | animal body for the purpose of diagnosis or visualization.

268 |
269 | ~~(5)(6)~~ "Dose" means absorbed dose or dose equivalent as appropriate. "Dose" or "Radiation dose" is a
270 | generic term that means absorbed dose, deep dose equivalent, shallow dose equivalent, or lens dose
271 | equivalent, as defined in other paragraphs of this section.

272 |
273 | ~~(6)(7)~~ "Dose equivalent" means the ~~absorbed dose in rads times certain modifying factors and is a quantity~~
274 | ~~that expresses on a common scale for all radiation a measure of the postulated effect on a given organ from~~
275 | ~~small amounts of radiation. The special unit of dose equivalent is the rem. product of the absorbed dose in~~
276 | tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose
277 | equivalent are the sievert (Sv) and rem.

278 |
279 | ~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or~~
280 | ~~compliance are under the purview of the Michigan Department of Consumer & Industry Services.]~~

281 |
282 | ~~(8)~~ "Dose limits" means the permissible upper bounds of radiation doses established in accordance with
283 | these rules. for purposes of these rules, "limits" is an equivalent term.

284 |
285 | ~~(9)~~ "Dose monitor unit (DMU)" or "monitor unit (MU)" means a unit response from the beam monitoring
286 | system from which the absorbed dose can be calculated.

287 |
288 |
289 | **R325.5008. Definitions E and F.**

290 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

291 **Rule 8. (1)** "Electrically grounded" means provided with an electrically conducting connection which joins
292 the electrical circuit or equipment to the earth or to the nearest available conducting body which serves in
293 place of the earth.

294

295 **(2)** "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of
296 the useful beam enters the patient.

297

298 ~~**(2)(3)** "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total~~
299 ~~charge of the ions of 1 sign produced in air when all the electrons (negatrons and positrons) liberated by~~
300 ~~photons in a volume element of air having mass dm are completely stopped in air. The special unit of~~
301 ~~exposure is the roentgen. "Exposure" (x) means the quotient of dq by dm where dq is the absolute value of the~~
302 ~~total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by~~
303 ~~photons in air of mass dm are completely stopped in air; thus $x=dq/dm$, in units of c/kg .~~

304

305 ~~**(3)(4)** "Exposure rate" means the exposure per unit of time, such as R/min, mR/h.~~

306

307 **(5)** "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

308

309 ~~**(4)(6)** "Facility" means the location, building, vehicle, or complex under one administrative control, at~~
310 ~~which 1 or more ~~devices or sources of radiation~~ machines are installed, ~~or located, and/or used within~~~~
311 ~~1 building or under 1 roof and are under the same administrative control.~~

312

313 ~~**(5)(7)** "Field emission equipment" means equipment which uses an x-ray tube in which electron~~
314 ~~emission from the cathode is due solely to the action of an electric field.~~

315

316 ~~**(6)(8)** "Filter" means material placed in the useful beam to absorb preferentially the less penetrating~~
317 ~~radiation.~~

318

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

319 ~~(7)(9)~~ "Fluoroscopic imaging assembly" means a component which comprises a reception system in
320 which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if any,
321 the primary protective barrier, and structural material providing linkage between the image receptor and the
322 diagnostic source assembly. "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons
323 produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It
324 includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between
325 the image receptor and diagnostic source assembly.

326
327 (10) "Fluoroscopy" means a technique for generating x-ray images and presenting them instantaneously
328 and continuously as visible images for the purpose of providing the user with a visual display of dynamic
329 processes.

330
331 (11) "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the
332 electrons accelerated from the cathode and from which the useful beam originates.

333
334 ~~(8)(12)~~ "Food and drug administration" or "FDA" means the United States food and drug
335 administration established by the federal food, drug and cosmetic act of 1938, as amended, being Public Law
336 75-717.

337
338 **R325.5009. Definitions G and H.**

339
340 **Rule 9. (1)** "Gantry" means that part of a radiation therapy system supporting and allowing movements of
341 the radiation treatment head about a center of rotation.

342
343 ~~(4)(2)~~ "General purpose radiographic x-ray system" means a radiographic x-ray system which, by design or
344 use, is not limited to radiographic examination of specific anatomical regions. Radiographic extremity only
345 uses, such as podiatry, are excluded from the definition of general purpose radiographic x-ray system.

346

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

347 | (3) "Gray" (Gy) means the system international (SI) unit of absorbed dose. One gray is equal to an
348 | absorbed dose of 1 Joule per kilogram (100 rad).

349 |
350 | (2)(4) "Half-value layer" or "HVL" means the thickness of specified material which attenuates the beam of
351 | radiation to an extent such that the exposure rate ~~AKR~~ is reduced to 1/2 of its original value. In this definition
352 | the contribution of all scattered radiation, other than any which might be present initially in the beam
353 | concerned, is deemed to be excluded.

354 |
355 | (5) "Healing arts screening" means the testing of human beings using an x-ray machine for the detection
356 | or evaluation of health indications when such tests are not specifically and individually ordered by a licensed
357 | practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or
358 | treatment.

359 |
360 | (6) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperage, and
361 | seconds, i.e., kVp x mA x second.

362 |
363 | ~~(3)(7)~~ "High radiation area" means an area, accessible to individuals, in which there exists such
364 | radiation, that an individual could receive in any 1 hour a dose in excess of 100 millirems. "High radiation
365 | area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the
366 | body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30
367 | centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

368 |
369 | (4)(8) "Human use" means the internal or external administration of radiation or radioactive materials
370 | to human beings.

371 |
372 | [Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance
373 | are under the purview of the Michigan Department of Consumer & Industry Services.]

374 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

375 | **R325.5010. Definitions I to K.**

376 |

377 | **Rule 10. (1)** "Image intensifier" means a device, installed in its housing, which instantaneously
378 | converts an x-ray pattern into a corresponding light image of higher energy density.

379 |

380 | ~~(1)(2)~~ "Image receptor" means a device, such as a fluorescent screen or radiographic film, which transfers
381 | incident x-ray photons into a visible image or into another form which can be made into a visible image by
382 | further transformations. "Image receptor" means any device, such as a fluorescent screen, radiographic film,
383 | x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons
384 | either into a visible image or into another form which can be made into a visible image by further
385 | transformations. In those cases where means are provided to preselect a portion of the image receptor, the
386 | term "image receptor" shall mean the preselected portion of the device.

387 |

388 | **(3)** "Image receptor support device" means, for mammography x-ray systems, that part of the system
389 | designed to support the image receptor during a mammographic examination and to provide a primary
390 | protective barrier.

391 |

392 | ~~(2)(4)~~ "Individual" means a any human being.

393 |

394 | **(5)** "Industrial radiography" means an examination of the macroscopic structure of materials by the
395 | nondestructive method of utilizing ionizing radiation to make radiographic or fluoroscopic images.

396 |

397 | **(6)** "Inherent filtration" means the filtration of the useful beam provided by the permanently installed
398 | components of the tube housing assembly.

399 |

400 | ~~(3)(7)~~ "Inspection" means an official examination or observation to determine compliance with the
401 | act, these rules, license conditions, registration conditions or orders of the department.

402 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

403 ~~(4)(8)~~ "Installation" means a location, having boundaries specified by the licensee or registrant, where for a
404 period of more than 30 days, 1 or more sources of radiation are used, operated or stored. A part of a building,
405 an entire building, a plant or plant site may be designated as an installation.

406

407 (9) "Isocenter" means the center of the circle or sphere through which the useful beam axis passes while
408 the gantry moves through its full range of motions.

409

410 (10) "Kerma" means the quantity as defined by the international commission on radiation units and
411 measurements. the kerma, k , is the quotient of de_{tr} by dm , where de_{tr} is the sum of the initial kinetic energies of
412 all the charged particles liberated by uncharged particles in a mass dm of material; thus $k=de_{tr}/dm$, in units of
413 J/kg, where the special name for the unit of kerma is gray (Gy). when the material is air, the quantity is referred
414 to as "air kerma."

415

416 (11) "Kilovolts peak" or "kVp" (see "peak tube potential")

417

418 **R325.5011. Definitions L.**

419

420 ~~Rule 11. (1) "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source~~
421 ~~assembly except for the useful beam and radiation produced when the exposure switch or timer is not~~
422 ~~activated. "Last-image hold" (LIH) radiograph means an image obtained either by retaining one or more~~
423 ~~fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating~~
424 ~~a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of~~
425 ~~the fluoroscopic exposure.~~

426

427 (2) "Lateral fluoroscope" means the x-ray tube and image receptor combination in a biplane system
428 dedicated to the lateral projection. it consists of the lateral x-ray tube housing assembly and the lateral image
429 receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

430

431 (3) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

432 (a) the useful beam; and

433 (b) radiation produced when the exposure switch or timer is not activated.

434

435 ~~(2) "Leakage technique factors" means the technique factors associated with the tube housing assembly~~
436 ~~which are used in measuring leakage radiation. They are defined as follows:~~

437 ~~(A) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for~~
438 ~~operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10~~
439 ~~millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.~~

440 ~~(B) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in~~
441 ~~an hour for operation at the maximum rated peak tube potential.~~

442 ~~(C) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube~~
443 ~~potential~~

444

445 (4) "Leakage technique factors" means the technique factors associated with the diagnostic source
446 assembly which are used in measuring leakage radiation. They are defined as follows:

447 (a) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-
448 rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the
449 maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10
450 mAs) or the minimum obtainable from the unit, whichever is larger;

451 (b) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the
452 maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation
453 at the maximum-rated peak tube potential; and

454 (c) for all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-
455 rated continuous tube current for the maximum-rated peak tube potential.

456

457 (5) "Lens dose equivalent (LDE)" means the dose equivalent at a tissue depth of 0.3 centimeter (300
458 mg/cm²). and applies to the external exposure of the lens of the eye.

459

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

460 | ~~(3)(6)~~ "Level" means radiation flux or intensity at a specific point. It is sometimes expressed in terms of the
461 | dose an individual would receive if he were at that point or location.

462

463 | ~~(4)~~ "License" means a license issued pursuant to parts 2 or 3 except where otherwise specified.

464

465 | ~~(5)(7)~~ "Light field" means the area of intersection of the light beam from the beam-limiting device and 1 of the
466 | set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points
467 | at which the illumination is 1/4 of the maximum in the intersection.

468

469 | ~~(6)(8)~~ "Line-voltage regulation" means the difference between the no-load and the load line potentials
470 | expressed as a percent of the load line potential; that is,

471

472 | Percent line-voltage regulation = $100 (V_n - V_l)/V_l$

473 | Where: V_n = No-load line potential and

474 | V_l = Load line potential.

475

476 | **R325.5012. Definitions M to O.**

477

478 | **Rule 12. (1)** "Manufactured" means produced or prepared for use or sale by an industrial manufacturing
479 | process. It includes factory assembly of components but does not include assembly of manufactured parts at
480 | the site of use.

481

482 | **(2)** "Maximum line current" means the rms current in the supply line of an x-ray machine operating at its
483 | maximum rating.

484

485 | ~~(3)~~ "Naturally occurring material" means radioactive material found radioactive in the normal isotopic
486 | distribution of elements rather than rendered radioactive by artificial means.

487

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

488 (3) "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with
489 one electron charge in passing through a potential difference of one million volts in a vacuum. [note: current
490 convention is to use MV for photons and MeV for electrons.]

491
492 (4) "Member of the public" means any individual except when that individual is receiving an occupational
493 dose.

494
495 ~~_(4) "Nuclear regulatory commission" or "NRC" means the United States nuclear regulatory commission~~
496 ~~established by section 201 of the federal energy reorganization act of 1974, being Public Law 93-438.~~

497
498 (5) "Minor" means an individual less than 18 years of age.

499
500 ~~(5)(6) "Occupational dose" means the dose received in the course of occupational exposure as calculated or~~
501 ~~estimated from dosimeters. the dose received by an individual in the course of employment in which the~~
502 ~~individual's assigned duties for the registrant involve exposure to radiation machines, whether or not the~~
503 ~~radiation machines are in the possession of the registrant. Occupational dose does not include dose received:~~
504 ~~from background radiation, or as a patient from medical practices, or from voluntary participation in medical~~
505 ~~research programs, or as a member of the public.~~

506
507 ~~_(6) "Occupational exposure" means radiation exposure received by an individual in a restricted area, or in~~
508 ~~the course of employment in which the individual's duties involve being exposed to radiation. It does not~~
509 ~~include exposure of an individual to radiation for the purpose of diagnosis or therapy of the individual.~~

510
511 ~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance~~
512 ~~are under the purview of the Michigan Department of Consumer & Industry Services.]~~

513
514 (7) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally
515 place some part of his body in the primary beam path during normal operation.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

516
517
518
519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542

R325.5013. Definitions P to Q.

Rule 13. (1) ~~"Particle accelerator" or "accelerator" (See 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~~ that individual.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

543 | (5) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the
544 | attenuation and scattering of radiation. This requires that both the atomic number (z) and the density of the
545 | material be similar to that of tissue.

546

547 | (5)(6) "Physician" means an individual licensed by this state to prescribe or dispense drugs in the practice of
548 | medicine.

549

550 | (6)(7) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce
551 | the radiation exposure for protection purposes.

552

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

555

556 | (8) "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure
557 | to radiation.

558

559 | (9) "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation
560 | exposure. the types of protective barriers are as follows:

561 | (a) "primary protective barrier" means the material, excluding filters, placed in the useful beam.

562 | (b) "secondary protective barrier" means the material which attenuates scattered and leakage radiation.

563

564 | (9) "Qualified expert" means an individual having the knowledge and training to measure ionizing
565 | radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example,
566 | individuals certified in the appropriate field by the American board of radiology, or the American board of
567 | health physics, or the American board of medical physics, or those having equivalent qualifications. With
568 | reference to the calibration of radiation therapy equipment, an individual having, in addition to the above
569 | qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

570 example, individuals certified in therapeutic radiological physics or x-ray and radium physics by the American
571 board of radiology, or those having equivalent qualifications.

572
573 **(10)** "Quarter" means a period of time of approximately 13 consecutive weeks equal to one-fourth of the
574 year observed by the registrant, providing that the beginning of the first quarter in a year occurs in January and
575 that no day is omitted or duplicated in consecutive quarters.

576
577
578 **R325.5014. Definitions Ra.**

579
580 **Rule 14. (1)** "Rad" is the traditional unit of absorbed dose. One rad is equal to an absorbed dose of
581 0.01 means 1/100 of a joule of absorbed radiation energy per kilogram of material, or 100 ergs per gram (0.01
582 gray) and is the special unit of absorbed dose.

583
584 **(2)** "Radiation" means ionizing radiation.

585
586 **(3)** "Radiation area" means an area, accessible to individuals, in which there exists such radiation that an
587 individual could receive in any 1 hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in
588 excess of 100 millirems. radiation levels could result in an individual receiving a dose equivalent in excess of
589 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the radiation source or from any surface that the
590 radiation penetrates.

591
592 **(4)** "Radiation machine" means a device capable of producing radiation except that which produces
593 radiation only from radioactive material.

594
595 **(5)** "Radiation monitoring" means the periodic or continuous determination of the exposure rate or
596 contamination level-integrated exposure in an area (area monitoring) or of the dose received by an individual
597 (personnel monitoring).

598

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

599 | **(6)** "Radiation protection supervisor" means the individual specified by the licensee or registrant who has
600 | the authority and the responsibility for radiation protection.

601 |
602 | ~~**(7)** "Radiation worker" means an individual assigned work with or around sources of radiation or who,~~
603 | ~~during the performance of his assigned duties, receives or is likely to receive a dose in any calendar quarter in~~
604 | ~~excess of 300 millirems.~~

605 |
606 | ~~**(8)** "Radioactivity" means the property of certain isotopes of the basic elements of spontaneously emitting~~
607 | ~~nuclear particles or gamma radiation or of emitting x-radiation following orbital electron capture or of~~
608 | ~~undergoing spontaneous fission.~~

609 |
610 | **(7)** "Radiography" means a technique for generating and recording an x-ray pattern for the purpose of
611 | providing the user with an image(s) after termination of the exposure.

612 |
613 | ~~**(9)**~~**(8)** "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the
614 | manufacturer at which the x-ray machine is designed to operate.

615 |
616 | ~~**(10)**~~**(9)** "Rated output current" means the maximum allowable load current of the x-ray high-voltage
617 | generator.

618 |
619 | ~~**(11)**~~**(10)** "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of
620 | the x-ray high-voltage generator.

621 |
622 | ~~**(12)**~~**(11)** "Rating" means the operating limits specified by the manufacturer.

623 |
624 | ~~*[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance*~~
625 | ~~*are under the purview of the Michigan Department of Consumer & Industry Services.]*~~

626 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

627 ~~[SKIP RULE 15?(IT WAS SKIPPED IN OLD RULES)]~~

628

629 **R325.5016. Definitions Re to Ro.**

630

631 **Rule 16. (1)** "Recording" means producing a ~~permanent form of a radiographic image resulting from x-ray~~
632 ~~or gamma-ray photons.~~ retrievable form of an image resulting from x-ray photons.

633

634 ~~(2) "Rem" means the absorbed dose in rads multiplied by appropriate modifying factors which are~~
635 ~~determined by the quality of radiation and the conditions of exposure and is the special unit of dose equivalent.~~

636 ~~For the purpose of these regulations, each of the following is considered to be equivalent to a dose of one~~
637 ~~rem:~~

638 ~~(a) An exposure of 1 roentgen of x or gamma radiation.~~

639 ~~(b) A dose of 1 rad due to x, gamma or beta radiation.~~

640 ~~(c) A dose of 0.1 rad due to neutrons or high energy protons.*~~

641 ~~(d) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of~~
642 ~~the eye.~~

643 **(2)** "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose
644 equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

645

646 As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in Table
647 1.

648

649 Table 1--Quality factors and absorbed dose equivalencies

650

<u>Type of radiation</u>	<u>Quality factor (Q)</u>	<u>Absorbed dose equal to a unit dose equivalent^a</u>
x-, gamma, or beta radiation	<u>1</u>	<u>1</u>
alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	<u>20</u>	<u>.05</u>
neutrons of unknown energy	<u>10</u>	<u>.1</u>
high-energy protons	<u>10</u>	<u>.1</u>

651

652 ^a absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

653

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

654 If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent
 655 rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 0.01 Sv (1 rem) of
 656 neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result
 657 from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient
 658 information exists to estimate the approximate energy distribution of the neutrons, the registrant may use the
 659 fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue
 660 dose in rads to dose equivalent in rems.

661
 662 Table 2--Mean quality factors, Q, and fluence per unit dose equivalent for monoenergetic neutrons

663

	<u>Neutron energy (MeV)</u>	<u>Quality factor (Q)^a</u>	<u>Fluence per unit dose equivalent^b (neutrons cm⁻² rem⁻¹)</u>
<u>(Thermal).....</u>	<u>2.5 X 10⁻⁸</u>	<u>2</u>	<u>980 X 10⁶</u>
	<u>1 X 10⁻⁷</u>	<u>2</u>	<u>980 X 10⁶</u>
	<u>1 X 10⁻⁶</u>	<u>2</u>	<u>810 X 10⁶</u>
	<u>1 X 10⁻⁵</u>	<u>2</u>	<u>810 X 10⁶</u>
	<u>1 X 10⁻⁴</u>	<u>2</u>	<u>840 X 10⁶</u>
	<u>1 X 10⁻³</u>	<u>2</u>	<u>980 X 10⁶</u>
	<u>1 X 10⁻²</u>	<u>2.5</u>	<u>1010 X 10⁶</u>
	<u>1 X 10⁻¹</u>	<u>7.5</u>	<u>170 X 10⁶</u>
	<u>5 X 10⁻¹</u>	<u>11</u>	<u>39 X 10⁶</u>
	<u>1</u>	<u>11</u>	<u>27 X 10⁶</u>
	<u>2.5</u>	<u>9</u>	<u>29 X 10⁶</u>
	<u>5</u>	<u>8</u>	<u>23 X 10⁶</u>
	<u>7</u>	<u>7</u>	<u>24 X 10⁶</u>
	<u>10</u>	<u>6.5</u>	<u>24 X 10⁶</u>
	<u>14</u>	<u>7.5</u>	<u>17 X 10⁶</u>
	<u>20</u>	<u>8</u>	<u>16 X 10⁶</u>
	<u>40</u>	<u>7</u>	<u>14 X 10⁶</u>
	<u>60</u>	<u>5.5</u>	<u>16 X 10⁶</u>
	<u>1 X 10²</u>	<u>4</u>	<u>20 X 10⁶</u>
	<u>2 X 10²</u>	<u>3.5</u>	<u>19 X 10⁶</u>
<u>3 X 10²</u>	<u>3.5</u>	<u>16 X 10⁶</u>	
<u>4 X 10²</u>	<u>3.5</u>	<u>14 X 10⁶</u>	

664
 665
 666 ^a value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder
 667 tissue-equivalent phantom.

668 ^b monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

669
 670
 671

From latest 10CFR 20 (NRC).

672
673
674
675
676
677
678
679

* 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)	No. of neutrons per square centimeter for a dose equivalent of 1 rem (neutrons/cm ²)	Average flux to deliver 100 millirem in 40 hours (neutrons/cm ² per second)
Thermal	970	× 10 ⁶
0.0001	720	× 10 ⁶
0.005	820	× 10 ⁶
0.02	400	× 10 ⁶
0.1	120	× 10 ⁶
0.5	43	× 10 ⁶
1.0	26	× 10 ⁶
2.5	29	× 10 ⁶
5.0	26	× 10 ⁶
7.5	24	× 10 ⁶
10.0	24	× 10 ⁶
10 to 3014	×	10 ⁶

680
681
682

(3) "Research and development" means either (a) theoretical analysis, exploration or experimentation, or (b) 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.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

687

688 | **(4)** "Response time" means the time required for an instrument system to reach 90% of its final reading
689 | when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux
690 | from zero sufficient to provide a steady state midscale reading.

691

692 | **(5)** ~~"Restricted area" or "controlled area" means an area access to which is controlled by a licensee or~~
693 | ~~registrant for purposes of protection of individuals from exposure to radiation or radioactive materials. It does~~
694 | ~~not include an area used for residential quarters, although a separate room in a residential building may be set~~
695 | ~~apart as a restricted area.~~ means an area, access to which is limited by the registrant for the purpose of
696 | protecting individuals against undue risks from exposure to radiation. Restricted area does not include areas
697 | used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

698

699 | **(6)** "Roentgen (R)" means 2.58×10^{-4} Coulombs/kilogram of air and is the ~~special~~-traditional unit of
700 | exposure.

701

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

704

705 | **R325.5017. Definitions Se to So.**

706

707 | **Rule 17. (1)** ~~"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule~~
708 | ~~or matrix designed to prevent release and dispersal of the radioactive material under the most severe~~
709 | ~~conditions which are likely to be encountered in normal use and handling.~~ "Scan" means the complete process
710 | of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously
711 | during a single scan for the production of one or more tomograms.

712

713 | **(2)** "Scan time" means the period of time between the beginning and end of x-ray transmission data
714 | accumulation for a single scan.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

715 |
716 | (3) "Scattered radiation" means radiation that, during passage through matter, has been deviated in
717 | direction.

718 |
719 | (2)(4) "Secondary protective barrier" means the material placed in the path of scattered and leakage
720 | radiation to reduce the radiation exposure for protection purposes.

721 |
722 | (3)(5) "Shall" means required to comply with these rules pursuant to the act and enforceable under the act
723 | and Act No. 306 of the Public Acts of 1969 as amended.

724 |
725 | (6) "Shallow-dose equivalent" means the dose equivalent at a tissue depth of 0.007 centimeter (7
726 | mg/cm²) averaged over an area of 1 square centimeter and applies to the external exposure of the skin or an
727 | extremity.

728 |
729 | (4)(7) "Should" means recommended when practicable to meet optimum radiation safety standards.

730 |
731 | (8) "SI" is the abbreviation for the international system of units.

732 |
733 | (9) "Sievert" means the si unit of any of the quantities expressed as dose equivalent. the dose equivalent
734 | in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

735 |
736 | (10) "Simulator (radiation therapy simulation system)" means any x-ray system intended for localizing the
737 | volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic
738 | irradiation field.

739 |
740 | (5)(11) "Source" as applied to x-ray means the focal spot of the x-ray tube.

741 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

742 | ~~(6)(12)~~ "Source-image receptor distance" or "SID" means the distance from the source to the center
743 | of the input surface of the image receptor.

744 |
745 | (13) "Source-skin" distance (SSD) means the distance from the source to the center of the entrant x-ray
746 | field in the plane tangent to the patient skin surface.

747 |
748 | ~~(7) "Source material" means uranium or thorium, or any combination thereof, in any physical or chemical~~
749 | ~~form; or ores which contain by weight 1/20 of 1% (0.05%) or more of uranium, thorium or any combination~~
750 | ~~thereof. Source material does not include special nuclear material.~~

751 |
752 | ~~(8)(14)~~ "Source of radiation" means ~~any radioactive material, or any device or equipment emitting or~~
753 | ~~capable of producing radiation.~~

754 |
755 | (15) "Solid-state x-ray imaging device" means an assembly, typically in a rectangular panel configuration,
756 | consisting of:

757 | (a) a transducer layer that intercepts x-ray photons and through a single or multistage process converts
758 | the photon energy into a modulated signal representative of the x-ray image, and

759 | (b) a matrix of integration and switching elements that are coupled to the transducer layer. an electrical
760 | signal representing the x-ray image is generated by a charge generation and transfer process within the
761 | integration and switching matrix. The electrical signals may undergo analog-to-digital conversion before
762 | leaving the panel to provide either a digital radiographic or fluoroscopic image.

763 |
764 | ~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance~~
765 | ~~are under the purview of the Michigan Department of Consumer & Industry Services.]~~

766 |
767 | **R325.5018. Definitions Sp to Su.**

768 |
769 | **Rule 18. (1)** ~~"Special nuclear material in quantities not sufficient to form a critical mass" means uranium~~
770 | ~~enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

771 quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of
772 them in accordance with the following formula: For each kind of special nuclear material, determine the ratio
773 between the quantity of that special nuclear material and the quantity specified above for the same kind of
774 special nuclear material. The sum of the ratios for all of the kinds of special nuclear material in combination
775 shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the
776 limitation and are within the formula:

$$\begin{array}{ccccccc} 778 & 175 & \text{(grams } & \text{---} & 50 & \text{---} & 50 \\ 779 & \text{contained U-235)} & + & \text{(grams U-233)} & + & \text{(grams Pu)} & = & 1 \\ 780 & 350 & \text{---} & 200 & \text{---} & 200 & \text{"Spot-film} \end{array}$$

781 device" means a device intended to transport and/or position a radiographic image receptor between the x-ray
782 source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of
783 the fluoroscopic image receptor for the purpose of producing a radiograph.

784
785 **(2)** "Stationary equipment" means equipment which is installed in a fixed location.

786
787 **(3)** "Storage" means a condition in which a machine or device is not being used for an extended period of
788 time and has been made inoperable.

789
790 **(3)(4)** "Survey" means a critical evaluation of a facility or area incident to the production, use, release,
791 disposal, or presence of sources of radiation under a specific set of conditions to determine actual or potential
792 radiation hazards. When appropriate, the evaluation includes tests, physical examination, source inventory
793 and accountability, and measurements of levels of radiation or concentration of radioactive material present. an
794 evaluation of the radiological conditions and potential hazards incident to the production, use, transfer,
795 release, disposal, or presence of radiation machines. When appropriate, such evaluation includes, but is not
796 limited to, tests, physical examinations, and measurements of levels of radiation present.

797

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

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

800

801 **R325.5019. Definitions T.**

802

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

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

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

807 ~~(C) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in~~
808 ~~seconds or the product of tube current and exposure time in mAs, the following:~~

809 ~~(a) for capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in~~
810 ~~milliamperes-seconds (mAs);~~

811 ~~(b) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray~~
812 ~~pulses;~~

813 ~~(c) for CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and~~
814 ~~either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per~~
815 ~~scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;~~

816 ~~(d) for CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current~~
817 ~~in ma and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time~~
818 ~~when the scan time and exposure time are equivalent; and~~

819 ~~(e) for all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in~~
820 ~~seconds, or the product of tube current and exposure time in mAs.~~

821

822 **(2)** "Test" means ~~a procedure for determining the characteristics or condition of a source of radiation, or~~
823 ~~circumstances relative thereto, the process of verifying compliance with an applicable regulation.~~

824

825 **(3)** "Therapeutic type tube housing" means:

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

826 **(a)** For x-ray therapy equipment not capable of operating at 500 kVp or above, an x-ray tube housing so
827 constructed that the leakage radiation averaged over any 100 cm² area at a distance of 1 meter from the
828 source does not exceed 8.8mGy per hour(1 roentgen per hour) when the tube is operated at its leakage
829 technique factors.

830 **(b)** For x-ray therapy equipment capable of operation at 500 kVp or above, an x-ray tube housing so
831 constructed that the leakage radiation averaged over any 100 cm² area at a distance of 1 meter from the
832 source does not exceed 0.1% of the useful beam dose rate at 1 meter from the source for any of its
833 operating conditions.

834
835 **(4)** "Thermoluminescent dosimeter" or "TLD" means a device used for radiation monitoring which
836 measures integrated dose by the principle of thermoluminescence.

837
838 **(5)** "These rules" means all parts.

839
840 **(6)** "Tube" means an x-ray tube, unless otherwise specified.

841
842 **(7)** "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage or
843 filament transformers and other appropriate elements when they are contained within the tube housing.

844
845 **(8)** "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in
846 terms of the technique factors.

847
848 **(9)** "Type 1100 aluminum alloy" means aluminum that has a nominal chemical composition of 99.00
849 percent minimum aluminum and 0.12 percent copper.

850
851 **R325.5020. Definitions U and ~~V~~ to W**

852

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

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

855 |
856 | ~~(2) "Unrestricted area" or "uncontrolled area" means an area access to which is not controlled by a~~
857 | ~~licensee or registrant for purposes of protection of individuals from exposure to radiation or radioactive~~
858 | ~~materials, or an area used for residential quarters. "Unrestricted area" means an area, access to which is~~
859 | ~~neither limited nor controlled by the registrant.~~

860 |
861 | ~~(3)(2)~~ "Useful beam" means the radiation which passes through the tube housing port and the
862 | aperture of the beam-limiting device when the exposure switch or timer is activated.

863 |
864 | ~~(4)(3)~~ "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for
865 | stepless adjustment of the x-ray field size at a given source-image receptor distance.

866 |
867 | ~~(4)~~ "Very high radiation area" means an area, accessible to individuals, in which radiation levels from
868 | radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5
869 | gray (500 rads) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation
870 | penetrates. Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and
871 | grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

872 |
873 | ~~(5)~~ "Visible area" means that portion of the input surface of the image receptor over which incident x-ray
874 | photons produce a visible image.

875 |
876 | ~~(6)~~ "Wedge filter" means a filter which effects continuous change in transmission over all or a part of the
877 | useful beam.

878 |
879 | ~~(7)~~ "Week" means 7 consecutive days starting on sunday.

880 |

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

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

883

884 | **R325.5021. Definitions X-ray to Y.**

885

886 | **Rule 21. (1)** "X-ray apparatus" means any source of x-ray and its high voltage supply.

887

888 | ~~(2) "X-ray control" means a device which controls input power to the x-ray high-voltage generator or the x-~~
889 | ~~ray tube or both. It includes equipment which controls the technique factors of any x-ray exposure. means a~~
890 | ~~device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes~~
891 | ~~equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the~~
892 | ~~technique factors of an x-ray exposure.~~

893

894 | **(3)** "X-ray equipment" means an x-ray system, subsystem or component thereof. Types of x-ray
895 | equipment are as follows:

896 | (a) "mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or
897 | casters for moving while completely assembled.

898 | (b) "portable x-ray equipment" means x-ray equipment designed to be hand-carried.

899 | (c) "stationary x-ray equipment" means x-ray equipment which is installed in a fixed location.

900 | (d) "transportable x-ray equipment" means x-ray equipment which is moved to different work sites by
901 | vehicle and may be used in a mobile or stationary method at the site.

902

903 | **(4)** "X-ray field" means that area of the intersection of the useful beam and any 1 of the set of planes
904 | parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the
905 | exposure rate is 1/4 of the maximum in the intersection.

906

907 | **(5)** "X-ray high-voltage generator" means a device which transforms electrical energy from the potential
908 | supplied by the x-ray control to the tube operating potential. The device may include means for transforming

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

909 alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical
910 protective devices and other appropriate elements.

911

912 | **(6)** "X-ray system" means an assemblage of components for the controlled production of x-rays. It
913 | includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting
914 | device, and the necessary supporting structures. Additional components which function with the system are
915 | considered integral parts of the system.

916

917 | **(7)** "X-ray subsystem" means any combination of 2 or more components of an x-ray system for which
918 | there are requirements specified in these rules.

919

920 | **(8)** "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-
921 | ray energy.

922

923 | **(9)** "Year" means the period of time beginning in January used to determine compliance with the
924 | provisions of these regulations. The registrant may change the starting date of the year used to determine
925 | compliance by the registrant provided that the change is made at the beginning of the year and that no day is
926 | omitted or duplicated in consecutive years.

927

928 **R325.5025. Prefixes.**

929

930 **Rule 25.** The following prefixes are used in these rules to mean the numbers indicated:

931

Symbol	Prefix	Quantity	Symbol	Prefix	Quantity
d	deci	(=10 ⁻¹)	da	deka	(=10)
c	centi	(=10 ⁻²)	h	hecto	(=10 ²)
m	milli	(=10 ⁻³)	k	kilo	(=10 ³)
μ	micro	(=10 ⁻⁶)	M	mega	(=10 ⁶)
p	nano	(=10 ⁻⁹)	G	giga	(=10 ⁹)
f	pico	(=10 ⁻¹²)	T	tera	(=10 ¹²)
a	femto	(=10 ⁻¹⁵)			
	atto	(=10 ⁻¹⁸)			

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

932

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

935

936

937

EXEMPTIONS

938

939 | **R325.5031. Departmental action.**

940

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

944

945 | ~~**R325.5033. Nuclear regulatory commission contractors.**~~

946

947 | ~~**Rule 33.**—An NRC contractor or subcontractor of the following categories operating in this state is~~
948 | ~~exempt from these rules to the extent that the contractor or subcontractor under his contract receives,~~
949 | ~~acquires, possesses, uses or transfers sources of radiation:~~

950 | ~~(a) A prime contractor performing work for the NRC at United States government-owned or controlled~~
951 | ~~sites.~~

952 | ~~(b) A prime contractor performing research in, or development, manufacture, storage, testing or~~
953 | ~~transportation of, atomic weapons or components thereof.~~

954 | ~~(c) A prime contractor using or operating nuclear reactors or other nuclear devices in a United States~~
955 | ~~government-owned vehicle or vessel.~~

956 | ~~(d) Any other prime contractor or subcontractor when the state and the NRC jointly determine that, under~~
957 | ~~the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be~~
958 | ~~accomplished without undue risk to the public health and safety and that the exemption of such contractor or~~
959 | ~~subcontractor is otherwise appropriate.~~

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

960
961 ~~[Note:—The requirements of this rule that pertain to radiation machine registration, licensing, or compliance~~
962 ~~are under the purview of the Michigan Department of Consumer & Industry Services.]~~

RECORDS, INSPECTIONS, TESTS AND ENFORCEMENT

R325.5041. Records.

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

R325.5042. 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~~ machines 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.

R325.5043. Impounding.

Rule 43. Sources of ~~r~~adiation machines are subject to impounding pursuant to section 5 of the act.

R325.5044. Tests.

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

988

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

992 | (a) ~~Sources of r~~Radiation machines.

993 | (b) Facilities wherein ~~sources of radiation~~ machines are used or stored.

994 | (c) Radiation detection and monitoring instruments.

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

997

998 | **R325.5045. Additional requirements.**

999

1000 | **Rule 45.** The department, by rule or order, may impose upon a ~~licensee or~~ registrant requirements in
1001 addition to those set forth in these rules that it deems appropriate or necessary to minimize danger to public
1002 health and safety or property.

1003

1004 | **R325.5046. Violations.**

1005

1006 | **Rule 46. (1)** Under authority of section ~~9~~ 13536 of the act the department may seek a court order enjoining
1007 violation of or directing compliance with the act or any rule or order issued thereunder.

1008

1009 | **(2)** Under authority of section ~~40~~ 13535 of the act, a person who performs any act for which ~~licensing or~~
1010 registration is required pursuant to these rules when that person is not ~~licensed,~~ registered, or exempted, is
1011 guilty of a misdemeanor and may be fined, imprisoned or both. ~~This provision shall not be effective until 90~~
1012 ~~days after the effective date of these rules.~~

1013

1014 | **R325.5047. Communications.**

1015

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

1016 **Rule 47.** Communications and reports concerning these rules, and applications filed thereunder, should
1017 be addressed to the Michigan Department of Public Health, Division of Radiological Health, 3423 North Logan
1018 Street, P.O. Box 30195, Lansing, Michigan 48909. Community Health, BHS, Radiation Safety Section, P.O.
1019 Box 30664, Lansing, Michigan 48909.

1020
1021 ~~*[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and*~~
1022 ~~*responsibilities of the radiation machine registration, licensing, and compliance program were transferred to*~~
1023 ~~*the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing*~~
1024 ~~*radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the*~~
1025 ~~*Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664,*~~
1026 ~~*Lansing, Michigan 48909.]*~~

1027
1028 **~~R325.5049. — Rescission.~~**

1029
1030 **Rule 49.** ~~The rules of the department entitled "Use of Radioactive Isotopes, X radiation and All Other~~
1031 ~~Forms of Ionizing Radiation," being R325.1301 to R325.1326 of the Michigan Administrative Code and~~
1032 ~~appearing on pages 3173 to 3203 of the 1964-65 Annual Supplements to the Code, are rescinded.~~