

1 **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**
 2 **RADIATION SAFETY SECTION**
 3 **IONIZING RADIATION RULES**

4
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21 **PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS**

22

23 **R325.5701. Purpose and scope.**

24

25 **Rule 701. (1)** This part establishes requirements governing the use of computed tomography (CT)
26 systems in the healing arts.

27

28 **(2)** This part applies to all registrants who use CT systems for the intentional exposure of humans
29 for the purpose of diagnostic imaging.

30

31 **(3)** CT systems with power ratings of 5 kilowatts or less are exempt from this part. CT scanners
32 used only for attenuation corrections and anatomical markers are also exempt from this part.

33

34 **(4)** In addition to the requirements of this part, all registrants are subject to the applicable provisions
35 of R325.5001 to R325.5665.

36

37 **R325.5703. Definitions.**

38

39 **Rule 703. (1)** As used in this part the definitions in 21 C.F.R. §1020.33 "Computed tomography (CT)
40 equipment" (June 10, 2005) are adopted by reference. Copies of these regulations are available at no
41 cost from the Radiation Safety Section, Michigan Department of Community Health, P.O. Box 30664,
42 Lansing, Michigan 48909 and from the Center for Devices and Radiological Health, U.S. Food and Drug
43 Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

44

45 **(2)** As used in this part the following definitions also apply:

46

47 **(a)** "Annual" means a period of twelve consecutive months.

48

49 **(b)** "Computed tomography (CT)" means the production of a tomogram by the acquisition and
50 computer processing of x-ray transmission data. Computed tomography includes the capability
51 of producing axial tomograms.

52

53 **(c)** "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

54

55 **R325.5705. Interpreting physicians.**

56

57 **Rule 705.** The following requirements apply to all physicians involved in the interpretation of CT
58 images.

59

60 **(a) Initial qualifications.** Before beginning to interpret CT examinations independently, a physician
61 shall be licensed under article 15 of the act and shall meet one of the following:

62

63 **(i)** Be board certified in radiology or diagnostic radiology by the American board of
64 radiologists, the American osteopathic board of radiology, the royal college of
65 physicians and surgeons of Canada, or le college des medecins du Quebec and have
66 interpreted or reviewed 300 CT examinations in the past 36 months; or

67

68 **(ii)** Have completed an accredited diagnostic radiology residency and have interpreted or
69 reviewed 500 CT examinations in the past 36 months under supervision; or

70

71 **(iii)** Have completed an accredited specialty residency, have a combined total of 200 hours
72 of category I continuing medical education (CME) in the performance of and

73 interpretation of CT in the subspecialty where CT reading occurs, and have interpreted
74 or reviewed 500 CT examinations in the past 36 months under supervision.
75

76 **(b) Continuing experience.** Following the second anniversary date in which the requirements of
77 subrule (a) of this rule were completed, the interpreting physician shall have interpreted or multi-
78 read at least an average of 9 CT examinations per month over the prior 24-month period. This
79 equates to interpreting at least 216 CT examinations in the prior 24-month period.
80

81 **(c) Continuing education.** Following the third anniversary date in which the requirements of subrule
82 (a) of this rule were completed, the interpreting physician shall have earned at least 15
83 continuing medical education units in CT, at least half of which shall be category I, in the prior
84 36-month period.
85

86 **R325.5707. Radiologic technologists.**

87
88 **Rule 707.** The following requirements apply to all radiologic technologists involved in the operation of
89 CT systems.
90

91 **(a) Initial qualifications.** Before beginning to perform CT examinations independently, the
92 technologist shall:
93

94 (i) Be currently registered by the American registry of radiological technologists (ARRT);
95 and
96

97 (ii) Document at least 20 hours of training and experience in operating CT equipment,
98 radiation physics, and radiation protection or have the advanced certification in
99 computed tomography from the ARRT.
100

101 **(b) Continuing education.** The technologist shall be in compliance with the ARRT requirements for
102 continuing education appropriate to his or her practice needs, which are 24 credits in a 2-year
103 period.
104

105 **R325.5709. Medical physicist.**

106
107 **Rule 709.** Each registrant with one or more CT systems shall employ or contract with a medical
108 physicist to review the quality and safety of the operation of the CT scanner. The medical physicist
109 shall meet the following:
110

111 **(a) Initial qualifications.**
112

113 (i) Be certified in diagnostic radiological physics or radiological physics by the American
114 board of radiology or by the Canadian college of physics in medicine; or
115

116 (ii) Have a graduate degree in medical physics, radiological physics, physics, or other
117 relevant physical science or engineering discipline from an accredited institution and
118 have coursework in the biological sciences with at least 1 course in biology or radiation
119 biology and 1 course in anatomy, physiology, or similar topics related to the practice of
120 medical physics.
121

122 **(b) Initial Experience.** Have 3 years documented experience in a clinical CT environment.
123

124 (c) *Continuing experience.* Following the second anniversary date of when the requirements of
125 subrules (a) and (b) of this rule were completed, the medical physicist shall have surveyed at
126 least 2 CT units in the prior 24-month period.

127
128 (d) *Continuing education.* Following the third anniversary date in which the requirements of
129 subrules (a) and (b) of this rule were completed, the medical physicist shall have earned at least
130 15 continuing medical education units in CT, at least half of which shall be category I, in the
131 prior 36-month period.

132

133 **Rule 710. Record retention for personnel.**

134

135 **Rule 710.** Facilities shall maintain records to document the qualifications of all personnel who worked
136 at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records
137 must be available for review by the department. Records of personnel no longer employed by the facility
138 should not be discarded until the next inspection has been completed and the department has
139 determined that the facility is in compliance with the CT personnel requirements.

140

141 **R325.5711. Equipment requirements.**

142

143 **Rule 711. (1)** The regulations in “Computed tomography (CT) equipment”, 21 C.F.R. §§1020.33(c),
144 (d), (f), (g), (h), (i), and (j) (June 10, 2005), are adopted by reference. Copies of these regulations are
145 available at no cost from the Radiation Safety Section, Michigan Department of Community Health, P.O.
146 Box 30664, Lansing, Michigan 48909 and from the Center for Devices and Radiological Health, U.S.
147 Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

148

149 **(2)** CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.

150

151 **R325.5713. Quality control program.**

152

153 **Rule 713. (1)** A quality control program shall be established and implemented under the supervision
154 of the medical physicist.

155

156 **(2)** Initial performance testing of the CT system shall be completed by the medical physicist before
157 use on human patients.

158

159 **(3)** Measurements of the radiation output of a CT x-ray system shall be performed with a calibrated
160 dosimetry system. The dosimetry system shall have been calibrated within the preceding 24 months
161 and the calibration shall be traceable to a national standard. During the calendar year in which the
162 dosimetry system is not calibrated, an inter-comparison to a system calibrated within the previous 12
163 months shall be performed.

164

165 **R325.5715. Annual medical physicist evaluation.**

166

167 **Rule 715. (1)** The performance of each CT machine shall be evaluated by the medical physicist at
168 least annually. This evaluation should include the following:

169 (a) Alignment light accuracy

170 (b) Alignment of table to gantry

171 (c) Table/gantry tilt

172 (d) Slice localization from scanned projection radiograph

173 (e) Table increment accuracy

174 (f) Slice thickness

175 (g) Image quality

176 (i) High-contrast resolution

- 177 (ii) Low-contrast resolution
- 178 (iii) Image uniformity
- 179 (iv) Noise
- 180 (v) Artifact evaluation
- 181 (h) CT number accuracy and linearity
- 182 (i) Display devices
- 183 (i) Video display
- 184 (ii) Hard-copy display
- 185 (j) Dosimetry
- 186 (i) Dose indicator such as computed tomography dosimetry index (CTDI)
- 187 (ii) Patient radiation dose for representative examinations
- 188 (k) Safety evaluation
- 189 (i) Visual inspection
- 190 (ii) Audible/visual signals
- 191 (iii) Posting requirements
- 192 (iv) Scattered radiation measurements
- 193 (l) Review of the continuous quality control program

194
195 **(2)** The medical physicist shall prepare a survey report that includes a summary of this evaluation
196 and recommendations for necessary improvements. The report shall include the type and date of the
197 last calibration or inner comparison of the dosimetry system used.

198
199 **(3)** The survey report shall be sent to the facility within 30 days of the date of the survey and shall be
200 maintained on file by the facility for a period of at least 5 years. Copies of the survey report shall be
201 made available to the department for review.

202
203 **R325.5717. Continuous quality control.**
204
205 **Rule 717. (1)** The CT facility shall establish a continuous quality control program with the assistance
206 of the medical physicist. The medical physicist shall determine the frequency of each test and who
207 should perform the test. An on-site radiological technologist should be identified to be responsible for
208 conducting routine quality control.

209
210 **(2)** The quality control tests shall be performed in accordance with written procedures and methods.
211 If the results of a quality control test fall outside of the control limits, corrective action shall be taken.

212
213 **(3)** The continuous quality control testing should include the following:

- 214 (a) Image quality
- 215 (i) High-contrast resolution
- 216 (ii) Low-contrast resolution
- 217 (iii) Image uniformity
- 218 (iv) Noise
- 219 (v) Artifact evaluation
- 220 (b) Alignment light accuracy
- 221 (c) Slice thickness
- 222 (d) CT number accuracy
- 223 (e) Display devices

224
225 **(4)** Records of the results from the continuous quality control program shall be maintained on file at
226 the facility for a period of at least 2 years.

227
228 **R325.5721. Facility design requirements**

229

230 **Rule 721. (1)** A CT equipment enclosure shall be in compliance with the requirements of
231 R325.5331.

232

233 **(2)** The operator shall be able to operate the equipment from a shielded position.

234

235 **(3)** Provision shall be made for two-way aural communication between the patient and the operator at
236 the control panel.

237

238 **(4)** Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit
239 continuous observation of the patient during irradiation and shall be so located that the operator can
240 observe the patient from the control panel.

241

242 **(5)** If the primary viewing system is by electronic means and that system stops functioning properly,
243 the system must be replaced or repaired before any further examinations are performed.

244

245 **R325.5723. Surveys.**

246

247 **Rule 723. (1)** All CT x-ray systems installed after *[insert effective date of the regulations]* shall
248 have a survey as defined in R325.5221 made initially before use on human patients. Those systems
249 not previously surveyed shall have a survey made within one year of *[insert effective date of the*
250 *regulations]*. In addition, such surveys shall be done after any change in the facility or equipment
251 which might cause a significant increase in radiation hazard. The surveys required by this subrule shall
252 be made by, or under the direct supervision of, a medical physicist.

253

254 **(2)** The registrant shall obtain a written report of the survey from the medical physicist, and a copy of
255 the report shall be made available to the department upon request.