

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

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

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PART 11. COMPUTED TOMOGRAPHY INSTALLATIONS

R325.XXX1. Purpose and scope.

Rule XXX1. (1) This part establishes procedures for the registration and the use of computed tomography systems.

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

R325.XXX2. Definitions a to c.

Rule XXX2. (1) As used in this part:

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

(b) "Computed tomography dose index" means the integral from $-7T$ to $+7T$ of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{n T} \int_{-7T}^{+7T} D(z) dz$$

where:

z = Position along a line perpendicular to the tomographic plane;

$D(z)$ = Dose at position z ;

T = Nominal tomographic section thickness;

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n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(c) "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

\overline{CTN}_x = of the material of interest;

\overline{CTN}_w = of water.

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

(e) "CS" (See "Contrast scale").

(f) "CT" (See "computed tomography").

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70 (g) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray
71 system including, but not limited to, nominal tomographic section thickness, filtration, and the technique
72 factors as defined in F.2.

73 (h) "CTDI" (See "Computed tomography dose index").

74 (i) "CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting
75 structures and frames which hold these components.

76 (j) "CTN" (See "CT number").

77 (k) "CT Number" means the number used to represent the x-ray attenuation associated with each
78 elemental area of the CT image.

$$\overline{\text{CTN}} = \frac{k (\mu_x - \mu_w)}{\mu_w}$$

79
80 where:

81
82 k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

83
84 μ_x = Linear attenuation coefficient of the material of interest;

85
86 μ_w = Linear attenuation coefficient of water.

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88 **R325.XXX3. Definitions d to n.**

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90 **Rule XXX3. (1) As used in this part:**

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92 (a) "Dose profile" means the dose as a function of position along a line.

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93 (b) "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation
94 properties of a body are depicted. (See also "Picture element").

95 (c) "Irradiation" means the exposure of matter to ionizing radiation.

96 (d) "Kilovolts peak" (See "peak tube potential").

97 (e) "kV" means kilovolts.

98 (f) "kVp" (See "peak tube potential").

99 (g) "Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray
100 transmission data simultaneously during a single scan to produce more than one tomogram.

101 (h) "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the
102 attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

104 where:

105 \overline{CS} = Linear attenuation coefficient of the material of interest.

106 μ_w = Linear attenuation coefficient of water.

107 s = Standard deviation of the CTN of picture elements in a specified area of
108 the CT image.

109 (i) "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile
110 taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

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117 **R325.XXX4. Definitions o to z.**

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119 **Rule XXX4. (1) As used in this part:**

120 **(a) "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or**
121 **treatment.**

122 **(b) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube**
123 **during an exposure.**

124 **(c) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the**
125 **attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density**
126 **of the material be similar to that of tissue.**

127 **(d) "Picture element" means an elemental area of a tomogram.**

128 **(e) "Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency**
129 **that such individual possesses the knowledge, training and experience to measure ionizing radiation,**
130 **to evaluate safety techniques, and to advise regarding radiation protection needs.**

131 **(f) "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.**

132 **(g) "Scan" means the complete process of collecting x-ray transmission data for the production of a**
133 **tomogram. Data can be collected simultaneously during a single scan for the production of one or more**
134 **tomograms.**

135 **(h) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-**
136 **ray system between successive scans measured along the direction of such displacement.**

137 **(i) "Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-**
138 **selected CT conditions of operation.**

139 **(j) "Scan time" means the period of time between the beginning and end of x-ray transmission data**
140 **accumulation for a single scan.**

141 **(k) "Shutter" means a device attached to the tube housing assembly which can intercept the entire**
142 **cross sectional area of the useful beam and which has a lead equivalency not less than that of the**
143 **tube housing assembly.**

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144 (l) "Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a
145 scan to produce a single tomogram.

146 (m) "Source" means the focal spot of the x-ray tube.

147 (n) "Technique factors" means the following conditions of operation:

148 (i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge
149 in mAs;

150 (ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, and
151 number of x-ray pulses;

152 (iii) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time
153 in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray
154 pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in
155 mAs;

156 (iv) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and
157 either tube current in mA and scan time in seconds, or the product of tube current and exposure time
158 in mAs and the scan time when the scan time and exposure time are equivalent; and

159 (v) For all other equipment, peak tube potential in kV, and either tube current in mA and
160 exposure time in seconds, or the product of tube current and exposure time in mAs.

161 (o) "Tomographic plane" means that geometric plane which is identified as corresponding to the output
162 tomogram.

163 (p) "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged
164 in a tomogram.

165 (q) "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

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

167 (s) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy
168 into X-ray energy.

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170 **R325.XXX5. Requirements for equipment.**
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172 Rule XXX5. (1) Means shall be provided to terminate the x-ray exposure automatically by either de-
173 energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data
174 collection. Such termination shall occur within an interval that limits the total scan time to no more than 110
175 percent of its present value through the use of either a backup timer or devices which monitor equipment
176 function.

177
178 (2) A visible signal shall indicate when the x-ray exposure has been terminated through the means
179 required by subrule (1).

180
181 (3) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of
182 scans under CT x-ray system control, of greater than one-half second duration.

183
184 (4) For any single tomogram system, means shall be provided to permit visual determination of the
185 tomographic plane or a reference plane offset from the tomographic plane.

186
187 (5) For any multiple tomogram system, means shall be provided to permit visual determination of the
188 location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

189
190 (6) If a device using a light source is used to satisfy the requirements of subrules (4) or (5), the light
191 source shall provide illumination levels sufficient to permit visual determination of the location of the
192 tomographic plane or reference plane under ambient light conditions of up to 500 lux.

193
194 (7) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if
195 applicable, whether the shutter is open or closed.

196
197 (8) Each emergency button or switch shall be clearly labeled as to its function.
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199 (9) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a
200 scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment
201 having all or some of these conditions of operation at fixed values, this requirement may be met by permanent
202 markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation
203 is possible.

204
205 (10) When data are not being collected for image production, the radiation adjacent to the tube port shall
206 not exceed that permitted by rule XXX(3). (General requirements for diagnostic x-rays)

207
208 (11) The angular position where the maximum surface CTDI occurs shall be identified to allow for
209 reproducible positioning of a CT dosimetry phantom.

210
211 (12) Requirements applicable to CT x-ray systems containing a gantry manufactured after September 3,
212 1985 include all of the following:

213 (a) The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5
214 millimeters.

215 (b) If the x-ray production period is less than one-half second, the indication of x-ray production shall be
216 actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point
217 external to the patient opening where insertion of any part of the human body into the primary beam is
218 possible.

219 (c) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1
220 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device
221 shall be incremented from a typical starting position to the maximum incremented distance or 30
222 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus
223 indicated scan increment may be taken anywhere along this travel.

224 (d) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT
225 conditions of operation prior to the initiation of another scan.

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227 **R325.XXX6. Facility design requirements**

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229 **Rule XXX6 (1)** Computed tomography room design and shielding shall comply with Part 6,
230 enclosures and radiation shielding rule xxx, and part 7, rule 331 for general purpose radiography.

231

232 **(2)** Provision shall be made for two-way aural communication between the patient and the operator at the
233 control panel.

234

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

238

239 **(4)** When the primary viewing system is by electronic means, an alternative viewing system (which may
240 be electronic) shall be available for use in the event of failure of the primary viewing system.

241

242 **R325.XXX7. Surveys.**

243

244 **Rule XXX7 (1)** All CT x-ray systems installed after ***[insert effective date of the regulations]*** shall
245 have a radiation protection survey made initially, before first use. All CT systems installed before ***[insert***
246 ***effective date of the regulations]*** shall have a radiation protection survey made within one year of ***[insert***
247 ***effective date of the regulations]***. In addition, such surveys shall be done after any change in the facility or
248 equipment which might cause a significant increase in radiation hazard. The surveys required by this subrule
249 shall be made by, or under the direct supervision of, a qualified expert.

250

251 **(2)** The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the
252 report shall be made available to the Agency upon request.

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254 **R325.XXX8. Radiation calibrations.**

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Rule XXX8. (1) The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

(2) The calibration of a CT x-ray system shall be performed before first use, at intervals not to exceed 12 months, and after any change or replacement of components which, in the opinion of a qualified expert, could cause a change in the radiation output.

(3) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

(4) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(a) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter (Lucite). The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode. Other accepted national standard phantoms may be approved by the department as necessary.

(b) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

(c) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(d) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

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(5) The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

(6) Calibration shall meet the following requirements:

(a) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than 3 nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness.

(b) The CTDI along the two axes specified in Rule xxx.(4)(b) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;

(c) The spot checks specified in R 325.xxx. shall be made.

(7) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

R325.XXX9. Spot checks.

Rule XXX9. (1) The spot-check procedures shall be in writing, shall have been developed by a qualified expert, and shall include, but not be limited to the following:

(a) Weekly

(i) CT number accuracy (water phantom evaluation)

(ii) Alignment light accuracy if used for therapy planning

(b) Monthly

(i) Display device evaluation

(c) Quarterly

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311 (i) Alignment light accuracy

312 (d) Annually

313 (i) Slice thickness

314 (ii) Image quality including high contrast (spatial) resolution, Low contrast resolution, Image
315 uniformity, Noise, and Artifact evaluation.

316

317 (2) The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a
318 capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the
319 resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or
320 other reference material.

321

322 (3) All spot checks shall be included in the calibration required by R325.XXXX.

323

324 (4) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the
325 same processing mode and CT conditions of operation as are used to perform calibrations required by
326 R325.XXXX. The images shall be retained, until a new calibration is performed, in two forms as follows:

327 (a) Photographic copies of the images obtained from the image display device; and

328 (b) Images stored in digital form on a storage medium compatible with the CT x-ray system.

329

330 (5) Written records of the spot checks performed shall be maintained for inspection by the agency.

331

332 **R325.XX10. Operating procedures.**

333

334 **RULE XX10. (1) The CT x-ray system shall be operated only by an individual who has been**
335 **specifically trained in its operation.**

336

337 **(2) Information shall be available at the control panel regarding the operation and calibration of the**
338 **system. Such information shall include the following:**

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339 (a) Dates of the latest calibration and spot checks and the location within the facility where the results of
340 those tests may be obtained.

341 (b) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks
342 appropriate for the system, allowable variations for the indicated parameters, and the results of at least the
343 most recent spot checks conducted on the system.

344 (c) The distance in millimeters between the tomographic plane and the reference plane if a reference
345 plane is utilized.

346 (d) A current technique chart available at the control panel which specifies for each routine examination
347 the CT conditions of operation and the number of scans per examination. Reduced technique settings must
348 be specified and used for children and small adults, as appropriate.

349
350 (3) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has
351 exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be
352 limited to those uses permitted by established written instructions of the qualified expert.

353